REPORT OF THE SPECIAL TASK FORCE
STUDYING THE PRACTICE OF THERAPEUTIC
INTERCHANGE

A STUDY OF THE PRACTICE OF THERAPEUTIC INTERCHANGE OF CHEMICALLY DISSIMILAR DRUGS IN VIRGINIA

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 57

COMMONWEALTH OF VIRGINIA
RICHMOND
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COMMONWEALTH of VIRGINIA

Department of Medical Assistance Services

JOSEPH M. TEEFEY
DIRECTOR

SUITE 1300
600 EAST BROAD STREET
RICHMOND, VA 23219
804 786-7933
804 225-4512 (Fax)
800 343-0634 (TDD)

January 7, 1998

TO: The Honorable George Allen

and

The General Assembly of Virginia

This report contained herein is pursuant to House Joint Resolution 630, passed by the 1997 General Assembly.

I am submitting this report on behalf of the Special Task Force Studying the Practice of Therapeutic Interchange of Chemically Dissimilar Drug Products. The report contains the discussions and recommendations of the Task Force.

Respectfully submitted,

Joseph M. Teefey, Director
Department of Medical Assistance Services

Report of the Special Task Force Studying the Practice of Therapeutic Interchange of Chemically Dissimilar Drugs in the Commonwealth of Virginia Pursuant to HJR 630 (1997)

Submitted to the General Assembly of Virginia
by Joseph M. Teefey, Task Force Chair
on behalf of the Task Force

December 1997

AUTHORIZATION

The work of the Special Task Force Studying the Practice of Therapeutic Interchange was completed pursuant to House Joint Resolution 630 passed by the General Assembly of Virginia during its 1997 Session. The full text of HJR 630 can be found in Appendix A of this report. A summary of the provisions of HJR 630 is provided below.

RESOLUTION SUMMARY

HJR 630 established a special task force to study the practice of therapeutic interchange of chemically dissimilar drug products. The special task force was directed to:

1. State the practice of therapeutic interchange to reach consensus on its incidence and prevalence.

2. Determine the impact of the practice of therapeutic interchange on health care, the affected professions, the overall costs of health care products and services, and patients.

3. Identify the components of the cost of the practice.

The resolution defined the membership of the Task Force and directed that the Department of Medical Assistance Services provide staff support to the Task Force. The Department contracted with the Virginia Commonwealth University School of Pharmacy to facilitate the Task Force meetings and provide documentation.*

* This report was written by Dr. Michael A. Pyles of the Virginia Commonwealth University School of Pharmacy, in his role of facilitator for the Task Force under contractual arrangements with the Department, and does not contain the personal views, opinions, positions or perspectives of Dr. Pyles or the School of Pharmacy.

TASK FORCE MEMBERS

Mr. Michael J. Ayotte
Pharmacist (Richmond)
Virginia Assn. Of Chain Drug Stores

Dr. Lawrence E. Blanchard, III
Physician (Richmond)
Medical Society of Virginia

Dr. Randall E. Dalton
Physician (Richmond)
Old Dominion Medical Society

Mr. Charles E. James, Sr.
Director (Richmond)
Virginia Dept. Personnel & Training

Dr. Thomas L. Moffatt
Physician (Richmond)
Medical Society of Virginia

Ms. Cynthia J. Pigg
Pharmacist (Glen Allen)
Academy of Managed Care Pharmacy

Mr. Mark A. Szalwinski
Pharmacist (Norfolk)
Virginia Society of Health Systems Pharmacists

Mr. William A. Towler
Pharmacist (Highland Springs)
Virginia Pharmacists Association

The Honorable I. Vincent Behm, Jr.
Democrat, District 91 (Hampton)
Virginia House of Delegates

Mr. James G. Council
Attorney (Glen Allen)
Pharmaceutical Care Mgt. Assn.

Dr. Douglas R. Hadley
Physician (Glen Allen)
Virginia Association of HMOs

Dr. Karen E. Knapp
Physician (Richmond)
Virginia Board of Medicine

The Honorable Stephen D. Newman
Republican, District 23 (Lynchburg)
Senate of Virginia

Ms. Marjorie E. Powell
Attorney (Washington, DC)
Pharmaceutical & Research Mfrs. Of America

Mr. Joseph M. Teefey [Chair]
Director (Richmond)
Virginia Dept. Of Medical Assistance Services

Mr. W. Tommy Walker
Pharmacist (Lawrenceville)
Virginia Board of Pharmacy

TASK FORCE MEETINGS

The first meeting of the Special Task Force was held on June 19, 1997, in Richmond. Subsequent meetings were held on July 16, 1997, August 20, 1997, and September 17, 1997. All meetings were held in House Room D of the Virginia General Assembly Building except the September 17 meeting, which was held in House Room C. Mr. Joseph M. Teefey, Director of the Department of Medical Assistance Services, and a member of the Task Force, served as chair of the Task Force and presided over all of its meetings.

Agendas and transcripts for each meeting can be found in Appendices B and C, respectively. Each meeting included a public comment period so that Task Force members could hear from interested parties concerning the practice of therapeutic interchange of chemically dissimilar drugs.

In an effort to ensure that Task Force members had access to as much pertinent information as possible, and to ensure that they would be able to make informed decisions concerning the practice of therapeutic interchange of chemically dissimilar drugs in the Commonwealth, several speakers were invited to make presentations and give comments on the topic.

INVITED SPEAKERS

Kenneth D. McArthur, Jr., Esq.
Durrette, Irvin, Bradshaw, P.C.
Richmond

Mr. McArthur's firm represents independent pharmacies throughout the Commonwealth of Virginia. In his remarks, Mr. McArthur noted that there are some very important issues that the Task Force needs to consider. He identified himself as one of the drafters of the failed Bill that was introduced last year to outlaw the practice of switching chemically dissimilar drugs where a monetary incentive is present. Mr. McArthur urged the Task Force to look at hard evidence produced by all interested parties and to make an informed decision on that basis.

Stephen Rosenthal, Esq.
Mays and Valentine
Richmond

According to Mr. Rosenthal, he was speaking on behalf of a large coalition that was involved in the previous legislation that generated this study and the Task Force. Mr. Rosenthal advised the Task Force to look closely at what is happening today in the health care market and warned them that anecdotal evidence was not sufficient to warrant any large scale, legislative action. Like Mr. McArthur, Mr. Rosenthal urged the Task Force to consider the facts and data presented by the staff and interested parties and identify whether there are any specific aspects of the practice that pose a risk to the public and, if so, to determine if the practice outweighs any associated benefits to the public.

Mr. David Shepherd, R.Ph.
DMAS, Pharmacy Supervisor
Richmond

Mr. Shepherd served as staff to the Task Force and was asked to give an overview of the Virginia Medicaid Pharmacy Program. Mr. Shepherd noted that prescribed drugs are among the 35 services available to eligible Medicaid recipients and one of 19 optional services provided by the program. According to Mr. Shepherd, prescribed drugs have been a part of Virginia's Medicaid

Program since its inception. In his overview Mr. Shepherd advised the Task Force that the operation of Virginia's Medicaid Program, and the prescription drug benefit, are under the oversight of the federal Health Care Financing Administration. Mr. Shepherd provided a great deal of information about the program and how it operates in the Commonwealth of Virginia.

Carol Pugh, Pharm.D.
Virginia Commonwealth University, School of Pharmacy
Richmond

Dr. Pugh was invited to share information about drug utilization review within DMAS. In her remarks Dr. Pugh informed the Task Force that she was a DUR consultant working under an Inter-agency Agreement between DMAS and Virginia Commonwealth University from January 1992 through January 1995. According to Dr. Pugh, DMAS is currently performing DUR using the program that she developed and implemented. Virginia's DUR program has both retrospective and prospective components and allows DMAS to monitor service utilization under its prescription drug program. Dr. Pugh noted that DUR is required by the federal government and that Virginia actually implemented its program before the required date.

Mr. Michael Worthington
Agency Management Lead Analyst, DMAS
Richmond

Mr. Worthington served as staff to the Task Force and provided a summary of the literature pertaining to therapeutic substitution and therapeutic interchange. Mr. Worthington acknowledged the assistance of Ms. Julie Sisler, who was a summer research fellow in the School of Pharmacy at VCU, in conducting the review of the literature. In his remarks, Mr. Worthington defined two key terms that are relevant to the work of the Task Force: Therapeutic Substitution and Therapeutic Interchange. In the case of the former, no physician approval is sought as opposed to the latter where the physician's approval is sought.

Norman V. Carroll, Ph.D.
Virginia Commonwealth University, School of Pharmacy
Richmond

Dr. Carroll was asked to share some of his insight regarding the practice of therapeutic interchange. Dr. Carroll is a professor of Pharmacy Administration in the School of Pharmacy at VCU and has conducted research in this area. In his opening remarks Dr. Carroll advised the Task Force that he was speaking as a researcher and individual and not as an official representative of VCU's School of Pharmacy. Dr. Carroll stated that there is a lack of empirical research on therapeutic interchange, specifically on drug switching. He cited three reasons for the situation: 1) a pharmacy regulation preventing pharmacists from sharing patient data with any one other than the physician or the pharmacist, 2) the common practice of PBMs and managed care organizations of making pharmacists sign confidentiality statements, and 3) a reluctance on the part of a lot of pharmacists and physicians to do anything which they think might antagonize or might criticize managed care organizations.

Howard Casway, Esq.
Asst. Attorney General
Richmond

Ms. Scotti Russell, R.Ph.
Virginia Board of Pharmacy
Richmond

Mr. Casway and Ms. Russell were invited to answer specific questions related to the practice of pharmacy in the Commonwealth raised by Task Force members. They provided answers and responses to questions such as "What are other states doing with regard to therapeutic interchange?", "Does state law prohibit the practice of therapeutic interchange/substitution?", "Does state law say anything about switching drugs based on rebates?", and "Does the Virginia Board of Pharmacy have the statutory or regulatory authority to regulate the practice of therapeutic interchange/substitution?"; among others. Mr. Casway and Ms. Russell assisted the Task Force in understanding the scope of practice of pharmacists in the Commonwealth and the extent to which the Board of Pharmacy has oversight for pharmacists and pharmacies. Ms. Russell, in a later presentation, also shared with the Task Force some of the legislative actions that the Board of Pharmacy will be pursuing during the 1998 session of the General Assembly.

DISCUSSION

The Task Force believed that it was very important to clearly define the term "therapeutic interchange of chemically dissimilar drugs." The following definition was unanimously adopted by the Task Force on August 20, 1997.

> **Therapeutic interchange is the dispensing of a drug, by any person authorized by law to dispense drugs, that is a chemically dissimilar alternative for the drug initially prescribed. The alternative drug is expected to have the same clinical results and similar safety profile, when administered to patients in therapeutically equivalent doses, as the drug initially prescribed, and is dispensed with the approval of the person who prescribed the initial drug, or their lawful designee.**

The adoption of this definition was crucial to the work of the Task Force as it attempted to describe the practice of therapeutic interchange of chemically dissimilar drugs and identify the impact of the practice in the Commonwealth. Prior to the adoption of this definition, the Task Force had an in depth discussion centering around this issue.

Two important questions emerged from Task Force deliberations.

1) Is the practice of therapeutic interchange harmful to Virginia residents?

2) How many Virginians are affected by this practice?

Is therapeutic interchange harmful?

The first question was addressed by interested parties representing two points of view. Interested parties who expressed concern that the practice is harmful and dangerous articulated the first point of view. Many of the comments made by speakers holding this point of view called attention to a piece of legislation that failed during the 1997 session of the Virginia General Assembly (SB 1114, see Appendix A) which sought to outlaw the practice of Drug Switching in the Commonwealth. The consensus of those persons holding this point of view is that the practice of therapeutic interchange is indeed harmful and dangerous and that we do not have sufficient empirical data to suggest otherwise.

The other point of view contends that accounts of the harmful and dangerous nature of the practice are inaccurate and rely solely on anecdotal evidence. The consensus of persons holding this point of view is that the practice must be allowed to continue because it makes good economic sense and any attempt to make the practice unlawful in Virginia, or otherwise restrict it, would result in substantial increases in health care costs for the residents of the Commonwealth as well as employers whose health care benefits include prescription drug coverage.

How many Virginians are affected by therapeutic interchange?

In an attempt to understand the potential impact of this practice in the Commonwealth, a Task Force member raised the question on the number of Virginians affected by the practice. The Task Force staff concluded that there is no exact answer to this question. At best, the number of Virginians covered by prescription benefit programs could only be estimated, since such data are not routinely or uniformly collected and reported. The staff estimates that over 5,000,000 Virginians are covered by such plans. Current population data indicate that 87% of Virginia's population is covered by health insurance. National health insurance data indicate that between 42% and 94% of persons who are covered by a health plan have coverage for their prescription drugs under those plans.

One issue that engendered a lengthy discussion by the Task Force was the statutory and regulatory authority of the Board of Pharmacy to oversee out-of-state pharmacies. Members of the Task Force raised questions about the dispensing of prescription drugs to Virginia residents by pharmacies operating in other states, especially by means of mail order. According to information that it received, the Task Force acknowledges that the Virginia Board of Pharmacy has limited regulatory authority over these out-of-state pharmacies and their dispensing operations.

CONCLUSIONS

The chair of the Task Force solicited policy options and recommendations from Task Force members and interested parties regarding the practice of therapeutic interchange of chemically dissimilar drugs in the Commonwealth. During the last meeting of the Task Force, members heard from the Executive Director of the Board of Pharmacy and considered policy options from a Task Force member and interested parties.

In the course of its deliberations, the Task Force came to the conclusion that additional information is needed before any specific recommendations regarding the practice of therapeutic interchange can be made. Although an abundance of information was disseminated to Task Force members, and despite the impassioned testimony of invited speakers and interested parties on both sides, it is the collective opinion of the Task Force that final recommendations about the practice of therapeutic interchange of chemically dissimilar drugs in the Commonwealth of Virginia be deferred.

RECOMMENDATIONS

After a lengthy discussion, and in light of its deliberations, the Special Task Force Studying the Practice of Therapeutic Interchange of Chemically Dissimilar Drugs made the following recommendations.

1. The addition of the following to the *Code of Virginia*, §54.1-3434.4, as subsection B thereof.

   It is unlawful for any nonresident pharmacy to dispense a drug that is chemically dissimilar from the drug initially prescribed without the approval of the prescriber or his lawful designee.

   This is a part of a policy option submitted by Matthew Jenkins in a letter to Mr. Joseph M. Teefey dated September 12, 1997.

2. The introduction of a joint resolution during the 1998 session of the General Assembly to continue the Task Force for another year so that the Task Force will have the opportunity to consider the findings of a study to be performed by the Virginia Commonwealth University School of Pharmacy pursuant to House Joint Resolution 574 from the 1997 session of the General Assembly.

   These recommendations were adopted by a unanimous vote of the Task Force.

APPENDIX A

BILLS AND RESOLUTIONS (1997)

House Joint Resolution 630
House Joint Resolution 574
Senate Bill 1114
House Bill 2714

HOUSE JOINT RESOLUTION NO. 630

Establishing a special task force to study the practice of therapeutic interchange of chemically dissimilar drug products.

Agreed to by the House of Delegates, February 22, 1997
Agreed to by the Senate, February 22, 1997

WHEREAS, issues have arisen regarding the practice of therapeutic interchange of chemically dissimilar drug products; and

WHEREAS, legislation has been proposed addressing this practice; and

WHEREAS, whether or not the legislation is enacted, further study of this practice is desirable; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That a special task force be established to study the practice of therapeutic interchange of chemically dissimilar drug products. During the course of this study, the special task force shall examine all aspects and effects of the practice of therapeutic interchange of chemically dissimilar drug products throughout the health care delivery system, including, but not limited to, its impact on health care, the affected professions, the overall costs of health care products and services, and patients.

The special task force shall be composed of 16 members, as follows: 1 member of the House of Delegates; 1 physician, upon the recommendation of the Old Dominion Medical Society; 1 practicing pharmacist, upon the recommendation of the Virginia Association of Chain Drug Stores; 1 representati of a manufacturer of brand name prescription drug products, which does not own a Pharmacy Benefits Manager (PBM) or have a strategic alliance with a PBM, upon the recommendation of the Pharmaceutical Research and Manufacturers Association; 1 pharmacist, upon the recommendation of the Virginia Society of Health System Pharmacists; and 1 representative of a health maintenance organization, upon the recommendation of the Virginia Association of Health Maintenance Organizations, all to be appointed by the Speaker of the House; 1 member of the Senate; 2 licensed physicians, upon the recommendation of the Medical Society of Virginia; 1 practicing independent pharmacist, upon the recommendation of the Virginia Pharmacists Association; 1 pharmacist, upon the recommendation of the Academy of Managed Care Pharmacy; and 1 representative of a PBM, upon the recommendation of the Pharmaceutical Care Management Association, all to be appointed by the Senate Committee on Privileges and Elections; the Director of the Department of Medical Assistance Services; the Director of the Department of Personnel and Training; and 1 representative of the Board of Pharmacy, upon the recommendation of the Executive Director of the Board of Pharmacy, to be appointed by the Speaker of the House; and 1 representative of the Board of Medicine, upon the recommendation of the Executive Director of the Board of Medicine, to be appointed by the Senate Committee on Privileges and Elections, both to serve ex officio without voting privileges. Nonlegislative members shall serve in a voluntary capacity and shall not be entitled to compensation or reimbursement for their expenses for participation in this study.

The Department of Medical Assistance Services shall provide staff support for the study. Technical assistance shall be provided to the special task force by the Board of Medicine and the Board of Pharmacy.

All agencies of the Commonwealth shall provide assistance to the special task force for this study, upon request.

The special task force shall complete its work in time to submit its findings and recommendations to the Governor and the 1998 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

Go to (General Assembly Home)

HOUSE JOINT RESOLUTION NO. 574

Requesting the Department of Medical Assistance Services to examine the impact of the practices of pharmacy benefits manager firms on the Commonwealth's citizens and upon the health care market.

Agreed to by the House of Delegates, February 20, 1997
Agreed to by the Senate, February 19, 1997

WHEREAS, as the health insurance industry reconfigures and managed care programs become pervasive, the effects on patient care and small businesses delivering health services are far-reaching; and

WHEREAS, a recent development in managed care approaches is the implementation of or contracting for pharmacy benefits management; and

WHEREAS, pharmacy services are essential to the well-being of many elderly and disabled persons for the maintenance of their health; and

WHEREAS, appropriate pharmacy services can prevent hospital admissions and the need for emergency care -- expensive services placing greater demands on society's resources; and

WHEREAS, the present management techniques practiced by some pharmacy benefits managers may interfere in the statutorily required physician-patient-pharmacist relationship; and

WHEREAS, personal consultation and direct knowledge of the patient's conditions and medications are an important part of handling many chronic conditions; and

WHEREAS, so-called "desk audits" are allegedly being conducted many months after the dispensing of prescriptions; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Department of Medical Assistance Services be requested to examine the practices of pharmacy benefits manager firms on the Commonwealth's citizens and upon the health care market. In conducting its study, the Department shall coordinate its efforts with any similar studies undertaken during the interim by the Department or by other state entities. In addition, the Department shall solicit input from such experts and interested parties as may be appointed to a special task force established pursuant to House Joint Resolution No. 630 (1997), relating to the practice of therapeutic interchange.

Technical assistance shall be provided by the Bureau of Insurance within the Virginia State Corporation Commission. All agencies of the Commonwealth shall provide assistance to the Department for this study, upon request.

The Department of Medical Assistance Services shall complete its work in time to submit its findings and recommendations to the Governor and the 1999 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for the processing of legislative documents.

Go to (General Assembly Home)

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HOUSE BILL NO. 2714

Offered January 20, 1997

A BILL to amend the Code of Virginia by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, relating to the Virginia Anti-Drug Switching Patient Protection Act; penalties.

Patrons-- Davies, Baker, Bloxom, Cooper, Councill, Cranwell, Crouch, Dickinson, Hall, Hargrove, Jackson, Johnson, Keating, McEachin, Melvin, Moran, Morgan, Nelms, Orrock, Plum, Spruill, Stump, Tate, Van Yahres, Wagner and Woodrum; Senators: Couric, Edwards, Gartlan, Hawkins and Trumbo

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Referred to Committee on Health, Welfare and Institutions

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, as follows:

CHAPTER 34.1.
VIRGINIA ANTI-DRUG SWITCHING PATIENT PROTECTION ACT.

§54.1-3480. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Advertisement" means a representation disseminated in any manner or means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of a prescription drug. The term does not include any act prohibited by the chapter.

"Attorney" means the Attorney General of Virginia, and the attorney for any city, county or town.

"Caregiver" means (i) a parent or guardian of a minor patient, (ii) a relative, close friend or employee of a patient who provides in-person physical assistance to the patient, or (iii) a person employed by another to care for a patient who provides in-person physical assistance to the patient.

"Chemically dissimilar" means a prescription drug which possesses one or more active ingredients that are different from those of another prescription drug.

"Deliver" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Dispense" or "dispensing" means to deliver a prescription drug to a patient by or pursuant to the lawful order of a prescribing practitioner.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or

prevention of disease in an individual; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of an individual; or (iv) articles or substances intended for use as a component of any article specified in (i), (ii), or (iii). "Drug" does not include devices or their components, parts or accessories.

"Employer" means a person who provides monetary or other compensation to another person for goods or services, whether the one receiving monetary or other compensation is an employee, agent, partner, independent contractor or other.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means or chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Manufacturer" means any person who manufactures and all agents of that person.

"Monetary incentive" means any rebate, discount, kick-back, fee, special charge or other financial incentive received directly or indirectly from a manufacturer.

"Patient" means an ultimate consumer of a prescription drug who obtains the prescription drug from a licensed pharmacist or practitioner who is authorized by law to prescribe or dispense prescription drugs.

"Pharmacists" means a person duly licensed by the Virginia Board of Pharmacy to practice pharmacy or a person duly licensed by any other state or U.S. territory to practice pharmacy.

"Practitioner" means a person duly licensed by the Commonwealth or by any other state or U.S. territory as a physician, dentist, osteopath, podiatrist, nurse practitioner, TPA-certified optometrist, or physician's assistant.

"Prescribing practitioner" means a practitioner who (i) prescribes a prescription drug for a patient and (ii) is authorized by applicable law to prescribe or administer such drugs.

"Prescription drug" or "prescribed drug" means any drug required by federal law of regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the Federal Food, Drug, and Cosmetic Act.

"Sells" or "selling" includes barter, exchange, transfer, or gift, or offer therefor.

§54.1-3481. Exceptions to applicability of chapter; no exemption from other provisions of title.

A. The provisions of this chapter shall not apply to any prescription drug prescribed by a scientific investigator for purposes of research or prescribed by a veterinarian. Where the solicitation or encouragement prohibited herein is directed to a practitioner, this chapter shall only apply to a solicitation or encouragement where the practitioner has a bona fide practitioner-patient relationship with a specific patient for whom a specific drug has been prescribed from which a substitution is sought.

B. This chapter shall not be construed as exempting any person from the requirements of Chapter 33

(§54.1-3300 et seq.) or Chapter 34 (§54.1-3400 et seq.) of this title.

§54.1-3482. Unlawful actions.

A. No person shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug which the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug, unless the person is the patient, another practitioner, or a caregiver of the patient. The foregoing shall in no way limit the ability of any person to contact a patient's prescribing practitioner to warn of a contraindication, precaution or adverse reaction

B. No practitioner shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug where a purpose of the substitution is to assist the practitioner, or an employer of the practitioner, in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

C. No pharmacist shall sell or dispense a prescription drug to a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, if the pharmacist possesses actual knowledge that (i) a person solicited or encouraged the patient's prescribing practitioner to substitute the originally prescribed drug with any chemically dissimilar prescription drug, and (ii) that a purpose of the substitution is to assist such person or any employer of that person in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

D. No person shall solicit or encourage (i) a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, (ii) a caregiver of the patient, or (iii) a practitioner of the patient to request the patient's prescribing practitioner to substitute a prescription drug the prescribing practitioner originally prescribed with a chemically dissimilar prescription drug where a purpose of the substitution is to assist such person or an employer of that person in receiving a monetary incentive from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

§54.1-3483. Presumption of violation.

For purposes of this chapter, where a person or a person's employer receives a monetary incentive from a manufacturer of a prescription drug based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar, it shall be presumed to be a violation of this chapter.

§54.1-3484. Violators entitled to bring suit.

A. Any person entitled to bring an action pursuant to this chapter as set forth herein may do so regardless of whether that person has violated a provision of this chapter himself.

B. Any practitioner who violates any provision of this chapter shall pay for each violation a civil penalty of not more than ten dollars, plus attorney fees and costs. However, if a practitioner or his employer receives in violation of this chapter any monetary incentive from another person for his assistance in substituting a chemically dissimilar prescription drug for the prescription drug originally prescribed in violation of this chapter, each practitioner or employer shall pay a civil penalty of not more than $100, plus attorney fees and costs. Any person other than a practitioner who violates any provision of this chapter shall, for each violation, pay a civil penalty of not more than $5,000, plus attorney fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such person and shall be paid into the Literary Fund.

C. Notwithstanding any other provisions of law to the contrary, the attorney may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, the city, county, or town, the Virginia Board of Pharmacy, or the Virginia Board of Medicine, respectively, to enjoin any violation of this chapter, to impose civil penalties as prescribed herein and to recover reasonable attorney fees and costs. Any circuit court having jurisdiction is authorized to issue temporary and permanent injunctions to restrain and prevent violations of this chapter notwithstanding the existence of an adequate remedy at law. In any action under this chapter, it shall not be necessary that damages be proven.

§54.1-3485. Investigative orders.

A. Whenever the attorney has reasonable cause to believe that any person has engaged in, or is engaging in, or is about to engage in any violation of this chapter, the attorney, if after making a good faith effort to obtain such information, is unable to obtain the data and information necessary to determine whether such violation has occurred, or believes that it is impractical for him to do so, he may apply to the circuit court within whose jurisdiction the person having the information resides, the person has a principal place of business in the Commonwealth, or where any part of the alleged violation occurred in the Commonwealth, which includes without limitation, the jurisdiction of the practitioner's place of business, the jurisdiction in which the patient resides, and the jurisdiction in which the patient's caregiver resides, for an investigative order requiring such person to furnish to the attorney such data and information as is relevant to the subject matter of the investigation.

B. The circuit courts are empowered to issue investigative orders, authorizing discovery by the same methods and procedures as set forth for civil actions in the Rules of the Supreme Court of Virginia, in connection with investigations of violations of this chapter by the attorney. An application for an investigative order shall identify:

1. The specific act or practice alleged to be in violation of this chapter;

2. The grounds which shall demonstrate reasonable cause to believe that a violation of this chapter may have occurred, may be occurring, or may be about to occur;

3. The category or class of data or information requested in the investigative order; and

4. The reasons why the attorney is unable to obtain such data and information, or the reason why it is impractical to do so, without a court order.

C. Within twenty-one days after the service upon a person of an investigative order, or at any time before the return date specified in such order, whichever is later, such person may file a motion to modify or set aside such investigative order or to seek a protective order as provided by the Rules of th

Supreme Court of Virginia. Such motion shall specify the grounds for modifying or setting aside the order, and may be based upon the failure of the application or the order to comply with the requirements of this chapter, or upon any constitutional or other legal basis or privilege of such person.

D. Where the information requested by an investigative order may be derived or ascertained from the business records of the person upon whom the order is served, or from an examination, audit or inspection of such business records, or from a compilation, abstract or summary thereof, and the burden of deriving or ascertaining the information is substantially the same for the attorney as for the person from whom such information is requested, it shall be sufficient for that person to specify the records from which the requested information may be derived or ascertained, and to afford the attorney reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts or summaries thereof.

E. It shall be the duty of the attorney, his assistants, employees and agents, to maintain the secrecy of all evidence, documents, data and information obtained through the use of investigative orders or obtained as a result of the voluntary act of the person under investigations and it shall be unlawful for any person participating in such investigations to disclose to any other person not participating in such investigation any information so obtained. Any person violating this subsection shall be subject to a civil penalty not to exceed $25,000 and contempt of court. Notwithstanding the foregoing, this section shall not preclude the presentation and disclosure of any information obtained pursuant to this section in any suit or action in any court of this Commonwealth wherein it is alleged that a violation of this chapter has occurred, is occurring or may occur, nor shall this section prevent the disclosure of any such information by the attorney to any federal or state law-enforcement authority that has restrictions governing confidentiality and the use of such information similar to those contained in this subsection.

F. Upon the failure of a person without lawful excuse to obey an investigative order under this section, the attorney may initiate contempt proceedings in the circuit court that issued the order to hold such person in contempt.

G. No information, facts or data obtained through an investigative order shall be admissible in any civil or criminal proceedings other than for the enforcement of this chapter and the remedies provided herein.

§54.1-3486. Tolling of limitation.

When any of the authorized government agencies file suit under this chapter, the time during which such governmental suit and all appeals therefrom are pending shall not be counted as any part of the period within which a private cause of action under this chapter shall be brought.

§54.1-3487. Individual action for damages or penalty; statute of limitations.

A. If a person who is not a practitioner solicits or encourages a patient, a caregiver of the patient or a practitioner of the patient in violation of any provision of this chapter or if a person who is not a practitioner violates any other provision of this chapter, the patient shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter.

B. If any practitioner solicits or encourages a patient in violation of any provision of this chapter or if

any practitioner violates any other provision of this chapter, the patient shall be entitled to initiate an action against such practitioner to recover actual damages, if any, or liquidated damages of ten dollars per violation whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter; however, if the practitioner or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the patient may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

C. Any caregiver or practitioner who is solicited or encouraged in violation of any provision of this chapter by a person who is not a practitioner shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs.

D. Any caregiver or practitioner who is solicited or encouraged in violation of any provision of this chapter by a practitioner shall be entitled to initiate an action against such practitioner to recover actual damages, if any, or liquidated damages of ten dollars per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs; however, if the practitioner or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the caregiver or practitioner may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

E. Except as provided in §54.1-3486, any claim arising under this chapter shall be brought within two years of the wrongful act or discovery of the act, whichever is later.

Go to (General Assembly Home)

977858667

SENATE BILL NO. 1114
AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Education and Health
on January 30, 1997)
(Patron Prior to Substitute--Senator Hawkins)

A BILL to amend the Code of Virginia by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, relating to the Virginia Anti-Drug Switching Patient Protection Act; penalties.

Be it enacted by the General Assembly of Virginia:

1. That the Code of Virginia is amended by adding in Title 54.1 a chapter numbered 34.1, consisting of sections numbered 54.1-3480 through 54.1-3487, as follows:

CHAPTER 34.1.
VIRGINIA ANTI-DRUG SWITCHING PATIENT PROTECTION ACT.

§54.1-3480. Definitions.

As used in this chapter, unless the context requires a different meaning:

"Advertisement" means a representation disseminated in any manner or means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of a prescription drug. The term does not include any act prohibited by the chapter.

"Caregiver" means (i) a parent or guardian of a minor patient, (ii) a relative, close friend or employee of a patient who provides in-person physical assistance to the patient, or (iii) a person employed by another to care for a patient who provides in-person physical assistance to the patient.

"Chemically dissimilar" means a prescription drug which possesses one or more active ingredients that are different from those of another prescription drug.

"Deliver" means the actual, constructive, or attempted transfer of any item regulated by Chapter 34 of this title, whether or not there exists an agency relationship.

"Dispense" or "dispensing" means to deliver a prescription drug to a patient by or pursuant to the lawful order of a prescribing practitioner.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in an individual; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of an individual; or (iv) articles or substances intended for use as a component of any article specified in (i), (ii), or (iii). "Drug" does not include devices or their components, parts or accessories.

"Employer" means a person who provides monetary or other compensation to another person for goods or services, whether the one receiving monetary or other compensation is an employee, agent, partner,

independent contractor or other.

"Manufacture" means the production, preparation, propagation, conversion or processing of any item regulated by Chapter 34 of this title, either directly or indirectly by extraction from substances of natural origin, or independently by means or chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container.

"Manufacturer" means any person who manufactures and all agents of that person.

"Monetary incentive" means any rebate, discount, kick-back, fee, special charge or other financial incentive.

"Patient" means an ultimate consumer of a prescription drug who obtains the prescription drug from a licensed pharmacist or practitioner who is authorized by law to prescribe or dispense prescription drugs.

"Person" means any individual, corporation, partnership, association, company, business, trust, joint venture, governmental agency, or other institution or legal entity.

"Pharmacist" means a person duly licensed by the Virginia Board of Pharmacy to practice pharmacy or a person duly licensed by any other state or U.S. territory to practice pharmacy.

"Practitioner" means a person duly licensed by the Commonwealth or by any other state or U.S. territory as a physician, dentist, osteopath, podiatrist, nurse practitioner, TPA-certified optometrist, or physician's assistant.

"Prescribing practitioner" means a practitioner who (i) prescribes a prescription drug for a patient and (ii) is authorized by applicable law to prescribe or administer such drugs.

"Prescription drug" means any drug required by federal law of regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503 (b) of the Federal Food, Drug, and Cosmetic Act.

"Sells" or "selling" includes barter, exchange, transfer, or gift, or offer therefor.

§54.1-3481. Exceptions to applicability of chapter; no exemption from other provisions of title; advertisements.

A. The provisions of this chapter shall not apply to any prescription drug prescribed by a scientific investigator for purposes of research or prescribed by a veterinarian. Where the solicitation or encouragement prohibited herein is directed to a practitioner or pharmacist, this chapter shall only apply to a solicitation or encouragement where the practitioner or pharmacist has a bona fide practitioner-patient or pharmacist-patient relationship with a specific patient for whom a specific drug has been prescribed from which a substitution is sought.

B. This chapter shall not be construed as exempting any person from the requirements of Chapter 33 (§54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.) of this title.

C. The provisions of this chapter shall have no application to advertisements for prescription drugs.

D. The provisions of this chapter shall also not apply to: (i) the Department of Medical Assistance Services, (ii) any health care provider while rendering services pursuant to a provider agreement with the Department of Medical Assistance Services, and (iii) any program implemented by the Department of Medical Assistance Services through a contract with an insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical, and surgical or major medical coverage on an expense-incurred basis, any corporation providing individual or group accident and sickness subscription contracts, and any health maintenance organization providing a health care plan for health care services.

§54.1-3482. Unlawful actions.

A. No person shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug which the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug, unless the person is the patient, another practitioner or pharmacist, or a caregiver of the patient. The foregoing shall in no way limit the ability of any person to contact a patient's prescribing practitioner to warn of a contraindication, precaution or adverse reaction.

B. No practitioner or pharmacist shall solicit or encourage the prescribing practitioner of a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, to substitute a prescription drug the prescribing practitioner originally prescribed for the patient with any chemically dissimilar prescription drug where a purpose of the substitution is to assist the practitioner or pharmacist, or an employer of the practitioner or pharmacist, in receiving a monetary incentive directly or indirectly from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

C. No pharmacist shall sell or dispense a prescription drug to a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, if the pharmacist possesses actual knowledge that (i) a person solicited or encouraged the patient's prescribing practitioner to substitute the originally prescribed drug with any chemically dissimilar prescription drug, and (ii) that a purpose of the substitution is to assist such person or any employer of that person in receiving a monetary incentive directly or indirectly from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

D. No person shall solicit or encourage (i) a patient residing in the Commonwealth, while that patient is physically located in the Commonwealth, (ii) a caregiver of the patient, (iii) a pharmacist of the patient or (iv) a practitioner of the patient to request the patient's prescribing practitioner to substitute a prescription drug the prescribing practitioner originally prescribed with a chemically dissimilar prescription drug where a purpose of the substitution is to assist such person or an employer of that person in receiving a monetary incentive directly or indirectly from the manufacturer of the chemically dissimilar prescription drug which is based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar.

§54.1-3483. Presumption of violation.

For purposes of this chapter, where a person or a person's employer receives a monetary incentive from a manufacturer of a prescription drug based upon the substitution of that prescription drug in the place of another prescription drug which is chemically dissimilar, it shall be presumed to be a violation of this chapter.

§54.1-3484. Violators entitled to bring suit; civil penalties.

A. Any person entitled to bring an action pursuant to this chapter as set forth herein may do so regardless of whether that person has violated a provision of this chapter himself.

B. Any practitioner or pharmacist who violates any provision of this chapter shall pay for each violation a civil penalty of not more than ten dollars, plus attorney fees and costs. However, if a practitioner or his employer or pharmacist or his employer receives in violation of this chapter any monetary incentive from another person for his assistance in substituting a chemically dissimilar prescription drug for the prescription drug originally prescribed in violation of this chapter, the practitioner or pharmacist shall pay a civil penalty of not more than $100, plus attorney fees and costs. Any person other than a practitioner or pharmacist who violates any provision of this chapter shall, for each violation, pay a civil penalty of not more than $5,000, plus attorney fees and costs. The civil penalty shall be in addition to any other causes of action or remedies that may exist against such person and shall be paid into the Literary Fund.

C. Notwithstanding any other provisions of law to the contrary, the Attorney General or the attorney for any city, county or town may cause an action to be brought in the appropriate circuit court in the name of the Commonwealth, the city, county, or town, the Virginia Board of Pharmacy, or the Virginia Board of Medicine, respectively, to enjoin any violation of this chapter, to impose civil penalties as prescribed herein and to recover reasonable attorney fees and costs. Any circuit court having jurisdiction is authorized to issue temporary and permanent injunctions to restrain and prevent violations of this chapter notwithstanding the existence of an adequate remedy at law. In any action under this chapter, it shall not be necessary that damages be proven.

§54.1-3485. Investigative orders.

A. Whenever the Attorney General or the attorney for any city, county or town has reasonable cause to believe that any person has engaged in, or is engaging in, or is about to engage in any violation of this chapter, the attorney, if after making a good faith effort to obtain such information, is unable to obtain the data and information necessary to determine whether such violation has occurred, or believes that it is impractical for him to do so, he may apply to the circuit court within whose jurisdiction the person having the information resides, the person has a principal place of business in the Commonwealth, or where any part of the alleged violation occurred in the Commonwealth, which includes without limitation, the jurisdiction of the practitioner's or pharmcist's place of business, the jurisdiction in which the patient resides, and the jurisdiction in which the patient's caregiver resides, for an investigative order requiring such person to furnish to the attorney such data and information as is relevant to the subject matter of the investigation.

B. The circuit courts are empowered to issue investigative orders, authorizing discovery by the same methods and procedures as set forth for civil actions in the Rules of the Supreme Court of Virginia, in connection with investigations of violations of this chapter by the Attorney General or the attorney for any city, county or town. An application for an investigative order shall identify:

1. The specific act or practice alleged to be in violation of this chapter;

2. The grounds which shall demonstrate reasonable cause to believe that a violation of this chapter may have occurred, may be occurring, or may be about to occur;

3. The category or class of data or information requested in the investigative order; and

4. The reasons why the Attorney General or the attorney for any city, county or town is unable to obtain such data and information, or the reason why it is impractical to do so, without a court order.

C. Within twenty-one days after the service upon a person of an investigative order, or at any time before the return date specified in such order, whichever is later, such person may file a motion to modify or set aside such investigative order or to seek a protective order as provided by the Rules of the Supreme Court of Virginia. Such motion shall specify the grounds for modifying or setting aside the order, and may be based upon the failure of the application or the order to comply with the requirements of this chapter, or upon any constitutional or other legal basis or privilege of such person.

D. Where the information requested by an investigative order may be derived or ascertained from the business records of the person upon whom the order is served, or from an examination, audit or inspection of such business records, or from a compilation, abstract or summary thereof, and the burden of deriving or ascertaining the information is substantially the same for the Attorney General or the attorney for any city, county, or town as for the person from whom such information is requested, it shall be sufficient for that person to specify the records from which the requested information may be derived or ascertained, and to afford the Attorney General or the attorney for any city, county, or town reasonable opportunity to examine, audit or inspect such records and to make copies, compilations, abstracts or summaries thereof.

E. It shall be the duty of the Attorney General or the attorney for any city, county or town, his assistants, employees and agents, to maintain the secrecy of all evidence, documents, data and information obtained through the use of investigative orders or obtained as a result of the voluntary act of the person under investigations and it shall be unlawful for any person participating in such investigations to disclose to any other person not participating in such investigation any information so obtained. Any person violating this subsection shall be subject to a civil penalty not to exceed $25,000 and contempt of court. Notwithstanding the foregoing, this section shall not preclude the presentation and disclosure of any information obtained pursuant to this section in any suit or action in any court of this Commonwealth wherein it is alleged that a violation of this chapter has occurred, is occurring or may occur, nor shall this section prevent the disclosure of any such information by the Attorney General or the attorney for any city, county or town to any federal or state law-enforcement authority that has restrictions governing confidentiality and the use of such information similar to those contained in this subsection.

F. Upon the failure of a person without lawful excuse to obey an investigative order under this section, the Attorney General or the attorney for any city, county or town may initiate contempt proceedings in the circuit court that issued the order to hold such person in contempt.

G. No information, facts or data obtained through an investigative order shall be admissible in any civil or criminal proceedings other than for the enforcement of this chapter and the remedies provided herein.

§54.1-3486. Tolling of limitation.

When any of the authorized government agencies file suit under this chapter, the time during which such governmental suit and all appeals therefrom are pending shall not be counted as any part of the period within which a private cause of action under this chapter shall be brought.

§54.1-3487. Individual action for damages or penalty; statute of limitations.

A. If a person who is not a practitioner or pharmacist solicits or encourages a patient, a caregiver of the patient, a practitioner of the patient, or pharmacist of the patient, in violation of any provision of this chapter or if a person who is not a practitioner or pharmacist violates any other provision of this chapter, the patient shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter.

B. If any practitioner or pharmacist solicits or encourages a patient in violation of any provision of this chapter or if any practitioner or pharmacist violates any other provision of this chapter, the patient shall be entitled to initiate an action against such practitioner or pharmacist to recover actual damages, if any, or liquidated damages of ten dollars per violation whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs expended in pursuit of the matter; however, if the practitioner or his employer or the pharmacist or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the patient may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

C. Any caregiver, practitioner or pharmacist who is solicited or encouraged in violation of any provision of this chapter by a person who is not a practitioner or pharmacist shall be entitled to initiate an action against such person to recover actual damages, if any, or liquidated damages of $5,000 per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs.

D. Any caregiver, practitioner or pharmacist who is solicited or encouraged in violation of any provision of this chapter by a practitioner or pharmacist shall be entitled to initiate an action against such practitioner or pharmacist to recover actual damages, if any, or liquidated damages of ten dollars per violation, whichever is greater, to enjoin the person from continuing such activities in the Commonwealth, and to recover reasonable attorney fees and costs; however, if the practitioner or his employer or the pharmacist or his employer receives any monetary incentive from another person for his assistance in committing an act that is in violation of this chapter, the caregiver, practitioner or pharmacist may recover actual damages or liquidated damages of $100 per violation, in lieu of the ten dollars liquidated damages provision, whichever is greater, in addition to injunctive relief, reasonable attorney fees and costs.

E. Except as provided in §54.1-3486, any claim arising under this chapter shall be brought within two years of the wrongful act or discovery of the act, whichever is later.

APPENDIX B

TASK FORCE MEETING AGENDAS

HJR 630 SPECIAL TASK FORCE

Initial Meeting

Thursday, June 19, 1997
House Room D

9:30 - 11:30 a.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Introductions and Statement of Purpose ..... **Mr. Joseph M. Teefey**

Task Force Operations ..... **Dr. Michael A. Pyles**
Task Force Facilitator

- **Membership Roster**
- **Meeting Schedule**

Presentations on Therapeutic Substitution (30 minutes each)

Mr. Kenneth D. McArthur, Jr.
Associate
Durrette, Irvin, Bradshaw, PC
Richmond, Virginia

Mr. Stephen D. Rosenthal
Partner
Mays & Valentine
Richmond, Virginia

Discussion ..... **Task Force Members**

Adjournment

HJR 630 SPECIAL TASK FORCE

Second Meeting

Wednesday, July 16, 1997
House Room D

8:30 a.m. - 12:30 p.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Public Comments ..... **Mr. Joseph M. Teefey**

Overview of Virginia Medicaid Pharmacy Program ..... **Mr. David Shepherd, R.Ph.**
DMAS Pharmacy Supervisor

Overview of Drug Utilization ..... **Carol Pugh, Pharm.D.**
Assoc. Prof., VCU School of Pharmacy

BREAK

Summary of Literature ..... **Mr. Michael Worthington**
DMAS Lead Management Analyst

Comments on Availability of Empirical Data on Drug Switching ..... **Norman Carroll, Ph.D.**
Professor, VCU School of Pharmacy

Review of Materials Sent to Task Force ..... **Mr. Kenneth McArthur, Esq.**
Durrette, Irvin, Bradshaw, PC

Mr. Stephen Rosenthal, Esq.
Mays & Valentine

Discussion of Drug Switching ..... **Mr. Michael Worthington**

Development of Task Force Consensus Statement on Drug Switching ..... **Dr. Michael A. Pyles**
Task Force Facilitator

Adjournment

HJR 630 SPECIAL TASK FORCE

Third Meeting

Wednesday, August 20, 1997
House Room D

8:30 a.m. - 12:30 p.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Review of Materials & Update ..... **Dr. Michael A. Pyles**
Task Force Facilitator

Public Comments ..... **Mr. Joseph M. Teefey**

Responses to Questions Raised
in July 16th Meeting ..... **Mr. Michael Worthington**
Lead Agency Management Analyst
Department of Medical Assistance Services

Mr. Howard Casway
Assistant Attorney General
Commonwealth of Virginia

Ms. Scotti Russell
Executive Director
Virginia Board of Pharmacy

Discussion and Adoption of
Consensus Statement ..... **Dr. Michael A. Pyles**

Initial Discussion of Outline for Task Force
Report and Recommendations ..... **Mr. Joseph M. Teefey**

Adjournment

HJR 630 SPECIAL TASK FORCE

Fourth Meeting

Wednesday, September 17, 1997
House Room C

8:30 a.m. - 12:30 p.m.

AGENDA

Call to Order ..... **Mr. Joseph M. Teefey**
Task Force Chair

Public Comments ..... **Mr. Joseph M. Teefey**

Policy Options from the Virginia Board of Pharmacy ..... **Ms. Scotti Russell**
Executive Director
Virginia Board of Pharmacy

Discussion to Reach Consensus on Recommendations and Report to General Assembly ..... **Mr. Michael Worthington**
Lead Agency Management Analyst
Department of Medical Assistance Services

Dr. Michael A. Pyles
Task Force Facilitator

Further Business Before Task Force ..... **Mr. Joseph M. Teefey**

Adjournment

APPENDIX C

TRANSCRIPTS OF MEETINGS

1 VIRGINIA:

2 DEPARTMENT OF MEDICAL ASSISTANCE

3

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5 IN RE: HJR 630 SPECIAL TASK FORCE

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8 Meeting of the Special Task Force held on

9 June 19, 1997, General Assembly Building, House Room D,

10 at 9:30 a.m.

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22 CRANE-SNEAD & ASSOCIATES, INC.
4914 Fitzhugh Avenue
23 Richmond, Virginia 23230
(804) 355-4335

24

25 ORIGINAL

1 DR. PYLES: We're going to go
2 ahead and get started. It's 9:30 and we have a
3 business agenda. To start off with I would like
4 for the people on the Task Force to introduce
5 themselves.
6 SPEAKER: I'm Dr. Karen Knapp
7 from the Board of Medicine.
8 SPEAKER: I'm Dr. Doug Hadley.
9 I am the Medical Director for Signa Health Care
10 of Virginia.
11 SPEAKER: Marjorie Powell from
12 the Pharmaceutical Research and Manufacturers of
13 America.
14 SPEAKER: I'm Joe Teefey and I
15 am the Director of the Medicaid program.
16 SPEAKER: I'm Mark Swenski.
17 I'm President of Virginia Society of Health
18 Systems.
19 SPEAKER: Cindy Pigg and I
20 work for Signa Health Care, but I'm here
21 representing the Academy of Managed Care
22 Pharmaceuticals.
23 SPEAKER: I'm Larry Blanchard.
24 I'm a practicing dermatologist. I'm here
25 representing providers.

1 SPEAKER: Jim Counsel. I'm
2 the general counsel for First Health Services in
3 Richmond. I'm here on behalf of Pharmaceutical
4 Care Management Association.
5 MR. TEEFEY: I have three
6 people that will help staff this: David
7 Sheppard, who is the pharmacist for the
8 Department will be one the staff members. I have
9 Mike Worthington, who is in the policy division
10 at Medicaid will be working with us, and Dr. Mike
11 Pyles.
12 We've contacted with the
13 Pharmacy School. We have 29 studies to do this
14 summer. We don't have quite enough people to do
15 them. So I contracted some of the studies out.
16 And the four studies dealing with pharmacy, we
17 will use the Pharmacy School at MCV. Mike will
18 be facilitator for the group here. And you'll
19 hear from all those people a little bit later.
20 I just want to make some
21 general remarks before we get started. The
22 reason we're here is because there were two
23 bills--House Bill 2714 and Senate Bill 1114--that
24 were introduced during the Session. They were
25 talking about the Virginia Anti-Drug Switching

1 Patient Protection Act.

2 During the arguments--and I

3 know it was a rather discussed subject during the

4 General Assembly--there were three main things

5 that came out of it.

6 The first one, I think I'll

7 refer to Dr. Blanchard and one of the arguments

8 he used about physicians' concerned about being

9 away and being in another environment, being in

10 another place when you have a call for

11 anti-switching. And I think he expressed himself

12 extremely well. So that's one of the concerns we

13 had.

14 The other concern was the

15 discounts and rebates to the pharmacies. There

16 was some discussion how that would be handled. I

17 think there was a lot of confusion on that.

18 The last thing was basically

19 the effect of the formulary. I tried to sit

20 through as many of the meetings and discussions

21 as possible. I think it got to be such a

22 discussed area that the House and the Senate both

23 felt a need to study it further. That's why

24 HJR-630 came about and that's the reason we're

25 here today.

1 We've got to define what the
2 similar therapeutic class drugs are, the affects
3 and the effect it will have on the deliberate
4 health care. We have to find out the impact it
5 will have on D-Mass with our rebate, probe and
6 retro-DUR programs and the limited
7 pre-authorization we do.
8 We have a big task in front of
9 us. I'm going to get Mike to review the
10 Legislation with you and talk about coming up to
11 some type of statement as far as the Committee is
12 concerned.
13 DR. PYLES: Good morning.
14 First of all, I'd like to just go through a few
15 quick housekeeping things if I could. Many of
16 you I did fax or Federal Express to you about two
17 days ago to you a form. I didn't have some
18 information that I think we'll be needing from
19 you. Before the end of day if you did not get
20 the form to me or never received it, please see
21 me before you leave so I can compile the official
22 roster of members for this Task Force.
23 Next, you should see a blue
24 page up there that has our meeting schedule. Let
25 me say that we're working with a very short

1 period of time as you know. We have basically
2 only about three months of work here.
3 We initially scheduled these
4 meetings for two hours. I've spoken to
5 Mr. Teefey and at this time we need to talk a
6 little bit about the future meetings. The
7 Thursday, August 14th meeting, if you would note,
8 we're going to change that to the following
9 Wednesday, which will be August 20th, instead of
10 August 14th. The other meetings I think are okay
11 as they are.
12 The future meetings at this
13 point are going to be in the Library of Virginia.
14 This one was originally put in the Register to be
15 there but it was confirmed at this room. We will
16 give you the exact locations of those future
17 meetings.
18 Mr. Teefey, I think at this
19 time it might be wise for us to talk about with
20 the work had ahead of us-- Maybe before we do
21 that, let me give you an outline of some of the
22 things that we have to accomplish.
23 What the Legislation has asked
24 this Task Force to do is to study is the practice
25 of therapeutic substitution and come up with a

1 statement about the extent to which it is going
2 on presently and also to assess it's impact on
3 various interested parties including the
4 pharmacists, prescribers as well as the patient,
5 to look at the cost associated with the practice
6 itself. So the work ahead of the Task Force is
7 quite ambitious for the time that we have. And I
8 really don't think that two-hour meetings will
9 suffice.
10 What I'm proposing is that we
11 think about longer meetings on the days that have
12 been indicated there. Perhaps maybe at least
13 three--at least four- to five-hour meetings
14 depending on what the Task Force wishes to
15 accomplish in each meeting.
16 Today's meeting is going to be
17 relatively straightforward. Following this brief
18 introductory period, we will hear from two
19 persons today. We will hear from Mr. Kenneth
20 McArthur, who is with Durrette, Irvin, Bradshaw.
21 We will also hear from Mr. Steven Rosenthal, who
22 is with Mays & Valentine. What we will do is
23 hear from them and plan our future meetings and
24 come up with an agenda for the next meeting.
25 I thought it would be

1 important for us to at least begin by getting a
2 grip on what we mean my therapeutic substitution.
3 It is used in various ways in the literature and
4 everyday language. I think that one of the
5 things we need to do is at least establish what
6 we mean by it, particularly the part dealing with
7 chemically dissimilar drug products and changing
8 classes. That's what we need to accomplish.
9 My proposal is that, for
10 instance, looking at the July 16th meeting, I
11 think a 9:30 start time is good, but I think we
12 need to go beyond 11:30, which will give us
13 enough time to discuss the issues more
14 thoroughly.
15 If we decide to bring in other
16 speakers or whatever, it will give us a chance to
17 hear them and have a chance to discuss among
18 ourselves what it is we would like to go on
19 record.
20 Our products at the end of
21 this whole process--what the Legislation asks for
22 is actually a document that will talk about, one,
23 the impact of the practice. And that is a
24 statement or what have you--whatever the Task
25 Force deems would be an appropriate way to do

1 that.

2 Then also we need to identify

3 what the components of the cost of the practice

4 are. To do that I suspect it means we would need

5 to have some idea, for instance, what it costs

6 the pharmacists, who often in terms of time is

7 the one there making phone calls, what have you.

8 They've also asked us to draft

9 legislation or what have you related to this

10 practice that could come before the General

11 Assembly in the next session for review.

12 As we get further along in the

13 process that will also be up to us with the help

14 of Division of Legislative Services to come up

15 with some draft legislation. That pretty much is

16 what we have before us.

17 My proposal, Mr. Teefey, is

18 that we might look at meeting from about 9:30 to

19 1:30 for the next meeting at least.

20 MR. TEEFEY: Okay.

21 MS. KNAPP: Is it

22 inappropriate to ask if we start earlier.

23 MR. TEEFEY: Is anybody coming

24 in from out of town? I think Ms. Powell is.

25 MS. POWELL: But I can be here

1 earlier.

2 MR. TEEFEY: That would be

3 great. We could start earlier.

4 DR. PYLES: What's a good

5 time?

6 MR. TEEFEY: 8:30.

7 DR. PYLES: At least for a

8 meeting, we can get in there any time.

9 SPEAKER: This room is

10 available and so is House Room 4.

11 DR. PYLES: I don't have any

12 preference. Do you, Mr. Teefey?

13 MR. TEEFEY: Either one would

14 be okay. Let's see which one would be the

15 easiest to get.

16 DR. PYLES: Was this building

17 pretty accessible to everyone?

18 TASK FORCE MEMBERS: Yes.

19 DR. PYLES: So we could look

20 at the future meetings being held in House Room

21 D.

22 MR. TEEFEY: Then we could

23 change the starting time to 8:30 in the morning.

24 DR. PYLES: The starting time

25 will be 8:30 at future meetings and continue to

1 meet in House Room D unless there is a problem
2 with availability. If that is the case, I will
3 let you know.
4 8:30 until what time?
5 MR. TEEFEY: Let's say 12:00,
6 12:30.
7 DR. PYLES: All right. Let's
8 go ahead then and say for the future meetings;
9 July 16th, August 20th and September 17th we will
10 begin at 8:30 in this room and go until 12:30.
11 And if something changes, I'll get back with you.
12 One last little piece: What
13 I'm going to try to do to expedite our meetings
14 is get information to you in a timely manner so
15 that if there are documents you've asked for, et
16 cetera-- The reason I Federal Expressed you that
17 form is so that I can get things to you either
18 E-mail-- We will use E-mail but also use
19 overnight delivery when that's necessary to
20 expedite things. That's why I need that
21 information from you. I think that's all in
22 terms of housekeeping details.
23 At this time, Mr. Teefey, if
24 it's okay with you, the first speaker we have for
25 this morning is Mr. Kenneth McArthur from

1 Durrette, Irvin and Bradshaw.

2 MR. TEEFEY: Before Kenneth

3 gets started-- This is a real important subject

4 and we have people in the audience-- After we

5 have the two presentations if anybody wants to

6 give--to be fair to the Task Force, if anybody

7 wants to give any type of two-minute statement,

8 we'll let you do that.

9 We just feel that this is an

10 important subject, and I want the Task Force to

11 have the benefit of any opinions that come out of

12 the audience.

13 MR. MCARTHUR: Good morning.

14 As Dr. Pyles said I'm Ken McArthur and I'm with

15 the Richmond based law firm of Durrette, Irvin

16 and Bradshaw.

17 The reason I'm here today, I

18 think, is because I was one of the drafters of

19 the Bill which was introduce dollars last year

20 which sought to outlaw the practice of switching

21 chemically dissimilar drugs where a monetary

22 incentive is present. That is a gross

23 oversimplification of the Bill but because of

24 time and that bill is not currently in front of

25 us I'm got not going to waste your time and waste

1 the limited amount of time I have here to present
2 our perspective on this issue to you by going
3 through the Bill from last year line by line.
4 Let me say at the outset that
5 I am not going to try to make every single
6 argument that I think could be made to criticize
7 the practice of switching chemically dissimilar
8 drugs for money. I don't think I have time in 30
9 minutes to do that, nor do I think that I need to
10 do that because I think most of the people who
11 are present here today already know them.
12 I'm also not going to try to
13 set forth specific terms of any Bill for next
14 year and suggest any language of any Bill that
15 would outlaw such practices. Again, because of
16 concerns with time and because I think that the
17 purpose of this Task Force is to work through
18 this issue and come up with language of such a
19 Bill and that's not my job.
20 So what I am going to do is
21 raise, what I hope, are some issues which I think
22 are critical for this Task Force to address. And
23 if they are not addressed, in my opinion and in
24 my humble opinion, this Task Force will not have
25 done its job.

1 Before I get into those issues
2 what I would like to do-- And I apologize to
3 those of you who are more knowledgeable perhaps
4 of some of the terms used in the health careen
5 industry even than I am. I have to modestly say
6 I have spent approximately 7,000 hours of my life
7 now over the past three years studying the
8 pharmaceutical industry. In fact, spending a
9 substantial majority of that time focussing on
10 this very issue which is before this Task Force.
11 Even though many of you
12 already know what many of these terms mean, just
13 to clarify for my purposes of raising this issue,
14 I would like to good ahead and define these terms
15 as I'm going to use them. I'm not going to try
16 to convince everybody that we should reach a
17 consensus on the definition of these terms. I
18 just want to define them so everybody knows what
19 I'm talking about when I raise these issues.
20 The first definition that I
21 would like to give is one of generic
22 substitution. My definition of generic
23 substitution is switching from a chemically
24 similar drug--from one drug to a chemically
25 similar drug. When I use the term chemically

1 similar, I'm using the language that I believe is
2 used by the Food and Drug Administration and is
3 reflected in its annual publication, which is
4 supplemented from time to time throughout the
5 year, which is known throughout the industry as
6 the Orange Book.
7 When the active ingredients in
8 a prescription drug are the same--there may be
9 one or more active ingredients--then the switch
10 from one drug to that other drug where the active
11 ingredients are the same is, in my definition, a
12 generic substitution.
13 It doesn't necessarily have to
14 be from a brand name drug to a generic drug. It
15 could be from a generic drug to a branded generic
16 by another manufacturer. It could be from a
17 branded generic to another branded generic from
18 another manufacturer. There are several
19 permitations but the thought is the same.
20 Generic substitution for purposes of my issues
21 that I'm going to raise today is switching among
22 chemically similar drugs.
23 In the industry there is some
24 confusion, I think, at last there appears to be
25 among people, of what the definition of

1 therapeutic substitution is. My definition of
2 that for purposes of raising issues today is
3 switching from one drug to another drug and for
4 purposes of my discussion today, will be a
5 chemically dissimilar drug, which simply means
6 that one are or more active ingredient are
7 different in the switched to drug from the
8 original drug.
9 The switching, however, is
10 done without consulting the prescriber on each
11 individual switch. There may be some protocol
12 whereby the prescriber, group of prescribers has
13 given advance permission, if you will, are or
14 authorization to certain individuals, usually
15 pharmacists, to make switches from one drug to a
16 chemically dissimilar drug.
17 Therapeutic interchange,
18 however, is something a little different.
19 Therapeutic interchange is switching among
20 chemically dissimilar drugs. So its like
21 therapeutic substitution in that sense. However,
22 in therapeutic interchange the prescriber is
23 consulted. There is a telephone call or some
24 other contact with the prescriber and the person
25 who is seeking the switch--seeking the solicitor

1 to encourage the switch asks the prescriber to
2 rewrite a brand new prescription for a chemically
3 dissimilar drug.
4 It is my understanding that in
5 the hospital in-patient setting the kind of drug
6 switching that goes on when there is drug
7 switching is therapeutic substitution. In the
8 ambulatory setting, which is virtually everywhere
9 else, if not everywhere else outside the
10 in-patient hospital setting, we're talking about
11 therapeutic interchange. Because it is unlawful
12 in those ambulatory settings to switch a
13 patient's drug to a chemically dissimilar drug
14 without consulting with the prescriber and having
15 a brand new prescription written for the drug.
16 Now, having clarified that,
17 let me say when I talk about the drug switching,
18 when I raise some issues with the Task Force over
19 the next couple of minutes, what I'm talking
20 about is therapeutic interchange.
21 The first point that I would
22 like to make--it really is not just a point.
23 It's eight points and a request of the Task
24 Force. The point is that I am concerned that I
25 have never seen any studies published anywhere

1 that show me that someone has conducted clinical
2 scientifically-based peer-reviewed research on
3 what risks are involved in switching from one
4 drug to a chemically dissimilar drug. I just
5 haven't seen any published studies.
6 Now, I have made an effort and
7 I have a network of co-counsel, and clients
8 around the country, and we have all made an
9 effort to seek out this information. So far, I
10 haven't found any studies that have been
11 published that fit that description that assess
12 the risk of switching from any drug to any
13 chemically dissimilar drug.
14 However, what I have seen and
15 what I think every member of this Task Force
16 would agree to is that health care providers seem
17 to me at least to agree throughout the industry
18 that there is a risk involved when you switch
19 from one drug to another drug.
20 There is a risk involved to
21 the patient's health. By the way, that risk
22 includes even when you are making a generic
23 substitution. You are switching among chemically
24 similar products. And I think certain state
25 legislatures have had the wisdom to recognize

1 that even chemically similar switching can be
2 dangerous and involves a risk, particularly when
3 it involves a class of drugs that is commonly
4 called the narrow therapeutic index drugs.
5 Despite the existence of this
6 risk and agreement among all health care
7 providers with whom I've ever spoken or
8 publications that I have ever read that there is
9 a risk involved, I have seen no risk assessment
10 studies. That's my point.
11 My question is: The Task
12 Force needs to ask whether such studies exist.
13 If they exist, they need to be produced so that
14 the Task Force can critique these and analyze
15 them and determine whether they're scientifically
16 based and whether they're valid and should be
17 considered in whatever the initiative the Task
18 Force may want to adopt.
19 The second point I would like
20 to make is that I have heard asserted by a lot
21 of--and I'm not going to pick on any particular
22 company or any particular individual, but I have
23 heard asserted and read in statements which have
24 been created by a lot of different people and
25 entities that there is a public policy reason

1 underlying switching chemically dissimilar drugs.
2 That public policy reason is that it is a managed
3 care cost containment tool. It is a way to
4 enforce a restricted drug formulary. It is a way
5 to affect cost savings for a plant and that is
6 desirable to third party plan sponsors, whether
7 they be government entities or private entities
8 or individuals.
9 I would like to make the point
10 and again make a request that I'd like to make
11 the point that I have never seen a published
12 scientifically peer-reviewed study anywhere in
13 the United States that shows that there is any
14 cost savings to any plan resulting from
15 chemically dissimilar switching of prescription
16 drugs. I have heard a lot of claims. I have
17 heard a lot of statements, but I have never seen
18 any evidence.
19 So my request is that if there
20 is such evidence, the Task Force should request
21 it and whoever has it should bring it forward and
22 it should be properly considered as part of
23 putting together any kind of initiative the Task
24 Force may choose to put together.
25 My third point, which is

1 somewhat related to the second point--I guess all
2 three points are related--is that I have also
3 seen in the marketplace a lot of studies and a
4 lot of articles published in scientific
5 publications that conclude that switching
6 chemically dissimilar drugs on patients, in fact,
7 increases overall health care costs.
8 Just to explain, although I
9 don't think it's necessary among this group, but
10 just for record to explain what I mean by that:
11 Health care costs are typically looked at in
12 components. There's a cost component analysis
13 approach to looking at the cost of health care.
14 There would be a drug component, how much you
15 spend on prescription drugs. There might be an
16 emergency room visit component. There might be a
17 doctor's visit component, a hospital stay
18 component. It doesn't matter how you cut it up.
19 There are different types of components of costs
20 within any given health care plan.
21 The Overwhelming majority--in
22 fact, not just the overwhelming majority, but all
23 of the studies published in scientific literature
24 that have read indicates that when you engage in
25 the switching of chemically dissimilar drugs, you

1 increase the cost in other components of the
2 health care plan.
3 To illustrate: A patient is
4 titrated on a particular blood pressure
5 medication. It's working well for the patient.
6 The patient is in a private health care plan.
7 The patient goes to the patient's physician and
8 sees the physician. The physician writes a
9 refill or an original prescription for a blood
10 pressure medication for this patient. The
11 patient goes into the patient's pharmacy.
12 The patient discovers from the
13 pharmacist that the pharmacist has received when
14 the pharmacist has submitted a claim across his
15 on-line claims adjudication system he or she
16 received a message from that plan--from that
17 insurance plan that this particular drug is not
18 going to be covered by that plan or that that
19 drug is not preferred by that plan. And
20 therefore, that pharmacist should talk to the
21 patient perhaps, talk to the doctor perhaps and
22 persuade the physician or original prescriber to
23 rewrite a new prescription for a chemically
24 dissimilar drug.
25 When that happens, the patient

1 may have to be retitrated on the new drug, which
2 may require additional visits to the doctor that
3 otherwise would not have been required had the
4 patient's drug not been switched.
5 In such a case, the five or
6 six additional doctor's visits that may go along
7 with retitrating that patient will cost enough
8 money that even if there were a cost savings
9 produced by switching the drug in the drug
10 component, it would be more than offset by the
11 additional cost of going to see the physician
12 that many times. That is a simple what I
13 consider relatively benign example.
14 There is a risk to the
15 patient. There is an additional increase in cost
16 to other health care components, but it may or
17 may not be life threatening. One of the reasons
18 we are so concerned about this issue is because
19 this is not the only kind of example that we have
20 seen in the Commonwealth of Virginia. There are
21 many, many examples that we have seen that are
22 life-threatening examples.
23 I would like to point out that
24 any statements that I make today I'm going to
25 produce--and I'm going to state this on the

1 record, I'm going to produce all the evidence
2 that I have alluded to to support the statements
3 that I make. I didn't bring it with me today but
4 I will be happy to submit it to the Task Force
5 before its next meeting.
6 We would urge the Task Force
7 to demand accountability from those entities
8 which are engaged in the practice of switching
9 chemically dissimilar drugs. We would ask the
10 Task Force to ask those engaged in this practice
11 or wish to be engaged in this practice, and
12 therefore oppose any legislative initiative which
13 would outlaw it to produce the evidence to
14 support their position.
15 We believe that the burden of
16 proof falls squarely on those who wish to engage
17 in the practice. There is a consensus among the
18 health care--among the people in the health care
19 community that this practice is risky. We don't
20 know how risky it is and don't have any evidence
21 that it is saving anybody any money, so there's
22 not even any public policy reason for it.
23 Therefore, we ask that those
24 would seek to engage in the practice the burden
25 of proof be placed on them to justify why they

1 should be allowed to engage that the practice.
2 And should they fail to meet their burden of
3 proof or should those who oppose the practice
4 sufficiently rebut the evidence they put forward
5 that this practice be outlaw until such time as
6 someone, if ever, can figure out a way to engage
7 in this practice that is safe and has some
8 benefit to society.
9 Before I end I want to address
10 a couple of points that I think need to be
11 addressed here in the outset while we're framing
12 this issue. I heard a lot of criticism of the
13 Bill that was introduced last year. I would like
14 to just very quickly go through and address some
15 of those criticisms.
16 One of the criticisms that I
17 heard was that we don't need to legislate this
18 problem because the private market place will
19 take care of it. I would like to address that
20 argument.
21 First of all, I'm not sure
22 that the private market place can address this
23 problem. What we have found is that third-party
24 plan sponsors are largely uninformed about this
25 issue. We actually went around and talked to

1 some employee benefits managers and some of the
2 Fortune 500 hundred companies here in Richmond.
3 When we started talking about the switching of
4 chemically dissimilar drugs and entities like
5 PBMs and that sort of thing, we were met with
6 glazed eyes and responses and questions like
7 what's a PBM.
8 In a study that was performed
9 a little over a year ago, six of the nation's
10 largest HMOs on condition of anonymity gave a
11 team of research scientists access to their
12 confidential proprietary competitively sensitive
13 documents and allowed them to have at it and
14 attempt to lay to rest criticisms of restrictive
15 drug formularies and any practice associated with
16 those including prescription drug switching.
17 I have talked to the person
18 who led that team, Dr. Susan Horn. She informed
19 me that when she began that study she was a big
20 believer in things like prescription drug
21 switching programs. But that after conducting
22 that study she became a convert and decided that
23 prescription drug switching was not a good idea.
24 And she informed the six HMOs of this after she
25 produced to them results from that study which

1 indicated that the more these kind of programs
2 were used, the higher the overall health care
3 cost in their health care plans.
4 She has informed me that as a
5 result of that study those 6 HMOs at least have
6 actually taken steps toward stopping some of
7 these practices.
8 The second criticism that I
9 heard most often was that this Bill was going to
10 negatively impact pharmaceutical care. Now I
11 find that very interesting because I think what
12 we have is a problem here again on definitions.
13 I think that most managed care
14 organizations define pharmaceutical care as
15 pharmacists engaging in prescription drug
16 switching programs. The managed care
17 organization enters into contracts with drug
18 manufacturers pursuant to which they get paid
19 money to attempt to affect what prescriptions get
20 prescribed for their plan participants. And to
21 the extent that a pharmacist is valued as a tool
22 in for in that process they might be paid to do
23 it.
24 That's my understanding of
25 many managed care entities definition of

1 pharmaceutical care, cognitive services, disease
2 state management and the like.
3 My clients, who are mostly
4 community pharmacists, define pharmaceutical care
5 in a very different way. They define
6 pharmaceutical care as an educated, trained,
7 experienced, licensed pharmacist making decisions
8 which in his or her professional judgment on a
9 patient-by-patient basis, that are in best
10 overall short and long term interest of that
11 patient. And hopefully when the information is
12 available to them in the market place, decisions
13 which will be cost effective for the plan.
14 I think that the dispute over
15 how to define pharmaceutical care is one that
16 should be addressed by this Task Force, as well
17 as the other points I've already mentioned.
18 A third criticism that I heard
19 about this Bill was that if this Bill were
20 enacted in law, it would cause health care costs
21 to rise. Together with that was the statement
22 that it would do away with drug formularies and
23 that those were supposed to somehow be linked to
24 each other.
25 Now, I've already made the

1 statement earlier so I won't repeat myself that I
2 have not seen any evidence that any cost results,
3 either in the drug component or in the overall
4 health care plan from drug switching practices.
5 So I'm not sure exactly what the statement that
6 this is going to increase costs means.
7 In fact, I've seen ample
8 evidence that it will decrease cost in the
9 overall health care plan. So in my view, passing
10 the Bill would decrease costs, not increase
11 costs.
12 Again, if there are those that
13 have information that is contrary to my belief, I
14 would encourage them to present it to the Task
15 Force and as Jerry McGuire says, "Show us the
16 money." Let's see it. Because I think it's
17 important that the Task Force members understand
18 that there is a flow of money from drug
19 manufacturers to managed care organizations of
20 all kinds.
21 But that flow of money needs
22 to be differentiated. It needs to be broken out
23 so that everyone understands that some of that
24 money has to do with generic substitution. Some
25 of that money has to do with certain educational

1 things that the managed care organization might
2 do. Some of that money has to do with other
3 things the managed care organization might do.
4 I think if anybody is going to
5 make a claim that this Bill is going to increase
6 the health care cost, they need to show to what
7 extent and how much.
8 The last point I would like to
9 make is that I hope that the Task Force members
10 will keep in mind as they go through this process
11 that the most important consideration that should
12 be made here is what kind of impact do these
13 practices have on patients in the Commonwealth of
14 Virginia. What does this do to Virginians? Are
15 we being penny wise and pound foolish? In this
16 process let's not forget that the patients are
17 the most important.
18 I hope also that as the Task
19 Force goes forward that the Task Force will be
20 sure to remember to look at hard evidence in
21 making its decisions. I don't expect to make any
22 more statements in front of the Task Force unless
23 I'm called upon to do so.
24 I hope that the Task Force
25 will not waste its time by listening to a lot of

1 statements from a lot of different people who
2 have opinions on the subject.
3 I hope instead what they will
4 do is look at the hard evidence that is produced
5 by all interested parties and make an informed
6 decision on that basis. Thank you very much for
7 this opportunity.
8 MR. TEEFEY: Thank you, Ken.
9 Can you make sure as soon as possible that you
10 get us all that information so we can get it to
11 the Task Force because I'm sure it will be a lot
12 of reading?
13 MR. MCARTHUR: Yes, sir, I
14 will.
15 MR. TEEFEY: If we could get
16 it as soon as possible.
17 MR. MCARTHUR: I would be
18 happy to. Thank you.
19 MR. TEEFEY: Mr. Rosenthal.
20 MR. ROSENTHAL: Members of the
21 special Task Force, thank you for the opportunity
22 to be here. I listened to Ken's comments with
23 interest because I think you're going to find a
24 lot of what I have to say is the same thing. We
25 may define terms different ways but in terms of

1 how this Task Force moves forward and the types
2 of things it looks at. Ken and I seem to be on
3 the same wavelength although we have not
4 discussed what our comments would be before
5 today.
6 Let me tell you who I am. I'm
7 Steve Rosenthal. I'm an attorney with Mays &
8 Valentine here in Richmond. I represent a large
9 coalition that was involved in the previous
10 legislation that generated this study and special
11 Task Force.
12 I don't know how many of you
13 saw last month's Money magazine. Did any of you
14 see that? I hope so because I may be showing you
15 something I shouldn't be. I want to read an
16 article. Those of you who were not in the
17 General Assembly last year will not recognize
18 this piece out of the article. Those who were,
19 like Dr. Blanchard and a few others, will
20 remember a woman who testified at a number of
21 committees about "drug switching." And I use
22 that term in quotes.
23 The lead article-- I just
24 want to read a couple of paragraphs. The lead
25 article says that Marie Williams, a 56-year-old

1 school bus driver and resident of Richmond. For
2 five years she had been using Zestril to control
3 her high blood pressure.
4 But when she went to her local
5 pharmacy on January 4th to get a refill, her
6 pharmacist had disturbing news. He would give
7 her Zestril, which successfully lowered her blood
8 pressure with no side effects only if she paid
9 the full cost of the drug because her health
10 insurance did not cover it any more.
11 On New Year's Day, Williams'
12 employer had switched health plans. And its new
13 insurer, Signa, preferred that certain blood
14 pressure patients take a different version of the
15 drug called Prinivil.
16 Without consulting Williams'
17 physician, who was Dr. Annette Reed, the
18 pharmacist switched her to Prinivil.
19 The article goes onto say that
20 a few days after taking the new drug, Ms.
21 Williams knew something was wrong. She was
22 lightheaded. She had headaches and her ears were
23 popping as though she were high up in the
24 mountains. She was a school bus driver for
25 children and this rightly concerned her.

1 This same testimony was given
2 to at least two committees that I know of on the
3 issue of drug switching, on the component side of
4 legislation.
5 If you look in the Physicians'
6 Desk Reference in fact what you find is that
7 Zestril and Prinivil are identical drugs. They
8 are both Lisinopril. There is no difference.
9 One is produced by Merck and the other is
10 produced by Zeneca.
11 Merck is the only company that
12 has the patent on Lisinopril and it has licensed
13 Zeneca to also produce it. I have copies if you
14 want them--and I'll pass them out later after the
15 meeting--to show you that the chemical make-up is
16 identical. It's not just similar, it's
17 identical.
18 Where am I going with this?
19 There was no drug switching. There was no
20 therapeutic interchange of chemically dissimilar.
21 There was no chemical dissimilarity. There was
22 literally no chemical change at all.
23 Yet, during the General
24 Assembly this poor woman, Marie Williams, who
25 apparently did have a problem and her husband,

1 were paraded through the Assembly, through the
2 committees as prime examples of the evils of
3 switching chemically dissimilar drugs.
4 Now why do I go through this?
5 It's for the same reason that Ken said to you
6 what he said earlier. It is this kind of
7 misinformation and this kind of hyperbole that
8 has generated this Task Force and this study.
9 You're not here to watch a
10 propaganda war. I can tell you from the
11 coalition that I represent that we're not here to
12 wage one. The whole problem with legislative
13 session was a total lack of reason, debate that
14 was grounded in fact.
15 Antidotal evidence won't
16 suffice. And we encourage this Task Force to
17 demand nothing short of objective data to support
18 any particular course of action.
19 As you can see from the Money
20 magazine article, and as we found during the
21 General Assembly, there has to be a careful use
22 of terminology as we discuss these issues. A
23 broadside condemnation of so-called drug
24 switching is not helpful, and it doesn't advance
25 any particularized understanding of the issues

1 that this body needs consider.
2 You as a Task Force were
3 constituted to bring to a complex issue diverse
4 expertise, background, training and experience
5 and to have the time to apply those qualities in
6 an environment free from the severe constraints
7 of a General Assembly session that tries to look
8 at thousands of Bills within a few week's time.
9 You are tasked to use that
10 expertise and the time to find out what those
11 facts are and how those facts impact a large
12 number of state holders. Not just independent
13 pharmacies and not just a large employer and not
14 just large coalitions, but also the Commonwealth,
15 Medicaid, HMO, managed care organizations, the
16 mental health community and most importantly the
17 Commonwealth citizens.
18 There has been talk-- In
19 fact, I even mentioned about the previous
20 legislation. Let me say very clearly that our
21 understanding is that--and we encourage you to
22 start with a clean slate, that failed legislation
23 is not the starting point. There are no
24 presumptions. Either the legislation is needed
25 or the legislation is not needed. Either way,

1 you should demand that the need or lack of need
2 be proven from the ground up before you.
3 You should not simply accept
4 antidotal evidence. It's not fair to you and
5 it's not fair to all those that will be impacted
6 by your decision. Any such antidotes, like the
7 one I mentioned earlier, must be carefully
8 examined and investigated by the State and this
9 Task Force. Without that kind of scrutiny, you
10 will fall victim to the same emotional appeal as
11 Money magazine.
12 The starting point is facts
13 and data. Facts and data to be gathered by your
14 staff and presented to you. Facts and data so
15 that you can make an informed and meaningful
16 policy recommendations.
17 We, too, like Ken, have
18 requests and ask that you look at certain things.
19 As you are studying this issue look and
20 see--identify what is going on in the market
21 today and why is it happening. Are there
22 specific practices that pose risks to the public
23 that outweigh any associated benefit to the
24 public? Who is doing what and why? Does the
25 identity or interest of the party engaged in a

1 particular practice matter?
2 This study raises important
3 questions about the physician, patient,
4 pharmacist relationship. As you work through
5 this complex area, before you decide on any
6 course of action, I encourage you to consider
7 these types of questions. Will it harm the
8 overall quality of care that is provided to
9 Virginians? Will it prevent pharmacists from
10 informing physicians of significant price
11 differences among alternative drug sources, such
12 as the two identical drugs I mentioned in the
13 beginning?
14 Will it cause the Commonwealth
15 to spend more on drugs for Medicaid beneficiaries
16 than necessary? Would it disadvantage the
17 competitive posture of Virginia businesses?
18 Would it eliminate practices Virginia would want
19 to encourage? Would it force employers to
20 restructure benefit plans to the detriment of our
21 citizens? What is the overall financial impact
22 to Virginia?
23 On this issue there's been
24 almost no consideration of a factor as important
25 as this. We say to you if there is something

1 wrong and a need to fix it by legislation, then
2 you have an obligation to identify the problem
3 and an obligation to suggest appropriate
4 solutions and report that to the General
5 Assembly.
6 But by the same token, if
7 there are no problems or none that call for a
8 legislative fix, then you need tell the General
9 Assembly that also.
10 All of these things: The need
11 to avoid allegations not grounded in fact,
12 starting with a clean slate, making sure that all
13 points of view are heard and considered, all of
14 those are really just another way of saying what
15 your enabling resolution says.
16 That resolution is that
17 special Task Force be established to study the
18 practice of therapeutic interchange of chemically
19 dissimilar drug products. The special Task Force
20 shall examine all aspects and effects of the
21 practice of therapeutic interchange of chemically
22 dissimilar products throughout the health care
23 system, including, but not limited to its impact
24 on health care, the affected professions, the
25 overall cost of health care products and services

1 and patients.

2 The coalition that I

3 represent, we are here honestly to assist in any

4 way we can. Our goal is to provide you and your

5 staff any information that's not confidential and

6 can't be released, any information otherwise that

7 will be helpful in attacking these issues.

8 We appreciate the time and I

9 know a lot of effort will be put into this. We

10 stand ready to help.

11 MR. TEEFEY: Again, Steve, we

12 have to sort through a lot of information.

13 Whatever information you have, if you could get

14 it to us as soon as possible.

15 MR. ROSENTHAL: Thank you.

16 MR. TEEFEY: Before we get

17 into the statements, would anybody in the

18 audience like to make a statement?

19 DR. PYLES: I would just ask a

20 identified yourself.

21 SPEAKER: My name is Cindy

22 Warner. I just wanted to make a statement just

23 to clarify one point so there would be no

24 misunderstanding. One of the things that Ken

25 McArthur stated was trying to differentiate

1 between different versions of what pharmaceutical
2 care is.
3 I think it's very important
4 and clarify that pharmaceutical care from the
5 pharmacist's perspective is meant to a
6 collaborative practice. They are there to aid
7 and assist, to provide information, to optimize
8 the drug therapy for that patient and that's done
9 in conjunction with the physicians.
10 The other point is--and I
11 don't think anybody really hit this on the head
12 and this is something that the Task Force I hope
13 they would really seriously consider would be who
14 is initiating the change or the request for the
15 change for that patient. I think the bottom line
16 for that is is it coming from a business decision
17 or is it coming from a patient-oriented decision
18 from the health care provider that best knows
19 that patient.
20 Thank you very much.
21 DR. PYLES: If have those
22 written, could I have a copy?
23 SPEAKER: Sure.
24 MR. TEEFEY: Would anyone else
25 like to make a statement?

1 From the statements that we
2 have now to look at, we have a pretty good job in
3 front of us.
4 DR. PYLES: Mr. Teefey, that
5 is pretty much what we had on the agenda for
6 today. If the Task Force members would like to
7 make comments at this point or requests of us,
8 you can do so at this time in terms of our next
9 meeting and what you would like to see for the
10 next meeting. If you could identify yourself for
11 me.
12 SPEAKER: My name is Cindy
13 Pigg. I'm just curious as to what our framework
14 will be so I can be prepared at our next meeting
15 on how do we begin to tackle this issue.
16 DR. PYLES: One of the first
17 things we would like to do is have the Task Force
18 on record with the statement of the practice of
19 therapeutic interchange and what it means in
20 terms of the Task Force's view. That is a
21 statement--a cogent statement that says this and
22 it involves this. So that's something that we
23 will probably be drafting and putting out to each
24 of you for your input so we can come to a
25 consensus of what we mean by that, and any other

1 issue or any other thing that needs to be defined
2 that the Task Force deems necessary to define.
3 MR. TEEFEY: Cindy, I had kind
4 of the same feeling you had. I go back to Ken;s
5 comment. Ken has really laid out a pretty good
6 sequence in here. He's got the definitions of
7 the two. And I think we've got to decide on a
8 definition.
9 I think the second thing is he
10 talks about particular studies. One of the
11 studies is there are no studies anywhere that
12 shows that this is a cost savings. I think we
13 have to look at the risks that he stated there.
14 He's laid out quite a few things.
15 I think what we've got to do
16 when we get in between the next two is to come up
17 with an agenda. Take Ken's and Steve's two talks
18 and lay out some of those things that they
19 brought out and get supportive information from
20 both of them so that we can start deciphering it
21 and coming up--
22 I think its real important we
23 come up with some statement. We know what the
24 legislation says but I think the statement is the
25 next thing.

1 SPEAKER: With all due respect
2 to Mr. Rosenthal and Mr. McArthur, both of whom I
3 had the opportunity to meet before, when they
4 give us their information, I'm not going to
5 assume that's all the information that is out
6 there. Do we have somebody that has the time to
7 dig through the literature for us?
8 DR. PYLES: Some of that is
9 going on Mr. Worthington who is the other staff
10 member of D-Mass and has done some of that. We
11 have identified I think an Inspector General
12 report that addressed this issue, looking at a
13 study I think of several states. So we do have
14 some things. Between now and the next meeting
15 perhaps we'll put together what we do have
16 already and get it to you.
17 SPEAKER: The other thing I
18 would ask is are there any other states that have
19 addressed this from a statutory--
20 DR. PYLES: Not to my
21 knowledge but we can check.
22 MR. TEEFEY: Ken, during the
23 General Assembly, I think you said a couple of
24 other states were looking at it and that--
25 SPEAKER: Could we see that

1 legislation?

2 MR. MCARTHUR: Yes. I'll be

3 happy to provide that for you. There are at

4 least three other states that I know of that have

5 either introduced legislation or planning to

6 introduce legislation.

7 MR. TEEFEY: I know Missouri

8 was one of them. What we can do is call those

9 states and get the legislation and whatever Ken

10 has. We'll look at the federal study that was

11 done and pull out study pieces out of that also.

12 SPEAKER: One other request:

13 Mr. McArthur, does that study where the HMO

14 formularies were examined, is that published

15 anywhere?

16 MR. MCARTHUR: It is.

17 SPEAKER: So you'll provide us

18 with that?

19 MR. MCARTHUR: Absolutely.

20 MR. ROSENTHAL: There are a

21 number of responses to that study that criticize

22 that. I assume you want those.

23 SPEAKER: Absolutely.

24 SPEAKER: I'm Doug Hadley. I

25 would just like to also comment on the article

1 that Mr. Rosenthal quoted from Money magazine.
2 Obviously, we're sensitive about that issue. I
3 think that's a good example of how we've got to
4 begin to, again, be objective and look at what is
5 the actual published evidence out there and not
6 be swayed by an antidote that comes up, which was
7 obviously used for purposes which really weren't
8 for what it was intended.
9 As you rightly pointed out,
10 that particular substitution was a generic
11 substitution and had nothing to do with
12 therapeutically dissimilar drugs and was
13 portrayed both in that article and I think when
14 she testified before the Assembly as if it were a
15 therapeutically dissimilar drug.
16 I have spoken with the
17 physician about this particular episode,
18 Dr. Annette Reed. In fact, she had been
19 consulted about the whole situation. She was
20 also interviewed by Money magazine and tried to
21 convince them that this was, in fact, a
22 particular kind of reaction that made no sense,
23 that it was probably some type of placebo or
24 psychological reaction. Despite telling them
25 that on several occasions, they proceeded to

1 publish it in that manner.

2 I agree that we can't accept

3 antidotal evidence. If there are such things,

4 they have to be presented in writing and

5 thoroughly let us evaluate them so we can

6 separate some of these things. Because there is

7 a lot of hysteria and hyperbole that is going on

8 in the media. I think if we're not careful we

9 can be dissuade. We know patients will, on

10 occasions individual patients will have very

11 unusual things that can be can't be explained by

12 normal means of science.

13 I agree with the statement to

14 not use antidotal evidence and that type of

15 testimony.

16 MR. TEEFEY: All right.

17 Dr. Blanchard.

18 SPEAKER: One additional piece

19 of information I think might be useful is make

20 sure we are armed with the current state

21 regulations that apply to bona fide patient

22 pharmacy relationship, ones dealing with

23 kickbacks.

24 There's been some talk--I

25 don't understand it--about Jane Woods recent

1 legislation of last year and how that may impact
2 this discussion.
3 The bottom line of what I've
4 been hearing up here is that the responsibility
5 taken on by the members of this Committee is to
6 be willing to take the time, the effort to sift
7 through a fairly voluminous set of data facts and
8 try to sort out antidote from factual
9 statistically significant and insignificant and
10 come up with a responsible recommendation to the
11 Commonwealth of Virginia.
12 I appreciate being given a
13 30-minute presentation as opposed to what seems
14 to me like a legislative process or two-minute
15 soundbite which do oversimplify things. So I
16 hope these lengthier meetings will produce the
17 kind of the results we want.
18 DR. PYLES: Dr. Blanchard, are
19 you asking for the particulars of the scope of
20 practice of the prescribers and pharmacists?
21 SPEAKER: Yes, that's correct.
22 I have some Virginia State title things that I've
23 been made aware that affects this, as well.
24 MR. TEEFEY: I think
25 truthfully and I've always held that our

1 legislature has a lot of good sense. I think
2 after we have seen what's happened here today, I
3 think having this Task Force put together assures
4 me that our legislature is using its good sense.
5 Because just getting the definitions I'm
6 confused.
7 SPEAKER: I would like us to
8 make sure we talk about these definitions. The
9 one definition Ken started talking about but was
10 not alluded to specifically was the difference
11 between switching a patient who is already on a
12 medication--is titrated on that medication, what
13 do they cost in (inaudible) of forcing or
14 encouraging that patient to switch to another
15 drug as opposed to the doctor switching before
16 the patient ever starts taking it.
17 SPEAKER: Mark Swenski.
18 Perhaps just enlarging the scope a tad, I think
19 there are some valid points about therapeutic
20 switching. But there was a time when I started
21 in pharmacy practice not too long ago that 20
22 percent or less of the business was managed care
23 business. When a patient came to the pharmacy to
24 pick up a $50 or $60 prescription, that they
25 could not afford, there was no coverage at all.

1 Many times the patient went without medication
2 because they could not afford that medicine.
3 In looking at this, I would
4 suggest that we try and understand what the role
5 of insurance is in financing the delivery of
6 pharmaceutical care and how throwing that piece
7 in has allowed more people access to drugs. It's
8 not quite as simple as: If I have insurance, I
9 ought to be able to pick the drug I want. It
10 seems like it should be that way, but it's not
11 that simple.
12 The insurance vehicle has
13 provided a lot of people coverage to prescription
14 medicines that they didn't used to have. I think
15 that there's a piece that we shouldn't neglect.
16 SPEAKER: Marjorie Powell. As
17 perhaps the only non-Virginian on this Task Force
18 it would be helpful to me to have an
19 understanding of what the Medicaid DUR program
20 is. Because I understand that Virginia has a
21 very effective DUR program. And I know there are
22 instances when a pharmacist would, under a DUR
23 program, call a physician to switch a patient for
24 what would be medically appropriate reasons.
25 I think because that's an

1 important distinction that Ken did point out, we
2 need to keep that in mind and it would help me to
3 have a sense of the kinds of things that
4 pharmacists look at within the DUR program.
5 MR. TEEFEY: For the next
6 meeting we'll have somebody come and go over our
7 DUR program. As a matter of fact, we'll go over
8 our whole pharmacy program.
9 DR. PYLES: Any other comments
10 from the Task Force members?
11 If not, Mr. Teefey, it appears
12 that what we will do between now and the next
13 meeting is to put together some information and
14 get it to you for your review. I encourage you
15 to be thinking very seriously about the
16 statement--the definition. I think that is the
17 most pressing thing at the moment in terms of
18 getting started and moving on with the rest of
19 our work.
20 Again, what we're looking
21 for--what was called for in the legislation was
22 that this Task Force come up with a statement of
23 the extent to which this practice occurs. But it
24 seems to me before we can make a statement about
25 the extent to which something occurs, we need to

1 agree that we're talking about the same thing.
2 So the definition and the description of what
3 we're talking about is perhaps one of the most
4 pressing things before us.
5 At the next meeting we should
6 be prepared to have some discussion on that and
7 reach consensus on that, among other things. I
8 will make sure that we get with the staff at
9 Medicaid and make available to you some of the
10 things you ask for today.
11 MR. TEEFEY: Ken and Steve,
12 can you all make sure you have some
13 representatives at each one of these meetings
14 because you're giving us supportive information.
15 We are probably going to have some questions, if
16 that's all okay.
17 MR. ROSENTHAL: Yes, sir.
18 SPEAKER: I think The Board of
19 Pharmacy and Board of Medicine is supposed to
20 offer assistance, too.
21 MR. TEEFEY: That would be
22 great.
23 I thank everybody for coming.
24 The main thing we wanted to do was surface both
25 sides of the argument and make sure that you

1 understand where we are. And we will have a lot
2 of information and we'll try to summarize some of
3 the information that we have to get to you so
4 that you don't have to labor through.
5 DR. PYLES: Before you all
6 leave, I did not have phone numbers for most of
7 you. Please make sure that if you did not get
8 the form that I sent to you, make sure that you
9 circle your name on the tentative roster and fill
10 in that information for me and give it back to
11 me. Thank you.
12 (CONCLUDED AT 10:40 A.M.)
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1

2 STATE OF VIRGINIA

3 COUNTY OF CHESTERFIELD, TO WIT:

4

5 I, Therese A. Rothchild, certify I reported

6 and transcribed the foregoing, which is complete

7 and accurate, to the best of my ability.

8 I am not related to nor employed by any

9 counsel, party or witness, and have no interest

10 in this matter.

11 Given under my hand this 1st day of July, 1997.

12

13

14 Therese A. Rothchild

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1 VIRGINIA:
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5 HOUSE JOINT RESOLUTION 630
6 SPECIAL TASK FORCE
Studying Practice of Therapeutic Interchange
7 of Chemically Dissimilar Drugs
8
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10
11
12 Second Meeting
13
14 July 16, 1997
15
16
17
18 When heard at:
8:30 a.m.
19 General Assembly Building
House Room D
20 Richmond, Virginia 23219
21
22
23
24 CRANE-SNEAD & ASSOCIATES, INC.
4914 Fitzhugh Avenue, Suite 203
Richmond, Virginia 23230
25 Tel. No. (804) 355-4335

1 APPEARANCES:
2 Mr. Joseph M. Teefey, Chairman;
3 Mr. Michael J. Ayotte;
4 Dr. Lawrence E. Blanchard, III;
5 Dr. Randall E. Dalton;
6 Mr. James G. Council;
7 Dr. Karen E. Knapp;
8 Dr. Thomas L. Moffatt;
9 Ms. Cynthia J. Pigg;
10 Mr. Mark A. Szalwinski;
11 Mr. William Alan Towler;
12 The Honorable Senator Stephen D. Newman;
13 Ms. Marjorie E. Powell;
14 Mr. W. Tommy Walker.
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1
INDEX
2
3
4 SPEAKERS: PAGE
5

6 Dr. Michael A. Pyles ———— 5
Ms. Cindy Warriner ———— 10
7 Mr. David Shepherd, R.Ph. ———— 15
8 Dr. Carol Pugh ———— 51
9 Mr. Michael Worthington ———— 109
10 Dr. Norman Carroll ———— 146
11 Mr. Kenneth McArthur ———— 151
12 Mr. Stephen Rosenthal ———— 170
13 Dr. Michael A. Pyles ———— 177

14
15
16
17
18
19
20
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1 July 16, 1997
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3 NOTE: The following hearing was called to be
4 heard at 8:44 a.m., viz:
5
6 CHAIRMAN TEEFEY: We're going to go ahead and
7 get started. It's a little past 8:30.
8 I'd like to thank everybody for coming. I'd
9 like to welcome everybody in the audience for coming.
10 I passed out some things when I came in.
11 Somebody asked for a little bit of information about
12 the Department of Medical Assistance Services, so I
13 passed out a little bit of information. That's in
14 your information and that's about our eligibility,
15 about our budget, some of the initiatives that we're
16 working on.
17 Mike Pyles will cover the notebook. He's put
18 together a notebook, and he wants to cover what's in
19 the notebook and the information that you'll be
20 getting.
21 We had a little bit of a mix-up last time.
22 We're going to have another whole big batch of
23 information coming to you today. Mr. Durrette was kind
24 enough to give us all of the backup information he had
25 when you made your presentation, and we're sending it

Page 5

1 out to the Task Force. We didn't get it from the other
2 side, and they brought it in today and we will FAX it
3 out to everybody, or we will get it out to you tonight
4 as soon as we copy it.
5 So, have you got copies?
6 DR. PYLES: We have copies for them.
7 CHAIRMAN TEEFEY: Oh, good. We've got copies
8 for everyone.
9 DR. PYLES: We'll pass them out in a moment.
10 CHAIRMAN TEEFEY: I wouldn't want you to read
11 it now, because I think it would take most of the day
12 to do that.
13 We tried to put on the agenda today the
14 information -- Some of the Task Force members asked
15 for specific information, and we're going to start off
16 today with that specific information that you asked
17 for, and then we're going to start expanding into what
18 we are here for.
19 But, to start off with, Mike, do you want to
20 go over the notebook first?
21 DR. PYLES: Yes, if you don't mind.
22 Good morning to everyone. What I would like
23 to do is just walk you through the notebooks. What I
24 have tried to do was to put together a notebook and
25 put some order to it so that, as we go along in our

Page 6

1 deliberations and meetings, as things come, you can
2 add it to specific sections, and I will walk through
3 those with you real quickly.
4 The very first page there should be a Table
5 of Contents which roughly corresponds to each of the
6 tabbed sections of the notebook, and I will walk you
7 through that.
8 Behind Tab Number 1, you should find a
9 current listing, updated listing, of the Roster of
10 Members. Again, I ask you to look over it and make
11 sure that that information is correct and let me know
12 if it's not.
13 I did send -- I put together a list server
14 for the Task Force, and I sent a message, oh, I guess
15 about the 7th or so. I think I got seven responses.
16 What I will do between now and the next meeting is to
17 continue to send information. If you have reason to
18 believe that you're not getting E-mail from me and we
19 do have your address, of course, let me know. But, you
20 will find that listing behind Tab Number 1.
21 And, then, behind Tab Number 2, what you will
22 find is a copy or you should find a copy of House
23 Joint Resolution Number 630, as well as Senate Bill
24 Number 1114. And, in the future, if we need to add
25 additional legislative documents, they will go behind

Page 7

1 Tab Number 2, and I will try to direct you, as we mail
2 things out or what have you, where things go. If you
3 don't like my particular order of things, of course,
4 you are welcome to make adjustments.
5 Behind Tab Number 3, this is where I thought
6 you could keep up with E-mail correspondence and other
7 internal documents. What you should have there right
8 now is a Revised Meeting Schedule. You will note that
9 the times for the August 20th and the September 17th
10 meetings we left at 8:30, and, at this point, unless
11 we change, we will continue to have them from 8:30 to
12 12:30 in this room, House Room D. So that's an updated
13 meeting schedule.
14 Behind Tab Number 4, you should find, today
15 you should find two Agendas, today's Agenda and the
16 Agenda for the initial meeting and the transcript from
17 the first meeting. As we get the transcripts
18 following a meeting, they will go behind Tab Number
19 4. What I had hoped is that we would have the
20 agenda/transcript, agenda/transcript, in that order,
21 from the most recent meeting to the earlier meetings.
22 That will be behind Tab Number 4.
23 The Agenda, I think, is pretty
24 straightforward today, as you can see there. And, if
25 you would like, you can take it out, if you would like

Page

1 to reference it as we go through the meeting today.
2 Behind Tab Number 5, you will find letters
3 that the Task Force Chair may receive from other
4 parties or even from among yourselves and copies of
5 that will be there. I believe that you already may
6 have received some of that, but any letters that are
7 addressed to the Chair and enclosures that come with
8 those letters, you can place behind Tab Number 5.
9 Behind Tab Number 6, you will find the
10 handouts from invited speakers, those persons that
11 addressed the Task Force during our meetings. And
12 what I will be doing is, as you get,-- What I suggest
13 is that as you get information, just add it on top
14 there. So that kind of keeps it current and you will
15 know approximately the order in which you received it
16 by just doing it in reverse chronological order there.
17 And, for today, you should have in there already
18 comments about the Virginia Medicaid Pharmacy Program,
19 which we'll hear from David Shepherd of DMAS. Also, a
20 literature review, we will hear from Michael
21 Worthington of DMAS. Then, also, the information that
22 you received in the mail prior to this meeting you can
23 place behind Tab Number 6, as well, and there was an
24 enclosures list with that mailing, and that
25 information should go behind Tab Number 6.

Page 9

1 I apologize if some of the pages seemed not
2 to be hole punched quite properly, but we did the best
3 we could.
4 Behind Tab Number 7, you will find materials
5 and handouts from other interested parties. These
6 persons may not have addressed the Task Force, but, as
7 we get the information, we will make it available to
8 you, and you can put it behind Tab Number 7.
9 Then, Tab Number 8, there is nothing back
10 there. You can use that to accumulate your own notes
11 and what have you. If there is anything that was
12 promised or that you have asked for that we don't
13 cover today, I ask that you give us a chance to go
14 through the meeting today, and if there has been
15 something omitted, an oversight on my part or what
16 have you, please let me know and I will make sure that
17 anything that you've requested either we have
18 attempted to get the information or we've just
19 neglected by an oversight to put it in the binders or
20 to get it to you. So I just ask at the end of the day
21 you let me know if there is an oversight.
22 I would also ask, when you have a moment, to
23 go back to the transcript from the first meeting and
24 look through that, and if you find any errors there or
25 what have you, names misspelled, misspelled words or

Page 10

1 what have you, please let me know by E-mail or giving
2 me a call. On the new updated roster, I think on the
3 second page of that roster, you will find the staff,
4 and my name is listed there with my E-mail address and
5 phone numbers.
6 Okay. Any questions from anyone?
7
8 NOTE: (No response.)
9
10 DR. PYLES: If not, Joe, then back to you.
11 CHAIRMAN TEEFEY: Okay. We're going to start
12 off every meeting with a public comments portion.
13 Is there anybody in the audience that wants
14 to make a comment?
15 DR. PYLES: Just for the record, I'd ask that
16 you state your name real clearly for the Reporter.
17 Thank you.
18 MS. WARRINER: Yes. My name is Cindy Warriner,
19 and I'm a licensed pharmacist practicing in the State
20 of Virginia, and my comments will be very brief today.
21 Since this is an opportunity to submit
22 documents, I have five documents that I would like to
23 submit to you as a Task Force for your review. I will
24 briefly describe each one and then summarize why they
25 are important for this particular study.

Page 11

1 The first document submitted is a form or
2 physician statement relating to an issue that was
3 addressed during the General Assembly a couple of
4 years ago. The Department of Medical Assistance
5 Services was attempting to contract its pharmacy
6 services through a PBM and opposed the initiative
7 based, in part, on the practices involving
8 PBM-developed formularies and how these formularies
9 were managed.
10 The second letter is from the National
11 Association of Chain Drug Stores highlighting their
12 disappointment of the Federal Trade Commission's
13 Consent Agreement with respect to Lilly's acquisition
14 of PCS. Specifically mentioned were some of the
15 practices engaged by PBMs and other manufacturers as
16 it relates to drug switching.
17 The third is a letter from Medco and Trigon
18 in response to the Department of Personnel Training's
19 RFP. Medco is one of the largest PBMs, and Trigon is
20 currently Virginia's largest single insurer and HMO.
21 Contained within the response is their
22 opinion and, in my opinion, criticism of drug
23 switching. The first is an editorial comment in
24 response from the June published issue of Money
25 Magazine sent in by the American Society of Health

Page 12

1 System Pharmacists. I would like to directly quote
2 from this letter the following statements:
3 "Unfortunately, the formulary system which our
4 organization helped pioneer in hospitals over the past
5 four decades is perverted by some managed care plans.
6 Rather than basing formulary selection based on the
7 best judgment of the physicians and pharmacists who
8 are involved in treating the patients locally, some
9 managed care plans are prone to design national
10 formularies with their large populations of patients
11 in ways that give individual practitioners little or
12 no input or volume. When combined with inflexible
13 rules for enforcing formulary restrictions this
14 approach has the potential of subverting good patient
15 care."
16 In addition to these documents, I know the
17 Board of Pharmacy has discussed concern regarding drug
18 switching practices and both the Medical Society of
19 Virginia and the Virginia Pharmacists Association
20 supported the previously-proposed legislation that
21 would have outlawed the practice. Therefore, my
22 premise in mentioning all of these is, in my opinion,
23 there seems to be already somewhat of a consensus by a
24 large number of the groups represented on the Task
25 Force that there is a problem with the practice of

Page 13

1 switching chemically dissimilar drugs, contingent upon
2 a rebate or a kickback.
3 The final document in the packet that has
4 been provided is an example of the potential negative
5 outcome which will probably become more prevalent if
6 this issue is not addressed. The document is a copy
7 of the recent amendment to a group policy contract. It
8 states that "The Company...," referring to the
9 insurance company, "... will determine whether a
10 particular generic prescription drug is equivalent to
11 a brand prescription drug." While the specific example
12 refers only to generic substitutions, which is
13 different from the specifics of what this Task Force
14 is addressing, in my opinion, the message is loud and
15 clear, "the Company" will make the final professional
16 medical decision.
17 The question I would like to raise is, I
18 realize that the Company may legally determine whose
19 product it will and will not pay for. But, it seems to
20 me this contract language usurps the pharmacist's and
21 a physician's professional judgment, as well as the
22 Virginia Voluntary Formularies' expertise in dealing
23 with equivalent drugs.
24 Is this appropriate and is this what we want
25 for Virginia's citizens and patients?

Page 14

1 Finally, as a licensed practicing Virginia
2 pharmacist, I would like to close with a quote, once
3 again, from the American Society of Health System
4 Pharmacists' letter. It is one of the best statements
5 I have read regarding this particular issue. "The
6 safe, effective and appropriate use of medications
7 requires the active partnership of the patient, the
8 physician and the pharmacist. All three players must
9 resist having their options dictated strictly on
10 economic grounds. Prescription drug products are
11 powerful therapeutic tools that should not be selected
12 for a patient by individuals who are not involved in
13 the patient's direct care."
14 Thank you.
15 CHAIRMAN TEEFEY: Thank you, Cindy.
16 Does anybody have any questions of Cindy?
17
18 NOTE: (No response.)
19
20 CHAIRMAN TEEFEY: Is there anyone else that
21 wants to speak?
22
23 NOTE: (No response.)
24
25 CHAIRMAN TEEFEY: Okay. David? David is going

Page 15

1 to give an overview of the Medicaid Program. Somebody
2 asked last week to give an overview of what we did in
3 Medicaid as far as pharmacists are concerned.
4 MR. SHEPHERD: Good morning, ladies and
5 gentlemen. My name is David Shepherd. I'm the
6 Pharmacy Supervisor for Virginia Medicaid. I also
7 serve as Staff for this Task Force, and we'll work
8 with Michael Worthington and Michael Pyles to
9 facilitate anything that you might need from the
10 Department.
11 There should be a handout in your notebook
12 under Section 6. It's my intent this morning to give
13 you some insight into the Virginia Medicaid Pharmacy
14 Program.
15 The first page is an outline of the topics
16 I'll try to briefly or quickly go over. Actually, the
17 first two sections are just some definitions,
18 acronyms, a Glossary of Terms. Since both the Federal
19 and the State Government like to use acronyms, it may
20 be helpful as a reference to you when I get to
21 referring to things such as AWP or NDC, et cetera.
22 The background of the Virginia Medicaid and
23 Pharmacy Program. Under the approximately 35 services
24 provided by the Virginia Medicaid Program, prescribed
25 drugs are provided to eligible recipients as an

Pag

1 optional service, along with 18 other optional
2 services. Prescribed drugs have been a service since
3 the inception of the Program and fundamental to
4 appropriate health care of the patients.
5 Prescribed drugs are simple compound
6 substances or mixtures of substances prescribed for
7 the cure, mitigation, or prevention of disease, or for
8 health maintenance, which are prescribed by a
9 physician or other licensed practitioner of the
10 Healing Arts, within the scope of their professional,
11 practice as defined and limited by Federal and State
12 law.
13 The drugs must be dispensed by licensed,
14 authorized practitioners on a written prescription
15 that is recorded and maintained in the pharmacist's or
16 practitioner's records.
17 Excuse me. I need to get my glasses. I
18 forgot.
19 Federal Medicaid Regulations dictate the
20 method for reimbursement under the Prescription Drug
21 Program. Reimbursement is made on a retrospective
22 fee-for-service basis, with payments limited to the
23 lower of pharmacy's usual and customary charge or
24 estimated acquisition cost of the drug plus, as
25 established, dispensing fee to cover the pharmacy's

Page 17

1 overhead and profit. (Some states have experimented
2 with enrolling Medicaid eligibles in Health
3 Maintenance Organizations under capitated payment
4 contracts, which is gaining favor throughout the
5 United States.) In 1976, using authority to set an
6 upper limit for services available under Medicaid
7 programs, as provided under Section 1902 of the Social
8 Security Act, the HCFA or the Health Care Financing
9 Administration of HHS implemented drug reimbursement
10 rules pertaining to upper limits for Medicaid and
11 other programs.
12 Specifically, these regulations provided that
13 the amounts the Department recognized for drug
14 reimbursement or payment was not to exceed the lowest
15 of: The maximum allowable cost of the drug as
16 established by HCFA's Pharmaceutical Reimbursement
17 Board for certain multi-source drugs. (Specifically
18 generic drugs), plus a reasonable dispensing fee.
19 It might be good if I explain to you that our
20 funds come both from the Federal Government and the
21 State Government--approximately 50 percent from each.
22 So, we have to comply not only with Federal
23 regulations, but we have to comply with State
24 regulations and sometimes they conflict. We have to be
25 very careful that, as we carry out our Program, that

Page 18

1 we comply in both areas. This is a very controversial
2 area, reimbursement, and that's why I'm spending quite
3 a bit of time on it.
4 The estimated acquisition cost or EAC of the
5 price, (the price generally and currently paid by
6 providers for a particular drug in the package size
7 most frequently purchased by providers for a
8 particular drug in the package size most frequently
9 purchased) as determined by the Program Agency, plus a
10 reasonable dispensing fee.
11 Third, the Provider's usual and customary
12 charge to the public for the drug. Usual and customary
13 usually defines what the cash paying customer would
14 pay, would actually pay for the prescription should
15 they not have any type of supplemental reimbursement.
16 The Regulations at 45 CFR established within
17 HCFA a pharmaceutical reimbursement board. The PRB as
18 it was identified, also identified multi-source drugs
19 for which significant amounts of Federal funds were
20 expended and was responsible for establishing the MAC
21 for these drugs.
22 During its decade of implementation, a number
23 of problems and concerns were voiced about the MAC
24 Program by the pharmacies and the pharmaceutical
25 industry. Specific concerns included: The quality of

Page 19

1 the multi-source drugs; two, the interpretation of
2 "widely and consistently available" as related to the
3 process used by the PRB in setting MAC limits; three,
4 the adequacy of drug reimbursement; and, four,
5 problems in administering the MAC and EAC Programs.
6 In 1983, a departmental task force was
7 established to review the Department's drug
8 reimbursement regulations at 45 CFR. Subsequent to
9 the Department's review process, a Notice of Proposed
10 Rule-Making was established August 19th, 1986.
11 The proposed rule was to remove the
12 Department's rule that limited drug reimbursement
13 under certain Federal programs, including Medicaid. In
14 1987, HCFA ruled again on the payment limits or upper
15 limits.
16 On July 31st, 1987, the Health Care Financing
17 Administration published a notice of the final rule
18 for limits on payments for drugs in the Medicaid
19 Program. In this final rule, they were attempting to
20 respond to public comments; two, provide maximum
21 flexibility to the states in their administration of
22 the Medicaid Program; three, provide responsible but
23 not burdensome Federal oversight of the Medicaid
24 Program; and, four, take advantage of savings in the
25 marketplace for multi-source drugs.

Page 20

1 To accomplish this, HCFA adopted a Federal
2 upper limit standard for certain multiple-source
3 drugs, based on application of a specific formula. The
4 upper limit for other drugs is similar, in that it
5 retains the EAC as the upper limit standard that state
6 agencies must meet. However, this standard is applied
7 only on an aggregate basis rather than on a
8 prescription-specific basis. State agencies are,
9 therefore, encouraged to exercise maximum flexibility
10 in establishing their own payment methods.
11 A multi-source drug is one that is marketed
12 or sold by two or more manufacturers or labelers, or a
13 drug marketed or sold by the same manufacturer or
14 labeler under two or more different proprietary names
15 or under a proprietary name and without such a name.
16 A specific upper limit for a multi-source
17 drug may be established if the following requirements
18 are met: All of the formulations of the drug approved
19 by the Food and Drug Administration have been
20 evaluated as therapeutically equivalent in the current
21 edition of the publication, "Approved Drug Products
22 with Therapeutically Equivalent Evaluations," which
23 are known as the Orange Book. Some of you are
24 probably familiar with it. This is all the published
25 approved drugs in the United States that the FDA --

Page 21

1 They make that available on a yearly basis with
2 supplements on a monthly basis.
3 At least three suppliers list a drug (which
4 is classified by the FDA as Category A in its
5 publication) in the current edition of published
6 compendia of cost information for drugs available for
7 sale nationally.
8 The upper limit for multi-source drugs for
9 which a specific limit has been established does not
10 apply if a physician certifies in his or her own
11 handwriting that a specific brand is "medically
12 necessary" for a particular recipient. This is unique
13 to Medicaid. I believe all the other programs that
14 employ Federal upper limits or use some type of
15 maximum allowable cost allow other types of
16 overrides. But Medicaid is specific. It is required
17 that the physician write "medically necessary" in his
18 own handwriting on the prescription.
19 If it's a phoned-in prescription, they must
20 send an actual handwritten copy to the pharmacy for
21 documentation. This is an audit process and it's very
22 important that the rules are followed with this. We do
23 recoup monies as a result of this particular issue not
24 being followed.
25 The handwritten phrase "medically necessary"

Page 22

1 must appear on the face of the prescription, but it
2 does not address the use of a two-line prescription
3 form. HCFA never has addressed a two-line prescription
4 form, so we still are operating under the 1987
5 upper-limit rules.
6 The formula used to calculate the aggregate
7 upper limit of payment for certain multi-source drugs
8 is 150 percent of the least costly therapeutic
9 equivalent that can be purchased by pharmacies in
10 quantities of a hundred tablets or capsules or, in the
11 case of liquids, the commonly listed size, plus a
12 reasonable dispensing fee.
13 The other drugs issued deals with all of the
14 drugs: A brand name drug certified as medically
15 necessary by the physician; two, a multi-source drug
16 not subject to the 150 percent formula; or, three, a
17 single-source drug. This is where the EAC
18 determination comes in, estimated acquisition cost.
19 I also handed out a sheet of all 50 states
20 relating to their pharmacy payment and patient cost
21 sharing. And, as you can see, it varies from state to
22 state as to what they define their EAC to be. HCFA was
23 very strict about making all states at least come to
24 some form of what they determine to be actual
25 acquisition costs or estimated acquisition costs.

Page 23

1 And, upon the threat, of course, of not allowing the
2 states to have their State Plan, thus, not having
3 Federal funds.
4 States may continue to use this existing EAC
5 Program or adopt another method, as long as their
6 aggregate expenditures do not exceed what would have
7 been paid under EAC principles. HCFA publishes a list
8 of multi-source drugs to which the upper Federal limit
9 formula applies, which is revised every six months
10 under the present rules and published, to my
11 knowledge, probably in most of the compendia or is
12 available through wholesalers.
13 The rule does not prescribe a preferred
14 payment method for the states, but gives states the
15 flexibility to determine how they will pay for
16 prescription drugs under Medicaid. As long as the
17 state's aggregate spending is at or below the amount
18 derived from the formula, the state is free to
19 maintain its current payment program or adopt other
20 methods. States can alter payment rates for
21 individual drugs, balancing payment increases for
22 certain products with payment decreases for other
23 drugs so that, in the aggregate, the program does not
24 exceed the established limits.
25 The next piece of legislation that impacted

Page 24

1 pharmacy and Medicaid was something known as OBRA
2 Now, this was a very important piece of legislation on
3 the Federal level. It actually involved some rewriting
4 of pharmacy issues. Virginia, prior to this
5 legislation being enacted, had passed two pieces of
6 legislation. One was a drug formulary, a restricted
7 formulary and the other was a new drug review. With
8 the passage of those two Bills, we had negotiated,
9 with certain manufacturers, rebates related to the
10 formulary. Actually, Merck Pharmaceutical had already
11 signed a contract with us, and we had several other
12 pharmaceutical companies negotiating for individual
13 rebate contracts.
14 As a result of OBRA '90, these two Bills were
15 repealed, subsequent to OBRA '90's enactment because
16 of the conflict in the legislation between Federal and
17 State.
18 OBRA '90 was very inclusive of several areas,
19 not only dealing with reimbursement, but also dealing
20 with the practice of pharmacy.
21 Rebate calculation, which was an important
22 part of this, was a very involved, complicated issue
23 and has been changed twice since its inception under
24 OBRA '90. There were approximately 450 manufacturers
25 that signed an agreement with HHS as a result of the

Page 25

1 rebate program. And, of those 450 manufacturers, most
2 of them are still under the rebate program, which has
3 been in place for approximately six years.
4 I don't think it's necessary that I go into
5 the actual calculations of the rebate percentages.
6 They are in my handout, and they were graduated from
7 calendar year '91 through '94, initially. They built
8 in the cap that, if there was a price increase, that
9 it could not exceed the Consumer Price Index-Urban or
10 CPI-U, from '91 to '93.
11 Another issue that was addressed under OBRA
12 '90 was prior authorization. Under OBRA '90, State
13 Medicaid formularies must include all prescription
14 products of manufacturers who have signed rebate
15 agreements. States may have or require physicians to
16 request and received official permission before a
17 particular product can be dispensed. But states could
18 not operate prior approval plans unless the state
19 providers had a response time of 24 hours or unless
20 the program had a response time of 24 hours of a
21 request and provided for a 72-hour emergency supply of
22 the medication. States could not restrict a
23 newly-approved pharmaceutical product until six months
24 after approval. States may restrict all drugs in the
25 therapeutic class, quantities per prescription and

Page 26

1 refills as necessary to discourage waste.
2 The Congressional intent of the prior
3 authorization provision was not to encourage the use
4 of such programs, but rather to make available to the
5 states for the purpose of controlling utilization of
6 products that have narrow indications or high abuse
7 potential.
8 OBRA '90 did not provide any set-aside monies
9 or allocations to increase pharmacy reimbursement.
10 But, until 1995, the Federal Government could not
11 modify the formula on reimbursement limits to reduce
12 reimbursement to pharmacies, as the result of a
13 moratorium for that time period. The purpose there was
14 to study the reimbursement levels nationwide in the
15 Medicaid Program. The moratorium was lifted and
16 subsequently there have been changes in reimbursement
17 structures.
18 Drug Utilization Review was a very important
19 piece.
20 Do you want me to go faster?
21 CHAIRMAN TEEFEY: We've got to go a little bit
22 faster because we have a lot to cover.
23 MR. SHEPHERD: Okay. I think Carol is going
24 to cover most of the DUR anyway, so I don't need to
25 worry about that.

Page 27

1 Another important piece of OBRA '90 was
2 electronic claims management, which Virginia
3 implemented in June of 1994 after a pilot program and
4 went statewide by August of 1994. Today we have 95
5 percent of our claims, in the Medicaid Programs,
6 submitted in the outpatient population on-line point
7 of sale.
8 Not only does that adjudicate the claim, it
9 tells the provider that the patient is or the
10 recipient is eligible, it tells them how much they're
11 going to get paid, and it carries with it the Pro-DUR
12 enhancement, which is a very important piece for
13 quality assurance. There are at least ten to eleven
14 Pro-DUR areas that are addressed that were initially
15 called alerts. We now have implemented three areas in
16 over-utilization known as early refill, therapeutic
17 duplication and dose duration and allowed a prior
18 authorization number or medical necessity to be
19 entered into the computer without having to go through
20 a paper process. This has proved to be a very cost
21 savings initiative and we are still gathering data as
22 to how effective that has been. That has happened
23 within the last two years.
24 OBRA '90 was subsequently amended at least
25 twice. In the Veterans' Health Care Act in '92, it was

Page 28

1 determined that the prices were being raised in the
2 Federal programs under the VA, Public Health. So they
3 had to amend OBRA '90 to allow the prices to be
4 reduced back to those particular entities. It also in
5 '93 allowed back or brought in an anti-formulary
6 provision. Formularies were not allowed under OBRA
7 '90. But, as of '93, states could initiate a
8 formulary, and a six-month window for new drugs was
9 changed.
10 Now, specifically, Virginia Medicaid Pharmacy
11 Program-- With our agreement with the Health Care
12 Financing Administration, under our State Plan, we
13 basically follow or comply with Federal guidelines. We
14 have some flexibility in certain areas, but we
15 primarily do not cover DESI drugs, drugs that have
16 been recalled, experimental or non-FDA approved drugs,
17 drugs used to promote fertility, drugs used for
18 cosmetic purposes such as hair growth and skin
19 pigmentation and vaccines for routine immunizations;
20 that's pharmacy specific pigmentation. Vaccines are
21 covered in one of the other programs.
22 We have complied with the Federal upper
23 limits since its inception and we also have Virginia
24 Maximum Allowable Drugs that go outside of the Federal
25 upper limits, but have their own criteria as far as

Page 29

1 determining whether or not we set a MAC on that
2 particular drug and that is subject to the Virginia
3 Voluntary Formulary.
4 Prior to 1990 reimbursement for prescriptions
5 were AWP plus $3.40 per prescription.
6 October, 1990 reimbursement changed to AWP
7 minus 9% plus $4.40.
8 During 1989 to 1990 the fee was also reduced
9 to allow only one prescription per drug for a specific
10 patient per calendar month.
11 In 1995, the dispensing fee was reduced to
12 $4.25 as a result of the moratorium sunset clause in
13 OBRA '90.
14 The rebate program was initiated in 1991.
15 And, as I spoke earlier, Virginia had already
16 implemented a state-specific rebate program, and that
17 was repealed.
18 Retrospective DUR was initiated in 1991 to
19 comply with Federal statutes.
20 The Virginia Health Outcomes Partnership,
21 also known as VHOP, was initiated initially to
22 facilitate voluntary prior authorization and has
23 evolved to a prototype disease management/outcomes
24 based program.
25 The Department is presently under request for

Page 30

1 proposal for a Disease Management and Outcomes
2 Management.
3 Other legislative initiatives have included
4 formation of a Pharmacy Liaison Committee made up of
5 representatives from the pharmacy community to address
6 pharmacy-related issues pertaining to DMAS. This
7 committee meets and has met approximately every month
8 for the last two years as a result of budget language
9 two years ago.
10 As of this year, we're participating in four
11 studies as a result of the '97 legislative session.
12 These studies include: HJR 630 of which you are a
13 part; two, budget item 322 representing the
14 feasibility of payments for cognitive services; three,
15 HJR-574 to study impact of the practices of PBMs on
16 the Commonwealth's citizens and upon the health care
17 market; four, HJR-623 Compliance with Pharmacy Freedom
18 of Choice.
19 All four of these studies have been through a
20 sister-agency agreement with the School of Pharmacy,
21 MCV. They are performing the studies, of which Michael
22 has this particular study.
23 Quickly over Pharmacy Expenditures. In the
24 back of your handout, there is a spread sheet that
25 gives you eight years of expenditures in the Pharmacy

Page 3

1 Program starting in 1989 through 1996. The headings:
2 Number of claims; expenditures in dollars; rebate
3 dollars collected starting in 1992; expenditures les
4 rebates; total Virginia Medicaid expenditures; and,
5 percent of total Medicaid expenditures attributable to
6 pharmacy.
7 As you can see, the trend has been over the
8 eight years for the cost to go up, increasing
9 practically every year, from 4.7 million in 1989,
10 excuse me, expenditures 71 million in 1989 to 220.5
11 million in 1996. The numbers of claims have also
12 increased almost double since 1989. 4.7 million
13 claims in 1989 and 7.9 million claims in 1996. There
14 are many reasons for this, one being our eligibility
15 base has increased tremendously due to Federal
16 programs, primarily.
17 OBRA '90 was a big impact in that, is that
18 correct, Joe?
19 CHAIRMAN TEEFEY: Correct.
20 MR. SHEPHERD: What has stayed consistent,
21 though, is that the percent of the pharmacy total has
22 remained around eight to seven percent of the total
23 budget. Pharmacy claims are the highest claim volume
24 service within the Agency, and we deal with an
25 extremely large data base. There are over two hundr

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1 thousand national drug codes in our file. We have a
2 monthly upload from First Data Bank, which is also
3 known as Blue Book, one of the national compendia for
4 AWP that lists all the drugs. This is a national
5 compendia book. This is the Red Book. There is
6 another one known as Medi-Span. Most states under the
7 Medicaid Program do subscribe to the Blue Book or
8 First Data Bank.
9 This is a highly intensive program that
10 requires monitoring or exclusive monitoring, not only
11 from compliance issues, but we're fortunate enough
12 that we have a good DUR Program, not only
13 retrospectively but prospectively that helps us in
14 that respect.
15 When OBRA '90 was initiated or implemented in
16 this State and the DUR Program came about, we
17 contracted with Carol Pugh to actually initiate the
18 program for us, and I will let her have the stage,
19 unless there are any questions.
20 CHAIRMAN TEEFEY: I think the important thing
21 I want you to remember is Medicaid does not have
22 formulary, so everything in that Orange Book, ever
23 drug in that Orange Book is eligible to Medicaid
24 recipients.
25 I think that's the first most important

Page 33

1 thing.
2 Yes, ma'am.
3 MS. PIGG: Can I ask you a question? The way
4 the rebate structure works in Medicaid, if a
5 manufacturer elected to not give you a rebate, would
6 their drug be covered?
7 MR. SHEPHERD: No.
8 CHAIRMAN TEEFEY: We have the option not to
9 cover it.
10 MR. SHEPHERD: Right.
11 MS. PIGG: Right.
12 So, can you describe for me the clinical
13 process around the whole rebate structure? I mean, you
14 don't use formularies, per se, but I think your goals
15 were to make sure the quality of care was good for our
16 citizens of Virginia, our eligibles, and also to
17 contain the costs. So, what is the clinical process
18 around the whole rebate structure? I don't quite
19 understand where the clinical piece comes into play.
20 If the information we have says that if they,
21 basically, agree to give you a rebate, you'll cover
22 their drug.
23 MR. SHEPHERD: Actually, there is no clinical
24 aspect related to the rebate portion of the statute.
25 The clinical aspect would be a result of the DUR or

Page 34

1 Compliance Review. Should there be a problem in a
2 particular therapeutic class, we would not allow our
3 recipients to be endangered. And, from the standpoint
4 of what the Federal Government requires, they do make
5 exceptions and you can make an exception with HHS
6 through the Secretary of HHS, should it be necessary.
7 So, they may not rebate, but if it's an essential drug
8 that's needed, then an exception could be made.
9 MS. PIGG: How about if it's a class like a--
10 MR. SHEPHERD: A total therapeutic class? A
11 total therapeutic class could be excluded. I'm sorry,
12 H2s?
13 MS. PIGG: Well, I am just using that as an
14 example. But, if Zantac came in and said, we will
15 rebate you in the absence of any clinical review,
16 which it doesn't seem like there is, but Zantac says,
17 we will rebate you; Pepcid says, we will not rebate
18 you. In that case, would Pepcid not be a covered
19 drug?
20 MR. SHEPHERD: Correct. There was a
21 conscientious decision made by certain manufacturers--
22 Roche being one--that certain drugs would not be
23 rebatable. One happened to be Valium, and Valium is
24 not covered in the Medicaid Program, as a result of
25 that.

Page 35

1 CHAIRMAN TEEFEY: The contract of rebate is
2 between HCFA and the drug manufacturers.
3 MR. SHEPHERD: Right. Which makes it very
4 problematic, because we actually administer the
5 program. The states administer the program, collect
6 the monies, do all the record gathering and send that
7 to HCFA. But the agreement is with the Health Care
8 Financing or through HHS.
9 MS. PIGG: But because they're rebate
10 contracts, even though they are with HCFA, that
11 ultimately determines what drugs the citizens of
12 Virginia can and cannot get, is that correct?
13 MR. SHEPHERD: Not in totality. I mean, you
14 can make the exception, should it be necessary. We
15 have means to do that.
16 Does that answer your question?
17 MS. PIGG: Yes.
18 DR. HADLEY: I have a question. I have a
19 question.
20 MR. SHEPHERD: Oh.
21 DR. HADLEY: What happens if a Medicaid
22 patient presents a prescription from their physician
23 for Valium. You just said it's not covered.
24 MR. SHEPHERD: It's not reimbursed.
25 DR. HADLEY: Okay. So there is no process for

Page 36

1 exception; that basically the patient would have to,
2 under that, whether it would be a therapeutic
3 substitution--
4 MR. SHEPHERD: We have had an appeal related
5 to Valium not being covered, since the inception of
6 OBRA '90. And those appeals actually were voted or we
7 did not cover it even with the appeal.
8 DR. HADLEY: So, in essence, in those cases,
9 the Medicaid patient either must find the means to pay
10 that out of pocket or agree upon its therapeutic
11 substitution--
12 MR. SHEPHERD: Correct.
13 DR. HADLEY: --with their physician.
14 MR. SHEPHERD: Correct.
15 DR. HADLEY: Another drug in that category.
16 MR. SHEPHERD: Correct.
17 DR. HADLEY: Okay.
18 MR. SHEPHERD: Diazepam is available
19 generically from numerous manufacturers.
20 DR. HADLEY: Oh, okay.
21 MR. SHEPHERD: There's a whole list of them in
22 the Virginia Voluntary Formula and Valium is Diazepam,
23 chemically.
24 DR. HADLEY: Okay. So its generic
25 substitution?

Page 37

1 MR. SHEPHERD: Yes.
2 DR. HADLEY: Okay.
3 CHAIRMAN TEEFEY: Yes, Larry.
4 DR. BLANCHARD: Yes. This is Larry Blanchard.
5 Is the mechanism for rebate just a strict
6 numerical rebate percentage that applies to
7 everybody? It's not based on the volume or market
8 share?
9 MR. SHEPHERD: No. The differentiation is
10 between generics and brand name or sole-source drugs.
11 DR. BLANCHARD: Right.
12 MR. SHEPHERD: It can go up as high as 50
13 percent on the sole-source, based on the best price
14 that that particular manufacturer sells that product
15 for.
16 DR. BLANCHARD: But it's not a negotiated
17 amount. It's pretty much set, according to what
18 their--
19 MR. SHEPHERD: Correct.
20 DR. BLANCHARD: --basic price in the
21 marketplace is.
22 MR. SHEPHERD: Correct. And this has been
23 audited by the OIG extensively--extensively.
24 DR. BLANCHARD: There's another comment in
25 your presentation that states, "... may not restrict

Page 38

1 a newly-approved pharmaceutical product until six
2 months after approval." That's still in incentives
3 for OBRA '90, is that true?
4 MR. SHEPHERD: Initially, the six-month
5 limitation under OBRA '90 did not allow us to restrict
6 any new product coming on the market, FDA approved,
7 for six months. In 1993, that was changed as a result
8 of an amendment to OBRA '90.
9 DR. BLANCHARD: So that restriction has been
10 completely eliminated?
11 MR. SHEPHERD: Right. Correct.
12 DR. BLANCHARD: Is the practice of your drug
13 program to evaluate those drugs promptly or, in
14 general, if the drug is released and you don't know
15 anything bad about it, it's approved until--
16 MR. SHEPHERD: Unless it meets one of the
17 criteria of a drug that may be an abusable drug or
18 something of that nature.
19 DR. BLANCHARD: Short of that--
20 MR. SHEPHERD: Right.
21 DR. BLANCHARD: --it's available to the
22 citizens once it's approved?
23 MR. SHEPHERD: Yes. As soon as we can get it
24 in the file.
25 MS. PIGG: What preempted your,-- Well, anyone

Page 39

1 connected with HCFA said you couldn't have a
2 formulary. But prior to OBRA '90 you we're going down
3 a path of a closed formulary in negotiating rebates
4 with the manufacturers. What was with your thoug...
5 process there? Were you going to have a clinical
6 review--
7 MR. SHEPHERD: Yes.
8 MS. PIGG: --to restrict drugs in order to
9 get--
10 MR. SHEPHERD: Yes. There was a committee.
11 There was a committee.
12 CHAIRMAN TEEFEY: Yes, sir.
13 SENATOR NEWMAN: I think you have calculated
14 what the lost impact would be to Medicaid that would
15 affect you. Have you guys looked into the cost that
16 that would affect you by?
17 CHAIRMAN TEEFEY: It would be hard to do that
18 since a recipient can appeal to us, and they have to
19 have that drug filled. We don't have a formulary and
20 that's why we have the presentation by Medicaid. The
21 thing I want to emphasize is Medicaid does not have a
22 formulary, and, if a drug is switched or is forced to
23 switch and the recipient appeals it, then they have to
24 get the drug that the physician prescribes for them.
25 SENATOR NEWMAN: Maybe I can ask you, then.

Pag.

1 When we start presenting information in the General
2 Assembly, it seems to me one of the vital pieces is,
3 one, how much is this going to cost the State,--
4 CHAIRMAN TEEFEY: Right.
5 SENATOR NEWMAN: --and I don't know how we're
6 going to calculate it, but I think we have to find
7 some way to try to calculate that. And, then, the
8 other question is, what's the medical implication of
9 what we're doing now and have there been ramifications
10 that have been detrimental to patients.
11 CHAIRMAN TEEFEY: You're exactly right. It
12 came on so fast during the General Assembly, we didn't
13 know how the rebate portion would be affected and
14 that's what our main argument was. If we discriminate
15 against the manufacturer and say, you can't switch or
16 you can switch to that drug, does it affect our
17 rebate--ability to get those rebates. And, since the
18 General Assembly, we have given it a lot of thought
19 and that person can get that drug anyway. If that
20 person appeals to Medicaid, then the pharmacy has to
21 fill the original drug that was prescribed for that
22 patient, because we don't have a formulary.
23 MR. COUNCIL: If it's not rebatable, it's not
24 covered?
25 CHAIRMAN TEEFEY: If it's not rebatable, we

Page 41

1 have the option not to pay for it, that's right. But
2 most of the drugs we have, most of the manufacturers
3 have a rebate agreement to protect them.
4 SENATOR NEWMAN: So, on a de facto basis,
5 there is no drug switching program in Medicaid now,
6 other than those few that are not covered?
7 CHAIRMAN TEEFEY: There might be drug
8 switching, but the individual recipient can get that
9 drug that was prescribed for them, if they appeal.
10 Yes, sir?
11 MR. AYOTTE: Do you grant all of your appeals
12 for drugs? Your Department has the ultimate say
13 whether or not a drug will be covered?
14 CHAIRMAN TEEFEY: Yes, sir. Any appeal that
15 comes in from a recipient has to be heard by Medicaid,
16 and it has to be ruled on within a 90-day period.
17 MR. AYOTTE: My question was, do you grant all
18 drug appeals or you have the ultimate say? I'm just
19 remembering that thing that Cindy passed out earlier
20 that said the Company has the determination. That
21 sounds very similar where there would be an appeal
22 process to be able to get the drug. But, you need to
23 appeal.
24 CHAIRMAN TEEFEY: Any appeal that is
5 registered with Medicaid has to be heard by Appeals

Page 42

1 Division.
2 MR. SHEPHERD: Right. Yes, and even to go to
3 an Administrative Law Judgment.
4 SENATOR NEWMAN: Mr. Chairman?
5 CHAIRMAN TEEFEY: Yes, sir.
6 SENATOR NEWMAN: Maybe I'm not quite getting
7 it. Can you help me? If someone comes in and has a
8 prescription for whatever it is, and they are told
9 that that is not covered, do they get that noncovered
10 drug immediately or are they rejected to get that
11 noncovered drug? What is the process for appeals and
12 how many of these people know about the appeals
13 process? Therefore, just take the other drug, and
14 what is the effect of that in the 90 days? Do they
15 then get the other drug and pay for it and be
16 reimbursed?
17 CHAIRMAN TEEFEY: Let me go back to the first
18 thing. If they bring a script in and they want that
19 script, under our HMO contracts and all of our
20 contracts, that pharmacist has to fill that script,
1 because we don't have a formulary. Most HMOs and most
22 insurance companies have a formulary.
23 And, if that drug is not on that formulary,
24 that means that the insurance company is not going to
25 pay for it. In our agreements we have with the HMOs,

Page 43

1 anything that is covered under our State Plan has to
2 be covered by that HMO. So, even though HMOs have
3 formularies, it doesn't take -- Medicaid is not ruled
4 by that formulary, because we have an open formulary.
5 And that's specified in the contract we have with the
6 HMOs.
7 MR. COUNCIL: But, she said, excuse me,
8 "Anything covered by the State Plan."
9 CHAIRMAN TEEFEY: The State Plan, there's a
10 State Plan. It's all of those pharmaceuticals that
11 are covered by the rebate program.
12 MR. COUNCIL: Okay.
13 MR. SZALWINSKI: Are there drugs that are not
14 covered by the rebate program?
15 CHAIRMAN TEEFEY: Valium.
16 MR. SZALWINSKI: Are there other drugs?
17 MR. SHEPHERD: Yes.
18 MR. SZALWINSKI: Are there any--
19 MR. SHEPHERD: Primarily generic companies
20 that really aren't--they don't have Nationwide
21 distribution. There have been companies that have
22 been, and primarily the generics again, that have been
23 dismissed from the rebate program for various
24 reasons.
25 MR. SZALWINSKI: So there is a formulary and

Page 44

1 there is a prior authorization program for things such
2 as drugs for cosmetic purposes and other things that
3 are exclusions that you do not cover?
4 CHAIRMAN TEEFEY: There are exclusions we
5 don't cover, right.
6 MR. SHEPHERD: Right.
7 MR. SZALWINSKI: So,--
8 CHAIRMAN TEEFEY: But it's not a formulary.
9 They're exclusions that the State has decided not to
10 cover.
11 MR. SHEPHERD: If we get into a definition of
12 formulary, it could be restrictive, open, closed, et
13 cetera, et cetera. We really considered having an
14 open formulary. That's what--
15 DR. BLANCHARD: 99 percent.
16 MR. SHEPHERD: Yes, probably 99 percent of the
17 drugs are covered. It's open.
18 Yes, ma'am?
19 DR. KNAPP: If somebody comes in with a
20 prescription for a drug that is not on the State Plan,
21 but there is a generic equivalent for it on the State
22 Plan, they will get the generic equivalent. But if
23 there is not a generic equivalent for it on the State
24 Plan, they will not get the drug?
25 MR. SHEPHERD: That is a possibility.

Page 45

1 DR. KNAPP: Unless they pay for it.
2 MR. SHEPHERD: That is a possibility.
3 DR. KNAPP: So there are medications that
4 patients could come with a prescription for--and
5 excuse the grammar, but there is no generic equivalent
6 for it, so they will not be able to get it, unless
7 they pay for it themselves or they appeal?
8 MR. SHEPHERD: Right.
9 CHAIRMAN TEEFEY: Right. That, I can tell you
10 that would probably happen once in a million times.
11 DR. KNAPP: Well, that was going to be my next
12 question, too.
13 MR. SHEPHERD: Yes.
14 CHAIRMAN TEEFEY: Because we have rebate
15 agreements with all the major manufacturers. And, if
16 they rebate, if those manufacturers rebate, we have to
17 have their drug on our Plan.
18 MS. PIGG: But the bottom line is your list of
19 things that are covered or the eligibles, call it a
20 formulary, call it not a formulary, is totally
21 economically driven by the rebate structure from the
22 manufacturers?
23 CHAIRMAN TEEFEY: Because HCFA says it has to
24 be that way.
25 SENATOR NEWMAN: Mr. Chairman?

Page 46

1 CHAIRMAN TEEFEY: Yes, sir.
2 SENATOR NEWMAN: Given that, if we did have a
3 Bill in Virginia that says that you cannot switch
4 drugs based on a rebate, would that do detriment to
5 your current agreements if all of them then started
6 pulling back from the rebate saying, we don't have to
7 give the rebates? And what would be the effect of
8 that on the Commonwealth of Virginia, as far as
9 Medicaid goes? Or, can we calculate that?
10 CHAIRMAN TEEFEY: I think when you put rebates
11 in there, I think you're asking for it. I would have
12 to get an opinion on that, Senator. I think you're
13 asking me something that I really can't answer right
14 now. But I will get you an answer on it. But I think
15 when you tie rebates in there, I think you're really--
16 you're really eliminating the program from anything.
17 MR. SHEPHERD: May I say something?
18 CHAIRMAN TEEFEY: Yes, ma'am?
19 MS. POWELL: I think it's important to
20 remember, however, that the rebate contract is a
21 national contract. So, if you decide not to offer, not
22 to pay the rebate in Virginia, as a manufacturer, your
23 drugs would not be reimbursed in any Medicaid program
24 around the country. So, that a manufacturer making a
25 decision about whether to sign a rebate contract needs

Page 47

1 to look at the entire contract.
2 SENATOR NEWMAN: But that raises a question
3 about whether, Mr. Chairman, we could possibly pass
4 the law to make Virginia required to break the law to
5 where you would be required to take a rebate; that we
6 would say, it would be unlawful for you to take.
7 MR. SHEPHERD: To my knowledge, Federal
8 statute would take precedence.
9 MS. PIGG: But do you want to treat your
10 Medicaid eligibles differently than the other citizens
11 of the Commonwealth?
12 MR. SHEPHERD: That was a primary reason that
13 we asked to be exempted from the legislation that was
14 introduced last year.
15 CHAIRMAN TEEFEY: Yes, ma'am?
16 DR. KNAPP: I mean, after listening to this, I
17 think the Medicaid citizens of the Commonwealth are
18 being treated differently. They have a bigger, more
19 open formulary. So, in that respect, it's
20 advantageous.
21 CHAIRMAN TEEFEY: We have a bigger and we have
22 an open formulary because the General Assembly has
23 decided that's the way it is going to be. I mean,
24 when we came over for a formulary a couple of years
25 ago, the General Assembly decided it was not in the

Page 4

1 best interests of the Medicaid recipients to do that.
2 MS. PIGG: But, did the General Assembly, I
3 mean, then you've got this HCFA, I mean, it's just too
4 many things that's going around. You have HCFA
5 saying, you pay us, you get covered; you don't pay us,
6 you don't get covered.
7 CHAIRMAN TEEFEY: But there are so few drugs
8 that are not covered by the rebate program. The
9 example that we use would be once in a million that
10 somebody would come in with that drug. If it's in that
11 book, it has an NDC number on it and that company
12 rebates us, then that drug is covered.
13 Just like David said, you have a few small
14 generic companies that are not in the book, that they
15 don't have contracts with.
16 MS. PIGG: But the issue is there is no
17 clinical basis to what is covered or not covered? It
18 is simply a monetary arrangement?
19 CHAIRMAN TEEFEY: It's a monetary arrangement
20 with HCFA and the drug manufacturers, you're exactly
21 right.
22 DR. BLANCHARD: But, Mr. Chairman, the one
23 exception that there is, is that the clinical basis is
24 FDA approval. So, there has been a clinical
25 assessment of safety and efficacy.

Page 49

1 But, the point is, at the end, and the other
2 gentleman, I think, is well taken, that one of the
3 reasons we're here is to see if any legislation that
4 would be recommended uses the word "rebate"
5 appropriately, so that we're not talking apples and
6 oranges when we're prohibiting "rebates," and I think
7 that's a good point.
8 MR. AYOTTE: Mr. Chairman, I also think it's
9 important that we talk about whether or not
10 legislation is needed. You know, looking at the
11 current Board of Pharmacy Regulations and things that
12 currently exist, it may not be a need for this, you
13 know, any other additional legislation that would
14 burden everybody.
15 CHAIRMAN TEEFEY: Well, I think before the day
16 is over, we're going to get a definition of exactly
17 what we're talking about. And I think that's what
18 we're leading up to. Because, you know, we have done
19 a lot of reading between the last meeting and this
20 meeting, and we have talked to hospitals, we have
21 talked to pharmacists, we have talked to physicians,
22 and it's all different. And, when Mike gets up there
23 he's going to point out some of these things.
24 MR. SZALWINSKI: Mr. Shepherd?
MR. SHEPHERD: Yes.

Page 50

1 MR. SZALWINSKI: Can I just make one request?
2 On your Sheet Number 1, your excel spread sheet in the
3 back, is there a way that we could get added in there
4 the number of covered people for the denial?
5 MR. SHEPHERD: Recipients?
6 MR. SZALWINSKI: Recipients--
7 MR. SHEPHERD: Sure.
8 MR. SZALWINSKI: –on an annual basis so there
9 is a denominator in there.
10 MR. SHEPHERD: Be glad to.
11 MR. SZALWINSKI: Would be helpful.
12 MR. SHEPHERD: Be glad to.
13 Any other request that I can help with?
14
15 NOTE: (No response.)
16
17 MR. SHEPHERD: Thank you.
18 CHAIRMAN TEEFEY: All right. We have Carol
19 Pugh, and Carol is a Doctor of Pharmacy, and she set
20 up our DUR Program, and it's been the model around the
Country. We get feedback from all of the Country that
22 they're using Virginia's Program, and we owe a great
23 deal to Carol. She did a marvelous job of this and
24 that's why we asked her to take time out of her busy
25 schedule to talk about DUR.

Page 51

1 DR. PUGH: Good morning. I'm a pharmacist in
2 Virginia, and I am also on the faculty at the MCV
3 School of Pharmacy, or, excuse me, the VCU School of
4 Pharmacy. And, I think you'll tell from my handout
5 material that I'm used to talking to people and giving
6 lectures, and so forth.
7 This morning I'm going to try to be very
8 brief. I have prepared a fairly comprehensive handout
9 for you so that I don't need to go through every
10 little detail. You will have it for your reference.
11 I didn't realize that you were going to have
12 three-ring binders or else I would have brought it
13 with three holes in it, but I apologize for that
14 oversight.
15 You have already heard about OBRA '90. David
16 has talked about it. What I'm here to talk to you
17 about is the DUR portion of OBRA '90. And, it
18 basically, has three major components related to
19 DUR-type activities. One was that it mandated the
20 creation of a retrospect and prospective DUR Program.
21 There were a number of items that had to be included
22 in this. There is a list of nine different types of
23 drug-related problems that are supposed to be included
24 in the program and they're listed for you on the
25 handout. I know you all can read, so I won't read

Page 52

1 through them all.
2 It also mandated that patient counseling be
3 offered to Medicaid outpatients. And, again, it
4 mandated a number of items that needed to be included
5 in the counseling. And, for those of you who are
6 pharmacists, there are things that are very obviously
7 things that we would want to include in counseling
8 anyway.
9 Then, finally, with respect to the DUR
10 portion of OBRA '90, it mandated that pharmacists keep
11 a profile. And, in Virginia, this is a little bit
12 redundant, because we already had a requirement within
13 the State to keep a profile. But, in OBRA '90 it
14 specified certain items that needed to be kept in that
15 profile for every Medicaid recipient.
16 Now, the thing to remember is that OBRA '90
17 was specifically for Medicaid recipients. And many
18 states, including Virginia, passed legislation or
19 regulations that made OBRA '90 generalizable to the
20 entire population. So the incentives for OBRA '90
21 compliance within Medicaid, as David has previously
22 mentioned, for the Agency, for DMAS, if they didn't
23 play along with this, HCFA had a pretty big stick. It
24 said, if you don't have this program in place by
25 January 1st, 1993, we're going to remove our funding

Page 53

1 for your drug budget, which, in this State, is about
2 50 percent of the money spent on drugs. So the Agency
3 had a very strong incentive to want to do this. Even
4 if it was the right thing, they had a really strong
5 incentive to want to do it, anyway.
6 For pharmacists, their incentive was
7 certainly not monetary, but, as I mentioned, Virginia
8 also has a, basically, OBRA '90 requirement that
9 applies to all citizens. And this actually went into
10 effect six months before the required OBRA '90 day.
11 So, there were incentives all the way round for this
12 program to occur.
13 If you will turn to the next page, I will
14 give you a little bit of history and explain what's
15 involved in the various components of the Program.
16 Now, I'm not a native Virginian, I will admit
17 that. All of my higher education is here in
18 Virginia. But, I have been told that in order to be a
19 true Virginian you have to give a history of what's
20 going on. So, I will give you a brief history of how I
21 became involved in this process.
22 I was hired as a DUR consultant by an
23 inter-Agency Agreement between DMAS and the VCU School
24 of Pharmacy. I started in 1992, in January, and my
25 job was to develop, implement, and manage the Program,

Page 54

1 with the idea that once it was up and running,
2 Medicaid would take over its management. And that,
3 indeed, happened three years later in January of 1995.
4 So, for the last two and a half years,
5 Medicaid has been running the Program that I helped
6 them develop.
7 Now, the DUR Program has two major
8 components. It has a retrospective component and a
9 prospective component, and I will first go through the
10 retrospective component.
11 Obviously, by the name, it is something that
12 occurs after a drug has been dispensed. And its main
13 purpose and utility is in identifying patterns of
14 prescribing, dispensing, and patient use of
15 medications. It uses claims that have already been
16 filed, and the Program in Virginia uses both pharmacy
17 and medical claims. Now a number of the states use
18 only pharmacy claims and there are some commercial DUR
19 programs that only use pharmacy claims. I think one
20 of the strengths of the Virginia program is that it
21 also factors in inpatient and outpatient claims for
22 hospitals, practitioner office visits, and laboratory
23 claims, along with all the pharmacy claims. So it
24 allows for developing a much better picture of what's
25 going on in service utilization.

Page 55

1 Initially, the criteria development process
2 used was, we identified therapeutic categories and
3 types of drug problems that were of concern. A DUR
4 board was named. It consisted of and still consists
5 of, to my knowledge, physicians, pharmacists,
6 representatives from the Schools of Medicine and
7 Pharmacy, various professional associations within the
8 State, and so forth. So, they're all practicing
9 physicians and pharmacists, and I believe nurse
10 practitioners are represented now on it, as well.
11 And, we also, when we did the first go round
12 with the criteria, because it was such a hot topic and
13 there was a lot of anxiety all over the place, we also
14 accepted input from representatives of the
15 pharmaceutical industry and various other people that
16 were interested in the process. In general, we did
17 get, almost on every set of criteria that were
18 developed for every therapeutic class, we did get
19 input from the industry. Generally, it was fairly
20 minimal because, as I tried to show them, and until
21 they saw it I guess they didn't believe it, we really
22 weren't out to get anybody. We were really interested
23 in picking out the most therapeutically appropriate
24 problems to look at and to try to solve.
25 Now, the way a retrospective DUR Program

Page 56

1 works is you need a really big computer, and it
2 doesn't work on a PC. Well, there are some programs
3 that work on PCs, but, basically, you need a really
4 big mainframe computer. And what happens is, six
5 months worth of the pharmacy and medical claims are
6 combined into one large file, and then they're sorted
7 by the recipient ID number so that you put all the
8 claims for one person together, and then again by the
9 date of service, so that you can look at things
10 chronologically. And this listing of claims for an
11 individual recipient is called a patient profile. So
12 we have for a six-month period all the medical claims,
13 all the pharmacy claims arranged in chronological
14 order for every recipient in the Medicaid Program.
15 Then, these profiles are checked against the
16 entire DUR criteria catalogue. I lost track of how
17 many criteria we had. It was up into the several
18 thousands when I left the Program. I'm not sure how
19 many are there now. I'm sure some have been added and
20 deleted and changed, and so forth, but it's a lot.
21 Any patient profile that has one or more, the
22 terminology is a criteria violation. In essence, a
23 drug interaction, a dose that's too high, a duration
24 of therapy that's too long, is known as an exception.
25 And when these profiles are marked electronically by

Page 57

1 the computer system and now, instead of just being
called a patient profile, we now call it an exception
profile, because it contains an exception to the
4 criteria.
5 Each month about a thousand exception
6 profiles for one or more therapeutic categories are
7 randomly selected for review. The reason we used a
8 random, or they used a random selection right now is
9 that there just would be too many profiles to be
10 reviewed if we looked at all of them. The exception
11 profiles contain all of the exceptions that have been
12 found. So, say the particular profile run was to look
13 at antibiotics. Well, if there were some other
14 problems that were noted with cardiovascular drugs or
15 pulmonary drugs or any other type of drug that was
16 noted for that patient, it will show up on the
17 profile, as well.
18 Over the course of the year, though, all the
19 therapeutic categories are covered through this DUR
20 process. So once a whole year is over, we've gone
21 through the entire criteria catalogue, run profiles
22 for them, and, basically, evaluated everything that
23 goes on.
24 Now, these profiles, these exception
profiles, are then reviewed by a group of pharmacists

Page 58

1 and physicians known as a DUR Committee, and it's
2 their job to take this computer sifting process, which
3 is clumsy at best, and really look at what's going on
4 with this particular patient. And, if, in their
5 judgment, the problem looks like it's been solved, it
6 may have been something that happened at the beginning
7 of the six months and looking through all of the
8 claims for the patient, you can tell that the problem
9 has been resolved, then they will say, this provider
10 does not need to receive a letter saying there is a
11 problem. The problem has been fixed.
12 The DUR Committee members then decide whether
13 or not an intervention letter needs to be sent. And,
14 they send the profiles back to Medicaid and the DUR
15 pharmacist reviews it one more time as a QA check of
16 sorts.
17 One of the problems I noted when I first
18 worked with the Program is, we had some really zealous
19 reviewers and some more reasonable reviewers, and what
20 we tried to do, the QA check step is an attempt to
make sure that we're sending letters out to the same
22 degree of problem. So, if somebody has a little bit
23 higher level or lower level or lower threshold of
24 concern, we make sure that we are not sending letters
25 out willy-nilly to people that we -- When we send

Page 59

1 letters, that they're worth looking at. And, when the
2 Program first began, I received a lot of feedback from
3 providers that said that we were, indeed, making that
4 happen because we were not getting a lot of letters
5 coming back or responses coming back saying, this is
6 dumb, this is a waste of my time, and so forth. Most
7 of them were very positive or at least neutral in
8 terms-- in their response.
9 Along with the letter is a response form, and
10 the provider is asked to send back some feedback as to
11 whether or not this is really a problem, what's going
12 to be done, then fix it, and so forth. When the
13 response form is received by Medicaid, it is then
14 posted onto the DUR data base. Then, six months later
15 a review profile is generated to check and make sure
16 that any of the other problems that were noted have
17 been fixed. This is another one of the reasons why
18 not every category is looked at every month, because,
19 if you did that, you'd be constantly dealing with the
20 same people over and over and over again. You need to
21 allow a little bit of time for the process to work for
22 changes to occur, and so forth. So, that's what's
23 involved in the retrospective DUR process.
24 Now, this process is not perfect, like most
25 things in the world. It has some advantages and

Page 60

1 disadvantages. I have listed those for you on the top
2 of Page 3. The major advantage is that it allows for
3 the determination of the trends of drug use across the
4 whole patient population. So, you can look at the
5 prescribing, the dispensing, utilization. It also
6 allows and serves as a backup for the prospective DUR
7 Program, which I'll talk about in just a minute.
8 Because of the nature of prospective DUR, we can't
9 always find everything right up front, and so we have
10 to allow for things that fall through the cracks and
11 that's what retrospective DUR is good at.
12 Its major disadvantage, and I will be the
13 first one to admit it, is that it occurs well after
14 the fact. The proverbial horse has left the barn and
15 now we're closing the door. The problem may have
16 already been solved and an intervention letter may
17 have gotten sent.
18 Another problem is that the profiles are
19 patient based rather than provider based. And, what
20 this means is that you can have a physician or a
21 pharmacist that has a patient, one patient that has
22 one problem and they will get a letter. A much more
23 efficient way of dealing with this would be to use a
24 provider profiling-type situation where you can send
25 letters to pharmacists or physicians that have

Page 61

1 multiple problem patients, rather than sending one
2 person one letter and then they don't hear from you
3 for another six months. Right now, because of this all
4 being based on the mainframe, the technology is a
5 little bit behind the times. Actually, when I asked
6 Medicaid to write the RFP, I asked for this, and it's
7 now just beginning to be offered by the vendor who is
8 providing the retrospective DUR services.
9 And, as I have mentioned, the process is
10 inefficient. Again, I'll admit this. The intervention
11 letters are generally sent out to only about ten
12 percent of the exception profiles. And part of this
13 is due to the nature of the mainframe computer and the
14 way the criteria work, and part of it is just due to
15 the fact that you're looking at a big time period and
16 problems often get resolved and letters don't need to
17 be sent out.
18 So that's sort of the quick view of what goes
19 on with retrospective DUR. Before I move on to
20 prospective, are there any questions?
21 DR. BLANCHARD: Can you give me an idea of the
22 number of prescriptions or the number of recipients
23 that receive prescriptions, compared to the number of
24 exceptions you find that might deserve a letter? Do
25 you know how many letters you sent out that's ten

Page 62

1 percent?
2 DR. PUGH: Well, roughly a thousand profiles
3 are generated each month, and roughly ten percent of
4 those result in letters, so that would be about a
5 hundred. I know the enrollment numbers have changed
6 since I was at Medicaid two and a half years ago. I'm
7 not sure what the number of recipients that receive
8 the drug benefits are.
9 CHAIRMAN TEEFEY: Do you know? We just, we
10 have a DUR report that we've done, and I can get you a
11 copy of that.
12 DR. PUGH: Yes, because the annual report to
13 HCFA is due June 30th each year.
14 CHAIRMAN TEEFEY: As a matter of fact, we just
15 signed off on it. I will get you a copy of it.
16 DR. PUGH: And that would have all the
17 denominator numbers for the Program and what all is
18 involved.
19 Other questions?
20
21 NOTE: (No response.)
22
23 DR. PUGH: Okay. The more exciting and
24 interesting are the--
25 CHAIRMAN TEEFEY: Can I ask you a question?

Page 63

1 Could you pick up drug switching in the retro DUR?
2 DR. PUGH: It would be difficult. You would
3 have to write -- I'm not sure the logic behind the DUR
4 system has a pattern that would enable you to find
5 that. Would it work as a therapeutic duplication-type
6 problem?
7 MS. PIGG: I think it would have to do with
8 the logic--
9 DR. PUGH: It would be very difficult.
10 MS. PIGG: – but what we could sort out was,
11 was it a switch, just a switch made because the first
12 drug wasn't working or was it a switch made due to the
13 intervention? We may have to figure that out.
14 DR. PUGH: Yes, that's one -- That's another
15 big drawback that I probably should have put on here
16 is that you're dealing with the claims data, and those
17 of you that are practitioners know, the numbers don't
18 tell you everything. The administrative data set we're
19 using for clinical purposes, and it's putting a square
20 peg in a round hole, and it somewhat fits but it's not
21 a perfect fit. So, that's another one of the reasons
22 for having a DUR Committee review the profiles.
23 Because, what the computer finds, once you have a
24 practitioner look at it, they will say, well, this is
25 nuts, this is not, you know, this is really not a

Page 64

1 problem in this patient given the fact, for example,
2 if it was a drug interaction that could cause toxicity
3 because of a decrease in the metabolism of another
4 drug, and you see evidence from the lab claims that
5 that drug level is being monitored, then you can
6 assume that the practitioner is aware that this is a
7 problem. They're taking care of it, and so you
8 wouldn't send a letter.
9 So that is, one of the problems is, is that
10 you don't know what's going on. It could have been an
11 honest switch because, for therapeutic reasons. It
12 could have been a switch because of, you know, other
13 reasons. But you can't tell, you can't assign it
14 that, as such.
15 DR. PUGH: Okay. Any other questions?
16
17 NOTE: (No response.)
18
19 DR. PUGH: Okay. On to prospective.
20 Obviously, from the name, this happens before the
21 prescription is dispensed, and it can be used to
22 prevent problems from happening. And, just to make
23 things complicated, there's not just one type of
24 prospective DUR, there's two types. The first type is
25 what's known as on-site prospective DUR. This occurs

Page 65

1 in the dispensing pharmacy before the claim is
2 submitted. It involves the pharmacy's computer system
3 and the patient profile that's on that system and any
4 system DUR criteria. Now, depending upon what
5 software the pharmacy is using, if they're using
6 Computer RX, I know that they use the First Data Bank
7 as their source of information for drug interactions
8 and other types of criteria. Other programs use
9 Medi-Span or the Red Book, as David referred to.
10 So, depending upon who the software vendor
11 is, it's kind of like whether you're talking about MS
12 Office versus Corell, versus a MAC or whatever. With
13 PCs you have a lot of different variations of ways of
14 doing word processing. There's also a lot of
15 different software programs available for pharmacies
16 to process the prescription dispensing process. And
17 what ends up happening is, depending upon the system
18 that's there, you may see slightly different types of
19 messages come across. But any pharmacy that's
20 computerized, I didn't want to state every one of them
21 does have this, but they all should have it and it all
22 should be turned on. And, one of the big problems
23 that practicing pharmacists run into is that some of
24 these programs have every interaction known to man,
25 even the most insignificant ones. But, most of the

Page 66

1 programs do allow for a switch to turn on or off
2 different levels of significance.
3 The majority of pharmacies do end up keeping
4 on with the major significant interactions and
5 problems and turning off the minor ones. So,
6 otherwise, almost every prescription would probably
7 end up with some kind of alert and nothing would ever
8 get done. So computers are nice, but they also kind
9 of mess things up sometimes. One of the important
10 things to remember about the on-site prospective DUR
11 is that it is the only way to screen for drug allergy
12 interactions. Because of the information that's
13 available in the claims file for the on-line
14 perspective DUR, which we'll talk about in a minute,
15 allergy is not part of that information, because
16 remember, we're dealing with claims that are submitted
17 to pay providers for the activities that they perform
18 for a patient.
19 Local pharmacies have allergy information and
20 their software can actually check for drug allergy
problems. The other nice thing about these systems is,
22 because it's locally within the pharmacy, generally,
23 they can use several months to even years' worth of
24 data so that you can look at a much longer period of
25 time to look for potential problems. So that it allows

Page 67

1 for you to go way far back into the history of the
2 patient.
3 On-line prospective DUR, on the other hand,
4 occurs at the claims processor after the claim has
5 been submitted, and it involves the claims processor's
6 computer, which is usually a large mainframe, and the
7 criteria that have been specified by DMAS, so that the
8 DMAS/DUR Board has determined the prospective DUR
9 criteria that are to be used for Medicaid recipients
10 and that's what's used. It's not somebody else's idea
11 of what's important. It's the DMAS/DUR Board's idea
12 of what's important.
13 Now, the nice thing about this system is that
14 it allows for the detection of problems regardless of
15 where the prescription has been filled. So, if you
16 have somebody that's going to 16 different pharmacies,
17 and we did have some cases like this, and there's drug
18 interactions, you can find them. If they're going to
19 16 different pharmacies and one is a Ukrop's, one is a
20 Rite-Aid, one is an independent, one is some other
21 chain, their systems don't talk to each other, and you
22 wouldn't be able to find that. This is important
23 therapeutically, but it's also important for abuse
24 issues, as well.
25 The only other problem or the other criteria

Page 68

1 to remember with this type of DUR is that because of
2 the system requirements, and by that I mean the amount
3 of time that's available for this whole electronic
4 transaction to occur, you can only use about two to
5 three months' worth of prescription data in the
6 screening process. Otherwise, it just takes too long
7 and the whole--the world, as we know it, will grind to
8 a halt, or maybe not quite that, but it's along those
9 lines. It's a pretty bad mess. If you talk to any
10 pharmacist who has ever had problems with a switch or
11 has had the system go down on them, it's close to the
12 end of the world.
13 So, what I'm now going to do is give you a
14 generic overview of the prospective DUR process. And
15 the reason I'm calling it a generic overview is
16 because I've added a few steps in there that aren't
17 necessarily things that Medicaid does, but I think
18 will help you with the overall picture and in getting
19 at some of the issues that you're dealing with as a
20 Task Force.
21 So, the first step is, is that a prescription
22 is presented to a pharmacist in a pharmacy and the
23 prescription information, the patient information are
24 entered into the computer. At this point, screening
25 goes on to look for potential DUR problems, and this

Page 69

1 is the on-site prospective DUR that we've just
2 recently talked about. Now, if problems are found, the
3 issues are clarified with the patient and/or
4 prescriber, depending upon the nature of the problem.
5 Often the physician needs to be called and there may
6 need to be a correction to the prescription or it may
7 be that a replacement prescription is needed, and this
8 is entered into the system.
9 If a new prescription is put in, it's again
10 screened. So, you can just keep doing this several
11 times. Usually, it doesn't take more than one go
12 around in that loop before you can move on.
13 If you're lucky and there are no problems
14 found, you can go to Step B, which is at the bottom of
15 Page 3. This is where the claim is submitted
16 electronically. Now, those of you that are familiar
17 with using the Internet know you have to dial up and
18 then wait and all of this kind of stuff goes on. The
19 same kind of thing happens, more or less, when an
20 electronic pharmacy claim is sent. The pharmacy needs
21 to use their modem to dial into a switch, which then
22 converts their information electronically to something
23 that the computer that's processing the claims can
24 understand. Now, the whole process for submitting a
25 claim and receiving a reply back from the processor

Page 70

1 can take more than about 30 seconds. It just won't
2 work. The switch is time out. It just -- The whole
3 process just takes too long, because it takes more
4 than 30 seconds. And the vast majority of this 30
5 seconds is involved in this transaction with the
6 switch to the processor and then the processor back to
7 switch, back to the pharmacy.
8 So, what I'm going to describe to you now, on
9 the top of Page 4, which are the various edits or
10 checks, this all takes place in probably less than
11 five seconds. The eligibility edits is first because,
12 obviously, if a patient is not eligible, there is no
13 sense going any further with trying to process the
14 claim. If the patient is not eligible, a denial
15 message is sent, and usually this is a denial that
16 can't be overridden, for obvious reasons. If the
17 patient is eligible, we can proceed to Step D.
18 This is where things may differ from what
19 Medicaid does. Is a number of programs now have some
20 other administrative edits, and these may be things
21 such as, is this drug on the formulary, is this a
22 prior authorization drug, and so forth. So there are
23 things that administratively deal with other programs
24 that are being used.
25 Again, if there is a problem, a denial

Page 71

1 message will be sent and, depending upon what the
2 health plan has decided it may be overridable; it may
3 not be overridable. It may require a phone call in
4 order to be overridable. There's all kinds of
5 variations out there as to what can be done.
6 Hopefully, the edits are passed, and we can proceed to
7 Step E. This is where the actual on-line prospective
8 DUR occurs. And, as is the case, we can have, either
9 you pass the edits or you don't. If the edits aren't
10 passed, the pharmacy is sent what's known as a DUR
11 alert message, and, depending upon the setup that the
12 plan has, it may or may not include a claim denial.
13 And, again, depending upon what the plan has decided,
14 this may or may not be overridable. And, if there is a
15 problem, then the pharmacist will have to deal with it
16 on the other end.
17 But, hopefully, we see Situation 2, which is
18 that the edits are passed and the pharmacy gets the
19 message that the claim has been approved, there are no
20 problems. So, basically, there are two major outcomes
21 from this process: One, is that--the one that we all
22 like to see--is that the claim passes all the edits
23 without any denials and the pharmacist may dispense
24 prescription. The other one is that you may have a
25 denial message or a DUR alert message, and then the

Page

1 pharmacist has to work to either override it and
2 explain the rationale for why they overrode it; they
3 have to make a phone call to do it; they may have to
4 confer with the prescriber if it's a drug interaction
5 problem, and if there's two different prescribers
6 involved, they need to talk with two different people
7 sometimes, and so this can be a fairly time-consuming
8 process.
9 So, that's sort of the generic overview of
10 what happens with that. I spoke with Mary Ann Rollins
11 on Friday to ask about what was being done now with
12 on-line prospective DUR since things have changed
13 since I was at Medicaid. Originally, DMAS was not
14 denying for any kind of on-line prospective DUR
15 alert. This is mainly because we were new at it. We
16 didn't want to overburden people with messages, and so
17 we decided to take a cautious route and kind of phase
18 things in.
19 My understanding is that now denials are
20 being issued for therapeutic duplications, which
21 generally means that's two or more drugs for the same
22 pharmacologic class, so if two drugs can do the same
23 thing, the patient really doesn't need to be on both
24 of them. One of them should take care of their
25 needs. Now, an important thing to remember about

Page 73

1 those denials that are being used by DMAS right now is that they can be overridden by pharmacists, and the pharmacists are asked to send a DUR response
4 indicating the rationale for their override. This is a
5 very reasonable approach compared to some other
6 private health plans. So, it's a very conservative
7 but very safe approach.
8 Another area that gets a denial message is an
9 early refill. I don't know. Are you using 75
10 percent? David, is it 75 percent that you're using?
11 MR. SHEPHERD: 75 percent.
12 DR. PUGH: Most plans use 75 percent. If the
13 prescription, for example, if it's before three weeks
14 of a one-month supply that should have been consumed
15 by the patient, then you'll get an early refill
16 message. This doesn't mean that the patient can't get
17 the drug. There are obviously reasons why people
18 would need it. You know, they may have lost it. They
19 be going out of town and need it. There's a number of
20 very good reasons for early refills. The instructions
21 may have changed, and they're using more drug than was
22 originally planned. So, this is, again, overridable
23 by the local pharmacist.
24 Another initiative is the excessive dose or duration of anti-ulcer medications. And this is mainly

Page 74

1 for clinical reasons, which also has a very big
2 economic component to it, as well. If a patient's
3 ulcer hasn't been cured within three months of using
4 these medications, they require reevaluation and may
5 require a totally different kind of therapy. So,
6 there's monetary reasons, but the more overriding
7 reason is the therapeutic reason. So, in a nutshell,
8 that's some of the specifics for Medicaid DUR, for the
9 on-line.
10 Now, like with the retrospective, there are
11 advantages and disadvantages. The major advantage is
12 that you can solve problems before they occur. It's a
13 very proactive process. It can also be used as a
14 direct abuse prevention tool, if the appropriate
15 administrative criteria are written. And, that's
16 something that requires a fair amount of criteria,
17 because there are so many different drugs that can be
18 used and some of them, it's not just you're looking at
19 one particular drug, you want to find, are people
20 getting a whole range of drugs, and so forth, but it is possible to use this system by writing
22 administrative edits to do that sort of thing.
23 The disadvantage is listed at the top of Page
24 5. You can only address the tip of the iceberg
25 because of the system's time requirements. So,

Page 75

1 although you might think that, well, prospective DUR
2 gets things before they happen, it's great, it's
3 wonderful. The problem is, because of the volume
4 that's involved, you can't find or send back messages
5 about every single problem or else the dispensing
6 world would grind to a halt and nobody would get their
7 prescriptions. So, because of the time requirements,
8 we can only go for the tip of the iceberg. So in
9 reality, you also need both the on-site and the
10 on-line DUR in order to catch most of the significant
11 problems. So, just running it on the processor's
12 machine isn't enough. It also has to be run at the
13 local pharmacy.
14 Now, are there any questions about the
15 prospective DUR?
16 CHAIRMAN TEEFEY: Yes.
17 DR. PUGH: Yes.
18 CHAIRMAN TEEFEY: Under D up there, under the
19 administrative edits,--
20 DR. PUGH: Yes.
21 CHAIRMAN TEEFEY: --this is where the
22 formulary comes in?
23 DR. PUGH: Exactly.
24 CHAIRMAN TEEFEY: Is this, and I'm going back
25 to the General Assembly now, and let's say a druggist

Page 76

1 has an agreement with the pharmacy or manufacturer
2 where they get a rebate for a drug. I think that's
3 one of the examples you-all used.
4 DR. PUGH: Okay.
5 CHAIRMAN TEEFEY: This wouldn't pick up that,
6 would it, the administrative fees? It would just pick
7 up the formularies that come from the actual insurance
8 entity?
9 DR. PUGH: Yes. But, this is going on, on the
10 health plans or the Agency's processor's computer. So
11 it would only know what's going on, like what your
12 rules are, or if this was for an HMO or for Key
13 Advantage, one of the plans that State employees use.
14 It would only know what they have said is on their
15 formulary or whatever. It is only -- It's specific
16 for that particular plan.
17 CHAIRMAN TEEFEY: All right. Let's go down to
18 E, and let's have the clinical edits.
19 DR. PUGH: Uh-huh.
20 CHAIRMAN TEEFEY: Would the clinical edits
21 pick up the chemical differences if they switched the
22 drug?
23 DR. PUGH: You would have to write specific
24 criteria for that and that is not a type of criteria
25 that's generally used in the clinical edits. It's

Page 77

1 similar to what you find with the retrospective DUR.
2 CHAIRMAN TEEFEY: Okay.
3 SENATOR NEWMAN: Mr. Chairman?
4 CHAIRMAN TEEFEY: Yes, sir.
5 SENATOR NEWMAN: That raises the question,
6 since we're here about drug switching, do your
7 computers, as strong as they are, can they determine
8 whether or not there has been a clinical problem with
9 a switch? And, if so, what is that evidence or are
10 your computers not doing that or able to do that?
11 DR. PUGH: The computers really are not able
12 to do that, especially with prospective because
13 problems usually develop after a patient has been
14 taking the drug. There have, in the hospital
15 environment, they have used some surrogate measures
16 that show that there has been a problem with the
17 drug. For example, dispensing Benadryl, which would
18 indicate that somebody may have had an allergic
19 reaction, and they needed that to help quell the
20 allergic reaction. And there's a few other things we
21 used in the hospital environment, but they're not
22 perfect measures.
23 In the outpatient arena, which is what we're
24 talking about here, I just don't see how it can be
25 done, given the current state of technology, and, at

Page 78

1 least, especially with the Medicaid program with what
2 is available to them, when maybe some other programs
3 that have much better data bases that can do things
4 better, but I kind of doubt it at this stage of the
5 game.
6 MS. PIGG: Would that get at that--I'm asking
7 Bill because it's been a while--where you can--
8 MR. TOWLER: On the claim.
9 MS. PIGG: Yes, on the claim.
10 MR. TOWLER: I don't believe that information
11 can be transmitted.
12 DR. PUGH: Yes. There's a whole series of
13 codes that have been put together by the National
14 Council for Prescription Drug Plan, NCPDP, that allows
15 pharmacists to respond back to DUR messages with a
16 coded message that would indicate different things
17 that could have happened; their reasons for things
18 that have been changed, and so forth. But, unless the
19 pharmacist submits that stuff, which is a separate
20 transaction, which costs them money to send it in,
21 that's probably, that would be the closest thing you
22 could do.
23 I was reminded by one of the observers here
24 that one thing you can also do, especially in the
25 Medicaid program, since you do have integrated claims,

Page 79

1 is you can look for certain types of
2 hospitalizations. So, if somebody stops using their
3 inhaler and all of a sudden needs to go to the
4 emergency room because they're in status hypnoticus,
5 then you end up with a situation where you can say,
6 umm, they didn't use their drug. Then this may have
7 been the cause of the hospitalization. But you're
8 still kind of out on limb because there may be some
9 other things going on. They may have received a
10 sample from their physician and there's all sorts of
11 other things that can explain that. So there is no
12 really good way to pin it, even with the computers
13 that we have.
14 Yes?
15 MR. AYOTTE: I just want to make sure that the
16 DUR Program which you're discussing and the people
17 that service DUR, and it does mirror your managed care
18 process, do they have the same formulary in their data
19 banks when the claim bounces up against it?
20 CHAIRMAN TEEFEY: The-- Ask that again.
21 MR. AYOTTE: Earlier we talked about open
22 formulary--no formulary or open formulary, whatever it
23 was, that goes in against the First Health Data
24 Banks. When a claim goes out in your capitated
25 program, is that bouncing against that same formulary

Page

1 or is that bouncing against--
2 CHAIRMAN TEEFEY: No, it's not.
3 DR. PUGH: Because they're not submitted
4 claims, are they?
5 CHAIRMAN TEEFEY: No.
6 DR. PUGH: So, that would be right. So the
7 ones that are in the managed care plans would not be
8 subject to this same DUR system. One would hope they'd
9 be -- They'd be subject to another one, though.
10 MR. AYOTTE: They would be subject to the DUR
11 system that is involved with the capitated process?
12 DR. PUGH: Whatever the plan is using.
13 DR. BLANCHARD: If we use this discussion as
14 an attempt to educate us in the process, not just for
15 Medicaid, but how the computer systems work in
16 pharmacies with, under managed care hands, am I
17 correct in assuming under D, that would be sort of the
18 point where a message might appear that, A, this drug
19 is not under the formulary; you need to talk to the
20 patient, Doctor, and get another medication? Here are
21 some recommended substitutions. Or, this drug is on
22 formulary but our plan prefers a cheaper or better
23 drug.
24 DR. PUGH: Exactly.
25 DR. BLANCHARD: This is the time to start

Page 81

1 asking. This is where that would pop up?
2 DR. PUGH: That's exactly correct. That's one
3 of the reasons for doing it this way.
4 MR. BLANCHARD: All sorts of messages could be
5 written in there to the pharmacist, at that stage,
6 depending on the incentives or whatever it might be.
7 DR. PUGH: Yes. Yes, depending on what the
8 plan was, yes.
9 MR. AYOTTE: Excuse me, Carol. You also have
10 to remember it's depending on the system that you
11 have, the capability to take those messages back.
12 Once again, in all these things, you have to have the
13 capacity to review that whole message.
14 DR. PUGH: But, that can be a problem, and the
15 other problem can be, sometimes the messages are on
16 more than one screen, and, you know, in a busy
17 pharmacy, they don't always have time to read through
18 all that stuff--
19 DR. BLANCHARD: Chaos.
20 DR. PUGH: --or don't want to or whatever.
21 And, I can remember when I was a Pharm.D. student at
22 MCV Hospital, that they have a physician order entry
23 computer system and the P and T Committee thought it
24 would be a great idea to educate House Staff about
25 formulary choices, and so forth. And they had all

Page 82

1 these nice educational screens as to why you wanted to
2 do this and why you didn't want to do this. And, it
3 didn't take most of the House very long to figure how
4 many clicks of that light pen it took to bypass all
5 those screens and get to where they needed to go. So,
6 is it five for this drug and two for this drug? And,
7 so, the same thing happens with pharmacists, as well,
8 when they get all these messages back. And, that's
9 one of the important things to remember, especially
10 with these prospective DUR systems, the on-line ones,
11 is that you get message overload.
12 So while they're wonderful tools, they can
13 just absolutely snow pharmacists with, you know, just
14 information overload that can't be assimilated. And,
15 in a very fast-paced pharmacy, it can be very
16 difficult to keep up with all of that stuff.
17 MR. AYOTTE: Mr. Chairman, you also, you
18 amended your earlier, you amended your number of
19 responses to return, correct? So, that they don't
20 receive that. Your high level interactions were the
only ones that get it.
22 DR. PUGH: Yes. The level of significance was
23 set at a high level in order to minimize false
24 positives.
25 MR. AYOTTE: I can see that throughout the

Page 83

1 industry.
2 DR. PUGH: Yes. And, we were very, very
3 careful about that when we first started out, and,
4 again, the feedback from the folks in the field was
5 that we were doing a reasonably good job and that most
6 messages we sent out were worth reading, so that was
7 encouraging.
8 MR. COUNCIL: Could there not be a lot of--
9 I'm referring to your outline again, Page 4.
10 DR. PUGH: Uh-huh.
11 MR. COUNCIL: Are there a lot of clinical
12 edits that the prescription may not pass that would
13 flip you back into D? Also, in which case it would be
14 necessary to call the prescriber?
15 DR. PUGH: Well, if there are clinical edits
16 that aren't passed, it would be under Item E, and it
17 would be Number 1. They'll send a DUR Message alert,
18 or alert message will be sent back to the pharmacy.
19 And, then, depending upon what needs to be done, if a
20 whole new drug needs to be prescribed, then you go all
21 the way back to the beginning and start at Step A and
22 go through all this again. And, you know, if it
23 happens to be a nonformulary drug this time, you will
24 hit up against those edits, and it would be a very
25 time consuming.

Page 84

1 But, by itself,--
2 DR. BLANCHARD: But, it's not an
3 administrative edit, the results of clinical edits,
4 which will throw you back into the loop.
5 DR. PUGH: No. Clinical edits would result in
6 either, yes, this will be a paid claim, there are no
7 problems; or, there are some problems, here they are,
8 and you decide what to do about it. And some plans,
9 as an example, here with Medicaid, there are a few
10 therapeutic edits or clinical edits that are denied.
11 But, the vast majority of the marks, so, for example,
12 a drug interaction wouldn't be denied. The
13 pharmacists would have used their judgment as to
14 whether something needed to be fixed or, for example,
15 it may be that the patient was taking two interacting
16 drugs, and because the other drug had been filled
17 recently, the computer says, oops, there's a big drug
18 interaction here. But, it could be that their
19 physician had instructed them, while you're taking
20 this medicine, stop taking your old drug. So, the
21 computer would think that there is a problem. But, in
22 reality, there wouldn't be
23 But, the pharmacist would then need to talk
24 with the patient and say, well, the computer says we
25 have this drug interaction here. And then the patient

Page 85

1 could say, well, you know, the doctor said, don't take
2 this other drug while I'm taking this, because of the
3 drug interaction. So, it just further enforces that
4 it's a situation that something may slip through the
5 cracks that can be taken care of. So it's an
6 educational kind of thing, rather than an
7 administrative kind of thing.
8 Other questions?
9
10 NOTE: (No response.)
11
12 DR. PUGH: I'd like to finish up very briefly
13 with what DUR is not.
14 This area is really confusing to people that
15 are in pharmacy practice, and I'm sure to physicians,
16 as well. It's, I'm sure, even more confusing to people
17 that don't deal with all these acronyms and all these
18 different kinds of systems all the time. So, what I
19 have attempted to do is to list out three things that
20 are commonly confused or mixed in with DUR programs
21 and talk about them very briefly. They have already
22 been touched upon by some other folks, so I will be
23 brief. But these are not the same thing as a DUR
24 Program.
25 The first thing is a formulary or rebate

Page 86

1 system. And you all know what a formulary is by now, I
2 think, based on the definitions and I have my version
3 of the definition down there for you. Basically, it's
4 a list of drugs that are going to be covered by the
5 health plan. And, depending upon the health plan, it
6 may be, in the best of all worlds, there's a formal
7 Pharmacy and Therapeutics Committee, also known as the
8 P and T Committee that's composed of practitioners.
9 They're involved in the drug selection process. And,
10 in the idle situation, the drugs that are selected are
11 selected because of therapeutic concerns, comparative
12 efficacy and safety and then cost comes in third.
13 That's the ideal situation. You have the whole
14 extreme there. There are some people that put the
15 cost stuff first. There's some people that definitely
16 do put the therapeutic stuff first.
17 So, it's important to find out how that plan
18 is operated, because you just can't say that because
19 it's being run by a PBM that automatically cost is no
20 one's concern. There are some PBMs in the health
21 plans that that is true for. There are also some
22 plans that that is not true for. Somebody once said,
23 once you've seen one formulary, you've seen one
24 formulary.
25 Once a formulary has been determined, the

Page 87

1 health plan generally tries to get its best price, and
2 that may or may not involve rebates. And, again,
3 rebates have been discussed here, so I won't go into
4 them any further.
5 One of the big problems with formularies is
6 adherence to them. It's variable and it requires a
7 lot of effort on everybody's part but, most notably,
8 the practitioners in the field. One thing and one
9 reason why DUR gets mixed in with formularies and
10 rebates is that you can use the administrative edits
11 of an on-line system to monitor and police and
12 maintain your system. So, some people think of that
13 as DUR. It is not DUR. It is an administrative edit
14 on the computer. DUR is really just the clinical
15 edit.
16 Then, we have the famous prior authorization,
17 the thing that gets everybody all up in a tizzy every
18 time it's mentioned. Basically, this is a cost
19 controlling strategy. And, again, it varies from
20 program to program. An amount of kneecap breaking is
21 involved in the process. Some programs are very
22 reasonable. Others make you jump through all kinds of
23 hoops and it just makes it not even worth even wanting
24 to try. So, again, if you have seen one prior
25 authorization program, you have seen one prior

Page 88

1 authorization program.
2 Generally, cost is a major concern. And,
3 again, one of the reasons why we end up getting into
4 problems with people thinking that this is the same
5 thing as DUR is, in the on-line system you can use the
6 administrative edit to make this system run as well.
7 Then, finally, Disease State Management
8 Programs, and since this is a newer term and the
9 definitions really haven't settled down quite as
10 nicely as they have for rebates, excuse me, for
11 formularies and prior authorization, I decided to use
12 a recent reference that I have found that provides
13 very nice, clear definitions of what exactly, at
14 least, one author's idea of the Disease State
15 Management Program, and this comes from the Annals of
16 Internal Medicine from last year. The basic premise
17 is that "there is a more optimal way to manage
18 patients, which results in lower costs and improved
19 health outcomes." I have listed for you the
20 assumptions and really what's going on here is this is
21 beyond DUR. It's a population-based approach and it
22 intervenes, as does DUR, but it measures outcomes and
23 it sort of involves--it's involved in a continuous
24 quality improvement cycle. So that DUR does have some
25 continuous quality improvement to it, but Disease

Page 89

1 State Management goes much further beyond this and is
2 a much, in my opinion, to be a preferred way of doing
3 things. As I mentioned, there's a lot of different
4 definitions out there and a lot of different
5 variations on programs. So, it's still kind of being
6 figured out right now.
7 And, again, one of the reasons why Disease
8 State Management might possibly be confused with DUR
9 is that the use of identifying a patient and looking
10 at their utilization can sort of be confused with
11 retrospective DUR and, indeed, you can use a
12 retrospective DUR system to kind of begin to build
13 profiles for what you're working with, but it's not
14 the same thing.
15 So, if you have any other questions?
16 MR. TOWLER: Yes. Have you ever served on, in
17 the past or currently, serve on any P and T
18 committees?
19 DR. PUGH: I served as Staff for P and T
20 committees in the hospital setting.
21 MR. TOWLER: Was that, basically, a closed or
22 an open system?
23 DR. PUGH: Well, in one hospital it was very
24 much a closed system. And, in another hospital, we
used to joke and say that our formulary was the PDR.

Page 90

1 So, I've been involved in the more rigorous
2 ones, and I have also been involved in ones that are
3 just P and T committees by name.
4 MR. TOWLER: Are those predominantly in the
5 hospital setting?
6 DR. PUGH: And predominantly in a hospital
7 setting.
8 MR. TOWLER: Would you say in a closed
9 formulary environment, are there any problems that you
10 think came out from that in a hospital setting?
11 DR. PUGH: Well, there's problems with
12 everything. One of the issues that, when I think of
13 the most rigorously closed formulary that I worked
14 with, would be an issue of when a nonformulary drug
15 was wanted and didn't happen to be readily available
16 and it might take as long as 24 hours in order to get
17 it. But rarely was there not another therapeutic
18 alternative that could be used in the interim or maybe
19 in place of, totally, that particular agent that was
20 wanted. So, in terms of harm to patients, I don't
hink I ever saw that occur. In terms of people not
getting what they wanted, that occurred fairly
23 frequently.
24 DR. BLANCHARD: I have a question. In that
25 same hospital, closed formulary, was there also a box

Page 91

1 to check when the doctor wrote the order so that he
2 could check off his preference that the closed
3 formulary preferred drug not be used, and that the
4 drug actually written for be used?
5 DR. PUGH: No, because the physicians entered
6 all the orders by computer, and if the drug wasn't on
7 the computer, they knew it wasn't on the formulary.
8 MR. BLANCHARD: But, then, if it wasn't on the
9 formulary, what did they to do?
10 DR. PUGH: They had to fill in a nonformulary
11 request.
12 DR. BLANCHARD: And, what percentage of the
13 time was that, was that allowed, assuming it was
14 available in the formulary?
15 DR. PUGH: I wasn't involved in fulfillment of
16 those requirements, so I don't know. You know, I do
17 know that when there were reasonable requests, they
18 were accommodated. When there were things that were
19 -- A person wanted a particular brand name, and it
20 was generically available, that wasn't necessarily
21 accommodated.
22 DR. BLANCHARD: Sure.
23 DR. PUGH: So I can't tell you, you know, what
24 was done in all cases. But, there was a procedure for
25 determining whether or not this was something that was

Page 92

1 necessary, to the patient's care and that was overseen
2 by the Pharmacy and Therapeutics Committee.
3 DR. BLANCHARD: Presumably, that appeal
4 process and decision was usually made on the basis of
5 hours or a day?
6 DR. PUGH: Oh, it's made, yeah, within--very
7 shortly after the request is made.
8 DR. BLANCHARD: It's a period of a 90-day
9 appeals process?
10 DR. PUGH: Well, no, because it was the
11 Hospital.
12 DR. BLANCHARD: I understand that.
13 DR. PUGH: Yeah, it's just a little bit
14 different situation.
15 DR. BLANCHARD: But not necessarily to a sick
16 person who is standing at the counter of a drugstore.
17 DR. PUGH: Well, I guess it depends on-- When
18 I think of the situations I've had being enrolled in a
19 health plan that has a formulary, there have been
20 times when a prescription was written and that drug
21 wasn't covered. So you just used another drug. And
22 very rarely do formularies, that I'm familiar with
23 anyway, there may be some out there, but the vast
24 majority of formularies that I'm familiar with,
25 usually have enough variety of different types of

Page 93

1 therapeutic classes of drugs so that pretty much every
2 situation can be covered. And, if something is not
3 covered and it is absolutely necessary, it's usually
4 done for the patient.
5 Now, with Medicaid, my guess is that the
6 patient--the pharmacist and the physician that are
7 taking care of that patient, aren't going to say,
8 well, go home, you can wait 90 days to get a drug.
9 They're going to come up with some other alternative
10 that can be used by that patient in the interim. Or,
11 else, I have known of situations where pharmacists
12 have "eaten" it. They have given a drug to the
13 patient and they have paid for it out of their packet,
14 because, maybe in their opinion and the opinion of the
15 prescriber, the alternatives were not acceptable.
16 So, I mean there's some pro bono care out
17 there, too. These days it's a lot less common. But,
18 when I was first starting in practice 15 years ago, I
19 know I did it a number of times. Because, when I was
20 Pharm.D. School, I worked retail relief.
21 DR. BLANCHARD: And, in the hospital setting,
22 you talked about that a formulary was decided upon and
23 agreed upon by the--
24 DR. PUGH: Pharmacy and Therapeutics
25 Committee.

Page 94

1 DR. BLANCHARD: --who reported back to the
2 Health Staff? Was this an academic center or--
3 DR. PUGH: Yes, academic center.
4 DR. BLANCHARD: That would be a little
5 different from a private hospital.
6 DR. PUGH: Yes. I have worked with a Pharmacy
7 and Therapeutics Committee in a private hospital and
8 it was a committee of the medical staff, and they
9 reported back to--I'm not sure who the Chairman of the
10 P and T Committee reported to.
11 DR. BLANCHARD: Generally, there's a pretty
12 good consensus, among the practicing physicians there,
13 that if a formulary is developed by the P and T
14 Committee themselves, and would buy into that and
15 they'd prove formulary, that's something that they
16 should feel comfortable practicing?
17 DR. PUGH: Right. And then with some of the
18 plans they also have, for example, looking at some
19 of--Kaiser-Permanente and some of those plans, they
20 have P and T Committees that are made of
21 practitioners, and so forth. It's just when you end up
22 contracting out that sometimes you don't know what
23 you're getting. They may have a nationally renowned P
24 and T Committee. But, if you down line, don't know
25 who is involved, it's the same thing as, you know,

Page 95

1 some green eyeshade accountant deciding what's going
2 to be done. So, unless you really know what the
3 process is involved in, you can't really tell.
4 MR. AYOTTE: Is there a quality assurance for
5 P and T Committees anywhere nationally? Is there a
6 national P and T Board?
7 DR. PUGH: Well, let's see. For health plans,
8 would it be NCQA? For hospitals, I guess the Joint
9 Commission on Accreditation of Healthcare
10 Organizations.
11 MR. AYOTTE: So, there is a body that
12 semi-regulates or monitors the qualify of the P and T
13 Committees?
14 DR. PUGH: Oh, yeah, from the hospital
15 setting, man, JCAHO has reams and reams and reams of
16 things that you have to comply with. I'm not quite as
17 familiar with what the NCQA standards are. But,--
18 MS. PIGG: NCQA is as rigorous as the Joint
19 Commission is. Thank you.
20 MR. TOWLER: One other question. Just in your
21 experience with formularies and drug selection in the
22 hospital setting, are they, basically, similar in the
23 drugs that are included, or do you find a lot of
24 differences from settings?
25 DR. PUGH: I think it depends on the nature of

Page 96

1 the setting. The needs of an academic teaching
2 hospital are going to be very different from those of
3 a community hospital. And then you can't even call
4 community hospitals community hospitals any more,
5 because we have places like Henrico Doctors that do
6 transplants. So, you know, it depends upon the nature
7 of the type of patients that are being cared for in
8 that facility.
9 Back in the good old days when we had
10 university teaching hospitals and everybody else,
11 there were very different types of formularies. And,
12 quite frequently, in the community setting, they were
13 a lot less loosely defined than they were in the
14 academic teaching centers.
15 MR. TOWLER: Could you tell, from the
16 formulary that you worked with, whether there was
17 maybe more preponderance of a cost factor in the
18 decision-making?
19 DR. PUGH: The only way one would be able to
20 determine that would be to look at the minutes of the
21 Pharmacy and Therapeutics Committee and see what kind
22 of discussions went on, what kind of materials were
23 prepared. When I served as Staff to the two P and T
24 Committees that I have worked with--actually, I have
25 worked with three of them now--my job was to write

Page 97

1 reviews, monographs, of the drugs that were being
2 considered for addition to the formulary and to look
3 for all the articles that talked about the safety and
4 efficacy of the drug, and also to look into the cost
5 issues. But, it was always, here's is the drug and if
6 it doesn't work, then you don't want to have it and
7 who cares what it costs.
8 So you deal with those issues first and then
9 you deal with cost.
10 MR. TOWLER: Was rebate information furnished
11 to you in those instances?
12 DR. PUGH: Back then, no. I know hospitals
13 used to get a lot better break than they do now. I
14 would work with whoever was responsible for pricing in
15 a hospital to find out what our price would be for
16 that drug if we put it on the formulary. So, I wasn't
17 familiar with all the behind-the-scenes of that.
18 Other questions?
19 MR. COUNCIL: Yes, follow-up for you.
20 DR. PUGH: Okay.
21 MR. COUNCIL: Back to my clinical edits
22 question, if a prescription failed a clinical edit
23 because of contraindications with another dosage,--.
24 DR. PUGH: Right.
5 MR. COUNCIL: --what would-- Would the

Page 98

1 pharmacist recommend an alternative there?
2 DR. PUGH: It would depend upon the nature of
3 the conflict. Again, if it's a situation where an
4 adjustment has already been made, no problem. If it's
5 something where the drug needs to be changed, the
6 pharmacist would have to confer with the prescriber
7 and ask, you know, let them know what was going on,
8 and they might recommend that a particular drug be
9 used, but it would be prescriber's decision as to what
10 would be prescribed in place of the conflicting drug.
11 MR. COUNCIL: So the pharmacist may well have
12 to go back to the prescriber?
13 DR. PUGH: Oh, always. Even if you want to
14 change dosage form, you have to go back to the
15 prescriber. You cannot -- A pharmacist cannot change
16 anything about a prescription without conferring with
17 the prescriber.
18 MR. COUNCIL: And, if they agreed upon a
19 change neither one of them would necessarily know if
20 the first prescription were rebatable or not or the
second prescription, the substitute were rebatable,
22 would they?
23 DR. PUGH: Probably not, given the fact that
24 most pharmacies cover 30 different health plans and
25 those physicians work with equally as many different

Page 99

1 groups, and it's virtually impossible to keep track in
2 your mind what's going on with whom. That's why we
3 use these computers.
4 CHAIRMAN TEEFEY: So you might have to call
5 twice?
6 DR. PUGH: Oh, for sure. I mean, that's not
7 unusual. So, and then, often you can't get through or
8 you talk to the nurse, and they won't let you talk to
9 the doctor.
10 MR. COUNCIL: But you could have had a
11 clinical switch, presumably, from a nonrebatable to a
12 rebatable drug.
13 DR. PUGH: No. Yes, that is possible. But it
14 wouldn't necessarily -- That might not have been the
15 intent, but that may be the outcome.
16 MR. COUNCIL: Right. Yes. You may not even
17 know.
18 DR. PUGH: You may not even know, exactly.
19 DR. BLANCHARD: In your experiences with
20 hospital formularies, have you ever seen a system
21 where the hospital pharmacist was aware of and
22 incentivized by a rebate or a kickback system to try
23 to shift market share from one drug company's drugs to
24 another drug company's drugs so that part of that
25 decision was --

Page 100

1 DR. PUGH: Only in the sense of-- I can think
2 of one very clear example from, when I was working at
3 a community teaching hospital outside of Philadelphia
4 where we would get a much better price if we used the
5 IV form of Pepcid as opposed to Zantac. And, so we
6 initiated a campaign and said, basically, you know,
7 the drugs are the same kind of thing. They really
8 don't have any advantages one over the other, and it
9 costs the hospital less if we use Pepcid. So, please,
10 use Pepcid.
11 DR. BLANCHARD: But, to your knowledge,--
12 DR. PUGH: The pharmacist didn't benefit from
13 it.
14 DR. BLANCHARD: The price had been proven by a
15 market share percentage? It was just that the price,
16 to start with, was a lot cheaper.
17 DR. PUGH: It was, yes. And, it may be
18 different now, although I've been out of hospital
19 practice for about five years, now. So, I don't know
20 what the current state of things is, but my guess is
21 the individual pharmacist that's working with that, is
22 not usually privy to that kind of information and does
23 not receive any kind of incentives from that.
24 MS. PIGG: From my hospital days, the pricing
25 there was not explicit, but it was definitely implicit

Page 101

1 in that when they knew, in your hospital setting, you
2 were going to use IV Pepcid, you weren't going to
3 stock IV Zantac. So there wasn't an explicit market
4 share component to the price, but they knew that they
5 were going to get the market with very little.
6 DR. PUGH: And they kind of knew how much you
7 used on average, so they kind of knew what they were
8 going to get from it.
9 MR. SZALWINSKI: Maybe, if I can add a little
10 bit to that, there are different levels of buying
11 groups in hospitals right now and different levels of
12 whether you are a voluntary or committed buying
13 group. And, in the committed buying group,
14 specifically, there are market-share-driven discounts,
15 and those are made available at Pharmacy and
16 Therapeutics Committee meetings, generally, that I
17 have been involved with, in order to help everyone
18 understand the economic incentives secondary to the
19 clinical facts surrounding the drugs. It's a total
20 decision that needs to be made, not a singular
21 decision. And so there are those kinds of situations
22 happening and there are Pharmacy and Therapeutics
23 Committees, well run Pharmacy and Therapeutics
24 Committees that I am aware of, and I participate in
25 that, take into account the clinical knowledge and

Page 102

1 facts about the drugs, as well as the economics.
2 Because, in today's market, you need to do both of
3 those. You can't do just one or the other. It's a
4 decision that cannot be made effectively in a vacuum.
5 MS. PIGG: Would you make a decision in your P
6 and Ts in your hospital that says, here are two drugs,
7 they both treat hypertension. We believe one drug
8 treats it more efficiently or better, whatever you
9 want to call it, but this drug that doesn't work as
10 well, we can get it a lot cheaper.
11 Would you make that decision?
12 MR. SZALWINSKI: No. No, we wouldn't make
13 that diagnosis. I was a little bit of a straw man. I
14 don't think that. But, no, our decisions are -- I
15 mean, we, in order of variables, we take safety first,
16 efficacy second, and economics third. And that's in
17 well-run Pharmacy and Therapeutics Committees that I
18 have had experience with and have served on, that is
19 the order you take the data. And, if it fails at any
20 one of those steps or specific agents are shown to be
21 safer or more effective, then that's the screening
22 process. And, in many situations, that screening
23 process makes it easier for physicians to deliver
24 better care, because a group of experts that they
25 respect has sat down and done the clinical review for

Page 103

1 them. And, in many situations where it's well-run,
2 well done, that process functions very effectively to
3 insure patients get the best therapy that's on the
4 market.
5 MS. PIGG: Where does the comparison to
6 alternative agents that treat the same conditions come
7 in? Because the FDA says this drug is safe and this
8 drug isn't effective before it gets on the market. So
9 there is another component, I believe, to your
10 analysis.
11 MR. SZALWINSKI: Well, it's the-- I've
12 reviewed clinical literature that's out there. You
13 know, we go to the clinical literature, do literature
14 reviews, have pharmacists and physicians who review
15 those reviews, and, where there are comparisons,
16 direct comparisons that are good comparisons, we use
17 those.
18 SENATOR NEWMAN: Mr. Chairman, if I could ask
19 a question.
20 I imagine that good medicine always makes
21 good policy because of our tort laws in Virginia,
22 which says, if you practice bad medicine, we'll sue
23 you. However, have you received any information in
24 your position on where drug switching has caused
25 clinical problems and what the effect of drug

Page 104

1 switching has been? Are you aware of any studies that
2 deal with it?
3 DR. PUGH: I have not reviewed the literature
4 on that subject. I know that there are, and I remember
5 hearing last summer some folks reporting on their
6 individual experiences. I'm sure there are some people
7 out there that have had problems. But, the vast
8 majority I do not think have. And, what often ends up
9 happening is you hear from those few that have had the
10 problems, and you don't hear from this multitude that
11 have not.
12 I can remember one person in particular
13 that--I can't recall which drug she was talking about
14 that she had been switched on and was concerned,
15 because she was having problems with it. Well, she was
16 switched to another generic brand, I mean another
17 brand of the same chemical entity. And so, you know,
18 when you get people like that out there in the news
19 and getting national press and stuff, it kind of makes
20 those people who really know what's going on, you
21 know, wonder about the quality of some of the
22 testimony.
23 SENATOR NEWMAN: But is it not true that if
24 you have chemically-similar drugs, that are different
25 bioavailabilities that allow, that is--

Page 105

1 DR. PUGH: Chemically-similar drugs are considered to be distinct chemical entities and so they are not considered to be the same. I think-- You
4 were talking about the same--different formulations of
5 the same medication, perhaps?
6 SENATOR NEWMAN: If you have a generic to a
7 brand, the generic manufacturer has to comply with
8 bioequivalency data?
9 DR. PUGH: Yes.
10 SENATOR NEWMAN: And they all comply to
11 different degrees.
12 DR. PUGH: Yes.
13 SENATOR NEWMAN: And there's a 20 percent
14 tolerance, I understand?
15 DR. PUGH: Yes.
16 SENATOR NEWMAN: So, if it's not or is more
17 available than the brand's standard, you can see some
18 toxicities, can you not?
19 DR. PUGH: Or some lack of efficacy. And,
20 there are certain drug classes that most pharmacists,
21 any good pharmacist and any good physician would agree
22 that you don't want to go switching around willy-nilly
23 on.
24 There are a lot of other drug classes, diuretics, where it doesn't matter. You know, it's

Page 106

1 just not that big a deal. So, I think it's-- If you
2 talk about it as putting all drugs into one big box
3 and saying, we're going to allow willy-nilly
4 substitution, then that is problematic, but it's
5 problematic because there is a small subset of drugs
6 that have a very narrow index that, you know, if you
7 have a little bit less, patients start having problems
8 because of a lack of efficacy. If you have a little
9 bit more, then they develop toxicity problems. Those
10 are the drugs that you need to be careful about and do
11 not use generic substitution on or make sure that, if
12 you're going to switch, that you're not switching back
13 different brands every month; that you make the switch
14 and you stick with it.
15 MR. TOWLER: But, with the same chemicals, you
16 could possibly see some of these anecdotal reports
17 coming from people that are experiencing some sort of
18 problem, and it may ally itself in the bioavailability
19 question of the products that are consumed.
20 DR. PUGH: Well, that may possibly be the case. But, again, for the vast majority of drugs,
22 that's not the situation. It's a very limited handful
23 and most pharmacists and physicians can probably tick
24 them off for you.
25 SENATOR NEWMAN: Mr. Chairman?

Page 107

1 CHAIRMAN TEEFEY: Yes, sir.
2 SENATOR NEWMAN: If I could, I want to play
3 off that point, because I suspect that the
4 neurotherapeutic drugs are possibly what is being
5 discussed here. However, the FDA has made it very
6 clear, especially in letters that have come to us
7 recently that I'll provide the committee that they go
8 to extraordinary lengths on their therapeutic drugs to
9 make sure that the percent is only five percent, plus
10 or minus, which is the very same, that one tablet
11 that's made right in front of the other can be of the
12 same manufacture.
13 So, if we're talking about neurotherapeutic,
14 which may be the most sensitive of all of these, the
15 FDA requires a much higher hurdle because of the
16 sensitivity of those drugs.
17 DR. PUGH: But, even so, I think most
18 practitioners, just because of the potential for
19 problems, usually shy away from it.
20 It's better to be safe than sorry, speaking
21 of torts.
22 MR. TEEFEY: Yes, sir.
23 MR. WALKER: Mr. Chairman, I have a question
24 on the hospital formulary. If a patient comes in to
25 the hospital, and they are controlled hypertensive on

Page 108

1 Drug X. Drug X is not covered by the hospital
2 formulary. Is that patient switched to the formulary
3 drug or is he put on the drug that he's been
4 controlled on.
5 DR. PUGH: It depend on the hospital. Some
6 hospitals will allow patients to bring in their own
7 medication and let it be administered. Some hospitals
8 will not, and they will assist on another formulary
9 alternative to be dispensed. So, it really depends.
10 It varies from institution to institution.
11 CHAIRMAN TEEFEY: Carol, we want to thank you.
12 DR. PUGH: You're welcome.
13 CHAIRMAN TEEFEY: The reason we got Carol up
14 here is to make it more complicated.
15 DR. PUGH: I do a good job of that.
16 CHAIRMAN TEEFEY: Thank you so much, Carol.
17 DR. PUGH: You're welcome.
18 CHAIRMAN TEEFEY: Do you-all want to take
19 about a five-minute break before we get into the next
20 level?
21
22 NOTE: (Affirmative response.)
23
24 CHAIRMAN TEEFEY: All right. We'll take a
25 five-minute break and be back then.

Page 109

1
2 NOTE: At this point a recess was had from
3 10:52 a.m. to 11:06 a.m., whereupon the hearing
4 proceeded, viz:
5
6 CHAIRMAN TEEFEY: The Pharmacy School at MCV
7 did a very, very, very in-depth literature search, and
8 Mike Worthington is going to cover what we came up
9 with, and then we will get Mr. McArthur and Mr.
10 Rosenthal to cover the information they sent us.
11 MR. WORTHINGTON: Thank you, Mr. Chairman,
12 Members of the Committee. My name is Michael
13 Worthington. I am Lead Management Analyst with the
14 Department of Medical Assistance Services, and my task
15 is to review selected literature. Although it's not
16 exhaustive, I think it's fairly representative of the
17 literature that's out there on therapeutic
18 substitution and interchange.
19 I would like to acknowledge Ms. Julie Sisler
20 in front of me from the,-- What's your title or--
21 DR. PYLES: She's the Summer Research Fellow--
22 MR. WORTHINGTON: Summer Research Fellow--
23 DR. PYLES: –at the School of Pharmacy.
24 MR. WORTHINGTON: –at the School of
25 Pharmacy. She assisted me very much in pulling all of

Page 110

1 this together. Thank you, Julie.
2 Also, I did my part to keep your notebooks
3 small--I copied on both sides. So, if I get extra
4 credit for that, I would appreciate it.
5 When I looked at the literature, and I
6 started asking myself some questions. Maybe I can
7 formulate the literature review in terms of questions,
8 but I decided, instead, to go up with the large
9 headings that you will see in front of you. It's in
10 Tab 6, I believe, my remarks.
11 So, let's start off, first, with definitions.
12 According to the several sources that I have looked
13 at, I think I could first define therapeutic
14 substitution. And, as indicated here, it's defined as
15 the practice by pharmacists of dispensing an alternate
16 chemical entity from the same therapeutic class for
17 the drug product prescribed by a physician.
18 Substitution is often authorized for classes of drugs
19 commonly believed to have similar pharmacologic and
20 therapeutic properties, such as antacids, antibiotics,
21 anticholinergics, antihistamines, thiazide diuretcis,
22 and so forth.
23 Some HMOs and third-party payers have
24 advocated substitution as a way to control pharmacy
25 costs. I think that's very clear in our deliberations

Page 111

1 here. And, interestingly enough, while some require
2 pharmacists to consult the patient's physician before
3 substitution, many do not. That was very clear in
4 literature.
5 I think Mr. McArthur, in the first meeting
6 that you all had --
7 MR. AYOTTE: Mike, can I ask you a question?
8 MR. WORTHINGTON: Sure.
9 MR. AYOTTE: I'm not sure that that is right.
10 Can you describe for me what you mean by an alternate
11 chemical entity? Are you looking at a substitution
12 from the Virginia Voluntary Formulary? Because
13 you've--
14 MR. WORTHINGTON: I'm sorry, Michael. I think
15 we'll get into that as I illustrate in some of the
16 research that's going on here.
17 MR. AYOTTE: You said that it alludes that
18 pharmacists are doing this on their own to change
19 drugs and not with other physicians' consult for
20 either.
21 MR. WORTHINGTON: Right.
22 MR. AYOTTE: Unless you're talking about a
23 substitution from within the voluntary formulary.
24 And, I would think that that needed to be added into
25 the definition.

Page 112

1 MR. WORTHINGTON: We could do that. I think as
2 I go a little further, some of that will come out. If
3 not, we'll come back to that.
4 Mr. McArthur, in the first meeting you-all
5 had, I think it was indicated that the definition of
6 therapeutic interchange is pretty much the same as
7 substitution. However, it's substitution with
8 physician approval. And I think that's what I found
9 in the literature, also.
10 Generic substitution, I know that's not your
11 concern, necessarily. However, I went ahead and put a
12 definition for generic substitution in here for you. I
13 think that's pretty much accepted.
14 Okay. What I call prevalence or where does
15 substitution occur. A couple of sources clearly
16 indicated that at least 30 percent of HMOs in the
17 United States currently permit substitution. Some
18 other research has indicated that it occurs in more
19 than 52 percent of the Nation's acute care hospitals.
20 Under the first bullet, I indicate there,
21 that the majority of HMOs practicing therapeutic
22 substitution report that physicians are not notified
23 when a substitution has been made.
24 Okay. Let's look a little bit at the risks
25 associated with therapeutic substitution, with

Page 113

1 therapeutic interchange. Within a particular class of medications, there are often many drugs available to physicians for their patients. In one patient, only
4 one of these medications may be tolerated and be of
5 benefit, while another patient may only tolerate and
6 benefit from another of the drugs available. With a
7 well-recognized individual variability in response to
8 medications there is no way of knowing, other than
9 through a systematic approach to each person's
10 particular circumstances, which drug or drugs will be
11 of benefit to an individual patient, or which will not
12 have deleterious side effects. The authors of this
13 research allege that physicians must choose
14 appropriately from the various drugs available.
15 There's further research on beta blockers as
16 in the occurrence of therapeutic substitution in their
17 case. Beta blockers are currently used for over 20
18 medical conditions. When the dosage of any available
19 beta blocker is titrated properly, it can be effective
20 in patients with arrhythmia, hypertension, or angina
21 pectoris.
22 (Addressing Ms. Sisler) Is that correct? That
23 term is pectoris?
24 MS. SISLER: Yes.
MR. WORTHINGTON: However, these drugs are not

Page 114

1 interchangeable, according to this research, since a
2 given agent may be more appropriate for some patients
3 in clinical situations. Moreover, the clinical
4 studies upon which the safety and efficacy profiles
5 of individual drugs are based excluded many patients
6 with underlying conditions that would make them more
7 prone to adverse reactions.
8 Then, that next bullet, I point out the three
9 classifications, if you will, on the basis of
10 pharmacokinetic properties for beta blockers. And,
11 based on those three classifications there, the author
12 alleges that retitration and careful patient
13 monitoring following therapeutic substitution is
14 essential.
15 The American College of Physicians has taken
16 a position that therapeutic substitution is
17 appropriate only in hospitals with an effectively
18 functioning formulary system and a P and T Committee.
19 We heard a little bit about that this morning.
20 The College of Physicians also states that
ıbstitution jeopardizes patient management when
22 ımmediate prior consent is not obtained from the
23 authorize prescriber, and when documentation at
24 substitutions is untimely or improper. The College
25 further states that practices such as that must not be

Page 115

1 permitted.
2 The next bullet, I think, is very critical.
3 It says, the practice of therapeutic substitution may
4 be acceptable in ambulatory settings that meet
5 standards comparable to those of institutional
6 settings.
7 However, the challenge is associated with
8 therapeutic substitution and the limited mechanisms to
9 monitor its practice and effects when done outside the
10 institutional setting make its practice unsafe in most
11 ambulatory settings.
12 Although no reports of adverse outcomes
13 associated with therapeutic substitution done on an
14 ambulatory basis have been published--I think this may
15 be getting into Senator Newman's question of a little
16 earlier--the American College of Physicians believes
17 that even when therapeutic substitution is done with
18 physician supervision, under strict protocols,
19 therapeutic inequivalence may be high for those
20 already stabilized on a drug, for patients taking
21 several medicines, for children, for patients with a
22 compromised capacity to absorb, metabolize or
23 eliminate drugs.
24 Therapeutic substitution is of particular
25 concern in outpatients since adverse or suboptimal

Page 116

1 effects may not be easily detected.
2 Let's get into NSAID. There was a good deal
3 of literature on therapeutic substitution in the NSAID
4 class, Nonsteroidal Antiinflammatories.
5 The next bullet, the second one on the top of
6 Page 3, I think, is very important to this group. It
7 says, during one two-year study, 49 percent of
8 patients were switched to another NSAID. Twenty
9 percent were switched two or more times and seven
10 percent were switched three times. Seven percent
11 received four or more different NSAID. So, that's
12 roughly 14 percent receiving three or more.
13 The data showed a very high prevalence of
14 product switching, indicating some level of
15 dissatisfaction with therapy on the part of the
16 patient or the physician or both. This process of
17 tailoring and individualizing the drug-
18 regimen-to-patient response may be negated if
19 therapeutic substitution occurs without detailed
20 knowledge of the patient history.
21 Furthermore, the potential for confusion is
22 great if a patient experiences an adverse effect from
23 a therapeutic substitute and the prescribing physician
24 thinks the patient has been taking the NSAID that was
25 originally ordered. It is, therefore, essential that

Page 117

1 physicians be informed of such substitution. There is
2 more there on NSAIDs.
3 It gives, I think, four reasons under the
4 next bullet, it says, therapeutic substitution of
5 NSAID for ambulatory patients may result in
6 compromised clinical outcomes because: Patient
7 response is unpredictable and selection of the optimal
8 agent must be tailored for each patient. Secondly,
9 substantial differences exist in adverse reaction
10 profiles. Third, drug interaction studies are
11 lacking. And, fourth, selection of an agent must be
12 individualized to insure compliance with the dosing
13 regimen.
14 The final prescribing decision, at least in
15 the NSAID category, must be based on seven factors:
16 Therapeutic efficacy; safety;--kind of what Mr.
17 Szalwinski was talking about--adverse reaction
18 profile; concurrent therapy; simplicity of dosage
19 regimen; patient acceptance and compliance; and, the
20 overall cost of treatment.
21 I don't know that those seven were listed in
22 order of importance. In other words, Number 7 may not
23 be the lowest one.
24 Okay. A little bit on cost data. You had
25 indicated that you would like to see some information

Page 118

1 on cost. You will see a couple of items here on some
2 cost studies, if you will. But, then, when they go
3 into the next category of where substitution or
4 interchange has worked, according to the literature,
5 you will also see more cost information. So it's kind
6 of scattered throughout these two headings here.
7 Someone had indicated at the first meeting
8 that there needed to be some discussion of the
9 ancillary cost associated with substitution. This
10 first bullet addresses that. It says cost, and it's,
11 again, dealing with NSAID. It says, cost savings
12 achieved through therapeutic substitution of NSAID may
13 be lost by additional overall treatment costs because
14 of adverse reactions or suboptimal therapy. The
15 occurrence of adverse or suboptimal effects in
16 ambulatory patients is more likely if NSAIDs are
17 substituted without full knowledge of the patient's
18 medical history and clinical status.
19 Communication between the pharmacy and the
20 prescribing physician regarding a patient's specific
21 needs is essential for rational substitution among
22 NSAID. I think we're starting to see some themes
23 here.
24 The next one was more of the more interesting
25 pieces of research to me.

Page 119

1 In a three-month study of arthritic patients
2 in the New Jersey Medicaid Program, the total cost of
3 therapy with aspirin was compared with that of
4 Piroxicam. Gastrointestinal problems were twice as
5 frequent in the aspirin group. Twenty-seven percent
6 of patients receiving aspirin also needed drugs to
7 treat the GI effects, as compared with 18 percent of
8 the Piroxicam patients. Three of the patients
9 receiving aspirins were hospitalized for peptic
10 ulcers. None of the Piroxicam patients were
11 hospitalized for peptic ulcers. The price of aspirin
12 per patient, $35.80, was much less than the price of
13 Piroxicam, which was $67.38. However, when the
14 GI-related hospital and physician costs were factored
15 in, the overall cost of aspirin therapy per patient
16 turned out to be $100.43, which was greater than that
17 for Piroxicam, which was $76.65. So, that addresses,
18 at least in this one instance, some of the ancillary
19 costs associated with these particular medications.
20 Okay. Where substitution or interchange has
21 worked, that's the next heading, I think, to summarize
22 this up front before I get into it more detailed.
23 From the literature, it indicates that it can "work"
24 in acute care settings for specific drugs under very
25 specific conditions. And, I think I'll get into those

Page 120

1 in a little bit. Just bear that in mind as I go
2 through here.
3 A therapeutic interchange program based on
4 institution-specific microbial patterns and
5 educational efforts by the Pharmacy Department
6 produced a change in physician prescribing --
7 ampicillin-sulbactam was substituted for cefoxitin.
8 Is that correct?
9 MS. SISLER: Yes.
10 MR. WORTHINGTON: The infectious disease
11 pharmacist provided education through one or more of
12 three methods, and I think this is a critical
13 component to making it work in an institutional
14 setting: That's education, communication. The first
15 thing--continuing education programs were made
16 available. Provision of concise guidelines for ways to
17 suggest antibiotic interchange to a prescribing
18 physician or follow-up to further enhance the
19 knowledge base of the pharmacist when lack of
20 knowledge by the pharmacist was determined to be the
21 apparent cause for any reluctance or inability to ma
22 a successful interchange.
23 The next bullet talks about a two-tiered
24 approach to therapeutic interchange in a hospital
25 setting. It argues that it can be successful in

Page 121

1 reducing costs. Again, I should point out that the
2 literature that I reviewed, at least in successful
cases, in cases where substitution allegedly worked,
primarily focused on the cost of the medication. There
5 was very little literature on the quality of patient
6 care.
7 This two-tiered approach, it says, in such a
8 system, some drugs are considered interchangeable and
9 are automatically interchanged by pharmacy for the
10 prescribed product. For other drugs, for which
11 therapeutic equivalence is not as close or the dosing
12 regimens differ, the concept of "class representative"
13 is used, i.e., only one drug, determined by price, is
14 on the formulary, and the physician is contacted to
15 change the order if a nonformulary alternative is
16 prescribed. When the "class representative" concept is
17 used, the pharmacy can switch the formulary status of
18 "equivalent" products without bringing the entire
19 issue before the P and T Committee.
20 Here is another one. In a nonteaching
21 community hospital, they were substituting -- Well,
22 let me read it. It was shown that Famotidine was as
23 safe and effective as IV Cimetidine or-- Help me,
24 David--
25 MR. SHEPHERD: Ranitidine.

Page 122

MR. WORTHINGTON: --Ranitidine. It sounds
2 like I'm stuttering.
3 And that it was feasible to add Famotidine to
4 TPN solutions. Blah, blah, blah. It was projected
5 that the interchange of IV Famotidine or Cimetidine or
6 Ranitidine would result in a total savings of over
7 $37,000 during the first year, due to reductions in
8 cost of drugs, supplies and nursing labor. More
9 examples, again, of specific drugs and specific cost
10 savings are through that part. I don't know that I
11 want to go over each one of them.
12 However, on Page 6, in the third bullet, I
13 think it points out, again, the programmatic aspects
14 of therapeutic substitution which are critical to it
15 working, when it is done in a hospital setting. It
16 says in a hospital setting a therapeutic interchange
17 program was initiated for drug products such as
18 vitamins and antacids. Products for which
19 interchanges are essentially noncontroversial. A
20 newsletter describing the Program was distributed and
21 in-service education sessions were held. A reminder
was placed on order forms that an interchange for
nonformulary drugs would be made, unless the
24 nonformulary agent was deemed "medically necessary" by
25 the doctor. In such cases, the physician was

Page 123

1 contacted to discuss the therapeutic alternative. As
2 acceptance of the Program and cost efficiencies were
3 demonstrated, more controversial agents were phased
4 in. Some agents, for example, third generation
5 cephalosporins were difficult to obtain approval for
6 addition to the program. That piece of literature I
7 remember very well David and I said why. Although we
8 can probably speculate. Again, more examples of where
9 the drugs have been substituted, where cost savings
10 have been realized and those programs that were
11 employed to substitute or follow.
12 Let's get in a little bit, then, to the next
13 heading which is "Legal Issues." Let's see, one
14 source says, of course, we all know this, the FDA
15 approves indications for drugs. Back on the NSAID,
16 again, different NSAIDs are approved for different
17 uses. Consequently, therapeutic substitution of one
18 NSAID for another may result in a situation in which
19 the patient received a drug that is not approved for
20 his or her condition. The legal implications of such
21 substitutions are unresolved.
22 The next bullet, I think, will illustrate for
23 all of us some of the scenarios we have been
24 discussing this morning about the relationship of a
25 patient to a pharmacist. Let's look at this one

Page 124

1 closely. In the chain of assumptions regarding a
2 hypothetical prescription, several events can occur.
3 Okay. Event one, let's look at that. Drug X1 is
4 substituted by a pharmacist without the patient's
5 knowledge from a formulary list of equivalent drugs.
6 The patient thought he was to get drug X not drug X1,
7 and his informed consent did not extend beyond X, a
8 brand name of a specified manufacturer. Or, two, drug
9 X1 is substituted by a pharmacist who informs the
10 patient that X1 is "the same as X," because, A, he
11 does not have X in stock or, B, X1 is a cheaper
12 anyway. The patient, thus informed, accepts the
13 pharmacist's recommendation and consents to the
14 substitution. In this scenario a serious reaction
15 attributed to X1 results.
16 Okay. The third scenario. Drug X1 is
17 substituted only after the patient says to the
18 pharmacist, don't you have anything cheaper but just
19 as good? Well, the pharmacist dispenses X1 without
20 informing the prescribing practitioner. A complication
21 allegedly results from the use of X1 in this case.
22 Okay. These three hypothetical substitution
23 problems illustrate how legal liability could shift
24 among potential defendants. Liability may not be
25 limited to the physician and the pharmacist,

Page 125

1 interestingly, but also it could possibly include the
2 formulary committee and/or the hospital, if the
3 hospital is solely controlling the pharmacy.
4 The next section of the literature review is
5 what I call "Commentaries and Positions." The
6 literature, at least what I have looked at, is rife
7 with both hard data, soft data--I think you all may
8 have referred to it as anecdotes before, and what I
9 call commentaries and positions.
10 Let's look at the first one. The American
11 College of Rheumatology opposes legislation or
12 regulation that would permit prescription therapeutic
13 substitution by a pharmacist as an action which is not
14 consistent with quality patient care and which will
15 pose unnecessary risks to patients' well-being.
16 The next one applies to generic
17 substitution. Let me go over that one. The practice
18 of therapeutic substitution represents an important
19 therapeutic modification with potential clinical
20 significance far beyond that of generic substitution.
21 Some political remarks. I guess this was
22 during health care reform. I wasn't clear of the date
23 of that particular piece of research.
24 The next to the last bullet on Page 8, is
25 very strongly worded. The term "therapeutic

Page 126

1 substitution" should be expunged from the pharmacists'
2 professional vocabulary. The term "substitution"
3 evokes deep, negative feelings, especially among
4 physicians. It means to them that a pharmacist
5 intends to change their orders, without their consent
6 and without their knowledge.
7 The next bullet. Active participation of
8 pharmacists with physicians in the drug therapy
9 decision-making process results in fewer drug-drug
10 interactions and adverse drug reactions, better
11 control of disease conditions, shorter lengths of
12 stay, lower costs, and so forth, than when that does
13 not occur. The key here is not to give all the credit
14 to pharmacy. It's not pharmacists alone who are
15 responsible for these positive outcomes. It's the
16 pharmacist-physician team that is responsible. It
17 transcends the individual pharmacist himself or
18 herself.
19 One author kind of waxed polemic on us. He
20 said a therapeutic interchange has been practiced
21 successfully in hospitals for so long as part of
22 formulary systems, why now is it becoming such a hot
23 topic? Well, the answer is that as the health care
24 system continues to change, and as more care is being
25 provided in nonhospital environments, pharmacists,

Page 127

1 physicians, administrators, and payers are looking to
2 apply the positive lessons of the formulary system to
3 the ambulatory sector. Efforts to duplicate hospital
4 outcomes in the ambulatory sector will be misguided
5 because they will substitute the decisions of facility
6 managers for those of pharmacist-physician teams.
7 There was some discussion of that, also, this morning.
8 Then, one more bullet. To summarize, I found
9 and I am not an advocate one way or the other. I'm
10 staffing the group. But, I found no position that
11 categorically supports the policy decision, if you
12 will, to therapeutically substitute or to
13 therapeutically interchange. However, I found and
14 reported to you specific instances where specific
15 drugs were determined to be substitutable--if that's a
16 word--and cost savings could result. But, I think,
17 based upon my analysis and synthesis of all this,
18 critical to doing that, is the approach to how you do
19 it. You know, involving pharmacists, involving the
20 P and T Committee, having a strong formulary,
21 communication, training, all of that. That's,
22 basically, the literature in a nutshell, as I see it.
23 Any comments or questions?
24 DR. DALTON: I'd like to comment. That was a
25 good summary, and I think that coming into this, I

Page

1 think we've recognized that we, as physicians, are
2 able to compromise and be flexible, as appropriate,
3 when it doesn't compromise patient care.
4 I think criticism of some of the drug
5 switching that was done was that the primary incentive
6 was economic, and I think we've focused on individuals
7 who were paid a specific bounty for switching drugs
8 and that was the reason for switching. And I think
9 that this next to the last bullet does summarize
10 things well, that, the extrapolation of the inpatient
11 type of patient management to outpatient management
12 and drug switching is fraught with a lot of potential
13 disaster, because of the controls not being in place.
14 I think there are instances of harm being
15 done that we, as physicians, are aware of. Someone
16 asked for cases. I know that, in one particular class
17 of drugs, the ACE inhibitors, angiotensin-converting
18 enzyme inhibitors, there's a specific side effect that
19 is present in all of those specific medications, to
20 some extent, but it ranges from one percent, maybe,
21 for one to up to eight or ten percent for others. And
22 that is a reaction where there is airway swelling and
23 compromise of breathing. Patients I am called in to
24 see on occasion and sometimes patients have been on
25 the medication for a while, it's hard to say why they

Page 129

1 have the reaction at a particular time after they were
2 started on it. And I think some of it is because they
were probably switched to another medication in the
class or other interactions may be involved. But I
5 think that we need to limit the reasons why we allow
6 substitutions, to the extent that's acceptable, and I
7 think that we need to carve out that part where the
8 primary reason to switch is for financial gain.
9 SENATOR NEWMAN: Mr. Chairman?
10 CHAIRMAN TEEFEY: Senator Newman.
11 SENATOR NEWMAN: This was hard work for you
12 guys, and I know, going out there and gleaning this
13 information is not easy. However, it appears from a
14 cursory view that it could have been called, because
15 of what you have to work with, the entire thing could
16 have been commentaried positions. And the reason is
17 because you're going out there and getting
18 commentaried positions of both sides. And, if I were
19 to think anecdotally about which example I would use
20 as a bad example, it would be with aspirin. We all
21 understand that aspirin can have negative effects, and
22 it's the perfect anecdotal reason. And that's what
23 I'm hoping that, while the document is maybe what's
24 out there, maybe what we're saying is there is not
25 much out there.

Page 130

1 MR. WORTHINGTON: Exactly.
2 SENATOR NEWMAN: Now, the other problem is
3 proving the negative on cost is almost as impossible.
4 Proving that it didn't save money in some cases is
5 almost impossible. So, I know this is the best that's
6 probably out there, but I'm worried about putting too
7 much stock in something like this, because it is
8 somewhat anecdotal and commentaried positions of
9 others.
10 MR WORTHINGTON: Well, there is a good deal --
11 I concur with most of what you said, Senator Newman.
12 But I think in the specific drug illustrations that
13 are provided in the literature, there are some hard
14 data indicating that some drugs may be substituted for
15 other drugs, at least in an acute care hospital
16 setting. It may be different. I think we'll get into
17 some of this, in any event. Dr. Carroll will probably
18 be addressing access to data, too. But, yeah, when
19 you start thinking about who funded the research and
20 for what purpose, and so forth and so on, you have to
21 look at all research with a, not necessarily a
undiced eye, but with a cautious eye, anyway. And I
23 think that the committee is wise to take that
24 approach.
25 MR. AYOTTE: Mr. Chairman?

Page 131

1 CHAIRMAN TEEFEY: Yes.
2 MR. AYOTTE: I have to go back to my original
3 point, Mike.
4 MR. WORTHINGTON: Okay, Mike.
5 What problem do you have with that
6 definition, if we try to buy off--
7 MR. AYOTTE: Well, my problem is very simply
8 this. And, again, representing the community setting,
9 it's illegal to make a switch, therapeutically, on a
10 chemically-dissimilar drug, without a physician's
11 consent. Now, this definition of therapeutic
12 substitution may exist in a closed environment or in a
13 closed hospital setting where that can occur.
14 Inferring into a definition that it can happen in the
15 retail setting, I think, is wrong. And I think in the
16 testimony that we got in the first meeting, if you
17 review it, someone had asked for a Board of Pharmacy
18 regulation to look at what really is there in writing
19 and in regulations now that would do this. And I
20 think you're saying that, yes, a therapeutic
21 interchange can occur with a physician; that's
22 perfect. But, also, I think a therapeutic substitution
23 in a nonclosed environment, okay, a nonhospital, which
24 a lot of these examples are hospital environments, I
25 think we need to clarify that so that we're all clear,

Page 132

1 because you don't have pharmacists out there
2 substituting without physicians' consent.
3 MR. WORTHINGTON: So there is no therapeutic
4 substitution then in an ambulatory care setting in
5 Virginia?
6 MR. AYOTTE: The only thing you can substitute
7 for ambulatory setting is if it's voluntary formulary
8 and it shows on the Virginia formulary, which is,
9 realistically, a list of drugs that are chemically
10 similar to each other.
11 MR. WORTHINGTON: And generic substitutions.
12 MR. AYOTTE: Right. But, the generic drugs are
13 listed in the Virginia voluntary formulary.
14 DR. KNAPP: And from the DHP perspective, I
15 can speak to that. I didn't bring my code book with
16 me. I apologize. But, I think the interpretation of
17 the scope of the practice of pharmacy would make that
18 a true statement that, without, in an ambulatory
19 setting, it would not be legal. Your definition of
20 therapeutic substitution would not be legal. It would
21 be outside of the scope of practice of a pharmacist in
22 the Commonwealth of Virginia, and they would be hauled
23 up in front of the DHP.
24 MR. WORTHINGTON: Has that ever happened, by
25 the way? Has it ever occurred, that someone has been

Page 133

1 punished?
2 DR. KNAPP: Not in the last five years, that I
3 can think of.
4 MR. WORTHINGTON: Okay.
5 DR. KNAPP: But I can't tell you
6 definitively. And that was going to be my question,
7 actually, assuming there is a pharmacist Code of
8 Ethics, are any of these assumptions about these
9 hypothetical situations, would this be considered
10 unethical?
11 Cindy, even from a pharmacy perspective, I
12 would think that most of them would be considered
13 either illegal or unethical, from a pharmacist's
14 perspective.
15 MS. WARRINER: I know that -- I agree with
16 Mike Ayotte's statement as far as what was occurring
17 in an ambulatory setting. The only exception I would
18 take is to believe there is some nonresident
19 mail-order pharmacies that are out-of-state that may
20 not necessarily comply with all of those statutes that
21 those practicing within the State would have to comply
22 with, and whether or not they adhere to the Virginia
23 voluntary formulary. I think that remains to be
24 seen. So, at least, with the ones that have their
25 buildings in Virginia, I think Mike's statement is

Page 134

1 accurate. So,--
2 MR. AYOTTE: Cindy, I'm sorry to interrupt
3 you. But you would then look towards amending current
4 Board regulations, because I believe Wyatt sent a
5 letter to the Board of Pharmacy last year indicating
6 the laws that exist and how they would be able to be
7 applicable for this situation. So, I mean, the Board,
8 I believe is also looking at telepharmacists and
9 having them registered within the State, I believe.
10 CHAIRMAN TEEFEY: Yes, sir?
11 MR. WALKER: Mr. Chairman, it's been alluded
12 to earlier today that the Board of Pharmacy does have
13 purview over the drug switching people. I'm Chairman
14 of the Board of Pharmacy, currently, and we've been
15 advised by Counsel that we currently do not have the
16 statutory or the regulatory authority to regulate
17 these now.
18 I believe, when the Durrette Group had their
19 Bill proposed, there was some alternative regulation
20 changes that would have given us that authority. But,
21 I think it was opted to proceed with the Durrette Bill
22 at that time. So, currently, the advice that our
23 Counsel gives us is that we do not have the ability
24 to, and I see that as a problem--a big problem. But
25 you do have the ability, if they do it without

Page 135

1 contacting the prescriber, it does fall within the
2 practice of pharmacy. ?
3 MR. WALKER: They are not, if they're not
4 licensed by the Board, then we have no authority, and
5 currently they are not.
6 MS. PIGG: Who is the "they"?
7 MR. WALKER: Whoever is, it would be alluding
8 to a pharmacy out-of-state or someone, you know,
9 whatever.
10 DR. KNAPP: But if it's a licensed pharmacy
11 from within the State, you've got jurisdiction.
12 MR. WALKER: Yes. We have jurisdiction over
13 that, yes. But if the switch, like I say, it was
14 mentioned today that we had authority over all the
15 parties that are involved, and we do not. Only the
16 pharmacists who are licensed by the State do. So,--
17 MR. SZALWINSKI: Well, a remedy to that might
18 be that all prescriptions dispensed for residents of
19 Virginia must be dispensed by pharmacists licensed in
20 Virginia.
21 DR. KNAPP: We have visited this issue on the
22 Board of Medicine lots of times and, actually, there
23 is wording to that effect running around out at the
24 DHP; that if you're going to practice, operate,
25 prescribe, or otherwise on a patient or on a resident

Page 1

1 of the Commonwealth of Virginia, that you need to be
2 licensed by the Board of Medicine in the
3 Commonwealth. And, obviously, that is a hugely
4 controversial perspective that I'm a sure a lot of
5 people don't agree with.
6 But, you know, I think to tell a pharmacy is
7 probably even a bigger problem or a mail order
8 pharmacy might even be a bigger problem than
9 telemedicine is for the moment, but not for the long
10 run. You know, I would question whether or not that
11 is a topic that we really want to tackle, but we may
12 have to.
13 DR. BLANCHARD: It is my opinion, based on
14 some of the comments last meeting, that it was at
15 least fairly clear to me that there was a distinct
16 difference between therapeutic substitution, as you
17 define it here, and therapeutic interchange. And
18 that, in fact, what we were looking for in this
19 committee, unless people are talking about legalizing
20 therapeutic substitution in Virginia, was a discussion
21 of the pros cons and risk benefits of therapeutic
22 interchange.
23 I think it would be very helpful if, as we
24 receive data from other people, and as we discuss it
25 among ourselves, that we are very clear on how we use

Page 137

1 those two terms. There is a huge difference between
2 whether a physician is consulted or whether the physician is not consulted. I would make one point,, to clarify that, though, is that if a formulary is
5 sufficiently restrictive, that therapeutic interchange
6 with a consultation back to the physician, it de facto
7 becomes therapeutic substitution, because there is no
8 other drug. And, in deference to the patient's
9 wallet, the physician, generally, is going to have to
10 defer and acquiesce to that substitution, if you will,
11 that interchange. But, I think we do need to keep in
12 mind that we're talking about therapeutic interchange,
13 and I would have liked to have seen this report or
14 would like to see in the future, more information on
15 pros and cons of therapeutic interchange, if they
16 exist.
17 MR. WORTHINGTON: It's not there. It's not
18 there.
19 DR. BLANCHARD: I'm particularly interested
20 that you chose not to review the paper that's been
21 bandied about right and left by Susan Horn with
22 respect to the cost to the total system and systems
23 that had what I understand were therapeutic
24 interchange and restrictive formularies and the effect
25 that had on total cost. And, members of this

Page 138

1 committee, I think, are interested in how they should
2 evaluate that particular study since it's--
3 MR. WORTHINGTON: Well, I guess it's, with all
4 due respect, Dr. Blanchard, it's like everything else
5 that I get involved in, anyway. I know that I'm
6 involved with the Liaison Committee, the Pharmacy
7 Liaison Committee, and language is thrown around, with
8 all due respect to the Legislature, language is thrown
9 around that's not always accurate. We had some,
10 referring to DUR that Dr. Pugh gave a presentation
11 about. There's some language on, DUR shall do this
12 and DUR-- When, in fact, it was prior authorization is
13 what they were talking about. So, I'm not so sure
14 that restricting ourselves to therapeutic interchange,
15 if that's what you're saying is necessarily our sole
16 charge. I think that, perhaps, the language
17 "therapeutic interchange" encompasses substitution,
18 and so forth and so on. I think we would be remiss if
19 we didn't at least address all of them.
20 DR. BLANCHARD: But Dr. Horn's study was--
21 MR. WORTHINGTON: Right.
DR. BLANCHARD: --not reviewed by you for a
particular reason or--
24 DR. PUGH: I didn't get it. It was just not
25 given to me. It was certainly not purposeful. I was

Page 139

1 not at the first meeting. I was under the impression
2 that you-all may have discussed some of that at the
3 first meeting. But, maybe that's erroneous--
4 DR. BLANCHARD: No. I think many of us have
5 not seen or read the entire--
6 MR. WORTHINGTON: I'll get that for the
7 Committee.
8 DR. BLANCHARD: --study. I certainly
9 appreciate the input from pharmacists and academicians
10 on how much faith to put into conclusions of that
11 particular study.
12 SENATOR NEWMAN: Mr. Chairman?
13 CHAIRMAN TEEFEY: Yes, sir.
14 SENATOR NEWMAN: Just one other comment. I
15 think that the comment that was just made is awfully
16 important, because the effects and risks associated
17 with substitution, if it is beyond our purview of our
18 discussion, then we're bringing in information that
19 really won't have an effect on our indecision if our
20 indecision is going to be something about interchange.
21 So, if the committee, I don't know Mr. Chairman, if it
22 is, but if we are, mostly on this particular subject,
23 going do be dealing with interchange, then we need to
24 be dealing mostly with risks as other things
25 associated with interchange and understand that there

Page 140

1 is something else out there called substitution, but
2 that's not what we are going to be discussing.
3 MR. WORTHINGTON: Well, I concur, then. I
4 think this afternoon, in this afternoon's session,
5 when Mike and I get together and work you through
6 that, that we may be able to come up with some
7 consensus on, not just definitions, but the purview of
8 the Committee, if you will.
9 To illustrate and, Michael, maybe you can
10 help me out a second. I won't take but one more
11 minute. But, I'm a subscriber or beneficiary,
12 whatever, with HealthKeepers, Blue Cross. I take, in
13 the fall, I get all sorts of sinus infections. I'm an
14 outdoor kind of guy, you know, work in the yard and
15 all that. And, I found--I've tried, everything. I
16 have switched, I guess, and Hismanal is the drug that
17 I found that does me the best to treat this sinus
18 infection stuff. I got a letter from HealthKeepers
19 back in February saying that this is no longer paid
20 for by HealthKeepers. We suggest you use Claritin.
21 And, if you have a problem with that, see your doctor.
22 Now, is that a substitute? What is that? Is
23 that therapeutic substitution? What is the basis of
24 that decision? I'm not addressing it just to you,
25 Mike, but illustrative of what I have been through. I

Page 141

1 don't know anything about Claritin. I know that
2 Hismanal works for me.
3 DR. BLANCHARD: Your doctor also received a
4 letter, as I did, saying that Mr. So and So is taking
5 Hismanal and Hismanal will no longer be covered
6 starting January 1. You need to make another
7 decision. We suggest, and they list whatever their
8 suggestion is. I would suggest that that is a request
9 for you to make a request--
10 MR. WORTHINGTON: To my physician.
11 DR. BLANCHARD: --for an interchange.
12 MR. WORTHINGTON: Got it.
13 DR. BLANCHARD: Because, obviously, the
14 pharmacist cannot fill Claritin in place of your
15 Hismanal without the physician's consent.
16 MR. WORTHINGTON: Okay.
17 CHAIRMAN TEEFEY: Does that clarify it?
18 MR. WORTHINGTON: Of course.
19 MR. SZALWINSKI: Dr. Blanchard,--
20 DR. BLANCHARD: Yes, sir.
21 MR. SZALWINSKI: -- can I ask you question?
22 Prevalence in the United States documented here, did
23 you find anything about prevalence in Virginia?
24 MR. WORTHINGTON: Did you find anything,
25 Julie?

Page 142

1 MS. SISLER: No.
2 MR. WORTHINGTON: No.
3 MR. SZALWINSKI: So, we don't know what the
4 prevalence is in Virginia?
5 MR. WORTHINGTON: At least, not based on our
6 search.
7 DR. PYLES: Not at the present time.
8 MR. SZALWINSKI: So, there is no literature to
9 substantiate any kind of a rate of this going on?
10 MR. WORTHINGTON: It's just not there. It's
11 just not there.
12 MR. SZALWINSKI: Were there criteria that you
13 used for pulling these studies? Were there specific
14 key words that you may have used or was there a
15 clinical review of the studies for how you chose to
16 include or not include them?
17 DR. PYLES: Yes. I directed Julie, based on
18 our discussions, and so she used key words, drug
19 switching, drug interchange, anything that was related
20 or came up in any of our previous discussions, are
21 pretty broad-based, across all the literature. We not
22 only looked at clinical journals, but we also looked
23 at economic literature, because you have to look
24 across the broad spectrum of literature to get at this
25 issue. So, we did do a pretty broad-based search

Page 143

1 across several data bases using the same key words in
2 each of the data bases.
3 MR. SZALWINSKI: About how many citations did
4 you come up with?
5 MR. WORTHINGTON: Julie, you gave me a
6 printout. Probably ten or twelve pages with maybe
7 four or five cites per page. Does that sound about
8 right? Maybe 60, I guess.
9 MR. SZALWINSKI: And the rationale for getting
10 from 60 pages to 20 studies was?
11 MR. WORTHINGTON: I read them all. Well, I
12 read everything that was given to me, and I pulled out
13 what I determined to be -- I mean, I could have cited
14 seven or eight of the same thing, that said the same
15 thing. However, I did some synthesis, if you will,
16 some analysis and said, well, I can't bring them all
17 here. Let's just use these as representative. And, as
18 I said in the beginning, this is not an exhaustive
19 list, although there is not much more out there that's
20 going to say anything different. But it is
21 representative of what the literature says that's out
22 there. I want to make that very clear.
23 But, what literature there is out there, I
24 believe these remarks reflect, to the best of my
25 ability, very accurately, the sentiments of the

Page 1

1 literature. Sentiments isn't the right word. The
2 positions, if you will, of the literature.
3 DR. PYLES: And I can also say that one of the
4 things that we did was, we looked, since the situation
5 in hospitals is different from the ambulatory setting,
6 and that's really where we are today, we have a lot of
7 older literature from institutional settings, so we
8 chose not to include a lot of that here, because we
9 felt that that would pretty much have been put to
10 rest. So, what we were trying to do is to look at
11 this situation from the ambulatory setting, and it's
12 just not there. It's not a lot of empirical. It's
13 just not there.
14 MR. WORTHINGTON: Mike, Dr. Pyles, is
15 correct. There were several cites, Mr. Szalwinski,
16 that go back to the early 1970s. And I thought those
17 were, perhaps, too dated for the group. I think I did
18 use one from 1975, making all the positions, but I
19 tried to stay as current as I could.
20 MS. PIGG: When you were reading the studies,
21 in the ones that you elected to report, did you read
22 them with a clinically critical eye of double-blinded,
23 randomized, passed the wrong pole.
24 MR. WORTHINGTON: I looked at the methodology,
25 sure. I didn't rate their methodologies, but I looked

Page 145

1 at the methodologies and, you know, these are
2 respectable journals. You know, I can't question the
Annals of Pharmacotherapy, and so I would assume that
4 their editorial Board selected research that was done
5 very well.
6 MS. PIGG: But, in our literature search, we
7 really did not do a critical review as far as the
8 validity of the actual study.
9 MR. WORTHINGTON: I don't think that's my
10 position to do that. No, I didn't do that, and I
11 wouldn't do that.
12 DR. PYLES: And, we're probably really not put
13 in a position to talk about clinical validity, except
14 what was reported there, in most cases.
15 MS. PIGG: Only to the point of, if you put a
16 conclusion down, it's nice to have a sense of whether
17 or not the study designed was valid, whether or not
18 you can put any weight on the conclusion.
19 MR. WORTHINGTON: I can attest to the ones
20 that are from the journals, the scientific journals.
21 They meet their standards. If our standards are
22 different, that's another issue. But they meet their
23 standards, and I think we have to go on that.
24 Okay. Anything else?
25

Page 146

1 NOTE: (No response.)
2
3 MR. WORTHINGTON: Thank you.
4 CHAIRMAN TEEFEY: Dr. Carroll. Dr. Carroll is
5 a Professor at the Pharmacy School at the Medical
6 College of Virginia.
7 DR. CARROLL: Thank you, Joe. My name is
8 Norman Carroll, and I'm a Professor of Pharmacy
9 Administration at the School of Pharmacy at the
10 Medical College of Virginia. Due to the sensitivity
11 of this issue, I need to tell you that I'm here
12 speaking as a researcher and as an individual and not
13 as an official representative of the School.
14 What I would like to comment on is the lack
15 of research information on therapeutic interchange,
16 specifically on drug switching. As someone who has
17 done research in this area or probably more precisely
18 who is trying to do research in this area, I have run
19 into three barriers to doing research. Okay. The
20 first is, there is a pharmacy regulation which
prevents pharmacists from sharing patient data with
any one other than the physician or the pharmacist.
23 Okay. From the point of view of a researcher, that
24 prevents you from going into community pharmacies and
25 getting drug switch information.

Page 147

1 The second barrier is the common practice of
2 PBNs and managed care organizations of making
3 pharmacists sign confidentiality statements. Again,
4 these statements say that the pharmacists can't reveal
5 patient information without the express written
6 consent of the PBM or the managed care organization.
7 So, again, there is a barrier to my going into a
8 community pharmacy and getting drug switch
9 information.
10 The last barrier is a little less obvious.
11 And, that is I think there is a reluctance on the part
12 of a lot of pharmacists and a lot of physicians to do
13 anything which they think might antagonize or might
14 criticize managed care organizations. The feeling is
15 that if I, as a pharmacist, antagonize an insurance
16 company, that company may then throw me out of its
17 network or no longer allow me to participate. So if
18 you think drug switching is something that might
19 antagonize a managed care organization, then you're
20 not going to get involved in research on it.
21 Now, these three restrictions substantially
22 increase the difficulty and the expense of doing
23 empirical research on drug switching. So, as a result,
24 I think if there is going to be any large scale
25 research efforts, they're going to have to be

Page 148

1 supported by the PBMs and the managed care
2 organizations which are doing the drug switching,
3 because they have the data. And until these
4 organizations do the research or until they share
5 their data with outside researchers, about all we're
6 going to know about drug switching and about all we're
7 going to know about the effect of drug switching on
8 patients is what we can glean from small-scale surveys
9 and anecdotal evidence.
10 Any questions?
11
12 NOTE: (No response.)
13
14 MR. SZALWINSKI: Just for the record, there is
15 legislation in Virginia which prevents managed care
16 organizations from excluding pharmacies from their
17 network, I believe. Am I correct?
18 SENATOR NEWMAN: Yes. Unless it's an ERISA
19 Plan.
20 MR. SZALWINSKI: Right, unless it's self
21 funded.
22 DR. KNAPP: Unless it's an ERISA plan, which--
23 MR. SZALWINSKI: Right. So commercial HMO
24 populations have to have an open network.
25 SPECTATOR: That legislation is qualified by

Page 149

1 the fact that the pharmacists or physicians who wish
2 to be providers in that network must be willing to
3 comply with all terms and conditions that other
4 providers are complying with. So, if one of those
5 conditions is a provision in the contract that
6 prohibits you from disclosing information about
7 planned participants to third party sources, you must
8 comply with that or you can breach your contract and
9 then the Freedom of Choice Law does not apply.
10 MR. SZALWINSKI: Maybe a reasoning behind
11 that, if, and I hope that you never are in a position
12 of having a terminal disease or one that you would not
13 like communicated to people that don't know you, you
14 would very much, as a consumer, want that information
15 to be kept confidential, I would imagine.
16 DR. CARROLL: Absolutely.
17 MS. PIGG: Norman, just for your information,
18 since I'm here as a representative of the Academy of
19 Managed Care Pharmacy, the Foundation of Managed Care
20 Pharmacy is actually trying to come up with a study
21 designed to look at some of this, but it was very
22 involved. They anticipate it to take three years.
23 They also anticipate a cost of well over a million
24 dollars and not desiring to seek funding from,
25 necessarily, pharmaceutical companies. I'm not sure

Page 150

1 where it's going to go either.
2 DR. CARROLL: Yes. I agree with all of that.
3 But, when you come down to why is there no data, it's
4 just hard.
5 MR. COUNCIL: I'd just note, too, that
6 HCFA-approved Medicaid contracts also have similar
7 confidentiality provisions. It's not just a matter of
8 managed care organizations and PBMs that are imposing
9 confidentiality.
10 CHAIRMAN TEEFEY: I think the reason Norm is
11 here is because, when we were searching through all of
12 this data trying to come up with something, Norm was
13 aware of it, and he wanted to make it clear to the
14 Task force why we have only what we have here,
15 basically. I think it's real important that we heard
16 that.
17 Thank you, Norm.
18 During the break we had a few questions about
19 materials that were handed in and some materials that
20 weren't handed in. We had the two individuals that
21 made presentations last time to really review the
22 materials they sent in so we make sure that the Task
23 Force has all the materials we need and the complete
24 materials we need.
25 Kenneth, do you want to review the materials

Page 151

1 you sent us?
2 MR. McARTHUR: Yes, sir. Thank you.
3 CHAIRMAN TEEFEY: Kenneth sent his in. The
4 next guy is the bad guy. He didn't send it in.
5 MR. McARTHUR: Let me state for the record
6 that I'm here against my will, but here to serve at
7 the pleasure of the Chairman. Because I do think that
8 attorney and/or lobbyist grandstanding on these issues
9 should be kept at an absolute minimum: preferably
10 there should be none at all. But I will, having said
11 that, very quickly go through and list for you,
12 without much commentary, because I don't think that
13 I'm nearly as qualified as the members of this Task
14 force to assess the validity of or analyze the data
15 that we have submitted to the Task Force.
16 Most of the lengthier documents that I have
17 submitted have their own executive summaries already
18 prepared by the authors and attached those documents,
19 so I won't try to substitute those authors' summaries,
20 either. And, moving on, then, to the list of documents
21 that I have already provided to the Task Force through
22 the facilitator, Dr. Pyles, and also in a letter to
23 the Chairman of the Committee, Mr. Teefey, we have
24 provided, to begin with, two letters which Wyatt
25 Durrette and I co-authored, which were sent to the

Page 15.

1 Virginia Board of Pharmacy last fall. And, in those
2 letters, we tried to summarize, as best we could, the
3 problem that we were seeing with drug switching in
4 Virginia. In particular, with some of the new
5 contracts that we saw emerging beginning last summer--
6 By "contracts," what I mean are Provider Agreements
7 that were being issued by certain managed care
8 organizations to pharmacists.
9 In those letters, we attempted not only to
10 bring what we saw clearly as a problem to the Virginia
11 Board of Pharmacy, but to review for them the existing
12 Virginia law that we thought would give them the
13 jurisdiction or authority to actually take action
14 against some of these companies for engaging in the
15 practices that we were seeing, which we believe were
16 harmful.
17 The Virginia Board of Pharmacy, I believe,
18 did look closely at this issue. I believe that they
19 publicly stated concern with the problem of drug
20 switching in Virginia. I believe they held a hearing
21 in which at least one PBM was present and attempted to
22 describe its policies in a particular contract that it
23 had issued to Virginia pharmacists. I don't know that
24 the Virginia Board of Pharmacy has taken any action,
25 any affirmative steps since then. It's my

Page 153

1 understanding that their legal counsel, who, of
2 course, is the Attorney General's Office, has advised
3 them that while they may have general statutory
4 authority to take action to regulate some of these
5 practices, it's the Attorney General's Office's
6 opinion that they do not have specific authority and
7 don't feel comfortable in advising the Virginia Board
8 of Pharmacy to take action absent that specific
9 authority.
10 Just as a word of explanation, that is what
11 led to the Virginia Anti-Drug Switching Patient
12 Protection Act last year. That was an attempt to get
13 that express authority. It would have provided that,
14 that statute would have provided that authority not
15 only to the Virginia Board of Pharmacy, but to the
16 Virginia Board of Medicine, to the Attorney General's
17 Office, who would have also created a private cause of
18 action.
19 Beyond those two letters, we provided, at
20 Dr. Pyles' request, a copy of the final version of the
21 Virginia Anti-Drug Switching Patient Protection Act
22 which was considered, in its last forum, by the House
23 Committee on Health, Welfare and Institutions, and
24 that was Senate Bill Number 1114, as amended. We also
25 provided a copy of a statement which was prepared and

Page 154

1 presented by the New York Public Advocate, Mark Green,
2 who, incidentally, had conducted, just prior to last
3 year's legislative session, a six-month long
4 investigation in the State of New York on the practice
5 of drug switching. His Staff had gone out into
6 pharmacies and into doctors' offices, and had looked
7 at documents provided by managed care organizations.
8 Having conducted this six-month long study, prepared
9 an approximately 100-page report in which the New York
10 Public Advocates Office denounced the practice of drug
11 switching, and pointed out examples of, specific
12 examples of patients who had suffered harm from the
13 practice, pointed out concerns voiced by various
14 health care provider and consumer groups, and also
15 made recommendations for legislation, which were
16 similar to what eventually became the language that
17 was advanced in the Virginia Anti-Drug Switching
18 Patient Protection Act here in Virginia.
19 Mr. Green, and by the way, we also included a
20 copy of that six-month-long study, as well as an
executive summary of the study. Mr. Green's statement
was included. These were his comments that he
23 presented to the House Committee on Health, Welfare
24 and Institutions during last year's General Assembly
25 session.

Page 155

1 In addition to that, we also produced a
2 document which was prepared by two PhDs who, I
3 believe, were contracted by the National
4 Pharmaceutical Council and these two individuals
5 surveyed the existing published literature on the
6 subject of restrictive drug formularies and the
7 various practices associated with enforcing those,
8 including drug switching, therapeutic interchange,
9 therapeutic substitution, generic substitution and a
10 host of others. I won't try to summarize that report,
11 but I will just read very briefly for the Task Force
12 Committee what the authors stated at the very
13 beginning of that report, which was that,-- That
14 report, by the way, was entitled, "Component
15 Management Fails To Save Health Care System Costs --
16 The Case of Restrictive Formularies," and it was
17 published in August of 1996. The statement at the
18 beginning of that report was, This report is a
19 comprehensive overview of the published literature
20 going back several decades on the impact of
21 restrictive formularies. This body of literature
22 indicates that such formularies often have a negative
23 impact on overall cost and quality of care; that they
24 often fail to achieve their fundamental goals and may
25 paradoxically exert adverse effects on budgets,

Page 156

1 patients, doctors and pharmacists. Taken together,
2 these studies show that although drug costs in the
3 restrictive category were often decreased, the
4 predominant effects of restriction were to shift costs
5 by increasing utilization of either nonrestricted
6 drugs or other health care services. None of the
7 studies clearly showed an association between drug
8 restriction and reduced costs in other health service
9 categories.
10 In addition to that survey of the literature
11 which we've produced, which, by the way, included the
12 study which was conducted by Dr. Susan Horn that I
13 believe Dr. Blanchard referred to earlier, we produced
14 an individual copy of the Susan Horn study, as well as
15 an executive summary of that study. In addition to
16 that, we produced a copy of a document which was some
17 50 or 60 pages in length. It was a document that was
18 prepared by the California State Senate Committee on
19 Insurance. That Committee is chaired by Senator
20 Herschel Rosenthal. That Committee has had hearings
21 and the Staffers from that Committee, I have talked
22 with them, have conducted an investigation, which I
23 believe is ongoing, into the practice of drug
24 switching and the use of restrictive drug
25 formularies. That document contains a number of

Page 157

1 statements by various health care provider
2 associations, consumer groups, and others concerned
3 with the potential harm and actual harm caused by drug
4 switching practices. That has been provided to the
5 study committee, as well.
6 Finally, we have produced to the Task Force
7 some, what I would call, just lobbying materials.
8 These were simply statements which were prepared last
9 General Assembly session in an effort to try to
10 summarize some of the arguments on the side of those
11 who supported the Virginia Anti-Drug Switching Patient
12 Protection Act. I asked Dr. Pyles whether he was
13 interested in those, and he said he was interested in
14 any information that we had on the subject, and so I
15 gave him those. There were also some documents which
16 were used to attempt to dispel some of the myths and
17 some of the confusion that I think surrounded the Bill
18 and what it did, what it did, in fact, do or would
19 have, in fact, done had it been enacted into law.
20 Finally, I also asked Dr. Pyles if he would
21 be interested in various articles related to this
22 subject which have appeared both in Virginia State,
23 local Richmond and even other state's publications and
24 in national publications, both trade press articles
25 specific to the pharmaceutical industry, articles that

Page 158

1 are a little broader in the sense that they would be
2 classified, I think, as health care articles, in
3 general, and not necessarily related, specifically, to
4 the pharmaceutical industry, and then articles that
5 appeared in the more popular press such as the Wall
6 Street Journal, the New York Times, transcripts of
7 programs that appeared in the CBS evening news, CNN
8 and the like. In these articles, there are quotes from
9 various interested parties in the issue of drug
10 switching. And, more interesting to me, I think,
11 there are some accounts of consumers who have been
12 affected by the practice of drug switching. What we
13 have not produced and which we intend to produce very
14 quickly, and I apologize that we haven't yet gotten
15 this to the Task Force, is all of the legislation that
16 we could find that we think is, either has been
17 considered, in some cases enacted, or is currently
18 being considered in other states. I would say that we
19 have, in the California Senate Committee on Insurance,
20 a report on this subject. There are, I believe,
21 there's at least one Bill there. I believe that there
22 is a Bill being considered in New York, which is
23 similar to the Virginia Bill from last year, and I
24 also understand, because I've called and checked on
25 this, and spoken with some folks last week, that a

Page 159

1 coalition of health care providers and consumer groups
2 in Maryland and D.C. are also currently considering,
3 and at least, at this point, favorably considering
4 Bills which have wording which are identical to the
5 Virginia Anti-Drug Switching Patient Protection Act,
6 which was introduced in Virginia last year.
7 I belief that is everything that we have
8 produced to the Task Force to date. We do have some
9 other documents which we're accumulating, including
10 the legislation, which we would like to continue to
11 offer to the Task Force. And, as we discover other
12 items, we would also like to be able to supplement
13 that, from time to time, if we could. I believe that
14 that is it.
15 CHAIRMAN TEEFEY: Do you have any, Mike?
16 MR. AYOTTE: I guess I want to piggyback on
17 Senator Newman's comment earlier about where we stick
18 on information concerning therapeutic interchange and
19 not formulating utilization and not switching. I
20 mean, I really want to stay focused on that one
21 terminology.
22 The other thing is, can we, when I spoke the
23 last time and that's on Page 29 of the transcript, we
24 were talking about cost factors and how there were
25 some statements made about increase in costs, and you

Page 160

1 stated that, in fact, I see ample evidence that will
2 decrease costs in the overall health care plan. So,
3 in my view, passing the Bill would decrease costs, not
4 increase costs. Is there any evidence that you can
5 show or any studies that you have that you would be
6 able to provide us?
7 MR. McARTHUR: I may not have understood your
8 question. Did you say, are there studies to show that
9 there would be an increase in overall health care
10 costs as a result of therapeutic interchange?
11 MR. AYOTTE: You stated on Page 29 that you
12 had evidence that it would decrease costs by passing
13 that Bill.
14 MR. McARTHUR: Oh, yes. Well, I think what
15 that is, is the corollary to the fact that there are
16 studies that show that the practice increases costs.
17 Logic would dictate that, if you end the practice,
18 then, that those costs would decrease.
19 MR. AYOTTE: There's no hard studies or facts
20 that show that?
21 MR. McARTHUR: Not to my personal knowledge,
22 no.
23 CHAIRMAN TEEFEY: Yes.
24 DR. KNAPP: I think you brought up a point
25 that needs to be clarified. What pharmacy practices do

Page 161

1 the Board, do the Board counsel say you don't have
2 jurisdiction over? If a pharmacist taking a $12
3 kickback for-- Let me step back.
4 The pharmacist gets the prescription from the
5 patient. If the pharmacist does not call the
6 practitioner who wrote the prescription and fills the
7 prescription with a different drug, that's legal or
8 illegal?
9 MS. WARRINER: That is illegal and you have
10 jurisdiction over that pharmacist and that
11 pharmacist's license.
12 MR. WALKER: Where we don't have the
13 jurisdiction is a third party being involved and
14 saying, we want you to make this switch.
15 DR. KNAPP: Right. Right. But you do have --
16 MR. WALKER: For the pharmacist that practices
17 in Virginia, of course, we do.
18 DR. KNAPP: Would it be considered unethical
19 conduct under the current Code regulating the practice
20 of pharmacy in the Commonwealth of Virginia, would it
21 be considered unethical conduct to accept a $12
22 kickback to change a prescription? Would you bring
23 somebody up before the Board of Pharmacy saying, we
24 consider this unethical conduct, if you've done this?
25 MR. WALKER: I'm not sure.

Page 162

1 DR. KNAPP: And you have never brought anybody
2 up?
3 MR. WALKER: To my knowledge, it has not been
4 done.
5 DR. KNAPP: So, where the counsel for the
6 Board of Pharmacy is telling you, you don't have
7 jurisdiction over the PCMs and the third party
8 pharmacies and all the rest, that would be--
9 MR. WALKER: That's correct.
10 DR. KNAPP: That's one of the same problems we
11 have in medicine.
12 MR. WALKER: That's right. Yes.
13 DR. KNAPP: I just think that's really
14 important, because I hear the whole issue of the $12
15 going to the pharmacists for changing the prescription
16 is one of the questions and one of the problems
17 they've been asked to address. Is that not ethical
18 conduct and that's something that can already be
19 addressed in the Code under the auspices of the Board
20 of Pharmacy?
21 MR. WALKER: I'm not sure that it is. We are
22 not allowed to take kickbacks from physicians or
23 physicians from us, as you know. But, as far are as,
24 you know, from other individuals, I'm not sure how
25 they -- I'd have to check on that.

Page 163

1 DR. BLANCHARD: Can we read the statute that
2 applies to that? I think it's just important. I
3 think we have it right here.
4 What is prohibited in Virginia, and I have
5 the Number 110-20 through 90. Pharmacists shall not
6 solicit or foster a prescription practice with a
7 prescriber of drugs or any other person providing
8 rebates, kickbacks, fee splitting, or special charges
9 in exchange for the prescription order, plus fully
10 disclose in writing to the patient and the third-party
11 payer. What's not clear, I guess, to me is whether
12 that's only a relationship between you and the
13 physician.
14 MR. WALKER: That's right.
15 DR. BLANCHARD: Or the interaction occurred
16 between you and the physician in order to get the
17 permission to get the switch, but the kickback comes
18 from a third-party payer. And, if it is unclear to
19 you, in your position, it certainly deserves some
20 attention by this Committee to make sure that we are
21 going to suggest that we don't need legislation, that
22 the Board of the Medicine can take, the Board of
23 Pharmacy can take care of this; that we need to make
24 sure that the statute is clearly written and fully
25 understandable of this.

Page 164

1 So I'm concerned that you're confused.
2 MR. McARTHUR: Mr. Chairman, would it be
3 possible for a representative of the Attorney
4 General's Office to prepare and appear at the next
5 meeting before the Task Force to address this issue?
6 CHAIRMAN TEEFEY: I think what the Attorney
7 General is going to want to do is respond to the Board
8 of Medicine, rather than come here.
9 I'm almost sure that's what they are going
10 to--
11 DR. KNAPP: They give you written legal
12 opinion on your jurisdiction.
13 SENATOR NEWMAN: Mr. Chairman?
14 CHAIRMAN TEEFEY: Yes, sir.
15 SENATOR NEWMAN: If I could, the Attorney
16 General sits over there to help us, though. I think
17 that we can ask him to come in here and give us some
18 opinions.
19 CHAIRMAN TEEFEY: Oh, I'll ask him. I'll ask
20 the Attorney General.
21 SENATOR NEWMAN: He's got a lot to do, but he
22 doesn't have--
23 MR. McARTHUR: You might want to let Senator
24 Newman ask him.
25 CHAIRMAN TEEFEY: I think it will go a lot

Page 165

1 farther. But, usually, when we have the Attorney
2 General come to a meeting like this, they always tell
3 us they would rather respond to the question that
4 comes from whichever Board. I think that's the
5 response we're going to get, unless Senator Newman
6 asks him.
7 MR. COUNCIL: Mr. McArthur?
8 MR. McARTHUR: Yes, sir.
9 MR. COUNCIL: Has the AG's Office even
10 expressed to you that it disagrees with the
11 conclusions in the September 10 letter to the Board?
12 MR. McARTHUR: No, sir. They have not
13 expressed disagreement with that to me. They have
14 expressed concern that the individual members of the
15 Board of Pharmacy and that the Board of Pharmacy, in
16 general, would be sued by managed care organizations
17 if they were to attempt to regulate the practice of
18 drug switching in Virginia.
19 MR. COUNCIL: Well, how does that -- I'm not
20 sure how that language jives with your conclusion.
21 MR. McARTHUR: I don't know. You have to ask
22 the Attorney General's Office, sir. That's why I was
23 suggesting that we --
24 Let me see if I understand what you just
25 said. I mean, as I understand what the Chairman of

Page 166

1 the Board of Pharmacy just said that if you're
2 Virginia licensed and you drug switch, they can
3 regulate you. And, if it is a drug switch, it's
4 unlawful, as that term has been used here, meaning
5 without the consent of the physician.
6 MR. McARTHUR: Right.
7 MR. COUNCIL: Okay. So, I mean, your response
8 was broad, then. You were talking about out-of-state
9 pharmacists who are not licensed in Virginia?
10 MR. McARTHUR: No, sir. My understanding,
11 from discussions with the representatives of the
12 Attorney General's Office is that it is not crystal
13 clear enough for the Attorney General's Office to
14 advise the Virginia Board of Pharmacy that they can or
15 should take action with comfort, even as against
16 licensed resident Virginia pharmacists.
17 A SPECTATOR: That's very interesting. The
18 issue is the therapeutic interchange where the
19 financial incentive is to the individual community
20 pharmacist. In that context, in our letter, we
21 throughout the Board did have the authority to reach
22 that and we set that out and cited the Code Section,
23 and so forth. In the meeting with the AG, as we
24 understand it, the one advising the Board, told the
25 Board that he was not as confident as we were, and

Page 167

1 that they may not have the authority to reach that
2 practice and that they risked being sued if they
3 sought to reach that practice.
4 MR. AYOTTE: Under current regulation?
5 A SPECTATOR: Yes.
6 MR. AYOTTE: Right. So regulation could
7 easily be changed to accommodate that problem.
8 MR. McARTHUR: Well, except that the Attorney
9 General's Office went on to say that they also are not
10 clear that there is express authority to promulgate
11 regulations that regulate the practice, and they feel
12 they--
13 MR. AYOTTE: Well, I would be willing to
14 discuss that with the Attorney General. I mean, there
15 are few Boards in the Commonwealth that don't have
16 widespread authority to regulate the practice that
17 they're directed to regulate.
18 MR. McARTHUR: Steve, understand that we--
19 SENATOR NEWMAN: We don't disagree with you.
20 MR. McARTHUR: We don't disagree with that. We
21 think they do have the authority. But, when our legal
22 opinion was put before them, the Attorney General's
23 representative disagreed with us. So,--
24 MR. AYOTTE: I understand.
25 CHAIRMAN TEEFEY: Are you in complete

Page 168

1 agreement with that?
2 SENATOR NEWMAN: Almost.
3 MR. WALKER: I'm in agreement with, as they
4 stated, that's the AG's response. I'm not -- Well,--
5 CHAIRMAN TEEFEY: I mean, not in agreement
6 with what, but I mean in agreement that the AG's
7 response --
8 MR. WALKER: Yes, sir.
9 CHAIRMAN TEEFEY: Okay. So we've got a problem
10 with the regulations?
11 DR. KNAPP: Yes.
12 MR. JENKINS: Mr. Chairman?
13 CHAIRMAN TEEFEY: Yes.
14 MR. JENKINS: I attended a Board of Pharmacy
15 meeting where one of the PBMs was asked to explain its
16 practices. And one of the issues that was covered in
17 that meeting has been glossed over here, and it's the
18 regulation that's cited in Mr. Durrette's letter of
19 September 10, to which Mr. Council alluded, and which
20 Dr. Blanchard read. That regulation is keyed to
21 disclosure. And, if you're doing this behind
22 somebody's back without disclosure, you violate this
23 regulation, and I didn't hear anyone from the Attorney
24 General's Office say that if this practice is engaged
25 in without disclosure, the Board could not take

Page 169

1 appropriate action.
The questions, some of the questions that were asked at that Board meeting, as I recall, had to
4 do with the adequacy of disclosure, and whether the
5 spirit that is embodied in the disclosure requirement
6 in this regulation was being honored. And, so, I think
7 that it may be necessary for the Attorney General to
8 state what its position is on the current regulations,
9 rather than all of us speculating as to whether the
10 Board does or doesn't have power. Because, if the
11 Board has power to regulate appropriately, then, to
12 Ayotte's question, why are we here? I haven't figured
13 that one out yet.
14 CHAIRMAN TEEFEY: Okay. We will get a -- I
15 will get with you-all and we'll see if we can't--
16 We'll get a clarification.
17 MS. WARRINER: I was going to say, Joe, to
18 clarify that, too, I think there was also some
19 confusion about the dollars that we talked about, the
20 $12 that you keep hearing, and whether or not that
21 was, in fact, payment for service provided to the
22 patient or whether or not, in fact, that was payment
23 for completing a drug switch. And I see those as two
24 separate entities, too, and I think there was some
confusion as to whether or not those were two separate

Page 170

1 entities.
2 CHAIRMAN TEEFEY: Okay. Mr. Rosenthal?
3 Steve kind of misunderstood what we talked
4 about last time, and he's brought his information in
5 today and we'll have it to all by tomorrow.
6 MR. ROSENTHAL: Yes. I apologize. There was
7 some conversation subsequent to the last meeting in
8 which I thought there was a different plan of action
9 and so I apologize for not getting this material to
10 you earlier. However, I'm confident that the quality
11 of material will more than offset my transgression.
12 I also apologize, having walked in and seeing
13 that you have notebooks in front of you, I apologize
14 for putting these in notebooks. I probably should have
15 just stapled them altogether with holes. But, be that
16 as it may.
17 Let me, while he's passing those out, I would
18 like to pick up on a comment that Senator Newman made,
19 and I believe some others at the end of the desk over
20 here made about the literature review and combing
through carefully how much weight should be put on
some of these things.
23 I notice, for example, I couldn't help, since
24 I'm a lawyer, I couldn't help noticing that under the
25 "Legal Issues" part that one of the cites is to an

Page 171

1 article that dates back to 1975, some 22 years old
2 now, and it applies to generic drug substitution. So,
3 and I say that, not at all to be critical, because I'm
4 not being critical. I say that in the sense that, as
5 Senator Newman said, we need to look at all of this
6 material carefully, look at the date of it, see if
7 there's been any new material since then, and, if
8 there are studies, who funded the studies, for
9 example, and what the quality of those studies is.
10 I did not include in my notebook any lobbying
11 materials. Believe me, we have plenty if you want
12 them, and they all relate to Senate Bill 1114. My
13 understanding is, I would hope that this Task Force,
14 as I suggested last time, starting from a clean slate,
15 and that that piece of legislation, which did not pass
16 the General Assembly, is not going to be used as a
17 springboard to whatever this Task Force does. That is
18 why I have not included any lobbying materials in
19 there, and I don't intend to, unless you ask me to.
20 Very briefly, since you have not had a chance
21 to review this material prior to the meeting, I will
22 just quickly go through and tell you what's here.
23 I have divided it into, if you look at the
24 Table of Contents, into five different sections. The
25 first section is, are documents, basic definitions and

Page 172

1 explanations of drug formularies, the ways that they
2 should be properly used, and therapeutic interchange.
3 Probably the most important section is the next
4 section which is Therapeutic Interchange/Clinical
5 Research.
6 Note importantly that none of this research
7 is older than a year. All of this is since, I believe,
8 the summer of,-- Well, since September of 1996. So,
9 this is all current literature. What most of these
10 are, are actual tests that were done on therapeutic
11 substitutions and what the results were. And I ask you
12 to look at those carefully, because, number one, you
13 will see how seriously these tests are taken and the
14 depth with which the researchers go, to which the
15 researchers go. And they are done by pharmacists,
16 PhDs. Two of them are from universities, schools of
17 pharmacy and schools of medicine. The last one is from
18 Creighton University, both the School of Pharmacy and
19 the School of Medicine. I'm referring now to Tabs 5
20 through 8.
21 What these show are two things. One is, the
22 first question they always ask, and the overall
23 question of value, is, what is the value the patient,
24 which I think we all agree is the most important
25 question. And these studies find, at least as to these

Page 173

1 drugs, that there were the same or better outcomes
2 from switching, number one, and, number two,
3 significant cost savings, which is the second value
4 issue. In one study, the savings, without any overall
5 adverse outcomes, savings of over a quarter of a
6 million dollars over a two-year period. These numbers
7 take into account, by the way, something that Mr.
8 McArthur mentioned to you at the last meeting, which I
9 think is important, and that is the components of
10 health care costs.
11 Mr. McArthur stated to you that while you may
12 reduce costs in one component area, you may increase
13 in cost in another component area or component areas.
14 For example, if a person doesn't do well on a
15 medication, having been put on that after taking the
16 first medication, the person may end up in the
17 emergency room, which is ultimately going to cost more
18 than if they had stayed on the first medication. And,
19 therefore, the total health care costs rise because of
20 that switch.
21 What you will find here is that these studies
22 do look at the component parts of health care costs,
23 and they quantify those and they show, again, after
24 finding value to the patient, they find significant
25 cost savings. So I ask you to look at those with the

Page 174

1 same critical eye that I mentioned earlier and the
2 same critical eye that Senator Newman suggested. Look
3 at who's doing the study, how it was funded, and the
4 parameters within which the study was done.
5 The third section is responses to the Horn
6 study. At the risk of being redundant and picking up
7 on Dr. Blanchard's comment, how seriously you should
8 take that study, I think, is well reflected in Tabs 9
9 through 13. I will not tell you what, I will not go
10 through in detail what those responses to that study
11 say. But, what you will find is it has been roundly
12 criticized as poorly modeled, extremely superficial,
13 with absolutely no correlation between the results
14 that were purported and the basis for those. In other
15 words, there is no causal connection between an
16 alleged switch and the results that they report.
17 That's what those responses are going to say.
18 Now, two of those articles are by a PhD,
19 Frederick Curtis. We will present to you, at the
20 appropriate time, at the appropriate meeting, Mr.
21 Curtis, who is from Texas. We will bring him up here
22 so that you will have the benefit of discussing this
23 issue directly with him.
24 The fourth section and earlier Mr. Green's,
25 Mark Green, the New York City Public Advocate, his

Page 175

1 comments were referenced and what they found. You
2 will find at Tab 14 an exhaustive analysis and
3 criticism of the study done by Mark Green, almost a
4 line by line analysis and the defects in that study.
5 Everything from the monolene to the results. While I
6 discussed the inadequacies last time of the Money
7 Magazine article, there is another article in the
8 fifth section of Tab 16 about how unfair that article
9 was.
10 I would hope that my example to you last time
11 showed how poorly done and how unfair and also the
12 comments by Dr. Hadley, who had spoken with the
13 physician involved in that case, how poorly and unfair
14 that article was done.
15 With that, we will continue to rummage the
16 record, see what we can find to try to be helpful, and
17 I hope this material is helpful to you, and I will get
18 with the Chairman and find an appropriate time to have
19 Dr. Curtis address you.
20 CHAIRMAN TEEFEY: Are there any questions?
21
22 NOTE: (No response.)
23
24 CHAIRMAN TEEFEY: There was some discussion at
25 the break that we didn't have the complete Horn

Page 176

1 study. Is this true?
2 DR. BLANCHARD: That's correct. At least, the
3 packet of material that I received did not include
4 much of the information that Ken McArthur suggested
5 was sent in. Obviously, that included that study.
6 CHAIRMAN TEEFEY: Ken, did you get a copy of
7 the complete study?
8 MR. McARTHUR: Yes, sir.
9 I think Dr. Pyles said he was going to
10 rectify whatever wasn't sent out.
11 DR. PYLES: It's a voluminous amount of
12 material, so we'll do the best we can.
13 Mr. Chairman?
14 CHAIRMAN TEEFEY: Yes, sir.
15 MR. AYOTTE: One of the things, and I know you
16 will probably get to it, just to get the information,
17 if this is all that's out there now from both sides of
18 the issue, that's great. But, if there is sometime
19 where we could get it and have time to review it, and
20 I know we have limited meetings left to make a
21 decision, it just seems to continue to gather
22 information and getting this stuff the day of the
23 meeting, I find it very difficult to absorb it. So,
24 if we can get that in advance, it would be very
25 helpful.

Page 177

1 CHAIRMAN TEEFEY: It's 12:30 right now, and I
2 have some physicians up here that told me if you think
this switching is bad, if I don't have them out of
4 here by 12:30, about the switching I'm going to get.
5 So, we have a couple other things on the
6 Agenda, and we might have to bypass those. But, I have
7 one important question. I need to know what the Task
8 Force needs, and what they want to do in our next
9 meeting. I think that's very important that we come to
10 this point right now. If we could just go through and
11 if you have some suggestions, what you need in the
12 next Task Force. One other thing, I would like to
13 bring speakers in from the different associations:
14 Pharmaceutical Association, the Medical Society, et
15 cetera, to give some testimony and probably take up
16 Mr. Rosenthal on his offer to bring that person in.
17 DR. PYLES: Mr. Chair, if I could just
18 interject one second before they tell us what their
19 needs are. Could I just bring us up-to-date in terms
20 of what I foresee in terms of getting to the final
21 report, and then we can hear what their needs are. Is
22 that all right? It will just take about a second.
23 CHAIRMAN TEEFEY: That's great.
24 DR. PYLES: As you-all are aware, one of the
things that we need to do in the report that we have

Page 178

1 to prepare is to make a statement about therapeutic
2 substitution or therapeutic interchange, and I think
3 we have pretty much, and, again, as you speak, you can
4 address this. I believe that we pretty much have
5 decided that we're not, in that report, and consistent
6 with the resolution, that we're not talking about drug
7 switching here, but we're looking at the impact of
8 therapeutic substitution and interchange. But,
9 because of the fact that these terms are often used
10 interchangeably, I think that one of the things that
11 we need to do pretty quickly, if we're going to move
12 along here, is we do need a statement, a consensus
13 statement at this point, from the Task Force in terms
14 of what it is we are talking about. Something that we
15 can all live with, that summarizes the issue, and I
16 think that's absolutely essential, Mr. Chair, before
17 we can move on to addressing the issue of impact.
18 Because, if one group or a couple of people are
19 talking about one thing, apples, and another group is
20 talking about oranges, we can't really talk about
npact.
So, I think that's one of the real key things
23 that we need to do. And, in the interest of time,
24 what I was going to suggest that we might do is,
25 before the next meeting, we need to circulate a

Page 179

1 statement; that's the starting point. We need to
2 circulate something that all of you would be
3 comfortable having your names attached to as this is
4 whatever it is. This is therapeutic substitution
5 therapeutic interchange. And, Mr. Chair, if it was
6 all right with you, I was going to suggest that, if we
7 could get a couple of people, maybe a subcommittee,
8 two or three, to work with me to develop that
9 statement and circulate it, and then, from there, we
10 could begin talking about how we can look at impact
11 and also what other speakers we need to bring in to
12 help us.
13 CHAIRMAN TEEFEY: All right. That would be
14 fine. But, I think I have been hearing it from a
15 couple of people that we are talking about therapeutic
16 interchange.
17 DR. PYLES: Okay.
18 CHAIRMAN TEEFEY: That we are not talking
19 about switching.
20 DR. PYLES: Right. Exactly.
21 CHAIRMAN TEEFEY: We are talking about
22 therapeutic interchange.
23 DR. PYLES: Okay.
24 CHAIRMAN TEEFEY: And I think that's the
25 starting point.

Page 180

1 DR. PYLES: That's the starting point.
2 CHAIRMAN TEEFEY: What we'll do is maybe get
3 four people, five people, on the Committee here and
4 we'll give you-all a call and set up a conference call
5 with some of them.
6 DR. PYLES: With a statement that--
7 CHAIRMAN TEEFEY: With a statement--
8 DR. PYLES: Right.
9 CHAIRMAN TEEFEY: --within the next week, so
10 we can send it out before the next meeting and
11 everybody will have it.
12 Go ahead, Dr. Blanchard.
13 DR. BLANCHARD: Mr. Chairman, I'm not sure
14 exactly where to start on suggestions on how we move
15 forward in the future. You made a comment at the first
16 meeting, that I didn't hear anybody object to, that
17 you have a lot of busy people on this committee that
18 have voluntarily given up their time to come in and
19 try to make the right sort of decisions; that we
20 already, that we agreed that we needed to do a lot of
21 homework, and we were willing to do the reading
22 necessary to take care of these problems. And, without
23 sounding disrespectful to people who make
24 presentations of written documents and knowing that
25 both sides of the issues have had at least three

Page 181

1 months to think about this process, I'm a little
2 concerned by the fact that we didn't have all the data
3 available from both sides way in advance of this
4 meeting.
5 I would personally prefer to have read these
6 documents at home, had a chance to think about them
7 and come in and ask pointed questions of those people
8 so that we can clarify the issues. Just as a starting
9 point, I might suggest, then, that we request and
10 expect that any interested parties that have
11 information related to our Task Force agenda provide
12 that information to Mr. Pyles no later than, say, next
13 Wednesday afternoon and that information submitted
14 after that be accepted with prejudice, unless we
15 honestly feel it is newly-discovered information.
16 Secondly, I had sent Mr. Pyles a letter
17 requesting information about 12 or 15 different
18 practices within the concept of therapeutic
19 interchange, and would hope, and I will be glad to
20 resubmit that letter if you didn't get it. I don't
21 have documentation that you got it, but those items
22 are the areas that I felt were of potential concern
23 within that topic. And I would hope that if people on
24 this subcommittee, this Committee, have requested that
25 sort of information, that we would get responses to

Page 182

1 that prior to the meeting.
2 Then, when we come to the meeting, then we
3 can talk among ourselves in a way to try to assess
4 where we should come down on these issues. I'm not
5 sure we all need to hear from a lot more speakers and,
6 in particular, Mr. Rosenthal's suggestion that we
7 might hear from somebody rebutting Dr. Horn's study, I
8 would think you would have to have Dr. Horn here, as
9 well. So, this could go on and on forever listening
10 to lawyer-type presentations.
11 I think we're very smart people on this
12 Committee. I think we ought to be able to do the
13 business of this Committee in fairly short order if we
14 can decide what it is we want to do and decide that
15 this is the data that we're going to deal with. And,
16 from that point on, it's up to our brains to make
17 those decisions.
18 CHAIRMAN TEEFEY: All right. That's a good
19 idea. And, if anybody wants to submit any materials,
20 we have to have them by next Wednesday so we can get
21 them to the Committee. Then, I think the next thing
22 that you expressed, we'll take those, that list that
23 you sent us, and we'll start working, the letter that
24 you sent, we'll work with that letter.
25 Yes, ma'am.

Page 183

1 DR. KNAPP: I think we do need to hear from
2 the AG's office one way or the other.
3 CHAIRMAN TEEFEY: All right. I will get with
4 the Board and we'll hook up with you and get Casway
5 and find out what the situation is.
6 CHAIRMAN TEEFEY: Yes, sir.
7 MR. AYOTTE: I think if you're going to have
8 speakers come at any point, and I agree with Dr.
9 Blanchard, I'm not sure at this point we haven't heard
10 pretty much all the argument. If they were going to
11 submit something, that they could go through the
12 Committee first and either give them their comments --
13 I just, when you look at the sheet, it just concerns
14 me, because the first meeting we talked so much about
15 facts, and that, to me, hasn't happened.
16 CHAIRMAN TEEFEY: Okay. Good. Do you have
17 anything? Senator Newman?
18 SENATOR NEWMAN: I'm glad what was mentioned
19 earlier was mentioned. I had written down "multiple
20 problems/multiple cures." As we talk along, I'm
21 identifying, for instance, things like the problem of
22 out-of-state vendors not going through the Board of
23 Pharmacy and these other things which are passing by,
24 which I see as solvable problems. Unless there is
25 some problem in the U.S. Constitution and the Commerce

Page 1

1 Clause or something, I think we should be able to
2 solve some of these problems. And, I'm wondering if
3 what has been done on the other end of the table might
4 be done by some of us, but maybe, more importantly, by
5 the opponents/proponents here where they can present
6 the multitude of problems. The large issue of drug
7 switching has many aspects to it that can be broken
8 down. And, if we can break them down, then we may
9 pick A, B and C, but we may not pick the rest.
10 We may be able to cure those and the rest we
11 may not be able to cure, and I'm wondering if we
12 cannot get from them the number of problems that exist
13 and then what their cures are and maybe hear from the
14 other side on what their cures are and maybe
15 collectively we can come up with some cures, as well,
16 and maybe even put some of them to bed quickly.
17 For instance, maybe we can ask that
18 legislation be drafted that requires everyone to go
19 through the Board of Pharmacy if they're going to
20 practice in Virginia, if we agree on that and, if
21 that's wrong, then we can build on that information,
22 and Staff has done such a great job. But if that's a
23 possibility of organization, that would help the guy
24 who is not a doctor on this Committee.
25 CHAIRMAN TEEFEY: Well, I think we have heard

1 what your needs and what your requests are, and we'll design the next meeting for those things, because I know we only have two more meetings left.

4 This is a hard subject to get your hands on.

5 I think we have defined part of it today by saying

6 we're dealing with strictly interchange and not with

7 switching, because we do get those two in together and

8 they're two different animals.

9 So I want to thank you all for coming, and we

10 will probably get with Dr. Blanchard, because we don't

11 have that letter, and make sure to get that.

12 Thank you all so much for coming.

13

14

15 * * * * * * * * * *

16 HEARING CONCLUDED.

17

18 NOTE: The hearing was concluded at 12:44 p.m.

19

20

21

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2 CERTIFICATE OF COURT REPORTER

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4 I, PATRICIA PRICE WHITE, hereby certify that

5 I was the Court Reporter in the hearing as captioned

6 on Page 1 hereof, when heard on the 16th day of July,

7 1997.

8 I further certify that the foregoing

9 transcript is a true and accurate record of the

10 testimony and other incidents of the HEARING herein.

11 Given under my hand this 21st day of July,

12 1997.

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16 PATRICIA PRICE WHITE, RPR, CP

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25 CRANE-SNEAD & ASSOCIATES, INC.

1 4914 Fitzhugh Avenue, Suite 203
Richmond, Virginia 23230
2 Tel. No. (804) 355-4335

3

July 21, 1997

4

5 Mr. Michael Worthington BY HAND DELIVERED
Dr. Michael A. Pyles July 22, 1997
6 Department of Medical
Assistance Services
7 600 East Broad Street
Richmond, Virginia 23219

8

IN RE: HJR 630- July 16, 1997 Hearing

9

Dear Mr. Worthing and Dr. Pyles:

10

Please find enclosed an original and one copy

11 of the transcript of the above hearing when heard on the 16th day of July, 1997.

12

Also, please find enclosed the miniscript

13 version I told you I would include at no charge. I thought this might help you with your copying time and

14 cost of paper.

15 Thank you for your business.

16

Very truly yours,

17

18

(Mrs.) Patricia Price White, RPR, CP

19

Enclosures

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Page 1

[1] VIRGINIA:
[2] DEPARTMENT OF MEDICAL ASSISTANCE
[3]
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[5] IN RE: HJR 630 SPECIAL TASK FORCE
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[8]
[9]
[10] Meeting of the Special Task Force held on
[11] August 20, 1997, General Assembly Building,
[12] House Room D, at 8:30 a.m.
[13]
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[19]
[20]
[21] CRANE-SNEAD & ASSOCIATES, INC.
[22] 4914 Fitzhugh Avenue
Richmond, Virginia 23230
(804) 355-4335
[23]
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Page 2

[1] MR. TEEFEY: I'd like to thank
[2] everyone for coming out on this nice rainy
[3] morning. And I want to thank Howard and Scotti
[4] for being here. They're with the Pharmacy Board.
[5] We talked to them numerous times on the phone
[6] during the month.
[7] We went into the minutes and
[8] took the questions that were asked at the last
[9] meeting and we reviewed those questions. Scotti
[10] and Howard will help us answer some of these
[11] questions.
[12] Mike, do you want to go over
[13] the materials and update?
[14] DR. PILES: Yes, sir.
[15] Good morning. You did receive
[16] quite a bit of material since our last meeting.
[17] I wanted to make sure you all got a copy of the
[18] letter that one of our Task Force members wrote,
[19] Larry Blanchard; also, the transcript from the
[20] last meeting. I noticed there was a missing
[21] page, which I have placed at each of your desks
[22] there. One single page representing 33 through
[23] 36 of that transcript. That missing page is
[24] there.
[25] We have also been working to

Page 3

[1] get some information. Earlier on someone had
[2] raised questions about some numbers in terms of
[3] how many Virginians may be covered by
[4] prescription-benefit programs. We're still
[5] working on getting that information. It's not in
[6] one location. I made several phone calls and may
[7] be on to something. It's kind of difficult to
[8] estimate. But we have been working on that.
[9] I have spoken to someone with
[10] the Bureau of Insurance at the State Corporation
[11] Commission. I think I'm getting to a point where
[12] I can come up, at least, with numbers in terms of
[13] how many Virginians are covered by
[14] prescription-benefit plans, so we might have an
[15] idea of, looking at impact, how they might be
[16] affected by that.
[17] Also, since our last meeting,
[18] you will hear some of this information today
[19] later, but I have included a copy of materials
[20] that we received from Scotti Russell from the
[21] Virginia Board of Pharmacy. She is the Executive
[22] Director. What you have are copies of material
[23] that she faxed to us. Those just came in so I
[24] provided them for you this morning on your desks.
[25] I think that's everything.

Page 4

[1] MR. TEEFEY: We polled the
[2] Committee-- There were some requests by both
[3] sides to bring in speakers. And we polled the
[4] Committee. I think Dr. Blanchard last time
[5] worded it extremely well that we heard enough
[6] from outsiders that we wanted to get the
[7] Committee and get this thing on the road.
[8] We are not going to have any
[9] speakers from outside come in, but we do have a
[10] public comment period. Mary wants to speak
[11] during the public comment period.
[12] I would like you to hold the
[13] comments to two or three minutes.
[14] MS. ROULEAU: Good morning,
[15] everyone. My name is Mary Rouleau. I represent
[16] Arlington, Virginia. I'm also representing the
[17] Consumer Federation of America. We're a
[18] federation of about 240 nationwide organizations
[19] providing membership of about 15 million people.
[20] CFA has been active on this
[21] drug switching issue. A week ago we held a press
[22] conference in Washington, D.C., along with public
[23] advocate for the state of New York, Mark Green.
[24] I believe you're all familiar with him.
[25] The big reason we held this

[1] press conference is because we think virtually
[2] none of the public and very, very few lawmakers
[3] are aware of either the industry's structure of
[4] the pharmaceutical benefit manager industry
[5] and/or the implications of drug switching.
[6] We have been involved for a
[7] couple of years in front of the Federal Trade
[8] Commission, Food and Drug Administration, and now
[9] we're taking our case to the Congress.
[10] We obviously have some very
[11] important anti-trust considerations associated
[12] with the vertical integration of this industry.
[13] But the major thrust of our press conference--our
[14] major concern--is the impact of drug switching on
[15] the quality of care for patients. We believe in
[16] some patients it presents very serious risks.
[17] I gave to Mr. Teefey's
[18] assistant here a packet of my material to give to
[19] you all.
[20] Suffice it say that the
[21] cornerstone of our press conference last week was
[22] a report from Mark Green's office. He had done a
[23] survey of pharmacists and physicians in the state
[24] of New York, and it's in the material.
[25] I just want to highlight a few

[1] of the findings. Of the physicians surveyed, he
[2] found that 83 percent of physicians are contacted
[3] by health care and pharmacists to change--to
[4] perform a drug switch, and 76 percent of
[5] physicians believe that a plan's use of
[6] therapeutic interchange significantly diminishes
[7] or diminishes the quality of care. 57 percent of
[8] the physicians responding reported that patients
[9] had problems after the prescription was switched.
[10] Mark Green's office also
[11] surveyed pharmacists in the New York City area.
[12] 74 percent believed that substitutions diminished
[13] the quality of medical care. 79 percent are
[14] somewhat uncomfortable making drug substitutions.
[15] This I find troubling: Almost
[16] half of the pharmacists responding believe that
[17] by not cooperating sufficiently with the plan
[18] substitution request, they will be penalized
[19] either by being audited or dropped from the
[20] network.
[21] Many pharmacists also
[22] testified at about four field hearings that they
[23] had in New York State on this issue, and several
[24] had to do it anonymously because they were afraid
[25] of retaliation. You'll find it in the material.

[1] Specific reports have been
[2] filed with the FDA regarding adverse impacts of
[3] drug switching, and other reports have been filed
[4] with the American Psychiatric Association.
[5] The report that you'll find in
[6] the materials builds on a December report release
[7] by Mr. Green, which describes at length the
[8] various tactics used on pharmacists and doctors
[9] in an attempt to get them to switch drugs.
[10] I will say generally, since
[11] this report--since we had our press
[12] conference--it got pretty good pick up
[13] nationally. I have had calls. Personally, I've
[14] had calls from the Pharmacy Board, a pharmacist
[15] and a patient all expressing their concern about
[16] these practices, and, basically, we are glad
[17] you're up front trying to do something. We're
[18] very concerned.
[19] I've given you a few facts and
[20] there's more in the materials. But I already
[21] know what the response is going to be from folks
[22] who think that the drug switching is not a
[23] problem.
[24] They'll say, "Well, this is
[25] nice, but this is all antidotal; isn't it?"

[1] Well, I have a couple of
[2] responses to that. First of all, how would you
[3] feel if the antidote was your mother or your
[4] daughter? I think we need to personalize these
[5] issues because these are happening to real
[6] people. Secondly, I find extremely troubling, is
[7] that this whole exercise is really premised upon
[8] the antidote that drug switching contains health
[9] care costs in a way that does not diminish
[10] quality. This is what the PBM industry says and
[11] it's about time they proved it. Make a mistake
[12] and the burden of proof is on the Industry, not
[13] on the patients or health care providers.
[14] The Industry is going to have
[15] to stop using the tired claim that this is
[16] proprietary data and can't give up certain
[17] information that people could use to quantify
[18] these claims.
[19] The government and private
[20] studies that I've reviewed, and I'm sure you all
[21] have them in your materials, suggest that the
[22] Industry has a long way to go before making its
[23] case. You know, for example, from the recent
[24] Inspector General's report that essentially no
[25] one is minding the stores. HMO is not

Page 9

[1] overlooking the practices of PBMs. That's why I
[2] think it's compelling for the state of Virginia
[3] to act.
[4] Now, CFA and our other
[5] partners are pursuing this issue at the federal
[6] level. Congress, as you probably know, is
[7] examining a whole range of issues regarding
[8] managed care. But we don't expect a quick
[9] resolution at the federal level. Among other
[10] things, there are splits in the jurisdiction over
[11] what these agencies can do. We believe that
[12] states can and should act in regard to formulary
[13] and drug switching practices.
[14] The patient needs the right to
[15] see the formulary list for their plan before they
[16] enroll. They need a quick-- And this applies
[17] also to the providers. They need a quick appeal
[18] process for doctor and patient when a
[19] non-formulary drug is prescribed. There needs to
[20] be oversight by the state, including issues such
[21] as whether the PMT Committee is really
[22] independent and what practices HMO and others
[23] engage in to secure formulary compliance.
[24] We believe that practices that
[25] allow financial considerations by HMOs or doctors

Page 10

[1] or pharmacists to overwrite some medical
[2] decisions should be prohibited, and there should
[3] be severe and certain penalty for noncompliance.
[4] You will find in the material
[5] there is a California bill pending right now that
[6] addresses many of these issues.
[7] Those are my remarks,
[8] Mr. Chairman. I would be happy to take any
[9] questions.
[10] MR. TEEFEY: Are there any
[11] questions?
[12] MS. PIGG: Can you give me an
[13] example of where a financial consideration should
[14] not be a part of the equation?
[15] MS. ROULEAU: Yeah. I think
[16] when you have flyers that are sent out to
[17] pharmacists that say, "Step right up. Get $12
[18] for hitting a home run," it sends the pharmacist
[19] to go beyond normal drug counselling, which I
[20] understand is not being performed that much
[21] anyhow because pharmacists are being overworked.
[22] It's improper financial consideration.
[23] In other words, it's clear
[24] that the amount of money on the table is on the
[25] table solely to get them to switch--encourage the

Page 11

[1] doctors to switch.
[2] MS. PIGG: So that's
[3] not--pharmacists should not receive payment for
[4] doing that service.
[5] MS. ROULEAU: For drug
[6] switching, no. I think they should be
[7] compensated for proper drug counselling. But
[8] it's very clear from the evidence, especially in
[9] Mark Green's uncover, this is not about patient
[10] counselling. This is clearly about incentive to
[11] get pharmacists to switch.
[12] Don't take my word for it.
[13] Look at the survey results from our survey. It
[14] is a limited survey. It is the New York City
[15] area. But it is some statistical evidence in
[16] response to the fact that it's all antidotal.
[17] I think there's a burden on
[18] the Industry to step forward and prove its case.
[19] MS. PIGG: So, from the
[20] consumer's point of view, do you think having a
[21] pharmacy benefit is valuable or should we go back
[22] to the old system where people pay for their
[23] drugs and physicians get a lot of their
[24] prescribing information from the drug
[25] manufacturer?

Page 12

[1] MS. ROULEAU: I think those
[2] are two different things you're saying. I think
[3] its important to have prescription drug benefits
[4] and health care plans. I don't have to tell you
[5] what that is for people who don't have that.
[6] It's important for the pharmacy benefits in a
[7] health plan. The benefits translate into a
[8] health system that allows pharmacy benefit
[9] managers to set the rules of the game.
[10] MS. PIGG: Is your concern
[11] solely with the PBM and not with the HMO that run
[12] their own type of business?
[13] MS. ROULEAU: No. It's with
[14] both. The thing that I find incredibly
[15] troubling-- It's in the Inspector General
[16] report. I'm assuming you're all familiar with
[17] it. It's in the material I gave you. It
[18] basically says HMOs are-- The use of PBMs is
[19] growing by HMOs. I think it's 75 percent. I
[20] could be off on that.
[21] So here is a bunch of HMOs
[22] that are contracting with these PBMs that provide
[23] virtually no oversight over their practices. To
[24] me that's unacceptable. The HMO has a
[25] responsibility to its enrollees to provide

[1] oversight. It's not just the PBM.
[2] Our particular concern, CFA's,
[3] on the PBM issue is that an industry that started looking one way in 1990 looks very different in
[5] 1997 because of drug integration. We think you
[6] cannot separate the two out. So we have some
[7] very compelling arguments to make about industry
[8] structure. But that doesn't necessarily address
[9] the subject of quality of care.
[10] MR. AYOTTE: One of the issues
[11] of the PMT Committee is, did you recommend
[12] independence for PBM?
[13] MS. ROULEAU: Absolutely.
[14] MR. AYOTTE: Wasn't that part
[15] of the PCS and Federal Trade Commission consent
[16] agreement?
[17] MS. ROULEAU: It sure was.
[18] But the question is are they effective. That is
[19] the $64,000 question. It's clearly built in the
[20] consent agreement. But the issue is, are they
[21] really independent.
[22] I don't know if you all saw
[23] the Money magazine article a few months ago.
[24] That was just impressed upon me. A statement of
[25] one doctor, who happened to be from Virginia by

[1] the way, about how she thought it was a rubber
[2] stamp.
[3] Yes, absolutely. Putting the
[4] word independent in a statute, frankly means
[5] nothing unless someone provides that oversight.
[6] What the Roosevelt Bill--California bill and it's
[7] in your materials, requires--would require these
[8] PMT committees to make their notes public.
[9] This is since the Department
[10] of Insurance oversees this stuff in California.
[11] The Department of Insurance would be able to look
[12] and see that these are independent bodies making
[13] independent decisions. It's an oversight
[14] question, I think, is where the problem is, not
[15] the language.
[16] MR. TEEFEY: Thank you.
[17] MS. ROULEAU: Thank you for
[18] your time.
[19] MR. TEEFEY: Are there any
[20] other speakers?
[21] We had a lot of very good
[22] questions asked of our member of the Task Force
[23] with the Pharmacy Board last time. We went back
[24] to the minutes and pulled these questions out and
[25] Howard Casway and Scotti Russell were kind enough

[1] to come today to answer those questions. We had
[2] talked to Scotti and Howard a number of times on
[3] the phone. I think a lot of answers will be
[4] given by them today.
[5] Michael, review the questions
[6] and Howard and Scotti can help us with this.
[7] MR. WORTHINGTON: Task Force
[8] members, as Mr. Teefey indicated I got on the
[9] telephone with Mr. Casway and Scotti Russell,
[10] Executive Director of the Board of Pharmacy,
[11] earlier this week. Dr. Piles and I did.
[12] We had previously gone over
[13] the transcript and looked through for the
[14] questions you had asked regarding legality issues
[15] surrounding that. I pulled four or five of them
[16] out of there. And I would like to summarize
[17] Mr. Casway's and Ms. Russell's responses. If we
[18] need further clarification, they are here.
[19] The first question I found is:
[20] What has been done in other states to address
[21] therapeutic interchange or substitution?
North Carolina recently passed
[23] a regulation requiring full disclosure if a
[24] pharmacist contacts a physician to try to switch
[25] drugs.

[1] The regulation reads: A
[2] permit holder or a register requesting a change
[3] for the prescription drug originally prescribed
[4] to a different prescription drug, shall disclose
[5] to the prescriber at the time of the request any
[6] business relationship between the permit holder
[7] or the register and the manufacturer of the
[8] requested prescription drug.
[9] This action was a result of a
[10] settlement agreement in 1995. In October of that
[11] year the Attorney General of 17 states, including
[12] North Carolina, entered into a settlement
[13] agreement with Merck & Company and prescription
[14] drug benefit management subsidiary, Medco
[15] Containment Services.
[16] The agreement recognizes
[17] Medco's practice of contacting prescribers that
[18] request changes of prescriptions from non-Merck
[19] drugs to Merck drugs. Payments were made by
[20] Merck Medco to each state in the amount of
[21] $115,000.
[22] The Medco practice was not
[23] prohibited. But Medco employees requesting a
[24] prescription change were required to disclose the
[25] relationship between Medco and Merck.

Page 17

[1] The next question: Does state
[2] law prohibit the practice of therapeutic
[3] interchange/substitution? Does the practice
[4] define the law? Does state law say anything
[5] about switching drugs based on rebates?
[6] The answer is: The law does
[7] not address the subject. Last year the Board of
[8] Pharmacy proposed the following language to the
[9] Division of Legislative Services as an
[10] alternative to Mr. Durrett's proposal--that was
[11] at Section 54.1.33.15, Code of Virginia.
[12] That proposal reads: Any
[13] pharmacist shall be considered guilty of
[14] unprofessional conduct who solicits the patient,
[15] prescriber or another pharmacist to permit
[16] substitution of a drug which is not the generic
[17] equivalent for the drug originally prescribed.
[18] Where the purpose for the
[19] proposed substitution is to assist the
[20] practitioner or the employer of the practitioner
[21] in receiving a rebate, kick back, fee, special
[22] charge or other monetary incentive directly or
[23] indirectly from the manufacturer of the drug to
[24] be substituted.
[25] For purposes of enforcing this

Page 18

[1] section it shall be assumed that the solicitation
[2] for the substitution of a drug which is not the
[3] generic equivalent to the drug originally
[4] prescribed, shall be for the purpose of receiving
[5] a rebate, kick back, fee, special charge or other
[6] monetary incentive.
[7] This section shall not apply
[8] where the drug substitution either reduces the
[9] actual cost, co-payment or co-insurance
[10] percentage payment required of the patient for
[11] the prescription or where the drug originally
[12] prescribed is not covered by the patient's health
[13] insurance plan.
[14] Next is: Is it illegal in
[15] Virginia for a pharmacist to switch a patient's
[16] drug to a chemically dissimilar drug without
[17] physician's consent?
[18] That's a roundabout way of
[19] asking the first question. The answer is: Yes.
[20] This practice is prohibited. The pharmacist has
[21] to dispense what the prescriber prescribed.
[22] Does the Virginia Board of
[23] Pharmacy have the statutory or regulatory
[24] authority to regulate the practice of therapeutic
[25] interchange/substitution? Are there any special

Page 19

[1] provisions for managed care organizations?
[2] The response: The Board of
[3] Pharmacy can regulate pharmacists and the
[4] practice of pharmacy. PBMs are beyond the
[5] Board's authority.
[6] Does Virginia law state that
[7] all prescription drugs dispensed for residents in
[8] Virginia must be dispensed by pharmacists
[9] licensed in Virginia?
[10] The answer is: The Board of
[11] Pharmacy regulates non-resident pharmacies. But
[12] all they have to do to conduct business in
[13] Virginia is to register with the Board of
[14] Pharmacy.
[15] The non-resident
[16] pharmacy--this is a definition--is any pharmacy
[17] located outside the Commonwealth of Virginia,
[18] which ships, mails or delivers in any manner
[19] Schedule II through Schedule VI drugs or devices
[20] pursuant to a prescription into the Commonwealth.
[21] The Board, again, has no jurisdiction over
[22] out-of-state PBMs.
[23] Mr. Casway and Ms. Russell are
[24] available if you have any questions.
[25] MR. TEEFEY: Howard, can I get

Page 20

[1] you and Scotti-- I've got two questions. The
[2] first one: Can you go over the responsibilities
[3] under the law of what the pharmacist's
[4] jurisdiction is and what the physician's
[5] jurisdiction is.
[6] MR. CASWAY: Speaking about
[7] the Board of Pharmacy's or the individual
[8] pharmacists?
[9] MR. TEEFEY: The individuals
[10] under the Board of Pharmacy.
[11] MR. CASWAY: The statue in
[12] Chapter 33 of 54.1 sets out the definition of the
[13] practice of pharmacy. Basically, among other
[14] things, is to dispense prescriptions.
[15] Counselling has been added to it. Let me look
[16] at--
[17] The practice of pharmacy means
[18] personal health service concerned with the art
[19] and science of selecting, procuring,
[20] recommending, administrating, preparing,
[21] compounding, packaging and dispensing of drugs,
[22] medicines or devices used in the diagnosis,
[23] treatment or prevention of diseases whether
[24] compounded or dispensed on a prescription or
[25] otherwise legally dispensed or distributed.

[1] MR. TEEFEY: So that's the
[2] pharmacist.
[3] MR. CASWAY: That's what the
[4] pharmacists' responsibility is.
[5] MR. TEEFEY: When the
[6] pharmacist gets a script, what can that
[7] pharmacist do with that script?
[8] MS. RUSSELL: The pharmacist
[9] can only dispense that prescription-- There's
[10] nothing that obligates him to dispense that
[11] prescription. But if he elects to do so, he can
[12] only dispense within the parameters of what the
[13] prescriber prescribed.
[14] MR. TEEFEY: So, if he changes
[15] that script al all, he has to get back with that
[16] physician.
[17] MS. RUSSELL: That's correct.
[18] The prescriber can, on the prescription, indicate
[19] his or her willingness to allow generic
[20] substitution by checking the formulary box or not
[21] checking the box at all. It would allow the
[22] pharmacist to substitute a formulary product.
[23] But if they are going to actually change the
[24] drug, they have to contact the prescriber.
[25] MR. TEEFEY: But it would have

[1] to be on the prescription to check off or
[2] something like that before--
[3] MS. RUSSELL: What the statute
[4] says--if you're talking about generic
[5] substitution now--is if voluntary formulary box
[6] is checked or no box is checked at all, then the
[7] pharmacist is bound to dispense the formulary
[8] product.
[9] MR. CASWAY: The product that
[10] is on the Virginia Voluntarily Formulary.
[11] There is also another box,
[12] dispense as written. That means the physician
[13] wants that drug to be the one that will be
[14] dispensed. Now, if there's a problem, that's
[15] when the pharmacist may have-- For instance, the
[16] insurance plan may not cover it. Many, many
[17] prescription plans do not cover name brands where
[18] there is a generic available.
[19] MR. TEEFEY: You have total
[20] control over all pharmacists and pharmacies in
[21] the state of Virginia; right?
[22] MR. CASWAY: If they're
[23] licensed and practicing, yes. If a pharmacist,
[24] by education a pharmacist, and practicing
[25] pharmacy but they're not licensed, then the Board

[1] has no jurisdiction. The court has jurisdiction
[2] through criminal prosecution or the Board could
[3] go in and seek injunctive relief to prevent the
[4] practice of pharmacy.
[5] MR. TEEFEY: Go over the state
[6] situation that Mike went over. Scotti, you went
[7] over it on the phone with me.
[8] MS. RUSSELL: Excuse me?
[9] MR. TEEFEY: The out-of-state
[10] mail order.
[11] MS. RUSSELL: A mail order
[12] pharmacy that actually dispenses drugs to
[13] patients who have residence in Virginia would
[14] have to register with the Board of Pharmacy as a
[15] non-resident pharmacy.
[16] In order to get that
[17] registration the only thing that the statute
[18] requires that they do is provide evidence that
[19] they are licensed in their resident state. They
[20] have to have an 800 number for the patient to
[21] contact them and they have be able to separate
[22] out the Virginia data of drugs dispensed upon
[23] request. They have to abide by all the laws and
[24] regulations of the resident state.
[25] They are not bound to abide by

[1] Virginia laws and regulations. So in a state
[2] that possibly allowed for therapeutic interchange
[3] without contacting the physician, if that was
[4] their resident state, then they could do that
[5] legally the way the law is written right now.
[6] In Virginia mail order
[7] pharmacies located in Virginia mailing out to
[8] other states, they typically somehow contact the
[9] physician either by fax or telephone and request
[10] permission for a therapeutic interchange.
[11] MR. TEEFEY: I have one more
[12] question. I'll hold that and see if anybody else
[13] has questions.
[14] MS. PIGG: What happened to
[15] the draft--working draft definition that
[16] addressed therapy, the switching by the
[17] pharmacist?
[18] MS. RUSSELL: Are you talking
[19] about the draft you were given this morning?
[20] MS. PIGG: Yeah, 5413300.
[21] MS. RUSSELL: Back in, I
[22] guess, November when we first saw Mr. Durrett's
[23] bill we provided--the staff of the Board of
[24] Pharmacy and Howard--we provided the Division of
[25] Legislative Services with a draft as a possible

Page 25

[1] alternative to that bill. We do that frequently
[2] if we look at something that's going to affect
[3] the Department of the Pharmacy.
[4] We offered that. We did not
[5] put that forward as a legislative proposal. This
[6] came up in November of last year. We saw it in
[7] June. So it was a little late for us to actually
[8] submit something as proposed legislation.
[9] We just offered this to the
[10] staff of Legislative Services in terms of
[11] technical assistance if they wanted to use it.
[12] They elected not to. It was offered as a
[13] possible alternative, but it was not used.
[14] MS. PIGG: Do you know why
[15] they elected not to use it?
[16] MS. RUSSELL: I assume the
[17] patron Butch Davie preferred to put in
[18] Mr. Durrett's bill instead.
[19] MS. PIGG: Help me understand
[20] the technical piece of this. The Board of
[21] Pharmacy felt that it affected therapeutic
[22] interchange or that issue that affected the
[23] practice of pharmacy, so you submitted
[24] legislation--language to deal with that.
[25] MS. RUSSELL: Let me correct

Page 26

[1] that. The Board of Pharmacy-- This was after
[2] the last Board of Pharmacy meeting for the year
[3] that we did this. The Board never met actually
[4] and approved this draft legislation. This was
[5] just some technical assistance the staff offered
[6] as a possible alternative. This was never-- At
[7] the time of last year, this was never adopted by
[8] the Board of Pharmacy as something they wanted to
[9] put forward.
[10] MS. PIGG: Where I'm going is
[11] if the staff of the Board of Pharmacy felt it was
[12] within their purview of the practice of pharmacy
[13] to submit language even addressing this issue, is
[14] that best where we put this, back to the Board of
[15] Pharmacy as opposed to legilsative efforts?
[16] MS. RUSSELL: The problem is I
[17] don't think the Board of Pharmacy has the
[18] statutory authority right now to deal with this
[19] issue in regulation.
[20] Maybe Howard can address some
[21] of the problems we might have with restraint of
[22] trade if we try to do something in regulation
[23] versus having some statutory authority
[24] specifically designed to deal with this problem.
[25] MR. CASWAY: What we attempted

Page 27

[1] to do-- The problem was brought up to the Board
[2] in the concept of-- The PCS program was brought
[3] to the Board and there was a fair amount of
[4] discussion and communication. And actually
[5] representatives from PCS came to the Board
[6] meeting prior to this November drafting of this.
[7] The Board was aware of what the problem was and
[8] we discussed some of the various things this
[9] committee is looking at.
[10] The problem that was clear,
[11] and as I stated before, the Board of Pharmacy
[12] regulates licensed activities within the state.
[13] There are a lot of things that may constitute the
[14] practice of pharmacy arguably. But certainly, if
[15] it's within the state, there are either criminal
[16] or civil sanctions to deal with it.
[17] However, if this is taking
[18] place outside the state--if a pharmacist or staff
[19] person from Arizona calls up a pharmacist in
[20] Virginia or calls up a doctor in Virginia
[21] regarding a prescription, the long arm of
[22] Virginia law does not extend that far.
[23] What we attempted to do was to
[24] create a mechanism as one of the alternatives
[25] that the Board of Pharmacy, by expanding the

Page 28

[1] scope of the practice of pharmacy, to include
[2] this kind of practice and then to expand as the
[3] result who had to register.
[4] Because pharmacists right now,
[5] as Ms. Russell indicated before, non-resident
[6] pharmacies have to register with the Board. What
[7] we tried to do is expand that to include
[8] PBMs--what essentially would be a PBM. That
[9] includes the practice of pharmacy. We expanded.
[10] I think the three things that
[11] we did was expand the practice of pharmacy; also,
[12] the definition of the term dispense to make the
[13] act of communication with the prescriber for the
[14] purpose of obtaining the authorization to
[15] dispense a different drug than the one originally
[16] prescribed to be in the practice of pharmacy.
[17] Secondly, we made it
[18] unprofessional--attempted to make it
[19] unprofessional the act of solicitation to permit
[20] this switch if there was a financial incentive.
[21] Last, the switch would benefit the patient.
[22] And thirdly, we changed the
[23] statute to make it non-resident pharmacies; to
[24] require any pharmacist located outside Virginia
[25] engaging in the practice of pharmacy with respect

Page 29

[1] to any Virginia citizen, to do so only in
[2] association with a non-resident pharmacy.
[3] What we attempted to do is
take the problem and bring it in clearly,
[5] statutorily within the control and regulation of
[6] the Virginia Board of Pharmacy.
[7] MS. RUSSELL: Also, we
[8] expanded the non-resident pharmacy to make them
[9] have to comply with the laws and regulations of
[10] Virginia, not just their resident state.
[11] MS. PIGG: It sounds like that
[12] process was started but never completed.
[13] MR. CASWAY: It was sort of,
[14] we through our hat into the ring and--
[15] MS. RUSSELL: --it didn't get
[16] picked up.
[17] MS. PIGG: Okay.
[18] DR. HADLEY: Can I just get
[19] some clarification? If we have a pharmacist who
[20] is registered with the Board in the state of
[21] Virginia, who makes a therapeutic substitution
[22] for a chemically dissimilar drug without
[23] consulting a physician, regardless of what the
[24] motivation is, whether financial gain or any
[25] other reason, you currently have jurisdiction

Page 30

[1] over that and that would be illegal.
[2] MS. RUSSELL: Absolutely.
[3] DR. HADLEY: Secondly then,
[4] how about clarifying again-- I understand the
[5] PBMs are an issue. But for a pharmacist or a
[6] mail order pharmacy outside the state of Virginia
[7] if they are registered with you, do you have that
[8] same level of control?
[9] If they make a therapeutic
[10] substitution without consulting the physician, do
[11] you have any ability, regardless of the reason,
[12] to discipline them?
[13] MS. RUSSELL: No. It's a
[14] non-resident pharmacy outside of Virginia.
[15] DR. HADLEY: But they're
[16] registered with you.
[17] MS. RUSSELL: The only thing
[18] we could potentially do is, in theory, I suppose,
[19] revoke or suspend their registration as a
[20] non- resident pharmacy. But do we have grounds to
[21] do that if the law says all they have to do is
[22] comply with the rules and laws of the resident
[23] state and if, in fact, their state permits that?
[24] MR. CASWAY: Also, the
[25] question would be getting jurisdiction over them.

Page 31

[1] Certainly, we could revoke their registration if
[2] there was a legal and factual basis to take
[3] action. They could perhaps continue to operate.
[4] It might be difficult for us to get jurisdiction.
[5] DR. HADLEY: Then for a
[6] pharmacist--again, let's confine this to a
[7] pharmacist in the state of Virginia, who is
[8] registered--would you, if a pharmacist calls a
[9] physician on a therapeutic substitution for the
[10] purpose of assisting a patient to comply with
[11] formulary requirements of their plan, whatever it
[12] is, so there is an economic benefit to the
[13] member, is that legal for the pharmacist, whether
[14] or not they're going to get a rebate from a
[15] company for doing such a service or payment?
[16] In other words, they do
[17] consult with the physician and it is for the
[18] purpose of aiding the patient to receive drugs
[19] under their formulary.
[20] MS. RUSSELL: For whatever
reason right now it would be not be illegal for a
pharmacist to contact a physician and request a
[23] switch.
[24] MR. CASWAY: That would be in
[25] compliance with the law. That would require the

Page 32

[1] pharmacist to do so.
[2] DR. HADLEY: Do we have a
[3] sense-- You mentioned earlier, Michael, that
[4] you're trying to get a sense of prescribing
[5] habits. Do we have a sense of what percentage of
[6] prescriptions are prescribed outside the state?
[7] Is it one percent, 10 percent?
[8] DR. PILES: No. It's real
[9] difficult to do that.
[10] MS. RUSSELL: There's probably
[11] a very small percentage prescribed outside of the
[12] state. Maybe how many are filled outside the
[13] state.
[14] DR. HADLEY: That's what I
[15] mean.
[16] MS. RUSSELL: I don't have
[17] that.
[18] DR. PILES: I'm still working,
[19] but it's hard to get that data.
[20] DR. KNAPP: Would
[21] legislation-- Would this be restraint of trade?
[22] The same issue we get into with medicine and one
[23] of the issues hammering legislation.
[24] We're going to get into
[25] trouble with restraint of trade if we mandate

Page 33

[1] licensure of a practitioner who is outside the
[2] Commonwealth of Virginia but essentially
[3] practicing medicine on a patient in the
[4] Commonwealth.
[5] If we expand the definition of
[6] the scope of practice, the pharmacy, which is
[7] clearly one of the things that needs to happen,
[8] and basically try and make pharmacists outside of
[9] the state somehow culpable, is that a restraint
[10] of trade issue?
[11] MR. CASWAY: I suspect that as
[12] long as those being kept out or restrained, are
[13] going to consider it so. I think-- I don't hold
[14] myself out as being an expert in restraint of
[15] trade. I don't think it would be. I think the
[16] states have a right to regulate, under the police
[17] powers, the matter dealing with health, safety
[18] and welfare of the public.
[19] DR. KNAPP: Are there any
[20] other states that have done this--passed either
[21] statutory change--changed the scope of the
[22] practice of pharmacy or somehow held pharmacists
[23] outside the state culpable?
[24] MS. RUSSELL: I only know of
[25] the North Carolina regulation that talks about

Page 34

[1] disclosure.
[2] DR. KNAPP: Do you think that
[3] does any good?
[4] MS. RUSSELL: I doubt it.
[5] That's fairly new. We don't have information on
[6] how that's worked so far.
[7] Idaho does apparently have
[8] enough in their definition of the practice of
[9] pharmacy that they had their Attorney General, I
[10] think, write a letter to a couple of PBMs and
[11] tell them what they were doing is practicing
[12] pharmacy in Idaho and that was prohibited unless
[13] they were licensed in Idaho. That's about the
[14] only other state that I know has done anything.
[15] DR. KNAPP: Do you think
[16] that's a good idea?
[17] MS. RUSSELL: I think it's one
[18] way to try to get a handle on it. Whether it
[19] works or not--
[20] MR. CASWAY: That doesn't
[21] resolve the ultimate question of whether or not
[22] therapeutic switching is good or bad. But it
[23] does resolve the question of who has the
[24] jurisdiction.
[25] It would clearly put the Board

Page 35

[1] with a clear state mandate to regulate those
[2] practices as opposed to attempting, based on a
[3] somewhat ambiguous or unclear or maybe even a
[4] grant of authority, to regulate the practice.
[5] A state law passed that
[6] directs the Board to do is eminently more
[7] defensible and would more clearly define what the
[8] issues are.
[9] DR. KNAPP: It seems to me
[10] that therapeutic interchange is a symptom, not
[11] the problem. And at least a piece of the real
[12] problem, aside from money and greed, is
[13] jurisdiction. That's a reasonable--at least one
[14] response to this.
[15] MR. CASWAY: Here it is in
[16] terms of who can do something about it.
[17] Certainly pharmacy, if it had jurisdiction over
[18] them, if a required pharmacist-- If you expand
[19] the scope to practice pharmacy to include
[20] out-of-state pharmacists in that scope, then the
[21] Board has jurisdiction to at least take some
[22] action.
[23] DR. HADLEY: Has the Board of
[24] Pharmacy ever investigated or disciplined in any
[25] way any pharmacist in the state of

Page 36

[1] Virginia--let's confine it to that--for
[2] therapeutic substitution without consulting the
[3] physician for the purpose of monetary gain? Has
[4] there ever been a case of that brought before
[5] you?
[6] MS. RUSSELL: No.
[7] MR. CASWAY: We've had
[8] pharmacists who write prescriptions without
[9] doctor's authority, and they have been
[10] disciplined. What their purpose was, whether for
[11] their own use or for conversion--
[12] MS. RUSSELL: But not for
[13] monetary gain.
[14] DR. HADLEY: Thank you.
[15] MR. TEEFEY: Any other
[16] questions?
[17] MS. PIGG: When the Board of
[18] Pharmacy, who governs the practice of pharmacy in
[19] the state of Virginia, throws that hat in the
[20] ring with the suggested language, who elected not
[21] to pick up that hat?
[22] MR. CASWAY: I think maybe
[23] he-- The Board never voted, never adopted it.
[24] Scotti and myself had, in the process of doing it
[25] for the Board, we were going to present it to the

[1] Board. The opportunity came to assist the
[2] legislative group that was looking at the issue.
[3] And we just suggested to them, here's another
[4] alternative to look at it.
[5] There were some concerns that
[6] the proposal that the committee was reviewing was
[7] fairly expansive and perhaps broader than it had
[8] to be.
[9] MS. PIGG: In reading some of
[10] the information I see here, the Board got a
[11] letter coming out of the Task Force on the demise
[12] of independent pharmacy and somehow or another--
[13] Can you help me understand how
[14] the demise of an independent pharmacy got tied
[15] into a regulation or statute, I don't know,
[16] regarding therapeutic interchange?
[17] I couldn't quite understand
[18] where that letter was coming from from the demise
[19] of independent pharmacy suddenly talking about
[20] therapeutic interchange.
[21] MS. RUSSELL: You've lost me.
[22] I'm not sure I know what you're talking about.
[23] MS. PIGG: There's a letter in
[24] this binder, and I don't know which tab--
[25] MS. RUSSELL: The letter from

[1] the committee?
[2] MS. PIGG: I guess it was.
[3] Can somebody help me who might have it.
[4] MS. RUSSELL: I didn't bring
[5] my book with me. I don't remember a letter from
[6] the committee.
[7] Now, Mr. Durrett's, about the
[8] PCS issue--
[9] DR. PILES: I think it's a
[10] related bill that dealt with the demise.
[11] MS. PIGG: It was a letter
[12] from Mr. Durrett or maybe from Mr. McArthur that
[13] started out talking about the demise of
[14] independent pharmacists and then flipped over and
[15] was talking about therapeutic interchange.
[16] I didn't make the conversion
[17] from what does that topic got to do with this
[18] one.
[19] MR. TEEFEY: Let me help out a
[20] little bit. Whenever a bill comes out, the
[21] Department, or whoever it affects, will write
[22] their opinion of that bill and try to give better
[23] language or credence to the bill. Some of the
[24] time it's accepted, and some of the time it's not
[25] accepted.

[1] But every bill that comes out
[2] of the General Assembly, we look at those bills
[3] that affect Medicaid, and we write a response
[4] back on those bills. I think that's basically
[5] what they did.
[6] If the legislator wants to
[7] accept what you give back, then they can use it.
[8] If not, they don't use it. I think that's--
[9] MS. RUSSELL: Thank you.
[10] That's exactly what happened.
[11] DR. BLANCHARD: If a
[12] pharmaceutical company approaches a pharmacist
[13] and says if you will offer patients the
[14] opportunity to switch from drug A to our drug, we
[15] will give you a significant kick back rebate, and
[16] we'll also give coupons to the patients for the
[17] next six months so they do not have to pay the
[18] co-pay, and a pharmacist goes along with that and
[19] calls physicians and encourages that switch,
[20] using whatever views appropriate, is that
[21] unethical behavior? My understanding from the
[22] current statute, that's the way things are
[23] written.
[24] MS. RUSSELL: The Board of
[25] Pharmacy does have a regulation that deals with

[1] kick back.
[2] However, this is an old
[3] regulation and it was written back years ago when
[4] what the Board was trying to prohibit was-- This
[5] was way before the current practice of pharmacy.
[6] What the Board was trying to prohibit was
[7] pharmacists giving a kick back to a prescriber, a
[8] physician, in order to foster prescription
[9] practice, a prescription directed to that
[10] particular pharmacy. That's the way that kick
[11] back regulation is written.
[12] It's a little bit difficult to
[13] look at the language in that kick back and twist
[14] it around to say it's not acceptable for a
[15] pharmacist to accept a kick back. Conceivably,
[16] you could. But still, there is still the
[17] allowance that it is okay to do the first thing
[18] as long as there is written disclosure to the
[19] patient and the prescriber.
[20] DR. BLANCHARD: Does the Board
[21] of Pharmacy consider that scenario still to be
[22] appropriate in the public opinion?
[23] MS. RUSSELL: I can't speak
[24] for the Board of Pharmacy. We're looking at that
[25] regulation as a part of our current regulation

Page 41

[1] review, but we're actually having a fairly
[2] difficult time with it since you're doing your
[3] study now.
[4] DR. BLANCHARD: The issue that
[5] Ms. Pigg was talking about is still under
[6] consideration by the Board of Pharmacy.
[7] MS. RUSSELL: As far as the
[8] Board is--
[9] MR. CASWAY: I think the Board
[10] is trying to find ways to get some control given
[11] the current statutory basis. What the Board has
[12] in-- The Board, in the few times it has come up,
[13] has indicated in one instance that it required
[14] clear disclosure.
[15] In the PCS matter, they had
[16] been calling it a performance drug program, which
[17] the Board felt it may be misleading in and of
[18] itself. Its performance could have a couple of
[19] different meanings.
[20] Secondly, it wasn't clear if
[21] there was a script that the pharmacist was
[22] offered and a script that the Board felt asked
[23] for more clarification from PCS as to how that
[24] was full disclosure to them--disclose the whole
[25] process to the patient before the patient would

Page 42

[1] authorize--go to the physician to change the
[2] drug.
[3] MR. TEEFEY: Howard, we keep
[4] talking about kick backs and incentives. I
[5] asked, when we talked on the phone, when we pay
[6] AWP minus nine to the pharmacist for the drugs
[7] that they fill for us--
[8] Let's say company A sells that
[9] drug to a pharmacist for the AWP minus nine.
[10] That's the average wholesale price minus nine
[11] percent. Let's say pharmacy B sells that drug to
[12] the pharmacist for AWP minus 20. It would be an
[13] incentive for that pharmacist to use the drug
[14] that is AWP minus 20 from pharmacy B.
[15] Wouldn't that be an incentive?
[16] Aren't we talking about-- Does it affect all
[17] discounts? Does it affect all rebates? Does it
[18] affect everything?
[19] I mean, we're talking about
[20] just kick backs now. We're talking about a
[21] bigger picture than what the bill was talking
[22] about.
[23] MS. RUSSELL: I think that's
[24] why we need to be careful in any statute we write
[25] or regulation, because there may be cases where

Page 43

[1] it would be appropriate for a pharmacist to call
[2] the physician to switch. Suppose a patient
[3] didn't have insurance and the prescriber wrote
[4] for a high-cost drug and there was a lower-cost
[5] drug alternative. It might be appropriate for
[6] the patient to call the prescriber.
[7] I think we need to be careful
[8] with this so we don't prohibit activity that we
[9] think is okay and not unethical.
[10] I think in the language we
[11] originally submitted we said the section should
[12] not apply to drug substitution reducing the
[13] actual cost, co-payment or co-insurance
[14] percentage payment required for the prescription,
[15] or where the drug originally prescribed is not
[16] covered by the patient's health insurance plan.
[17] I'm not sure if that
[18] completely covers it, but it's a start. I don't
[19] think it's unethical in every case. You have to
[20] look at the individual circumstances.
[21] What the Board was trying to
[22] do is get some kind of control or handle over
[23] these things so that we could look at it on a
[24] case-by-case basis.
[25] DR. BLANCHARD: Without asking

Page 44

[1] you to speak for the Board of Medicine, do you
[2] perceive-- I'm trying to understand this.
[3] There's a difference between
[4] Advil versus Aleve, pharmaceutical companies. On
[5] the recommendation of a patient who comes in who
[6] has a headache, which one do I use? Which one is
[7] on sale? Do we transfer that same approach of
[8] sale items to our prescription medication, where
[9] the physician actually made a decision that drug
[10] A is what he or she wants, if the same
[11] pharmaceutical company came to the physician's
[12] office and offered me the same rebate along with
[13] coupons to hand to patients. Would that be
[14] perceived differently ethically?
[15] My contention is it would be.
[16] I'm having difficulty trying to assimilate all of
[17] this. If that's unethical, why isn't it the same
[18] degree of unethical if the pharmaceutical company
[19] pays my pharmacist to lobby on their behalf to
[20] the physician? Why is it not similarly unethical
[21] for a PBM to direct the creation of formulary
[22] where the PBM is owned by that pharmaceutical and
[23] that's above reproach because it's a PBT
[24] committee?
[25] I'm fully sympathetic to the

Page 45

[1] concept of trying to keep a competitive market
[2] place. I understand the implications of keeping
[3] open formularies out there.
But it's a perceptual problem
[5] and ethical problem for the physician and
[6] pharmacist to engage in that sort of very
[7] intimate relationship with the pharmaceutical
[8] companies, who obviously have incentive to get
[9] their drug sold to the patient as opposed to
[10] their competitors' drug. Some of it doesn't
[11] smell right.
And I agree with you. It's
[13] difficult to write legislation.
HON. NEWMAN: The other side
[15] of it, of course, is what this side does like,
[16] that side doesn't like. The difference between a
[17] physician and a contract is that Blue Cross-Blue
[18] Shield, or whoever it is, is in business to keep
[19] those health care costs low.
They are not in the business
[21] the same as the doctor is. They are there to say
[22] we want to make sure that a drug that will do the
[23] same job that we are covering. We are covering
[24] X, that's the contract you contracted with us to
[25] get. You have not contracted for every drug out

Page 46

[1] there. And if you did, your insurance premium
[2] would be Y instead.
The question is whether we
[4] want to get into the widest base of formulary to
[5] be the bottom of the contract basis. I agree
[6] with part of what he says. But I also think that
[7] the industry needs to be able to draw up those
[8] contracts to keep health costs at a reasonable
[9] level, too.
MS. RUSSELL: I don't have any
[11] answer for either, just a comment. I think that
[12] if companies that contract with someone to manage
[13] their health care benefits knew up front what
[14] they were contracting for. I think that's
[15] important. Again, it goes back to the issue of
[16] full disclosure.
Maybe if the physician knew
[18] ahead of time that the patient could walk in with
[19] a copy of the formulary with them, maybe the
[20] physician would prescribe that in the first
[21] place.
I think a lot of the problem
[23] is you don't always know what drugs are on the
[24] formulary. I'm not sure if people contracting
[25] with these PBMs actually know that.

Page 47

[1] HON. NEWMAN: That's a major
[2] problem with, as I knew it, the incentive of the
[3] Hawkins bill. That if you do have a good person
[4] out there who wants to call that pharmacist and
[5] make a good recommendation, this is not covered
[6] by an insurance company; you're prescribing a
[7] $400 item for this person; they need help; they
[8] need another option, that would have been
[9] possibly illegal.
DR. KNAPP: I think you speak
[11] to the other problem relative to this. Again,
[12] the therapeutic substitution/interchange is a
[13] symptom, not a problem.
You addressed it beautifully.
[15] I think the underlying assumption that the
[16] formulary saves money is not proven. We have a
[17] lot of good studies. There are some good points
[18] in many of these.
I do think that part of what
[20] this committee should recommend is that HMOs not
be allowed to say anymore that this is
proprietary information. This needs to be proven
[23] once and for all.
Unless somebody says to them,
[25] they need to cut loose with this information so a

Page 48

[1] good study can be done. We simply cannot answer
[2] some of the questions we have been charged to
[3] answer.
MR. TEEFEY: Any other
[5] questions?
MR. AYOTTE: Can we request
[7] that proprietary information be made public?
I guess what I want to focus
[9] on is the issue that if we have a multitude of
[10] approaches to this issue. One may be the Board
[11] of Pharmacy language that they recommend they
[12] propose. The other may be something through the
[13] Bureau of Insurance that talks about the
[14] disclosure up front with the patient and the
[15] insurance company and the PBM.
I just want to make sure that
[17] the counsel understands that. Recommend what we
[18] can legally request of them.
DR. KNAPP: I think the Task
[20] Force-- I don't mean to make this leap. But
[21] it's certainly within the realm of recommendation
[22] of this Task Force to recommend a statutory
[23] ability to do this or regulatory ability to do
[24] this. You have to be careful when you're
[25] attacking something from a multi-pronged

Page 49

[1] perspective.
[2] But if you look at the
[3] questions they asked us or charged us with, we
[4] can't answer the question of how many Virginians
[5] this affects. We're how far into this and we
[6] don't even know that basic number. How can we
[7] possibly presume that we're going to able to
[8] answer the majority of questions they charge us
[9] to answer? We very simply don't have the data.
[10] That seems to be one of the problems.
[11] DR. HADLEY: I would make the
[12] comment to that that I think it would be very
[13] difficult for this Task Force to really answer
[14] the scientific question of are formularies cost
[15] effective or not.
[16] I mean, look at the
[17] sophistication, the length of time and the
[18] studies that went into the Horren (phonetic)
[19] study, which is a very provocative study.
[20] I think it's not realistic for
[21] us to say that we're going to have that
[22] information. That's going to have to be
[23] something that's going to have to be debated in
[24] scientific literature.
[25] What I would say is if the

Page 50

[1] findings of the Horren study are validated, I
[2] think you can pretty well assume that HMOs and
[3] others that run formularies are going to take
[4] that into consideration. Since they are in the
[5] business of lowering costs, they are not going to
[6] do something that's against their basic charter.
[7] And just to try to follow
[8] troublemaker cost, which is what the Susan Marr
[9] article is about, is very difficult and not an
[10] easy thing to do. I don't think it's realistic
[11] to say this committee will have that scientific
[12] question answered. That's going to have to be
[13] further litigated scientifically.
[14] It seems to me that the basic
[15] problem is one of jurisdiction. It sounds like
[16] the Board of Pharmacy has adequate resources at
[17] its hands to regulate the kinds of unethical
[18] behavior that I think we all have a sense for,
[19] where a pharmacist wants to make a switch where
[20] it's not in the best interest of the patient, not
[21] consulting the physician, or doing it simply for
[22] a kick back, which in and of itself has a
[23] negative connotation.
[24] That's completely different
[25] than organizations trying to structure health

Page 51

[1] care programs that will be as cost effective as
[2] they can. You already admitted that that is
[3] acceptable.
[4] I think that, to me, seems to
[5] be the problem here. You don't have the
[6] jurisdiction or the out-of-state or the PBM. And
[7] you can't get a handle on that same unethical
[8] behavior as you can for the in-state pharmacy.
[9] MR. TOWLER: Just a comment in
[10] regard to the HMO industry responding to cost
[11] elevating across the board which has been an
[12] overall expense scenario. They seem to be moving
[13] into a capitated fee agreement. In a capitated
[14] system, I don't think they would take that into
[15] consideration. If there were more doctor visits
[16] being referred for drug switching, that would not
[17] be an issue to them.
[18] DR. HADLEY: I would tell you
[19] that it is because in any capitated program, when
[20] you negotiate for rates on that and a renewal of
[21] a contract, because those things don't go
[22] forever, I can tell you every physician that I
[23] dealt with when it comes time for renewal is
[24] looking at what is the visit rate, surgery rate,
[25] whatever it might be. They do take that into

Page 52

[1] account. It does get figured in.
[2] The only thing that capitation
[3] does is fix the cost for a period of time; one
[4] year, two years, whatever it is. But what are
[5] the inputs to the system are very clearly taken
[6] into account in setting that cap rate. They are
[7] not set in a vacuum.
[8] MR. SZALWINSKI: Mr. Chairman,
[9] if I could just try to perhaps identify some of
[10] the major issues. I think you can put them into
[11] a level of ethical issues and then jurisdiction
[12] issues.
[13] I've heard a lot about
[14] incentives. Who has them and who doesn't have
[15] them. If we look at the market place today, I
[16] think we need to recognize that there are lots of
[17] providers of care with varying levels of
[18] incentives now.
[19] There are lots of people, lots
[20] of providers; pharmacists, physicians
[21] administrators, lots of people accepting what one
[22] would call in loose relationships, gratuities or
[23] whatever.
[24] I'm speaking of the pharmacist
[25] or the physician who goes on a golf outing with a

Page 53

[1] drug company or the alleged CE that is something
[2] more akin to a recreational affair; the dinners,
[3] the plays. There are all kinds of incentives out
[4] there today and we don't regulate those.
[5] We look at professional
[6] judgment of the providers to stay out of the red
[7] zone, if you will, to make sure that what they
[8] feel they are doing passes the test. Those are
[9] fairly loose relationships between vendors and
[10] providers. They're not contractual.
[11] We hear about the pharmacist
[12] who has the best interest of the patient at heart
[13] who doesn't have insurance and wants to be sure
[14] that that patient gets the lowest cost therapy
[15] that would provide the same outcome and make the
[16] switch because their incentive is to keep that
[17] patient healthy and do the right thing for them
[18] and to continually get that patient's business.
[19] Then you translate that to a
[20] formalized contract between an insurance company
[21] and an insured beneficiary. You get to the point
[22] where who's controlling that best interest of the
[23] patient. Herein lies, I believe part of the
[24] nexus is, who has that jurisdiction.
[25] If we can understand that we

Page 54

[1] need to be sure in that formalized setting, we're
[2] comfortable with the jurisdiction, I think we'll
[3] go a long way to fixing the drug switching piece.
[4] It all kind of interweaves in
[5] there. It's a matter of understanding who we
[6] trust to help us deliver the best care at the
[7] lowest cost.
[8] I don't know if that of-- I
[9] kind of rambled.
[10] MR. TEEFEY: I think you
[11] summarized it real well. The ultimate
[12] responsibility comes back to the physician. I
[13] think that's what-- The physician is the one
[14] that prescribes the drug in the first place.
[15] DR. BLANCHARD: The physician
[16] may still come back afterwards and suggest that
[17] there is-- Perhaps the difference we ought to
[18] consider in this process between the patient that
[19] is already well managed on a medication, and his
[20] employer going to a new HMO, he then becomes
[21] subject to a new formulary.
[22] Even with informed consent and
[23] incentives it's quite--from a physician's
[24] perspective quite appropriately uninterested in
[25] changing that medication. We're not talking

Page 55

[1] formulary change where there's a safety issue.
[2] Likewise, a patient who's in
[3] an HMO, is on the same medication, on the
[4] formulary, well managed, and January 1st they
[5] changed their formulary because you have a new
[6] contract or cheaper version. Every time you
[7] change drugs, you have some risk of new side
[8] effects.
[9] The solution to that, to me,
[10] is to grandfather--for the HMO industry to
[11] develop systems to grandfather protection for
[12] those patients. Recognizing that in the grand
[13] scheme of things this is not the largest part of
[14] the financial pie.
[15] Does that need to be
[16] legislated? Not if the industry changes it
[17] before the public demand. There are issues here
[18] that-- If you will, the market place could
[19] change if they were willing to change. Many of
[20] these problems could be softened if the HMO
[21] industry would take a compassionate view, as they
[22] claim to, to put the patient first. That would
[23] help us out a lot here.
[24] There's a big difference
[25] between somebody trying to educate people, fill

Page 56

[1] me, as they do, with information why I should use
[2] drug A instead of drug B while I'm considering
[3] writing the prescription. But a whole different
[4] set of ethics are involved when I am faced with a
[5] request to change somebody when they are doing
[6] quite well. I see those as two separate problems
[7] that require two separate solutions. I would
[8] request that the Task Force continue to keep
[9] those two issues separated.
[10] I'm not sure all of that
[11] discussion we had earlier about out-of-state
[12] pharmacists and therapeutic substitutions without
[13] consulting a physician is particularly germane
[14] with what we are considering. Therapeutic
[15] substitution without consultation with a
[16] physician almost never occurs.
[17] The question we're talking
[18] about is therapeutic interchange when we do call.
[19] The question is why are they calling and how
[20] strongly should we listen to those requests to
[21] change somebody already on medication and already
[22] has a prescription written.
[23] DR. HADLEY: Dr. Blanchard, I
[24] think that question has been answered. I sent a
[25] letter to our Chairman July 23rd, in which I

Page 57

[1] enclosed--that should be available in your
[2] packet--a survey that we took of the HMOs in the
[3] state of Virginia. Of the 10 health plans that
[4] have a closed formulary, in which this would
[5] apply-- The difference between a closed and open
[6] formulary; a open formulary means they are
[7] recommended drugs but you don't have to prescribe
[8] off of it. The HMO will fill the drug. The
[9] closed formulary is the one they have the problem
[10] with. If it's not on the formulary, it's not a
[11] benefit.
[12] In our survey that we looked
[13] at of all the HMOs in Virginia that's not a
[14] closed formulary, 100 percent have a process for
[15] formulary exceptions. So that a physician can
[16] call and explain the situation where the patient
[17] is on the drug, even though it's no longer on
[18] your formulary, they're stable on it and obtain
[19] an exception.
[20] Also, we looked at the
[21] grandfather issue that you raised. Grandfather
[22] issue is where a patient is currently on a
[23] chronic medication, and either they just joined
[24] the health plan or the PMT committee removed a
[25] drug from the formulary.

Page 58

[1] Of the HMOs, 70 percent have a
[2] grandfather rule so that patients can be kept on
[3] that if there's a formulary change for the type
[4] of patient I talked about that's stable and on
[5] chronic medication.
[6] This is one of the safety
[7] provisions that the PMT committee will insist on.
[8] We don't think you need to legislate that.
[9] We think the vast majority of
[10] the HMOs in the state are already following these
[11] kinds of rules in the interest of quality care.
[12] We don't see that as a problem in these
[13] legislations.
[14] DR. BLANCHARD: The purpose of
[15] my comment earlier was to suggest that it may not
[16] require legislation. And it would be unlikely
[17] that I would come pressuring for legislative
[18] changes if that figure were 93 percent. I think
[19] it would be associated with the 30 percent. You
[20] might have a grandfather clause that works.
[21] And whatever percentage of
[22] HMOs--100 percent that have the mechanism in
[23] place for review is sometimes irrelevant when
[24] that review requires a letter and a several week
[25] determination and the patient is calling me from

Page 59

[1] the pharmacy.
[2] Again, I think there's room in
[3] the HMO industry for setting up criteria for good
[4] behavior, which would be a several hour turn
[5] around for simple drug request and the pressure
[6] to get more than 70 percent of the industry
[7] having a grandfather clause.
[8] Just as with whether it's
[9] drive through or out patient. A lot of the
[10] hassles of the industry in which I practice-- I
[11] practice with 30 percent of my business in HMOs.
[12] A lot of the public relations problems come about
[13] because of failure of the industry to recognize
[14] those public relations potential fiascoes and
[15] solve them before they reach this level of
[16] debate.
[17] I don't have any reason to be
[18] here other than to give my--don't want to call it
[19] antidotal, but my experience with having to make
[20] those phone calls. I explained to you today with
[21] one of my phone calls to your company resulted in
[22] a two-minute phone call and a quick approval.
[23] Whereas, my phone call
[24] yesterday to another HMO, I was told I had to
[25] write a letter. The letter takes awhile to get

Page 60

[1] there and awhile to get back. The reasons for
[2] denial are not ever stated. The reasons for
[3] inclusion of one drug in the formulary as opposed
[4] to another drug are not stated--the rationale.
[5] It's hard to phrase a letter that will fit the
[6] screen that somebody will read off on the
[7] computer.
[8] I concur with you. I saw the
[9] data in the information piece that a lot of HMOs
[10] handle this properly. The purpose of the
[11] government is try to insure that those who don't
[12] follow the same good practice standards that
[13] you're suggesting everybody should emulate.
[14] Let me clarify that. The
[15] question that we asked was does your house plan
[16] have a protocol to grant exceptions where the
[17] patient is maintained on a non-formulary drug at
[18] the time the patient becomes a member of the
[19] plan. That's a grandfather rule.
[20] 30 percent said, no, they
[21] don't have a protocol, but 100 percent of those
[22] have a regular exception clause. So 100 percent
[23] of HMOs in the state have a process, whether they
[24] call it the grandfather protocol, they all have
[25] an exception process. And you're right, some are

Page 61

[1] easier than others. Some give you an 800 number
[2] to do it and take care of it right on the phone.
[3] Others require a letter or something, more
[4] documentation from the physician. I think that
[5] is a difficult thing to legislate.
[6] We could make recommendations
[7] to the HMO Association as to what might be good
[8] practices. But, again, I would say, currently
[9] 100 percent of patients--the physicians have
[10] access to getting exceptions in this state.
[11] DR. KNAPP: Dr. Hadley, I
[12] didn't mean to suggest that we were going to be
[13] able to come up with a scientific resolution
[14] about whether or not formularies are cost
[15] effective.
[16] Everybody has a vested
[17] interest in knowing whether or not that is true.
[18] After you read the title of the article, you read
[19] who responded to it. I think that there's nobody
[20] who can read the scientific literature with a
[21] critical eye that they wouldn't be jaded if an
[22] article regarding the cost efficiency of
[23] formularies came out of HMO. I don't think it
[24] necessarily needs to be legislation.
[25] My point was, and after

Page 62

[1] listening to you, the HMO would be in favor of
[2] this. In the interest of finding the answer for
[3] the public to somehow strongly recommend that
[4] this be investigated.
[5] Part of the public perception
[6] and part of the problem is who is overseeing the
[7] process. To have somebody accountable who can
[8] either perform a study or whatever to help answer
[9] that question and really look at the data.
[10] You're right. It's something
[11] very difficult to do but would be very useful.
[12] We had a young man from VCU last time that said
[13] this is what he wants to do but can't do it. I
[14] can't do it because I can't get the data. Would
[15] that not be a worthwhile thing to undertake for
[16] all interested parties? Again, I would challenge
[17] us also to remember that we are here for the
[18] Commonwealth.
[19] DR. HADLEY: Wasn't the Horne
[20] study jointly founded by the Rand corporation and
[21] the six HMOs that participated in that? I think
[22] the Industry is interested in that issue. They
[23] need to know this; whether or not restriction of
[24] formularies will effect total medical cost.
[25] Whether it's happening in the Commonwealth of

Page 63

[1] Virginia, I don't know.
[2] MR. TEEFEY: Are there any
[3] other questions of Scotti and Howard?
[4] Thank you for coming down.
[5] The two Mikes worked real hard
[6] with members of the committee to come up with a
[7] statement of a therapeutic interchange statement.
[8] Do you want to go over that?
[9] DR. PILES: I trust that you
[10] all did receive the E-mail of that statement. I
[11] would add that in the development of that
[12] statement we did have two conference calls with
[13] the subcommittee and two of the members were out
[14] of town or on vacation at the time, Drs. Dalton
[15] and Blanchard.
[16] At this time, basically, what
[17] we need to do so that we can decide what our next
[18] course of action will be is to come to a
[19] consensus that we are all talking about the same
[20] thing and singing from the same sheet of music.
[21] I have placed before you a
[22] copy of the current proposed definition of
[23] therapeutic interchange that this Task Force will
[24] use for its work and that will lead us to our
[25] next task.

Page 64

[1] I guess for the sake of
[2] getting started I will read it here and you all
[3] have copies.
[4] Therapeutic Interchange is the
[5] dispensing of a drug, by any person authorized by
[6] law to prescribe drugs, that is an alternative
[7] for the drug initially prescribed and that is of
[8] the same pharmacological class and/or therapeutic
[9] class as the drug initially prescribed. The
[10] alternative drug is expected to have the same
[11] clinical results and safety profile, when
[12] administered to patients in therapeutically
[13] equivalent doses, as the drug initially
[14] prescribed, and is dispensed with the approval of
[15] the person who prescribed the initial drug, or
[16] their lawful designee, and the consent of the
[17] patient.
[18] That's only two sentences
[19] believe it or not.
[20] DR. HADLEY: The first problem
[21] is you can't dispense and prescribe. Therapeutic
[22] interchange is the dispensing of a drug
[23] prescribed by any person authorized by law.
[24] The physicians prescribe. The
[25] pharmacists dispense. The way it's written is

Page 65

[1] the dispensing by any person authorized by law--
[2] DR. PILES: To dispense a
[3] drug, you mean. So, that second line "to
[4] prescribe" should be to dispense.
[5] MS. PIGG: No.
[6] DR. HADLEY: Which was
[7] prescribed by any person.
[8] MS. PIGG: One the first line,
[9] is the dispensing of a drug, prescribed by any
[10] person authorized by law to prescribe drugs.
[11] DR. PILES: Just prescribe in
[12] there. So, it would be therapeutic interchange
[13] is the dispensing of a drug prescribed by any
[14] person authorized by law to prescribe drugs.
[15] Does that fix it?
[16] HON. NEWMAN: I have a concern
[17] about another part of it. That is, this as
[18] written will go to generic drugs, which is
[19] required by law to switch. And so I think the
[20] Doctor may have in our discussion maybe a bit of
[21] language speaking about chemically dissimilar
[22] alternatives to help fix that problem. That
[23] would go on line two of the non-bolded area,
[24] chemically dissimilar alternative.
[25] DR. PILES: That is a

Page 66

[1] chemically dissimilar alternative.
[2] HON. NEWMAN: That would cover
[3] generic drugs being switched.
[4] DR. PILES: That is a
[5] chemically dissimilar alternative for the drug
[6] initially prescribed and that is of the same
[7] pharmacological class and/or therapeutic class as
[8] the drug initially prescribed.
[9] DR. BLANCHARD: I have two
[10] editorial suggestions. I'm not completely
[11] comfortable with suggesting that the alternative
[12] drug is expected to have the same clinical
[13] results. It's hard for something to have the
[14] same safety profile. I wondered--
[15] DR. PILES: Similar, perhaps.
[16] It would read the alternative drug is expected to
[17] have--
[18] DR. BLANCHARD: You don't want
[19] to change the drug. You don't want to suggest
[20] the interchange unless you'll have pretty close
[21] to the same clinical results. I think what
[22] you're trying to get at is similar.
[23] DR. PILES: And similar safety
[24] profile.
[25] DR. BLANCHARD: Right.

Page 67

[1] DR. PILES: Clinical results
[2] and similar safety profile.
[3] DR. BLANCHARD: Additionally,
[4] I would like the Task Force's opinion on my
[5] feeling about adding before the word "consent" on
[6] the last line, lawful designee and the informed
[7] consent of the patient. I think what we may end
[8] up discussing is how informed the patient should
[9] be.
[10] DR. PILES: Actually, that was
[11] a part of the discussion when we were doing this.
[12] Basically, we did raise that question. What does
[13] consent of the patient really mean in this
[14] context?
[15] DR. BLANCHARD: I have to
[16] refer to the lawyers. Does it make a difference
[17] between when you say informed consent or consent?
[18] What I have to get from my patients is something
[19] called informed consent. I've always been told
[20] it's different than consent.
[21] DR. PILES: One of the things
[22] we did talk about and one of the scenarios that
[23] we considered when we were putting this together
[24] is that since the patient is standing at the
[25] counter and some other conversation may be going

Page 68

[1] on between the pharmacist and physician or
[2] pharmacist and insurer, the patient may, of
[3] course, be asking questions.
[4] But ultimately, the only thing
[5] that I think we were getting at is that the
[6] patient would be aware of the fact that the
[7] pharmacist needs to call someone, had done so,
[8] and this is what they authorized them to do.
[9] That was, I think, what was suggested to me as
[10] informed consent.
[11] DR. BLANCHARD: I think I
[12] would be more comfortable if the word informed
[13] was in there.
[14] HON. NEWMAN: He might be
[15] right, but it is a reasonably large policy
[16] decision if we go this way now. Let me tell you
[17] why. The definition is what we're working on
[18] now. If we want to go into the decisions of the
[19] finality, he has great ideas. What we're looking
[20] for is just a common ground on the definition.
[21] After prescribed, three lines
[22] up, in which follows "and is dispensed with the
[23] approval" goes beyond the definition. And it
[24] goes into what we may want or not want the
[25] process to be one day.

Page 69

[1] I think if what we're doing is
[2] just giving a definition to what therapeutic
[3] interchange is, it should stop at "prescribed"
[4] and include a period. Unless you want to put the
[5] next little bit in that says you do it by law,
[6] which means you have to have approval before you
[7] do it.
[8] I would urge that we consider
[9] at least not putting that part in, and especially
[10] the amendment yet until we get to a discussion of
[11] whether or not we want that policy or another
[12] policy.
[13] I don't know what the
[14] committee thinks about that. But I think the
[15] definition itself should end after "prescribed".
[16] DR. PILES: One of the things
[17] we did talk about was the fact that we needed a
[18] definition for common ground and that any of the
[19] nuances beyond that ground go beyond the scope of
[20] what we're doing.
[21] You suggested that it should
[22] read, and is dispensed with the approval of the
[23] person who prescribed the initial drug, period.
[24] MR. TEEFEY: No. He's saying
[25] after prescribed on the third line--

Page 70

[1] DR. PILES: I'm sorry.
[2] MR. TEEFEY: Put a period and
[3] just eliminate the rest of it.
[4] DR. PILES: I'm sorry. I was
[5] on the wrong line.
[6] MR. AYOTTE: I think the issue
[7] became that we're trying to determine between
[8] therapeutic interchange and therapeutic
[9] substitution. At the substitution level, in a
[10] hospital, closed environment, where there was no
[11] approval necessary. On the interchange you're in
[12] an out-patient environment where that prescriber
[13] has to be informed. You have to have that
[14] discussion with the doctor. I think that's why
[15] that piece was added into this definition.
[16] MS. PIGG: I understand where
[17] you're coming from in the basic definition, but I
[18] think inherent in therapeutic interchange are the
[19] other pieces that it has to be the same similar
[20] drug that does the same similar thing.
[21] Otherwise, it's just an interchange. It's not a
[22] therapeutic interchange.
[23] HON. NEWMAN: I'm not taking
[24] that part out. "Prescribed" on the third to last
[25] line is where we're talking about. All we would

Page 71

[1] be taking out is the consent of the patient or
[2] not consent of the patient, which is a discussion
[3] currently not in law. And if we made the
[4] recommendation, it would be a change.
[5] DR. PILES: That second
[6] sentence would read: The alternative drug is
[7] expected to have the same clinical results and
[8] similar safety profile when administered to
[9] patients in therapeutically equivalent doses as
[10] the drug initially prescribed.
[11] DR. BLANCHARD: If what we're
[12] trying to do is keep things in the current
[13] confines of law, I don't think the period
[14] actually ought to go after "is dispensed with the
[15] approval of the person who prescribed the initial
[16] drug." Because the current law requires that the
[17] doctor be consulted. It does not require the
[18] patient be consulted.
[19] HON. NEWMAN: I would concur
[20] with that.
[21] DR. BLANCHARD: Where is the
[22] difference between current law and where the
[23] policy might try to enhance things if we put the
[24] period after initial drug or their lawful
[25] designee.

Page 72

[1] HON. NEWMAN: That's fine.
[2] DR. BLANCHARD: Leave out "and
[3] the consent of the patient."
[4] DR. PILES: That sentence
[5] would then read: The alternative drug is
[6] expected to have the same clinical results and
[7] similar safety profile when administered to
[8] patients in therapeutically equivalent doses, as
[9] the drug initially prescribed, and is dispensed
[10] with the approval of the person who prescribed
[11] the initial drug, or their lawful--
[12] HON. NEWMAN: No. Period.
[13] DR. PILES: He suggested
[14] lawful designee, period.
[15] HON. NEWMAN: That states
[16] current law.
[17] MR. TEEFEY: We eliminate "and
[18] informed consent of the patient."
[19] DR. PILES: Yes.
[20] MR. TEEFEY: Is there any
[21] disagreement with that?
[22] MS. POWELL: Mr. Chairman, to
[23] address Ms. Pigg's concern, do we need to
[24] indicate that we're talking about in the retail
[25] or non-institutional setting?

Page 73

[1] MS. PIGG: I'm okay with it
[2] the way it is. I was on the wrong "prescribed".
[3] DR. PILES: Ms. Powell, what
[4] the subcommittee had talked about was a
[5] definition that we thought could be used in any
[6] setting. The only difference was-- We did talk
[7] about the hospital or other institutional
[8] setting. And they have in place a procedure. It
[9] still goes through law. It's just they have
[10] another piece of it where the physician is able
[11] through a mechanism established in a hospital to
[12] give a blanket approval to that kind of thing
[13] occurring.
[14] MR. TEEFEY: Go through the
[15] whole thing again.
[16] DR. PILES: Therapeutic
[17] interchange is the dispensing of a drug
[18] prescribed by any person authorized by law to
[19] prescribe drugs that is a chemically dissimilar
[20] alternative for the drug initially prescribed and
[21] that is of the same pharmacological class and/or
[22] therapeutic class as the drug initially
[23] prescribed. The alternative drug is expected to
[24] have the same clinical results and similar safety
[25] profile when administered to patients in

Page 74

[1] therapeutically equivalent doses as the drug
[2] initially prescribed, and is dispensed with the
[3] approval of the person who prescribed the initial
[4] drug or their lawful designee.
[5] MR. TEEFEY: Any disagreement?
[6] HON. NEWMAN: I don't want to
[7] take this and draw it out, but if we're going to
[8] make this statement, and because there will be
[9] three other times that this committee meets, we
[10] may want to hear from proponents and opponents of
[11] this thing for a minute or two. Just to make
[12] sure that we're not doing something that somebody
[13] could correct very quickly.
[14] I wondered if the Chair might
[15] consider amending it or so, if there is any
[16] concern from the public about what we are doing.
[17] MR. TEEFEY: No problem at
[18] all.
[19] MS. RUSSELL: I just had a
[20] technical problem with the way you changed--when
[21] you put "prescribed by any person authorized by
[22] law to prescribe drugs."
[23] I think what you mean to say
[24] is the dispensing of a drug by any person
[25] authorized by law to dispense drugs. Because you

Page 75

[1] don't want to put that that person dispensing has
[2] prescribed, because it hasn't. They're
[3] dispensing something else for the drug originally
[4] prescribed.
[5] DR. PILES: I follow you.
[6] MS. RUSSELL: It would read:
[7] Therapeutic interchange is the dispensing of a
[8] drug by any person authorized by law to dispense
[9] drugs, that is a chemically dissimilar
[10] alternative for the drug initially prescribed.
[11] DR. PILES: Which would
[12] suggest then that the rest of the process would
[13] be that that dispensing occurs only as a result
[14] of those other things happening. That is, doing
[15] what they needed to do.
[16] Again, Ms. Russell's
[17] suggestion is that it would read, therapeutic
[18] interchange is the dispensing of a drug by any
[19] person authorized by law to dispense drugs.
[20] Was the rest of it okay?
[21] MS. RUSSELL: Yes. I don't
[22] have a problem with it.
[23] MR. TEEFEY: Let's take a five
[24] minute recess. I'm going to give you all an
[25] opportunity so that you can get your thoughts

Page 76

[1] together.
[2] (A brief recess is taken,
[3] after which hearing continued as follows:)
[4] MR. TEEFEY: Senator Newman
[5] suggested that we give the audience an
[6] opportunity to speak on the therapeutic
[7] interchange definition. And I think
[8] Mr. Rosenthal--
[9] DR. ROSENTHAL: Two people
[10] have mentioned this to me. The suggestion is
[11] that in the third line, strike all that part that
[12] says that it is of the same pharmacological class
[13] and/or therapeutic class as the drug initially
[14] prescribed.
[15] There are two reasons for it.
[16] One is, it seems to me that that phrase doesn't
[17] matter as long as what you accomplish is covered
[18] in the next paragraph. That is that it has the
[19] same effect.
[20] Secondly, there are several
[21] drugs out there that are switchable, if you will,
[22] but not of the same pharmacological or
[23] therapeutic class.
[24] MS. PIGG: A couple of
[25] examples; the use of H2 prior to a proton

Page 77

[1] inhibitor. I think one of the other pharmacists
[2] said that perhaps the use of an ace inhibitor in
[3] place of a channel blocker may be a situation
[4] that may be limited by this. What you're trying
[5] to achieve is that the outcome is the same.
[6] DR. BLANCHARD: The second
[7] example, similar therapeutic class, it does the
[8] same general thing for a general disease.
[9] DR. HADLEY: There is no
[10] scientifically accepted definition of how big you
[11] make a therapeutic class. You could say a
[12] therapeutic class is all GI drugs. In which
[13] case, H2 blockers and proton inhibitors are in
[14] the same therapeutic class. So I think you would
[15] have a very difficult time defining something.
[16] From a legal point, is it or
[17] isn't it in the same pharmacological class? It
[18] probably is irrelevant as long as it has the same
[19] functional results and similar safety profile.
[20] DR. BLANCHARD: I think
[21] particularly in light of the fact that the
[22] suggested substitutions that I've had recommended
[23] to me are not in the same pharmacological class.
[24] That's reflective of the way this practice is
[25] being practiced in Virginia, to leave those words

Page 78

[1] out. I'm sure what people are desiring is
[2] greater flexibility in controlling the asthma or
[3] whatever. I don't have any objection.
[4] MR. TEEFEY: What do you want
[5] to strike out?
[6] DR. ROSENTHAL: On the third
[7] line beginning with "and". Strike "and" through
[8] the end of the sentence.
[9] DR. PILES: That sentence then
[10] would read: Therapeutic interchange is the
[11] dispensing of a drug--and actually we left with
[12] two possibilities at that point, but I will read
[13] the one that we had before the break--dispensing
[14] of a drug by any person authorized by law to
[15] dispense drugs, that is a chemically dissimilar
[16] alternative for the drug initially prescribed.
[17] That's the latest suggested change. A period
[18] after "prescribed" in line three.
[19] MR. TEEFEY: And then the next
[20] sentence?
[21] DR. PILES: The next sentence
[22] would read; the alternative drug is expected to
[23] have the same clinical results and similar safety
[24] profile when administered to patients in
[25] therapeutically equivalent doses as the drug

Page 79

[1] initially prescribed, and dispensed with the
[2] approval of the person who prescribed the initial
[3] drug or their lawful designee, period.
[4] MR. TEEFEY: Any problems?
[5] Okay. Can we accept that if
[6] there is no one that has any problems with it?
[7] MR. SZALWINSKI: I might just
[8] ask that--to be sure that I'm clear about
[9] this--we don't intend for this to apply to the
[10] hospital basis of care. It's solely for the
[11] out-patient arena; is that correct?
[12] DR. PILES: The subcommittee,
[13] when we talked about it, thought it would apply
[14] across the board. But that's up to--
[15] MS. PIGG: The differentiation
[16] was that therapeutic substitution applied to
[17] hospitals where you may have implied consent, not
[18] direct consent. Where this was really-- The
[19] definition was formed on the basis of
[20] out-patient.
[21] DR. HADLEY: But the
[22] definition would apply wherever these activities
[23] would occur. And it would up to regulation to
[24] say whether it's appropriate or inappropriate in
[25] the hospital, out-patient. This is just a

Page 80

[1] definition. It doesn't state whether it's
[2] positive or negative in any given environment.
[3] MR. SZALWINSKI: In the
[4] hospital you have the approval of the medical
[5] staff that applies to the approval of the
[6] therapeutic committee to conduct a substitution
[7] without contacting the prescriber every time.
[8] DR. PILES: Correct.
[9] DR. HADLEY: That's the origin
[10] of the phrase lawful designee.
[11] MR. SZALWINSKI: Okay.
[12] DR. BLANCHARD: Or the
[13] differentiation from this and therapeutic
[14] substitution. We should be clear about
[15] therapeutic interchange. This is the definition
[16] of therapeutic interchange.
[17] DR. PILES: Right.
[18] MR. MCARTHUR: I would
[19] respectfully caution the Task Force members to be
[20] careful with the second sentence. The
[21] alternative drug is expected to have the same
[22] clinical results and similar safety profile.
[23] It's unclear to me from this definition who would
[24] have the expectation and who would make the
[25] determination.

Page 81

[1] I think one of the core issues
[2] that's being debated in this Task Force issue is
[3] which drugs are in fact substitutionable for
[4] others with an adequate amount of safety for the
[5] patient.
[6] I want to caution the Task
[7] Force members to be careful not to assume away or
[8] accept that there is a consensus among the Task
[9] Force members as to either which drugs are safety
[10] substitutionable and to who would make a
[11] determination.
[12] Looking at the materials that
[13] have been submitted, I saw precious few studies
[14] on the subject. That is my only comment.
[15] DR. PILES: Perhaps one more
[16] reading to make sure everybody has the periods
[17] and commas.
[18] MR. TEEFEY: I think we're
[19] okay.
[20] We're down to the discussion
[21] where do we want to go from here.
[22] Jim Counsel, who is on the
[23] Task Force, couldn't be here. He sent a letter
[24] that Mike Worthington is going to read.
[25] MR. WORTHINGTON: This is a

Page 82

[1] letter from James Counsel, vice-president and
[2] corporate counsel of First Health and a member of
[3] this Task Force, dated August 18th.
[4] In re: Special Task Force.
[5] Dear Mr. Chairman, I regret to advise you that I
[6] will not be able to attend the August 20, 1997,
[7] meeting of the above. The executive committee of
[8] our new parent company is flying in to meet with
[9] us on Wednesday.
[10] Since our last Task Force
[11] meeting I have been on the phone with other
[12] members to discuss refinement of our definition
[13] of therapeutic interchange. My impression is
[14] that there is general agreement on the definition
[15] at this time. Not withstanding that,
[16] modifications may be made to this definition at
[17] the upcoming meeting. It appears to me that a
[18] consensus exists that any definition must include
[19] pervago that such an interchange--there's a word
[20] missing--that such an interchange can be made
[21] with the consent of the person prescribing the
[22] initial drug.
[23] Given the above and
[24] Mr. Walker's statement at the last meeting to the
[25] effect that the Virginia Board of Pharmacy has

Page 83

[1] jurisdiction over interchanges made by
[2] pharmacists who are licensed by the state, it
[3] appears to me that sufficient patient protection
[4] is in place under existing regulations.
[5] In addition, other regulations
[6] govern the regulation of prescription drugs by
[7] pharmacists and impose disclosure requirements.
[8] Based on the above and the
[9] various documents I have reviewed and arguments I
[10] have heard at Task Force meetings, I am of the
[11] mind that no legislation would be appropriate.
[12] I note that those in favor of
[13] legislation have also argued that in fact the
[14] practice of which they complain result in higher
[15] health care costs. It appears to me that there
[16] is much conflict among the authorities on this
[17] issue.
[18] More importantly, it is my
[19] view the cost issue is one that should be
[20] addressed by employers and others providing the
[21] pharmacy benefit, not by a legislative body.
[22] Again, I regret that I cannot
[23] be in attendance. Very truly yours, James G.
[24] Counsel.
[25] MR. TEEFEY: Where do we go

Page 84

[1] from here?
[2] DR. PILES: Mr. Chairman, if I
[3] might, what I've done is just gone back to the
[4] resolution and what it calls for and where we are
[5] today. We do have now on the table a definition
[6] that we're comfortable with.
[7] The rest of our task includes
[8] now describing in our report to the General
[9] Assembly the practice. In fact, what it says
[10] here in the resolution was that we would
[11] determine the impact of the practice on
[12] therapeutic interchange, as we have just
[13] described it, on health care, affected
[14] professions, the overall cost of health care
[15] products and services and patients.
[16] DR. KNAPP: With all due
[17] respect, we can't do that. I mean, we can't even
[18] get the numbers of people in Virginia that this
[19] affects. I guess that's the really frustrating
[20] part. We can't get to that. If there is
[21] something wrong with the answer, how do we
[22] propose to find out?
[23] MR. TEEFEY: One of the
[24] problems that we have is that the Pharmacy Board
[25] doesn't know, because we have talked to them.

Page 85

[1] You have HMO. You have private insurers. You
[2] have-- Really, the Bureau of Insurance is trying
[3] to put some figures together. But I don't know
[4] how effective those figures will be.
[5] DR. PILES: I spoke to Rebecca
[6] Shelton, and she said they did not have figures.
[7] She gave me the names of a few people that I have
[8] contacted. One of them was a person at Trigon
[9] Blue Cross. But the only problem we would run--
[10] There are two sources that I contacted that I'm
[11] waiting to get some information.
[12] One is called the Employee
[13] Research Benefit Institute, or something like
[14] that, in Washington, D.C. They may, in fact,
[15] have figures but I'm not--employee/employer.
[16] That would only cover employer-based plans.
[17] Then from Trigon we probably
[18] could find out from all of their plans that they
[19] cover. But that's about as close as we can come
[20] to real numbers without knowing every single
[21] citizen's insurance status and who covered them.
[22] MR. TEEFEY: Senator, do you
[23] have a recommendation?
[24] HON. NEWMAN: I don't know
[25] where everybody out there is. We have received,

Page 86

[1] I understand, a list of things that they would
[2] like to be considered. I've seen some from the
[3] other side where they would like to make
[4] arguments where these are good ideas.
[5] My concern is that there is a
[6] current, concurrent study going on with the
[7] Harvey Morgan study out there right now to study
[8] the base of these things, these PBMs, to
[9] understand how that component works and the
[10] affects of that component.
[11] Quite honestly, we have been
[12] stumbling around with who am I, why am I here,
[13] since we got here. My wondering aloud is whether
[14] or not we should not have the opportunity and the
[15] permission from the Assembly to wait until after
[16] the Morgan study is complete on that intricate
[17] portion of PBM and then have some discussions
[18] after that some time next year.
[19] I wonder, Mr. Chairman, if you
[20] have any thoughts from Mr. Rosenthal and some
[21] about what they think about that.
[22] I don't want to postpone the
[23] inevitable. I don't think we have enough
[24] information this time and I think the Harvey
[25] group is studying a very important component and

Page 87

[1] of what we are studying.
[2] MR. TEEFEY: Steve, do you
[3] have any thoughts on that?
[4] DR. ROSENTHAL: I have no
[5] problem with it. I know that PBM has been
[6] mentioned a lot. I know that study is directed
[7] to PBM. I assume that study will also address
[8] the out-of-state piece.
[9] MR. TEEFEY: I think most of
[10] the PBMs are from out of state anyway.
[11] MR. SZALWINSKI: Could
[12] somebody educate me about what the Harvey Morgan
[13] study is?
[14] DR. ROSENTHAL: Yes.
[15] HON. NEWMAN: If all we do is
[16] say we don't know-- The General Assembly with a
[17] bill like what we had last year, and say we're
[18] going to solve it, we're going to kill it, or
[19] whatever we're going to do this time, but they
[20] didn't know. I think that with more information
[21] and extending this Task Force for another year,
[22] after we can get information from the Morgan
[23] study, at least we come out with cohesive
[24] thoughts about whether we should or not. I think
[25] if you brought the two minds together it might be

Page 88

[1] available.
[2] MR. TEEFEY: Would you read
[3] that statement?
[4] DR. ROSENTHAL: This is House
[5] Joint Resolution 574. I believe this is the
[6] latest version of it. Whereas, the health
[7] insurance industry, figures in managed care
[8] programs become pervasive, the effects on patient
[9] care in small businesses delivering all services
[10] are far reaching; and whereas, a recent
[11] development in managed care approaches is the
[12] implementation of contracting for pharmacy
[13] benefits management. Whereas, pharmacy services
[14] are essential for the well-being of many elderly
[15] and disabled persons for the maintenance of their
[16] health.
[17] And whereas,(inaudible)
[18] pharmacy services can prevent hospital admissions
[19] and the need for emergency care, extended
[20] services, place a greater demand on society
[21] resources; and whereas, the present management
[22] techniques practiced by some pharmacists may
[23] interfere in the statutory required condition
[24] patient-physician relationship; and whereas,
[25] personal consultation and direct knowledge of the

Page 89

[1] patient's conditions and medications are an
[2] important part of handling many chronic
[3] conditions. Whereas, so-called desk audits are
[4] allegedly being conducted many months after the
[5] dispensing of the prescriptions.
[6] Therefore, we have resolved,
[7] by the House of Delegates concurring, that the
[8] Department of Medical Assistance Services be
[9] requested to examine the practices of the
[10] pharmacy benefits management firms.
[11] In conducting its study, the
[12] Department shall coordinate its efforts with any
[13] similar studies that are taking place in the
[14] interim by the Department or by other state
[15] entities. In addition, the Department shall
[16] solicit input from such experts as may be
[17] appointed to a special task force established
[18] pursuant to House Joint Resolution 630 in
[19] relation to the practice of therapeutic
[20] interchange.
[21] Technical assistance shall be
[22] provided by the Bureau of Insurance of the State
[23] Corporation Commission. All agencies for the
[24] Commonwealth shall provide the (inaudible) for
[25] the study upon request.

Page 90

[1] The Department of Medical
[2] Assistance Services shall complete its work in
[3] time to submit its finding and recommendation to
[4] the Governor and the General Assembly as provided
[5] in the procedures of the automated system for the
[6] processing of legislative documents.
[7] MR. TEEFEY: It does go beyond
[8] PBMs. It goes to HMO.
[9] We contracted with Norm
[10] Carroll. He's the professor from MCV that came
[11] up and chatted with us two meetings ago--the last
[12] meeting. We contracted with him to start this
[13] study to get the information together. We are
[14] pretty much on a way as far as the study is
[15] concerned.
[16] I totally agree with the
[17] Senator that the information we get from that
[18] study would be extremely beneficial in what we
[19] are trying to do here.
[20] Is Ken still here?
[21] MR. MCARTHUR: Yes, I am here.
[22] And I do have a comment.
[23] I appreciate Senator Newman's
[24] suggestion. However, I am gravely disappointed
[25] in the notion that this Task Force is not

Page 91

[1] suitable or at a point where they can make a
[2] recommendation about some of these practices.
[3] I think this issue was
[4] discussed and debated in front of a committee two
[5] years ago. It was discussed in the General
[6] Assembly session last year.
[7] This Task Force was
[8] specifically created as a vehicle through which
[9] there would be time to have reason--debate on
[10] both sides and come out with a recommendation for
[11] the General Assembly for next session.
[12] I think that the PBM study
[13] that's been referenced here is broader in one
[14] sense and narrower in another. I think it's
[15] broader in that it addresses a whole range of
[16] practices that PBMs are engaged in, which include
[17] drug switching, but also include other practices.
[18] I think it's broader in that sense.
[19] It's narrower in the sense
[20] that it focuses primarily on PBMs and does not on
[21] a whole range of other entities, which are also
[22] engaged in the practice.
[23] I would strongly recommend
[24] that the Task Force address this issue and make
[25] recommendations to the General Assembly before

Page 92

[1] this upcoming session.
[2] DR. KNAPP: I didn't mean to
[3] imply that we couldn't do anything. I would ask
[4] people if there are some recommendations--
[5] If I was hearing people
[6] correctly, I'm hearing a fairly strong feeling to
[7] expand the powers of the Board of Pharmacy is
[8] appropriate. I'm hearing that people aren't
[9] hearing from the citizens of the Commonwealth
[10] that accountability is an issue. I'm hearing
[11] that the HMOs are open to letting people know
[12] that they have good PMT committees.
[13] I think some recommendations
[14] about education or expanding the jurisdiction of
[15] the Board of Pharmacy, encouraging us to wait for
[16] some study, our reason would be recommendation--
[17] I guess at this point, what do
[18] we feel comfortable recommending? I don't
[19] believe that there's nothing at this point.
[20] MR. TEEFEY: I would like to
[21] clarify one point. It is not uncommon to have a
[22] task force extended to another year. I want to
[23] make sure I lay that out. We have one right now
[24] that was due two years ago that you just couldn't
[25] do in a year, and we had to extend it for another

Page 93

[1] year. It's not uncommon to extend the authority
[2] of the Task Force for another year if you feel
[3] you do not have a good solution to what the
[4] General Assembly is looking for.
[5] DR. HADLEY: I agree with
[6] that, generally, and also the letter from
[7] Mr. Counsel. I think there are a lot of
[8] controversies and unanswered questions. I think
[9] there are a lot of things in the market place
[10] that is going to affect the kind of changes that
[11] we're looking at, and it may be premature to
[12] interfere in that process.
[13] I think that the most
[14] propounding thing that I heard is that the Board
[15] of Pharmacy does have the authority to deal with
[16] those factors that we think are unethical. It
[17] seems to me the problem again is trying to get a
[18] handle on some of the out-of-the state issues and
[19] PBMs.
[20] If there was any
[21] recommendation, it would be around that, to get
[22] some more authority to the Board of Pharmacy to
[23] deal with that. I think that is the proper way
[24] to deal with it. Because most of the issues that
[25] we're talking about it's a question of

Page 94

[1] professional judgment. Did the pharmacist or the
[2] physician, did they properly deal with this
[3] issue, or did they use whatever incentive there
[4] was in an improper way?
[5] We know that those
[6] professional Boards are really the best place to
[7] have those kinds of very fine judgment and
[8] disciplinary action. That would be my lien, to
[9] somehow assist the Board of Pharmacy in what they
[10] need to do with that.
[11] MS. RUSSELL: I just wanted to
[12] clarify. I'm not sure we do have all the tools
[13] we need right now to deal with what we might
[14] consider unethical conduct even by practitioners
[15] in the state.
[16] Our kick back regulation, as I
[17] mentioned before, is not very well worded to
[18] cover what's going on today. I think we still
[19] need to make changes.
[20] I think the problem is our
[21] unprofessional conduct definition in the statute
[22] is very narrowly drawn. It's difficult to pull
[23] other things in. I think we need some statutory
[24] relief to be able to deal with the unethical
[25] practices and to we consider unethical practices

Page 95

[1] in the state.
[2] MR. TEEFEY: Are you looking
[3] into these even beyond this Task Force?
[4] MS. RUSSELL: We are looking
[5] into clarification of the regulation but we're
[6] kind of stuck right now with the some statutory
[7] problems.
[8] Something similar to what we
[9] submitted last year would assist even-- If you
[10] notice there is a part in there that talks about
[11] unprofessional conduct. There was some language
[12] in that draft to assist us even with
[13] practitioners in the state, an authority we don't
[14] currently have.
[15] DR. BLANCHARD: Mr. Chairman,
[16] I would like to see the Task Force accomplish
[17] whatever it accomplishes. The perception is
[18] process as legitimate.
[19] Although it is not unheard of
[20] to have task forces to go onto the next year, we
[21] in effect here are voting on extending to next
[22] year without ever having a chance to discuss,
[23] much less vote on any policy options. We spent
[24] the better part of the last few months just
[25] coming up with a definition of what we have to

Page 96

[1] study. There are copious quantities of data we
[2] have been exposed to.
[3] I would think it would lend
[4] some legitimacy to the Task Force's final
[5] recommendations, if any, if we had another
[6] meeting in which to discuss possible policy
[7] options and recommendations.
[8] I don't think anybody is
[9] prepared today to make specific resolutions. I
[10] would think it's not unreasonable to say that
[11] September is plenty of time to have to suggest
[12] recommendations. The Task Force ought to have
[13] the opportunity, I think, to vote ye or nay on
[14] those recommendations at the next meeting.
[15] Having done that, you can at
[16] least say in public that we've considered some
[17] recommendations and have decided yes or we
[18] decided.
[19] No. I think the Senator
[20] suggested we may not have the ability to make any
[21] legislative recommendations. I would feel much
[22] more comfortable having had the opportunity to
[23] review both sides of their ideas on policy
[24] options.
[25] MR. AYOTTE: May I suggest

Page 97

[1] that if we had an opportunity to submit the
[2] proposals that we wanted to have and let staff
[3] take those proposals, and give us some idea of
[4] what the impact would be of those proposals.
[5] If it is through the Board of
[6] Pharmacy, what move has to happen through the
[7] Board of Pharmacy to make it happen. If it is
[8] through the Bureau of Insurance, what things need
[9] to happen. If it is done, then what impacts are
[10] there so we're not coming in September, if that's
[11] what the pleasure of the Committee is, to discuss
[12] and debate what we're going to do.
[13] In other words, be prepared in
[14] advance for what side of the road to go to, what
[15] options we'll have in front of us so we can make
[16] a good, intelligent decision and think and sleep
[17] on them and make sure they're right. Rather than
[18] saying, that's a great idea. Let's do that.
[19] I also don't want to make a
[20] decision that may not be--you know, tell Scotti
[21] this is the way we want the Board of Pharmacy
[22] heading this way. It may not be something they
[23] can do on their own. They may need additional
[24] support from either us or another body.
[25] MR. TEEFEY: Whatever

Page 98

[1] recommendations that we get in, we have to have
[2] them in early because we have to work with the
[3] Bureau of Insurance and with the Board of
[4] Pharmacy to make sure we have those intelligent
[5] answers.
[6] HON. NEWMAN: If we want to
[7] have more meetings, that's fine by me. If we do
[8] and if we're looking for information though, the
[9] two pieces of information I found would be
[10] helpful, and even with this much information we
[11] haven't gotten or been able to get it, and that
[12] is what is health care costs, up or down, of the
[13] closed or open formularies. Is there a
[14] definitive answer on that?
[15] Two, is there a cost effect--a
[16] health cost effect of therapeutic interchange.
[17] We have discussed back and forth that currently
[18] we don't have that information. If we come back
[19] and if we have that information, those two things
[20] would be helpful. So it can help make a
[21] decision.
[22] If not, I think the Committee
[23] might want to consider waiting for the Morgan
[24] study and then asking that we go out in the next
[25] year and find all this information--as much of

Page 99

[1] this information as we possibly can.
[2] Because we are currently in
[3] the same position as the General Assembly. They
[4] had a lot of this information. We're still
[5] searching for what they're searching for. To
[6] make a recommendation to them right now is just
[7] our judgment versus their judgment based on the
[8] information.
[9] I think the Doctor may have a
[10] reasonable idea. Maybe get together in September
[11] and some of this information can surface and we
[12] can get some resolution. I hope that we won't
[13] make a recommendation without some of this
[14] information, which is base information we should
[15] have before we make a recommendation.
[16] MR. TEEFEY: I think we have a
[17] couple of PBMs here and I would like to ask them
[18] a question.
[19] Can you answer the question
[20] related to PBMs that the Senator just asked?
[21] The only way we're going to
[22] get the answer is to ask the PBMs to give us the
[23] answer to that question.
[24] DR. ROSENTHAL: Are we talking
[25] PBM and/or HMO?

Page 100

[1] Senator, could you state your
[2] question again?
[3] HON. NEWMAN: Well, I can, but
[4] let me put this one caveat to it. The question
[5] is: If you get this information, is the
[6] Committee going to believe what comes from the
[7] HMO?
[8] The second question: What is
[9] the cost impact, in other words by having
[10] therapeutic interchange, are you saving health
[11] care dollars that are decreasing premium or is it
[12] costing more as has been discussed by some of the
[13] other groups? The second part is: Is there a
[14] health care cost effect and if so what is it on
[15] therapeutic interchange? If you're changing the
[16] drug, what is the effect of it? Has it been a
[17] nominal effect, and therefore, there is very
[18] little effect?
[19] How many people might drop off
[20] health care if you raise the premium again? But
[21] if that information was made available to us
[22] maybe it wouldn't take as long as a year. If
[23] it's not, then maybe another year might be
[24] needed.
[25] DR. ROSENTHAL: I'll vouch to

Page 101

[1] you, I'll do my best to see if I can. I'm
[2] familiar with one PBM that I represent. I can
[3] certainly ask those questions. I don't know if
[4] it even exits.
[5] MR. TEEFEY: How about the
[6] HMO?
[7] DR. HADLEY: I think it's very
[8] difficult information to get. It gets back to
[9] the kind of information process that you have to
[10] do to see what affects total health care costs.
[11] One of the articles we looked
[12] at and read; it's difficult to isolate one
[13] component of your health care costs. And if you
[14] change that, what effect would it have on the
[15] others?
[16] I think that the problem that
[17] the HMO industry has in dealing with this is that
[18] in many cases it is difficult to link pharmacy
[19] information to specific diagnosis. I know in my
[20] own company--and I think this is fairly
[21] typical--the database for pharmacy claims is kept
[22] in one file.
[23] As you know, or maybe you
[24] don't know, when you fill a prescription and then
[25] send that in to have it paid, you are not

Page 102

[1] required to put a diagnosis with that particular
[2] claim. So if a drug is filled, you haven't got a
[3] way to link that back to a diagnosis.
[4] We did a study in our own HMO
[5] locally trying to look at the prescribing of
[6] stimulant medication, which is used for children
[7] with ADHD. We had a devil of a time trying to
[8] link it up to children that actually that
[9] diagnosis. It turned out we had twice as many
[10] people receiving the drug as we had those with
[11] the diagnosis.
[12] There's a real problem here in
[13] the industry in devising ways to link this up and
[14] what it's going to take to solve this. Again,
[15] this is a problem that I think the HMO is very
[16] interested in because we want to control total
[17] medical costs. And if we were to adjust the drug
[18] cost of formulary, it increases our ER visits or
[19] hospitalizations. We're not going to do that.
[20] The problem is we're still
[21] struggling to figure out that problem. And it is
[22] a very difficult information process to find a
[23] solution. I don't think it's a proprietary
[24] issue. I think it's an issue that the HMOs
[25] really don't have the information. There's a lot

Page 103

[1] of controversy on that study. It's still a very
[2] provocative study. And if that is borne out, I
[3] guarantee you that HMOs don't want to do things
[4] to increase medical cost.
[5] I don't think we have the data
[6] to share with you that would be convincing, any
[7] more than what you have seen.
[8] These are active problems.
[9] But it's going to take a different level, a next
[10] generation of databases to be able to answer
[11] these questions.
[12] What you're talking about is
[13] called epidemiology of cost or disease management
[14] strategies. I was talking with Dr. Blanchard
[15] about this before we started. How our company
[16] has been able to do some disease management
[17] strategies. Primarily, have gotten involved with
[18] the drugs that are given for asthma and have
[19] lowered our hospital cost and ER visits and so
[20] forth for asthma by about 17 percent.
[21] But I don't know really what
[22] the costs or the prescription drugs are because
[23] again we can't link the prescribing patterns back
[24] to the specific diagnosis. I think it's going to
[25] be awhile before that information is out there.

Page 104

[1] I guess the only information I
[2] would like to see in the near future is what are
[3] the Board of Pharmacy's recommendations of what
[4] they would like to see from a regulatory point of
[5] view. I think that would be very useful
[6] information.
[7] You made reference to a
[8] previous bill, which I haven't seen. I think
[9] that's the base of information I would like to
[10] see.
[11] MR. MCARTHUR: I cannot resist
[12] making a point right here and now at this moment
[13] in time. At the very first meeting--at the very
[14] beginning of the first meeting I stated to the
[15] Task Force members that I would like to see
[16] evidence that the practices engaged by HMOs, PBMs
[17] and others in Virginia that effect Virginia's
[18] patients, that evidence be produced to show that
[19] these practices were sufficiently safe and that
[20] there was some public policy reason for engaging
[21] in them. That there is some evidence that there
[22] is cost containment, there is some cost savings.
[23] I have sat out here patiently
[24] for three months waiting for someone to ask the
[25] questions to those who are engaged in the

Page 105

[1] practice to produce this evidence. I'm thrilled
[2] that finally today it's happened. However, what
[3] I'm hearing is that the evidence doesn't exist or
[4] that for some other reason it can't be produced.
[5] I would submit to the Task
[6] Force that what this means is that these
[7] companies engaged in drug switching practices in
[8] Virginia are engaged in a practice which is based
[9] on untested assumptions. They are engaging in a
[10] practice for which they have absolutely no
[11] studies whatsoever to support that they are safe
[12] and absolutely no evidence to show that there's
[13] an overall health care cost reduction.
[14] In light of that, I would ask
[15] the Committee to consider immediately
[16] legislation, which would outlaw this practice
[17] until such time that such evidence is produced to
[18] protect the health and safety and welfare of
[19] Virginians.
[20] HON. NEWMAN: You and I agree
[21] on some things, but that statement I particularly
[22] disagree with. I can't imagine us going around
[23] to Virginia businesses and saying prove to us
[24] what you're doing is good or we're going to make
[25] it illegal. We don't do that. I can't imagine

Page 106

[1] it being true here.
[2] If there is a public safety
[3] problem, which I think you enumerated some
[4] concerns, that need to be discussed at this
[5] Committee and the Harvey committee and others.
[6] We need to discuss them on the effects of them,
[7] but not the presumption that if you don't show us
[8] where this is good, then we'll make it illegal.
[9] I've just never seen that in legislation.
[10] MR. MCARTHUR: Your point is
[11] very well taken. I apologize. I did not have a
[12] prepared speech on this point. I didn't know
[13] this point was going to come up.
[14] I did leave out one critical
[15] component to this whole problem. That is that
[16] health care provider groups, both in Virginia and
[17] around the country, have submitted documents to
[18] this Task Force telling the Task Force members
[19] that they have personally observed problems with
[20] this practice. Consumer groups have now appeared
[21] and told the Task Force that they had concerns
[22] about it. Studies have been produced and shown
[23] that there are problems.
[24] I don't think that I'm
[25] suggesting legislation to address something that

Page 107

[1] no one has spoken to or some problem that no one
[2] has proven exists. I think it's clear the
[3] problem exits. The extent to which the problem
[4] exists has not yet been determined.
[5] I would submit that part of
[6] the problem with that is that those engaged in
[7] the practice aren't telling us what they're
[8] doing.
[9] DR. ROSENTHAL: I'm very
[10] concerned about Mr. McArthur's comments. When
[11] Dr. Hadley, not three minutes ago--well, not ten
[12] minutes ago told you precisely what the problem
[13] is with the data. You ask me whether my client,
[14] which is a client, is intentionally withholding
[15] data. The answer is no.
[16] I told you all I will try to
[17] get the data Senator Newman suggested. That's
[18] important data. The fact is, the data doesn't
[19] exist, at least not at this point.
[20] I agree with Dr. Hadley that
[21] we're talking about another level of databases
[22] some time in the future when this information's
[23] had time to be gathered.
[24] I can't say strongly enough
[25] how I agree with Senator Newman that we don't do

Page 108

[1] business by telling businesses what Mr. McArthur
[2] would have us tell them.
[3] SPEAKER: Mr. Chairman, I
[4] wonder if it's presumptuous to wonder if this
[5] answer is ever going to be obtained. One of the
[6] components of obtaining this answer, facilitating
[7] it, is going to have diagnoses on prescriptions.
[8] I know that is a fairly revolutionary and
[9] dramatic thing to suggest.
[10] But if diagnoses were on
[11] prescriptions either by ICN-9 codes or some
[12] mechanism that was coded in, then the answer
[13] could be obtained in a relatively short period of
[14] time, in a year or two I would think, over a
[15] large patient population.
[16] I wonder if we can make a
[17] fundamental recommendation that might allow the
[18] information to be gathered quickly to get to the
[19] answer. I know that's not done now. It would
[20] cause a big change.
[21] DR. BLANCHARD: I think that's
[22] a good example of the type of recommendation we
[23] may end up making that will not necessarily be
[24] germane to that one little charge that we have.
[25] I think we spent a lot of

Page 109

[1] people's intelligent time in the last few months
[2] evaluating the situation. Again, I think this
[3] lends some legitimacy, if you give us a chance to
[4] express what we think, to what might be a
[5] solution to the problem.
[6] Then when one side or the
[7] other goes to the legislature in January, they
[8] can appoint the Task Committee as having provided
[9] some basis on the answer to make decisions in the
[10] next General Assembly.
[11] MR. TEEFEY: I think we took
[12] the Senator's recommendation-- We haven't voted
[13] on it. I think some of you feel that we already
[14] accepted Senator Newman's recommendation to
[15] extend it another year. I don't think we've done
[16] that.
[17] HON. NEWMAN: It's just one
[18] suggestion given the impasse where we are or may
[19] be. If there is a desire for a meeting or two
[20] meetings or a number, I know that Mr. Durrett's
[21] group has come out and Ken's come out with some
[22] policy options, if you want to look at those,
[23] that's fine.
[24] I don't know if the underlying
[25] data to make a decision on some of these is there

Page 110

[1] yet. I'm hoping that with the Harvey commission
[2] and with what we're doing, that maybe together by
[3] the end of next year, if we can't come to a
[4] consensus, we'll be able to give the General
[5] Assembly more than we can give them right now by
[6] extending it another year. I'm not opposed to
[7] other meetings if there is more information to
[8] come.
[9] DR. BLANCHARD: I wonder if
[10] it's acceptable to the Task Force members to have
[11] parties interested in any sort of policy options,
[12] have them submitted to Dr. Piles by two to three
[13] weeks from now. That will give us two weeks to
[14] circulate and come back here.
[15] MR. SZALWINSKI: I'm not
[16] interested in having 10 more meetings. I'm
[17] particularly not interested in having more
[18] meetings if we don't have a basis to make any
[19] progress.
[20] MR. TEEFEY: The big thing we
[21] have to do is the report and get it to the
[22] Committee and General Assembly. That would be no
[23] problem at all as long as we get your policy
[24] early enough for us to work with the appropriate
[25] people to get the responses back.

Page 111

[1] DR. BLANCHARD: My feeling is
[2] that what we're trying to do is urge people to
[3] work quickly and not slowly.
[4] HON. NEWMAN: If we do get
[5] that information in, which I would hope Ken and
[6] Steve and all those who give information to the
[7] staff, so it's not just coming from us, but that
[8] that information be allowed to be given to
[9] everybody else at least a week ahead of time so
[10] we can get an argument on why policy
[11] consideration thirteen is a good idea. Then
[12] there at least can be a cogent debate as to why
[13] it is not heard.
[14] MR. TEEFEY: How many weeks do
[15] we have before the next?
[16] DR. PILES: September 17th.
[17] MR. TEEFEY: Four and a half
[18] weeks. If we could have everything in within a
[19] week and a half, it would give us two and a
[20] half-- But he wants it before.
[21] DR. BLANCHARD: A week to
[22] disseminate it.
[23] DR. PILES: What I could do to
[24] expedite things is as soon as we get some of
[25] this--I think he would like a summary after we

Page 112

[1] get everything. But at the same time as things
[2] come in, I can get it out as fast as I get it.
[3] MR. TEEFEY: The sooner you
[4] get it in, the faster we can get it out. We'll
[5] try to have it to you longer than a week prior to
[6] the next meeting.
[7] DR. PILES: Right. At the
[8] very latest a week before. With a deadline of
[9] getting everything in, will give us an
[10] opportunity to put it together in some cogent
[11] fashion that will facilitate your next
[12] discussion.
[13] MR. AYOTTE: I think-- To the
[14] Senator's point earlier, I would hope that in our
[15] report, we not give final recommendations until
[16] after the Morgan test is done. We all have been
[17] exposed to how things can be chopped and taken
[18] out of context. I would hate for our preliminary
[19] evaluations to be used as our final evaluations.
[20] I think that we may find information from that
[21] subcommittee that would be very helpful in making
[22] our final.
[23] MR. TEEFEY: Mike, do you feel
[24] we could make recommendations as to who supports
[25] the Board of Pharmacy?

Page 113

[1] MR. AYOTTE: Yes. As long
[2] as-- What the Senator said earlier, that Ken
[3] McArthur has given where there are some policy
[4] proposals. I don't have them in front of me to
[5] look at.
[6] I would hate to have whatever
[7] we give as a preliminary be assumed as a final,
[8] because I think that what comes out of the Harvey
[9] study may give a final recommendation which
[10] encompasses all of that at one time. But I think
[11] we may have preliminary issues that we need to
[12] start on now. But I would hate anybody to take
[13] that as our final word.
[14] MR. TEEFEY: Are we all in
[15] agreement that you'll get your policy statements
[16] in? We'll work on those policy statements--
[17] DR. PILES: And I'll get
[18] things in the interim.
[19] MR. TEEFEY: --just as soon as
[20] we get some answers. We'll try to have
[21] everything to you longer than a week before the
[22] next meeting.
[23] In the policy statement, don't
[24] give us a thesis, please. Come out with a policy
[25] statement--specific policy statements because

Page 114

[1] I've four or five of these notebooks now. Some
[2] of these people are brave. They only brought one
[3] of them. Somebody even gave us a hand truck to
[4] use over the holidays so we could deliver these
[5] things. We want to make sure they're good,
[6] concise policy statements.
[7] DR. PILES: The next meeting
[8] will be in House Room C instead of D, but I will
[9] remind you.
[10] DR. HADLEY: Will we get from
[11] Ms. Russell from the Board of Pharmacy, will we
[12] get your policy recommendations in that time
[13] interval?
[14] MS. RUSSELL: I would be glad
[15] to supply you with some staff recommendations.
[16] The problem is I will not have a Board meeting
[17] prior to that date. My regulation meets on the
[18] 15th of September and could review staff policy
[19] options.
[20] I can certainly tell you
[21] whether it would have been approved by the
[22] regulation committee, but I have to get them to
[23] you prior to the regulation committee seeing
[24] them. So there may be changes or modifications
[25] from the committee.

Page 115

[1] DR. HADLEY: Okay.
[2] MR. TEEFEY: Is there anything
[3] else? I think we all know what our mission is
[4] prior to the next meeting.
[5]
[6] (CONCLUDED AT 11:25 A.M.)
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Page 116

[1]
[2] STATE OF VIRGINIA
[3] COUNTY OF CHESTERFIELD, TO WIT:
[4]
[5] I, Therese A. Rothchild, certify I reported
[6] and transcribed the foregoing, which is complete
[7] and accurate, to the best of my ability.
[8] I am not related to nor employed by any
[9] counsel, party or witness, and have no interest
[10] in this matter.
[11] Given under my hand this 2nd day of
[12] September, 1995.
[13]
[14]
[15]
[16] Therese A. Rothchild
[17]
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1 VIRGINIA:
2
5 HOUSE JOINT RESOLUTION 630
6 SPECIAL TASK FORCE
Studying Practice of Therapeutic Interchange
7 of Chemically Dissimilar Drugs
8
9
10
11 Fourth Meeting
12
13
14 September 17, 1997
15
16
17
18 When heard at:
8:30 a.m.
19 General Assembly Building
House Room C
20 Richmond, Virginia 23219
21
22
23
CRANE-SNEAD & ASSOCIATES, INC.
24 4914 Fitzhugh Avenue, Suite 203
Richmond, Virginia 23230
25 Tel. No. (804) 355-4335

1 APPEARANCES:
2 Mr. Joseph M. Teefey, Chairman;
3 Mr. Michael J. Ayotte;
4 The Honorable I. Vincent Behm, Jr.; (Absent)
5 Dr. Lawrence E. Blanchard, III;
6 Dr. Randall E. Dalton;
7 Mr. James G. Council;
8 Dr. Douglas R. Hadley;
9 Dr. Karen E. Knapp; (Absent)
10 Mr. Charles E. James, Sr.; (Absent)
11 Dr. Thomas L. Moffatt;
12 Ms. Cynthia J. Pigg;
13 Mr. Mark A. Szalwinski;
14 Mr. William Alan Towler;
15 The Honorable Senator Stephen D. Newman;
16 Ms. Marjorie E. Powell;
17 Mr. W. Tommy Walker.
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1
I N D E X
2
3
4 SPEAKERS PAGE

5 Ms. Cindy Warriner ---------- 5
6 Mr. Stephen Rosenthal ---------- 7
7 Ms. Scotti Russell ---------- 8
8 Mr. Michael Worthington ---------- 55
9 Dr. Michael A. Pyles ---------- 59
10 Mr. Matthew Jenkins ---------- 95
11 Mr. Wyatt Durrette ---------- 100

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1 September 17, 1997
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3 NOTE: The following hearing was
4 called to be heard at 8:40 a.m., viz:
5
6 CHAIRMAN TEEFEY: All right. We'll
7 want to go ahead and get started, if we can. I know
8 some people are not here, and they'll probably be
9 coming in a little bit later. I want to welcome
10 everybody and thank you-all for coming.
11 I have two short announcements
12 that I'd like to go over. There was a piece that was
13 FAXed out by the Virginia Hospital and Health Care
14 Association. Did everybody get this? It was FAXed
15 out, I think, Monday. If you didn't get it, I've got
16 ten copies here that I --
17 A SPECTATOR: We have some extras,
18 too.
19 CHAIRMAN TEEFEY: I think some
20 people didn't get it. Can you give those out, if you
21 would?
22 DR. PYLES: May I have one, if you
23 would? Okay.
24 CHAIRMAN TEEFEY: Then, the other
25 thing is, we have a Court Reporter who is going to do

Page 5

1 the minutes for us as they have done each time, and
2 would you -- There are some blind spots in the room,
3 so, when you make a comment, if you would identify
4 yourself, it would surely help her.
5 All right. We want to get right
6 on into it. So, we'll start with the public comment
7 period. What I would like to do is make sure that we
8 hold the public comments to no more than three
9 minutes, because we want the Task Force to be
10 long-winded and not the public comments to be
11 long-winded. So whoever wants to speak, speak.
12 Cindy?
13 MS. WARRINER: My name is Cindy
14 Warriner, and I am here representing today the
15 Virginia Pharmacists' Association.
16 My first is just a question and a
17 concern, and I apologize for missing the last
18 meeting. I was enjoying the sunny beach. The
19 definition of therapeutic interchange. The original
20 discussion of what has been handed out included the
21 fact that there was some type of patient knowledge.
22 And I noticed in what was printed and sent out had
23 dropped the patient knowledge or consent, and that
24 that was a concern or a question, as far as, that I
25 wanted to raise. I read the transcript, and I didn't

Page 6

1 see, unless I overlooked it, any discussions about
2 that. And then on to the comments.
3 The recommendations of this Task
4 Force need to be patient focused, industry embraced
5 and practical for the health care providers to
6 implement. It's amazing to me the number of groups
7 which are still confused about this issue and the
8 positive impact oversight would have with regard to
9 patients' quality of care.
10 There are three points I wish to
11 make. The intent of oversight would be to eliminate
12 the bad programs and support the good programs. A
13 good compromise as opposed to outlawing the practice
14 altogether. This process would not create one state
15 formulary, but rather allow approved programs to
16 function and still ensure the safety for the patient.
17 Number 2, the oversight of the
18 individual therapeutic interchange programs. Once
19 again, I want to emphasize "programs." It would not
20 cripple formularies nor would it outlaw them. The
21 members of the Task Force or the groups that they
22 represent have all acknowledged that not all
23 formularies nor all methods of enforcing those
24 formularies are consistent throughout the health care
25 marketplace. There are other methods of enforcing

Page 7

1 formularies, such as influencing physicians' original
2 prescribing, detailing the pharmacists for generic
3 substitution, distributing the information to the
4 payer and the patients to crease their knowledge of
5 what is covered, et cetera. None of those mechanisms
6 are influenced by therapeutic interchange.
7 My third and final point, drug
8 therapy decisions contingent upon monetary incentives
9 do not best serve the patient. Oversight would enable
10 and ensure better marketing of the drug products
11 based on the positive clinical aspects of the drug,
12 as well as the impact on the patient populations.
13 Thus, once again, improving and identifying patient
14 quality of care as a number one priority.
15 Thank you.
16 CHAIRMAN TEEFEY: Thank you,
17 Cindy.
18 Yes, Steve?
19 MR. ROSENTHAL: Mr. Chairman, I
20 just--I'm Steve Rosenthal--I just have an
21 administrative matter. On the list of entities
22 supporting the policy options sent out by Matt
23 Jenkins' office, there is one deletion and one
24 addition. Prudential Insurance Company should be
25 deleted. I just haven't received final approval of

Page

1 that yet. And, added to that list, should be the
2 Academy of Managed Care Pharmacy.
3 CHAIRMAN TEEFEY: Okay. Great.
4 Thank you.
5 Is there anyone else that would
6 like to speak?
7
8 NOTE: (No response.)
9
10 CHAIRMAN TEEFEY: Scotti Russell
11 has worked extremely hard trying to help us
12 understand what we are doing in my Department, and
13 Scotti would like to present some policy options that
14 the Virginia Board of Pharmacy has come up with.
15 MS. RUSSELL: I apologize. These
16 would have been in your packet earlier, but the
17 committee didn't meet until yesterday, and I didn't
18 have a chance to review what staff had drafted.
19 Does everybody have a copy of the
20 draft?
21
22 NOTE: (No response.)
23
24 MS. RUSSELL: The first suggested
25 policy option would be to somehow define Pharmacy

Page 9

1 Benefit Manager to include any current PBMs, HMOs or
2 any other third-party payers or managers of pharmacy
benefits, and do a statute to require registration
with the Board of Pharmacy in order to operate in
5 Virginia.
6 The Board of Pharmacy really does
7 not have the ability, at this point in time, to
8 effectively carry out its statutory obligation to
9 regulate the practice of pharmacy in Virginia,
10 because so many decisions that affect the practice of
11 pharmacy are being made by entities other than those
12 which we license or register. This would give the
13 Board the ability to have some oversight over these
14 entities that are currently operating in Virginia and
15 impact the practice of pharmacy so greatly.
16 The Board, at this time, doesn't
17 want to specifically make recommendations as to what
18 they do and don't consider appropriate practice, but
19 allow you, the Committee, or the public pharmacists
20 to have plenty of time to develop regulations as to
21 what may or may not be considered appropriate in the
22 drug-switching issue. We've had other problems
23 related to, I think I mentioned last time, the sale
24 of confidential patient-specific information. We're
25 now having problems with imposition of certain

Page 10

1 requirements on pharmacies in Virginia that are
2 contrary to other State laws and regulations, such as
3 time lines for the length of time that a prescription
4 would be good for that's contrary to current State
5 laws and regulation that are affecting the practice
6 of pharmacy. Different types of activity that some
7 oversight by the Board would be, would give the Board
8 the ability to truly regulate the practice of
9 pharmacy.
10 The second policy option that the
11 Board would like to see considered would be to
12 require, and I think I heard last week that just
13 about all PBMs and HMOs do have some type of an
14 appeals process, but require all PBMs to have a
15 written appeals process whereby a patient or a
16 practitioner may appeal a PBM's denial of payment for
17 a prescribed drug in favor of a preferred or
18 formulary drug and require that the denial of the
19 prescribed drug not take effect until after the
20 completion of the appeals process.
21 The third option that the Board
would like you to consider, and realizing that this
23 would be a lengthy process, would be to consider
24 possibly setting up an independent board or committee
25 to develop standards and guidelines, maybe something

Page 11

1 similar to the Virginia Voluntary Formulary that sets
2 standards for exchange of generic drugs for brand
3 name drugs, to set up a Board which would set
4 standards for therapeutic interchange as to which
5 drugs could be maybe safely, in some cases,
6 substituted for other drugs; define what therapeutic
7 classes really are. And, after that is done, consider
8 changing the prescription blank format to have a
9 third check box wherein physicians, prescribers
10 could, up front, allow therapeutic interchange with
11 complete knowledge of what that meant, and in cases
12 where they felt it maybe didn't impact public safety.
13 This might eventually cut down on
14 a lot of the phone calls that pharmacists have to
15 make, allow the physician some choice up front, and,
16 cut down on some of the workloads for both PBMs,
17 pharmacists and prescribers.
18 I don't think we could be quite
19 ready to put a proposal together in time for this
20 particular General Assembly session. I mean, this
21 would take a lot of work. But I think it's
22 something, if we're going to keep using formularies,
23 if PBMs are going to keep using preferred drug lists
24 as a mechanism for reducing cost, then this might be
25 something we would want to consider looking at.

Page 12

1 Questions?
2 MS. PIGG: This is Cindy Pigg.
3 Scotti, can you just help me
4 understand, are there practices that you're hearing
5 reports of that said, and it's kind of jumping off of
6 your point, too, here, I think, that there is a
7 distinction between what the contract between the
8 patient, the member, and their insurer is versus the
9 patient care.
10 And, point number two, and then
11 maybe even in point number three, but that's not the
12 point, it seems like the Board is getting--the
13 assumption is that just because the prescription is
14 not paid for, that means that the patient cannot have
15 it. And that's a contractual relationship. I don't
16 know that there are PBMs, and maybe there are, that
17 are saying, you can't dispense this drug. I don't
18 think they're saying you can't dispense it. They're
19 saying it's not a covered part of the contract.
20 MS. RUSSELL: Well, I think that's
21 a problem that all the health professions are having
22 to deal with. Yeah, you're right, the PBMs are
23 saying, we're not going to pay for it, not that you
24 can't have it or you can't comply with the State law,
25 but we're just not going to pay for it. If you

Page 13

1 dispense it for two years then, you know,--
2 But, as a matter of, you know,
3 fact, in a lot of cases, that does create a denial
4 for that patient, because they can't afford to pay
5 for it.
6 MS. PIGG: But, if they didn't
7 have a drug rider at all, would you feel it was the
8 Board's responsibility to say to the pharmacist,
9 you've got to give that drug to the patient, even if
10 they can't pay for it? I'm just wondering; I guess my
11 question is, is the Board interested in entering into
12 the relationship that's a contract between the
13 employer and the member and the payer?
14 MS. RUSSELL: No. I mean, I think
15 some of the business aspects of this are best left to
16 the Bureau of Insurance, but only, I mean, I think
17 that certain policies by PBMs do affect the practice
18 of pharmacy, such as a company saying, we are not
19 going to pay for a prescription that's over a year
20 old or over six months old, when, in fact, State law
21 regulations may allow it to be refilled for a longer
22 period of time. It creates additional workload for
23 pharmacists, which ultimately can create additional
24 mistakes. It creates extra workload on the
25 prescriber when the doctor--when pharmacists have to

Page 14

1 call and get a second prescription. And it also
2 creates the situation where you've got two open
3 prescriptions for the same drug for the same patient,
4 and I think that's a problem.
5 Whether we would -- What we would
6 want to do to resolve that, I don't have that answer
7 at this point in time, but, yeah, I do think when
8 policies, business decisions, affect, get into
9 affecting the actual practice of pharmacy, that maybe
10 the Board should have some oversight. But only to the
11 extent that it does affect the practice of pharmacy
12 and not necessarily the business decisions or the
13 contract. I doubt many patients really know what's in
14 the fine print of their contract.
15 MS. PIGG: I can't speak to that.
16 The information is there. They may or may not elect
17 to read it.
18 MS. RUSSELL: Or may or may not
19 get it even.
20 DR. HADLEY: Ms. Russell?
21 MS. RUSSELL: Yes.
22 DR. HADLEY: Dr. Hadley. Your
23 recommendation about how the denials should be
24 handled with respect to the appeal process, I think,
25 is problematic, and that would be a little bit

Page 15

1 different than how appeals are handled for other
2 things of which there are already statutes involving,
3 that have been, you know, set up for HMOs.
4 Typically, in a situation like
5 that, if there is and then, first of all, you don't
6 even--an HMO doesn't always know, if a denial is
7 issued, whether or not it is even going to be
8 appealed. Typically, there is a period of time that
9 you allow up to 60 days. So, if a denial is issued,
10 maybe only, you know, a fraction of those are even
11 going to be appealed.
12 So I think that that is very
13 problematic to say that if an HMO or a PBM issues a
14 denial that that doesn't take effect until somebody,
15 you know, appeals it, and they go through that whole
16 process. And you're allowed, you know, by the State
17 statutes, a certain period of time to respond to
18 those.
19 So, I think what would be better,
20 if there would be something like that, would be rules
21 that would be consistent with the other kind of
22 appeals. And, typically, what that would mean is, if
23 the appeal was won by the patient, that the payment
24 for that would then be retroactively applied. But
25 not that the denial wouldn't take effect until there

Page 1

1 had been an appeal and it had been heard.
2 I think just technically that
3 would be very difficult to do what you're talking
4 about.
5 MS. RUSSELL: The difference I see
6 with pharmacy benefits and other types of denials is
7 that you've got to have immediate permission to make
8 that switch before the drug is dispensed. So, if it's
9 denied, I mean, if you call the prescriber and the
10 prescriber says, no, I do not want this drug
11 switched, then you've got, I mean, you've got
12 immediate notification that they're appealing. I
13 mean, --
14 DR. HADLEY: Well, there are
15 expedited appeal procedures. I mean, you know,
16 that's allowed by current statute for the HMOs.
17 But, to give you another example
18 of this, I mean, there are more than just the
19 therapeutic interchange kinds of appeals that take
20 place. Some of them have to do with the generic
21 drugs.
22 MS. RUSSELL: And that's not what
23 we're talking about.
24 DR. HADLEY: Patients are
25 appealing, you know. They want the brand name or

Page 17

1 they appeal, you know. And it's very clear in their
2 contract that there are certain drugs that are
xcluded by a contract, you know, such as the
osmetic ones we talked about--Minoxidil for hair
5 loss. I mean, believe it or not, even though that's
6 written clear in black and white in the contract,
7 people appeal that sort of thing.
8 MS. RUSSELL: And that's not what
9 we're talking about.
10 DR. HADLEY: So, I think that's
11 the problem.
12 MS. RUSSELL: Yes, and maybe I
13 didn't make that clear. I'm not talking about generic
14 versus brand, and we're not talking about drugs that
15 would be normally denied, blanketly denied because
16 they're for cosmetic purposes or whatever reason. I'm
17 talking about the issue that you're here to talk
18 about, which is the drug-switch issue, the switching
19 of chemically dissimilar drugs for the same
20 therapeutic purpose where you would pay for one drug
21 in a therapeutic class, but not necessarily another.
22 MS. PIGG: But it does get to the
23 same issue as covered versus noncovered, because,
24 again, getting back to the contract, it says drugs
25 not on the formulary are not covered benefits, unless

Page 18

1 the exception process is gone through. So it really
2 is the same issue of covered/noncovered. That's what
3 formulary equals, covered; nonformulary equals
4 noncovered.
5 MS. RUSSELL: But, again, you have
6 got a drug for a prescription and you're going to
7 probably-- If something was not covered for cosmetic
8 purposes, for example, you would tell the patient
9 right then it was not covered. If you want it, you
10 have to pay for it.
11 In the other situation, you
12 wouldn't tell the patient that. You would say, let me
13 call the prescriber and see if we can get them to
14 switch to this other drug that is covered. The
15 patient may or may not have been on the other drug
16 for a period of time. And you're either going to get
17 a yes or a no within a certain period of time whether
18 they want to switch or not. And I guess the committee
19 or Board felt that if the PBM had to pay for the
20 denied drug until they could get through the appeals
21 process, that it might have the effect of making the
ppeals process go a little bit faster.
MS. PIGG: But, again, that
24 recommendation would go directly in conflict with the
25 contract. And, again, I just think the Board needs

Page 19

1 to consider that and-- Well, I heard you say that's
2 not where you're going with this at all. You're
3 trying to focus in on the practice of pharmacy,
4 things that may affect the practice of pharmacy.
5 But, I think you're -- It needs to be real -- The
6 Task Force needs to be very cautious in the fact that
7 it's very explicitly stated or else you do have a
8 problem with the Bureau of Insurance that
9 nonformulary drugs are not covered benefits.
10 DR. HADLEY: Again, I think you
11 have the problem, too: suppose you require the PBM to
12 pay for a drug until it is appealed. Again, the
13 majority of these are never even appealed. So does
14 that mean they're supposed to pay for that drug
15 ad infinitum? You would set up a situation where it
16 would be in the patient's and the doctor's interest
17 never to appeal it, because you'd have to pay for
18 that until "an appeal was worked through."
19 MS. RUSSELL: Not necessarily.
20 DR. HADLEY: So, I think, the
21 other thing, just one other point. I think the other
22 thing that we might need to make a distinction on, I
23 think, which is not apparent in this, there are
24 differences--I think Dr. Blanchard has brought this
25 out in some of his discussions--where sometimes a

Page 20

1 patient will present a new prescription, has never
2 been on a particular drug entity. They have just
3 been diagnosed for whatever condition, presents with
4 a drug in a particular therapeutic category. They're
5 informed, this particular drug is not on our
6 formulary, but we have another drug in our formulary
7 in the same drug, you know, class. We'd like to
8 substitute that. There's really-- The patient has
9 never been put on that drug, has never been titrated
10 and that probably is a different situation than the
11 patient who, let's say, joins a particular health
12 plan and has maybe been on Drug A for ten years, well
13 titrated, doing well, and this is the transition-type
14 of situation that we talked about. That may be a
15 specific situation where, you know, some things, such
16 as you're talking about, a patient who is on a
17 chronic medication, was well titrated, well
18 controlled, no side effects, that may require some
19 special handling.
20 But I think to make a blanket
21 statement like that, that, you know, you have to pay
22 for it until the appeals process is worked through,
23 would be very difficult and problematic. Again, there
24 are expedited appeal situations so that if the doctor
25 and the patient decided to take advantage of that

Page 21

1 for, say, a transition drug, I mean, then you could,
2 for example, have a rule where you dispense, you
3 know, 72 hours worth of medication. And an expedited
4 appeal is supposed to be resolved within two business
5 days.
6 So, you know, perhaps something
7 like that, but not to leave it completely open that
8 you could get the medication forever by just not
9 appealing, it doesn't seem to me to make sense.
10 MS. RUSSELL: And I don't think
11 that's what we had anticipated, and this is not, by
12 any means, worked out in detail.
13 DR. HADLEY: Yes.
14 MS. RUSSELL: It's just a concept
15 whereby the patient would not be immediately denied.
16 If you call the physician to make a switch, and he
17 says, no, to me, that ought to institute the appeal
18 process. I mean, if he says, no, I don't want to
19 switch, because, you know, I want this patient on
20 this particular drug for whatever reason, you're
21 going to deny payment of the drug to that patient
22 until they can get it worked out.
23 DR. MOFFATT: I've got a handful
24 of problems, and I am not sure where they all come
25 from.

Page 22

1 It started out-- I certainly
2 share your concern. I can't make the company pay for
3 a drug just because I've liked it forever and stall
4 appeal until my patient doesn't need the drug
5 anymore. So, obviously, that needs a little
6 polishing. I don't find that a cogent argument
7 against your point in saying that they have got to
8 provide the drug at first. I think that's a technical
9 problem that is certainly surmountable.
10 I'm very uncomfortable with the
11 Defense, if that's the right word, that "it's in the
12 contract." The patient should have read the contract.
13 All right. That's talking about a legal gotcha.
14 That's not talking about the practice of medicine.
15 Maybe I'm a little pollyanna about this, but I see a
16 significant difference.
17 I don't know what the drugs are
18 that are included in my insurance. I would wager
19 most patients don't. To know that my patient
20 understands the difference between being given Biaxin
21 and being given Erythromycin, so that when he signs
22 the contract, he really has informed consent on what
23 he's buying is ludicrous. That's not going to
24 happen. Our challenge here is to protect the
25 citizens of the Commonwealth, not to rape the

Page 23

1 insurance companies or the HMOs or anybody else. But,
2 you can't use that kind of gotcha mentality when
3 you're talking about taking care of patients' lives.
4 The last thing, and I promise to
5 shut up after that, is your proposal number three.
6 Were you not happy with the definitions that are
7 being made of therapeutic interchange the last time
8 through? Because I think that addresses the problem.
9 The problem with having an extra box on a
10 prescription pad is that if two or three physicians
11 have such prescription pads, and we all check the
12 boxes, then we end up with patients taking Macrolides
13 biotics, antiulcer medications and antifungal
14 medications, and getting cardiac arrests because we
15 don't really know what drug our patient is taking.
16 If you specify drugs that you
17 know are safe, regardless of the fact that your
18 patient is also seeing an allergist and everybody
19 else, then you feel much more comfortable about
20 that. I don't think we can use this kind of a
21 blanket approach to therapeutic interchange.
22 Although it's probably well-intended, I think it's a
23 little misguided.
24 Thanks.
25 MS. RUSSELL: I didn't mean it to

Page

1 be an easy, quick solution, and I think, again, there
2 would need to be a lot of details worked out. I think
3 that if a change was made, the physician, prescribing
4 physician, should be immediately notified in writing
5 that that change was made and what it was switched
6 to. I think there should be a limitation on the
7 number of switches you could do per prescription,
8 like maybe one, as a maximum. And I think there
9 should be a book like the formulary. You know which
10 drugs could possibly be substituted for a brand name
11 drug that was prescribed and you okay that by
12 checking a voluntary formulary box.
13 If you know-- When I say define
14 therapeutic interchange, yeah, I'm comfortable with
15 the definition that was done last time. But I think
16 that needs to be expanded upon. I mean, we don't
17 really know what a therapeutic class is. We don't
18 know, if you said that right now, you wouldn't know
19 what that really meant, what the pharmacist was going
20 to do. If the pharmacist had a book and could only do
21 exchanges within certain parameters, that this drug
22 was approximately equivalent to this dose of this
23 drug, given at these particular times, and you knew
24 what the choices were, you might have a little bit
25 more of a comfort level, maybe. And, in some

Page 25

1 patients, say you've never had a patient on a
2 particular class of drugs before, it was a new drug,
and you didn't really care which one he was put on as
part of the formulary, if you knew it was--that an
5 independent body had looked at this and said, okay,
6 this one, this one, this one are okay within certain
7 parameters. And this may not even be able to be
8 done. It was just a suggestion. I mean, I have
9 heard concerns that the formulary committees for the
10 various HMOs and the PBMs, you know, are not truly
11 independent, and maybe if we had some State
12 independent body that was coming up with standard
13 guidelines for this type of thing, that might be a
14 better way to do it.
15 MR. SZALWINSKI: If I may, Mr.
16 Chairman, it's Mark Szalwinski.
17 I would hesitate to make that
18 blanket statement. There are many very good P and T
19 and formulary committees out there with significant
20 local control. And I think that there is really a
21 risk of taking that local control away by putting
22 some supra authority over designing that. And you
23 could really -- You run the risk of really hurting
24 those processes that are functioning well and have
25 established good credibility with physicians in the

Page 26

1 community and members.
2 So I would just, I would caution
3 that. There are those committees that are doing very
4 well and are independently functioning. But, I'd like
5 to also go back to Cindy's point and remind everyone
6 that there is data out there from IMS that last year
7 prescription drug volume grew 10.1 percent in real
8 dollars and in real prescription numbers due to and
9 attributable to the coverage of prescriptions by
10 managed care. Patients are getting more drugs because
11 managed care is covering them. And there's a cost
12 and a benefit to that, and managed care is doing the
13 best they can by trying to administer the cost and
14 provide that additional benefit.
15 I would just be very cautious
16 because it is our job to protect the consumer, and
17 the consumer has benefited by additional drug
18 coverage. So, we need to be very careful how we now
19 try and regulate that practice, and I don't think
20 that there is any real, the intent behind these I
21 could support, but we need to be very sensitive,
particularly to the appeals process and for
regulating the P and T process that we aren't onerous
24 or obstructionists in allowing the managed care to
25 continue to provide that additional benefit.

Page 27

1 MS. RUSSELL: And I don't disagree
2 with you. That's why the Committee would recommend
3 not doing anything on option number three this year,
4 but take a year with a Committee to even take a look
5 at what could be done. It may not be possible.
6 DR. DALTON: Dr. Randall Dalton.
7 Your point number three concerns me, like a lot of
8 the discussions we have that make it look like
9 physicians are going to get to the point where we are
10 not writing for prescriptions, but writing a
11 diagnosis and saying, well, prescribe something for
12 our patient for this, because it's going to -- It's
13 out of our hands as it is.
14 Right now prescriptions aren't
15 determined in a vacuum. The physician has a lot of
16 history on the patient, background, his thought
17 process as to the likely pathogens that are involved,
18 if it's an antibiotic that's being prescribed, the
19 side effects, additional costs that would be involved
20 if you need to get laboratory work if you're going
21 with a limited spectrum-type of antibiotic as opposed
22 to going with something that covers more pathogens
23 and being able to treat more empirically on patients.
24 A lot of things go into that, and I think that we're
25 taking the physician out of the process more and more

Page 28

1 as we sort of broaden the options that the patient
2 can get from the pharmacy, and I think that most
3 physicians are willing to be flexible with changes,
4 generically, changes within a class of medications.
5 But, we need to be involved in
6 that with a phone call and checking a box, probably,
7 is being a little too insensitive to the input of the
8 physician, even though you said you sent a letter out
9 saying this is what the patient got. And I think we
10 need to remember that the patient is getting
11 something that the patient needs in order to get
12 better and that the more times he gets that specific
13 medication, the more times, of course, a treatment is
14 going to be successful.
15 CHAIRMAN TEEFEY: But haven't we
16 gotten to a point now, and I hear the discussion,
17 haven't we got to the point now that we are calling
18 for a switch because the drug is not on the
19 formulary, and if they don't get the switch, they
20 don't get anything?
21 MS. PIGG: They don't get
22 anything. Again, they don't get anything as a
23 covered benefit. Nowhere does the PBM say you cannot
24 have that. Again, I didn't mean to convey it's kind
25 of a gotcha attitude. That's why we set up appeals

Page 29

1 processes, because it would be very shortsighted for
2 us to say, just like my homeowner's when my roof got
3 ripped off. They said, sorry, it's not in the
4 contract and that's all, end of discussion. It
5 wasn't really an appeals process.
6 But because HMOs or managed-care
7 entities really are charged with looking at the total
8 health care cost, that's why we set up appeals
9 processes, because I agree, if we use the gotcha
10 mentality when that wasn't the best choice for the
11 patient. That would be shortsighted.
12 CHAIRMAN TEEFEY: Well, and I
13 agree. But, do we set up an appeals process to make
14 a person go through an appeal knowing they're not
15 going to get anything out of the appeal? And I think
16 that appeals process, if we do that, it's wrong
17 having an appeals process.
18 I think what Scotti is trying to
19 say is, really it might not be a Pharmacy Board
20 issue. It might be a Bureau of Insurance Board
21 issue, because, you know, we're all thinking about
22 the patient and good practice as far as the patient
23 is concerned. But I think we've gotten to a point
24 where, in our interchange, are we calling the
25 physician to tell the physician that the prescription

Page 30

1 you wrote we can't fill because it's not on the
2 formulary, and if you don't switch it to this new, to
3 the drug that I have prescribed, then the patient,
4 the person has got to pay for that drug?
5 MS. PIGG: I think it's real
6 important to use the right terminology, though, to
7 say--
8 CHAIRMAN TEEFEY: Yes, and that's
9 what I want to lay out and make sure that everybody
10 understands that.
11 DR. HADLEY: If they have to,
12 we'll pay it out of pocket--
13 MR. SZALWINSKI: But, that's a
14 communications issue, and that's a, you know, that's
15 a very important communication that needs to be done
16 well. I mean, it's not a black and white issue.
17 There can be expertise in accomplishing that.
18 MR. COUNCIL: Mr. Chairman, if I
19 can speak to your question and also I think some
20 comments that Dr. Moffatt had.
21 I think, first of all, we're
22 making a big mistake in addressing this issue
23 because, so far, everyone has referred to insurance,
24 and insurance is not the full picture here. You know,
25 insurance does a lot of good for a lot of people, but

Page 31

1 I haven't met anybody lately that stood up and sang
2 their praises. All pharmacy benefits are not insured,
3 and I can't give you figures on it, but I can tell
4 you that hundreds of thousands of pharmacy benefits
5 are straight employer, self-funded. So, I think we're
6 making a mistake if we think about this entire
7 benefit in terms of insurance.
8 Then, the second comment is, it
9 is a specific legal mistake to talk about that all
10 this could be regulated by the Department of
11 Insurance, because, to the extent there are
12 self-funded plans, there's not going to be any
13 jurisdiction there in insurance.
14 So, I think we have to talk about
15 it as a pharmacy benefit plan, not necessarily as
16 insurance. My second comment is really to Dr.
17 Moffatt, and I think there's a big, big mistake to
18 look at the issue of what an employer is willing to
19 provide as a benefit as just some legalistic
20 argument. It's not legalistic. It's not law school
21 debate for the fun of it. It is what employers have
22 sat down and determined that they can afford to
23 provide as a benefit to their employees and
24 regardless of what more we may try and sit here and
25 say they need to add to that plan, there are going to

Page 32

1 have to be parameters. And, if they're not
2 parameters for those employers, then what we're going
3 to see with the pharmacy benefit is the same thing
4 we've seen in the last 15 years with our old pension
5 defined benefit plans.
6 I would say 15 years ago,
7 probably more employees in this Country were covered
8 by defined benefit plans, which are real retirement
9 plans. Government made it so expensive for employers,
10 so burdensome to administer, that I bet you can
11 hardly find a defined benefit plan anymore. And if
12 we think about this as nothing but patient care, and
13 it is patient care, but if we fail to acknowledge
14 that somebody up front has determined how much they
15 can pay to provide some pharmacy benefit to its
16 employees, then we're going to lose sight, I think,
17 of how the whole pharmacy benefit operates. We have
18 just heard some suggestions right there that, in
19 fact, many, many more prescriptions are being written
20 as a result of pharmacy benefits being offered by
21 employers.
22 So, it is not just a legalistic
23 argument. It is a business issue of an employer
24 having to sit down and decide how much he can afford
25 financially to devote to providing a benefit to his

Page 33

1 employee. And, over and above that benefit, it
2 becomes the employee's financial responsibility. If
3 we sit here and continue and continue to tell the
4 employer what he has to provide, to the point that
5 employers decide they don't want to offer the
6 benefit, then I really don't think people are going
7 to feel like that we acted in the benefit of the
8 consumers here.
9 DR. BLANCHARD: Mr. Chairman,
10 Larry Blanchard.
11 CHAIRMAN TEEFEY: Yes, sir.
12 DR. BLANCHARD: Sort of two
13 comments. One is, I hope we can recognize that Ms.
14 Russell didn't come here to be a symbolic target of
15 all our discussion that should take place among us.
16 And Scotti is sitting up here having to feel the
17 brunt of it and just propositions that may not be any
18 more hair-brained than others that we will come up
19 with later.
20 I couldn't let it rest without
21 one comment on the contractual issue and without
22 arguing with your concept of what's covered and
23 what's not covered. The employer, whether he's
24 buying coverage for himself and his family or
25 employees and their families, no doubt is reassured

Page 34

1 by a language in the contract that says something
2 along the lines of we will be covering all medical
3 and necessary treatments. And it doesn't necessarily
4 get communicated to the employer or the employee that
5 this is determined at the sole discretion of the
6 insurance company and not by the patient's physician.
7 There is an assumption that
8 reasonable treatments have a reasonable chance of
9 being covered. There is not anything in there that
10 says, we are going to try to limit your coverage for
11 given diseases to one out of a possible 30 choices.
12 And, I would suggest that the employer, as I do when
13 I buy insurance, assumes that there's going to be
14 some choices in there that are appropriate. The
15 arguments tend to come, as Mr. Teefey has suggested,
16 as to when a drug prescription that is a reasonable
17 choice for your neighbor paying the same premium with
18 another insurance company next door is determined to
19 be an unreasonable choice by the insurance company
20 that you're covered by. It's difficult for physicians
21 and patients to understand that logic. We're not
22 talking about drugs that are eliminated because of
23 safety reasons. We're talking about when it comes
24 down to four, five or six drugs that are quote
25 therapeutically equivalent, but with slightly

Page 35

1 different side effects, each insurance company is
2 coming up with a formulary that says, CIGNA will
3 cover this one; Aetna will cover this one; Prudential
4 will cover this one. That doesn't necessarily make
5 much sense to the public.
6 There are only two parts to the
7 contract. You can say what you said, but I think the
8 public has a perception that the contract also says
9 they will be covered by reasonable choices. It may
10 be a communications problem, but I don't think that's
11 clear up front. Because, when the presentations are
12 made to the Employee Benefits Manager, they are
13 reassured repeatedly that, yes, we have a good
14 formulary. We are going to cover the things that
15 need to be covered.
16 DR. HADLEY: Larry, I think that
17 that's not really what the contract is about, the
18 prescription benefits are all about. Almost always
19 they are a rider to the contract, because employers
20 have the option of selecting or not selecting the
21 pharmacy rider. So, again, this gets back to the
22 issue of the employers are voluntarily supplying this
23 as a benefit to their employees, but that doesn't
24 mean they have to. But these are typically a rider to
25 the contract. And the language that I see in all of

Page 36

1 them is very clear that the drugs that are covered in
2 this are those that are on the formulary. And, if
3 it's not on the formulary, either you have to pay it
4 out of pocket or pay some percentage out of pocket
5 that would be greater.
6 In some cases, the nonformulary
7 drug may be covered but at a lower benefit. And,
8 they're very clear that it isn't saying you get all
9 drugs. It's saying, you know, these drugs are
10 excluded and those that are on the formulary are
11 excluded. So, I think that it's not really a bait and
12 switch kind of thing. I think it's very clear and up
13 front. And, you know, unfortunately, there are a lot
14 of the physicians are writing drugs that aren't
15 consistent with that, and I think one of the problems
16 we have, of course, is that there are different
17 formularies from one company to the next. In part,
18 that's due to the competitive marketplace which
19 allows different insurance companies and PBMs to
20 negotiate better rates. And, to that extent that
21 that drives down the cost of drugs, that's good.
22 The fastest rising part of the
23 Health Care Bill right now is the pharmaceutical
24 bill. I mean, there is no question that's being
25 subject to the highest inflationary rate. So it's a

Page 37

1 big problem.
2 MR. AYOTTE: Mr. Chairman, can I--
3 CHAIRMAN TEEFEY: Yes, sir.
4 MR. AYOTTE: I feel like I'm in
5 between the -- I'm the pharmacy group, so I guess I
6 want to talk to a couple of points that I just want
7 to clarify in my head.
8 First of all, the State has the
9 authority, although Virginia pharmacists use
10 therapeutic interchanges? We have established that?
11 The doctor in Virginia has the final say on
12 therapeutic interchanges in Virginia? The Board of
13 Pharmacy has, at the current time, no oversight over
14 prescriptions filled for the citizens in other
15 states?
16 MS. RUSSELL: Correct.
17 MR. AYOTTE: Okay. So, I guess
18 what I would like to do is kind of refocus, if we
19 can. You know, it just seems like Senator Newman, at
20 the last meeting, brought up an outstanding point,
21 and it seems more outstanding today than it did the
22 last time, is that Delegate Morgan's subcommittee on
23 PBMs can deal with many of the issues that I hear
24 today that we may not be able to. You know, whether
25 it's the degree of the ability for someone to appeal;

Page 38

1 the ability for someone to cover an open formulary
2 issue; some issue that has to do with one formulary
3 book.
4 I guess I just want to make sure
5 that we're still focusing on alternatives to this.
6 And I know Scotti worked hard on the ones that you
7 have, and there are some good points in there. But,
8 I want to make sure that we don't get off and never
9 get to the point of coming up with some
10 recommendations.
11 DR. BLANCHARD: Can we excuse Ms.
12 Russell?
13 CHAIRMAN TEEFEY: Well, yes.
14 MS. PIGG: I just have one more
15 question. As I tried to kind of look into the
16 Board's thoughts, and I know I can't speak for the
17 whole Board, but some of the practices being
18 implemented by PBMs are affecting the practice of
19 pharmacy and specific things that pharmacists have to
20 comply with. In the scenario where you mentioned that
21 the phone calls,--the pharmacists having to call the
22 physicians back, potentially is interrupting the work
23 flow and leading to adverse outcomes. But, I want to
24 understand. Is the standard going to be applied
25 across all types of customers in that if the PBM, as

Page 39

1 the payer, says, we're not paying for this, that,
2 potentially, is interrupting the work flow? But, if a
3 patient comes in, a cash-paying customer, and says,
4 that's too, as the payer, and says, that's too
5 expensive, can you call the doctor and get something
6 less expensive, do you think that the same standard
7 applies there? It's the payer saying that's too
8 expensive, please call the doctor in that practice,
9 because the payers are now such a big volume and are
10 affecting the practice of pharmacy and their work
11 flows?
12 I mean, I'd hate for the tried
13 and true thing of the patient coming in and saying, I
14 can't pay for that, and the pharmacist saying, let's
15 see what else we can find, I have to call the
16 physician to discuss that, being usurped by-- It's
17 all the same thing. The payer says, it's too
18 expensive. Call the physician. And I would hate to
19 see that cash paying customer --
20 MS. RUSSELL: I don't think I have
21 said anything that would make you think that the
22 Board is considering prohibiting the ability of the
23 pharmacist to call the physician in either one of
24 these cases. Like, in option number three, it was
25 maybe a way we could look at, explore for the future

Page 40

1 in cutting down on some of these calls. I think what
2 I talked about was that a problem that we're seeing
3 with some PBMs blanketly saying, we're not going to
4 honor any prescriptions over "X" number of months or
5 one year old, when, in fact, the physician expects
6 that it's going to be honored for two years. The law
7 says it can be honored for two years, and there's
8 really no, you know, that I'm aware of, good reason
9 why the PBMs are doing that.
10 Looking at that, I haven't even
11 said that that's -- I think all the Board would like
12 -- And we get people, pharmacists calling us, why
13 can't you do something about this practice? Because
14 we don't have jurisdiction over the people making the
15 decisions. We don't have any jurisdiction.
16 My thought right now, just at
17 this, you know, at this juncture, is to give the
18 Board some ability to register these people who are
19 impacting the practice of pharmacy in Virginia and
20 even, at first, on a case-by-case basis. I mean if
21 there is some fraudulent practice going on, that
22 somebody could do something about it. You know, if
23 it impacted the practice of pharmacy, it ought to be
24 the Board of Pharmacy that has the ability to do
25 something about it.

Page 41

1 MR. TOWLER: Mr. Chairman?
2 CHAIRMAN TEEFEY: Yes, sir.
3 MR. TOWLER: Briefly, in regard to
4 some of the things I have seen at the street level,
5 very early on, it has been going on for years, is in
6 regard to, say, generic substitution. Some parts,
7 not only PBMs, we're being told to dispense or the
8 benefits would be increased to the patient. But, in
9 a therapeutic interchange sense, I see a bait and
10 switch going on in some regards where an Imitrex
11 prescription is covered and the patient walks in for
12 their refill and it is not covered, and it's a very
13 sudden event. To have some sort of an override
14 capability that would be short-term, I think would be
15 reasonable, in regard to having time for the patient
16 to address these issues. What we're seeing now is
17 kind of a run-into-the-wall effect, and it's having a
18 lot of adverse impact on the work place condition.
19 CHAIRMAN TEEFEY: Well, I hope we
20 never even think about taking the right away from the
21 individual.
22 MS. RUSSELL: Oh, absolutely not.
23 CHAIRMAN TEEFEY: I just hope we
24 never, ever think about taking that right, because
25 that individual is the one that everybody is

Page 42

1 concerned about, the medical community, the
2 pharmaceutical community, and I just hope we never
3 think about taking that freedom of choice away from
4 the individual.
5 MS. PIGG: But that doesn't
6 inflate the payment or nonpayment.
7 MR. SZALWINSKI: Well, I'm curious
8 as to what rights, specifically, you're speaking of.
9 CHAIRMAN TEEFEY: Denying that
10 person the right to have the pharmacist call the
11 doctor. That is all I'm saying. I just think that
12 they're the, that's the center of the nucleus right
13 there, and I just hope we never take that right away
14 from the individual to do it by checking any box or
15 anything.
16 MS. RUSSELL: No.
17 CHAIRMAN TEEFEY: I'm not a
18 pharmacist or a doctor, either.
19 MS. RUSSELL: No. And I guess--
20 CHAIRMAN TEEFEY: And you weren't
21 suggesting that?
22 MS. RUSSELL: No, not at all. And
23 I guess our policy option number one is what we would
24 really like to see and what the Board feels it needs
25 in order to start having some control over the

Page 43

1 practice of pharmacy again.
2 Number two is sort of a wish
3 list.
4 And number three is something
5 that we would like the Committee to look into as a
6 future option. I know it can't be done right now.
7 CHAIRMAN TEEFEY: I think the
8 three suggestions you brought are excellent, and I
9 think it does open up a whole other arena of thought.
10 And, again, Scotti, you know, you
11 and the Board do a wonderful job, and we really want
12 to thank you for coming down here.
13 MS. RUSSELL: Thank you.
14 MR. SZALWINSKI: Can I just add
15 one more thing? If we do proceed ahead with number
16 one, we may want to consider that someone from
17 managed care be added to the Board of Pharmacy. A
18 pharmacist in the practice of managed-care pharmacy
19 be on the Board of pharmacy, because you would want
20 that input on a regular basis if you were regulating
21 managed care and PBM.
22 MS. RUSSELL: Frankly, we don't
23 have any required composition of the Board of
24 Pharmacy now. It's, you know, whoever the Governor
25 wants to appoint. You know, I don't have any problem

Page 44

1 with that. I mean, it would be nice to have
2 pharmacists from all walks represented on the Board.
3 CHAIRMAN TEEFEY: Thank you,
4 Scotti.
5 I know some of the members of the
6 Task Force have sent some things in over the past
7 couple of weeks. Does anybody on the Task Force want
8 to go over any of the information that they sent in?
9 DR. DALTON: I sent in a letter
10 that a patient brought in to me that they got from
11 Rite Aid that pretty much gives us an idea of the
12 direction a lot of these switches are taking.
13 It was a letter telling a patient
14 that--they had a recent prescription filled for a
15 topical steroidal nasal spray, and Rite Aid suggested
16 that the one that the prescription was written for is
17 not the best, and that they could provide the patient
18 with a better one that's going to be cheaper for the
19 patient and the patient would get some other
20 benefits. And, it, obviously, had a disclaimer at
21 the bottom that you need to talk to your physician
22 since he's the one who ultimately has to make the
23 decision. And, it also included information that the
24 mailing had been paid for by the manufacturer of the
25 product that they were pushing.

Page 45

1 I think that this is something
2 else that undermines patient/physician relationships.
3 It shows that the physician can be bypassed and taken
4 out of the loop. At least, when we get a call from
5 the pharmacist about switching, we know what's going
6 on. This is something that if the patient hadn't
7 brought in this mailing to me, I'd have no idea that
8 it was going on. And I think it's something that we,
9 as we deliberate about these issues, need to know
10 that if we don't put down some guidelines or
11 parameters, that these things are going to get even
12 more blatant.
13 SENATOR NEWMAN: Mr. Chairman?
14 CHAIRMAN TEEFEY: Yes, sir.
15 SENATOR NEWMAN: The doctor knows
16 much more about these things than I do. But, I was
17 somewhat thrilled by the letter, and let me tell you
18 why. I trust patients with all the information they
19 can possibly get. And, if they can be given
20 information that there is a cheaper alternative drug
21 out there, and then they have to go back to their
22 doctor to determine whether or not that's the
23 appropriate item to choose or not, I think this
24 letter causes no problems, except maybe to the
25 medical profession who is a bit concerned that it

Page 46

1 does undermine some of their authority, although I
2 don't really think it does that.
3 So, I think there's two sides to
4 the way to look at this letter. I think this is full
5 information, and I think it's wholly appropriate. I
6 hope that there will be even more information like
7 this out there.
8 DR. DALTON: Okay. Who determines
9 if this is cheaper? What is a cheaper comparative?
10 It's information that implies
11 that this is a public service to the patient; that
12 this is cheaper, this is better; that your doctor
13 doesn't know what's going on; he doesn't know what
14 one brand costs. We make our prescription decision
15 based on the knowledge that this is out there, this
16 is out there, I've got them all lined up, and, yes,
17 we are being taken out of the loop. And, if you
18 don't think that's a problem, then it's no problem
19 except the doctor thinks that his relationship with
20 his patient management is being undermined. So? So
21 what?
22 That is the type of problem that
23 we're going to see as long as you don't see a problem
24 with this type of thing.
25 MR. AYOTTE: Mr. Chairman, I have

Page 47

1 a question for the Doctor.
2 Your feelings on the
3 advertisements that are in Parade on Sunday, I mean,
4 you know, I mean, every commercial on TV, everybody
5 that comes in, and I can tell you from practicing
6 pharmacy and would challenge someone to tell me that
7 a physician knows the prices that either a plan is
8 going to pay for or a patient is going to pay for on
9 any level of antibiotics, unless it has been brought
10 to him by the representative of that company, that
11 says, here, you prescribe mine, because it is at this
12 price point, there is no knowledge base of what it
13 costs.
14 I know you're making your
15 diagnosis based on what the patient needs, and for
16 years we've talked about patients being informed, the
17 consumer asking questions, and, to me, this letter,
18 just asks a question. This--
19 DR. DALTON: The advertisements in
20 Parade is not directed toward my individual patient
21 who went in to fill an individual prescription. His
22 name was kicked out of the computer as someone who is
23 on a topical steroid nasal spray. So, therefore,
24 we're going to entice that patient to be changed to
25 our preferred brand. That is a different issue.

Page 48

1 This is targeting a specific
2 patient that I made a specific therapeutic decision
3 on. And, if there was a suggestion for change, I
4 think that that's where it should have kicked in at
5 the point where, Doctor--the phone call--Doctor, how
6 about putting this patient on Lanacort because he can
7 get it cheaper or whatever else. But this is kicking
8 the doctor out of the loop. And, if you don't see a
9 problem with it, then, as I said, that is a problem.
10 MR. AYOTTE: But, if I can go back
11 one step. When we began this discussion many moons
12 ago, we talked about the volume of phone calls that
13 are received, and the workload issues at the doctors'
14 offices. I just want to make sure that -- I mean, I
15 don't see any malice in this. However, if you wanted
16 the pharmacist to call, I mean, I would think that
17 that's an alternative to this process. But, that, to
18 me, an easy way is to just say, this is available;
19 we're not forcing you to do this; we're not forcing
20 the patient to switch. We're informing the patient
21 that there is availability. If they want to, they
22 can follow it up versus the pharmacist saying to
23 them, you know, this is not going to be a covered
24 benefit, but we want you to switch to this.
25 DR. DALTON: I don't think there

Page 49

1 is a pharmacist in this room or many pharmacists, I
2 mean, physicians who really object to the phone
3 calls, to generate the phone calls from the
4 pharmacist. I think in a lot of cases, when we're
5 informed, we'll change it if it's appropriate. If the
6 patient can't afford the drug, we'll say, come on by,
7 pick up some samples, and other things.
8 So, I don't think that the fact
9 that, oh, we're trying to save you some work by
10 communicating directly with the patient, and I think
11 that's bogus.
12 MS. PIGG: Part of the driver,
13 though, I think, and the whole reason for the
14 legislation is that the pharmacists don't want to
15 call.
16 DR. MOFFATT: I think we do have a
17 problem. I don't mind being second-guessed so much--
18 I'm getting kind of used to it--but, what bothers me
19 about this letter is not what bothers Dr. Dalton.
20 What bothers me is, why the pharmacy wants this
21 change to happen. If Astra is paying Rite Aid to push
22 Astra's product and that's why Rite Aid is
23 approaching my patient, I have a problem.
24 If it really is just that I'm not
25 bright enough to know that Lanacort is just as good

Page 50

1 as the other drug I'm using with a similar side
2 effect profile. That's my problem, really.
3 But, what really bothers me is
4 whether there is something underneath the surface
5 that's making them push this drug on my patient. Now,
6 what happens, as I understand it now, is an
7 interesting double whammy on a doctor.
8 I have my choice. When a
9 pharmacist calls me up and says, listen, this isn't
10 in the patient's formulary. If you change it to drug
11 "Y," then he gets a break. I can either be a real
12 schmuck and make my patient pay more money. Or, I
13 can accede to the switch, and be held liable if there
14 is a side effect. I don't like that combination. And
15 I really want to know what's making the pharmacist
16 ask for this change. I believe, if I look back far
17 enough in these proceedings, that will be one of our
18 original worries whether what the PBMs are doing is
19 culpable by having, basically, a kickback problem.
20 And, I would rather you look there and look into
21 looking whether or not this really is a cheaper
22 alternative for a drug, that there are two of them
23 out on the market.
24 DR. BLANCHARD: Mr. Chairman?
25 CHAIRMAN TEEFEY: Dr. Blanchard.

Page 51

1 DR. BLANCHARD: Is it appropriate
2 to slightly change the subject and start talking
3 about policy recommendations? I understand what
4 we're talking about here. It's another one of many
5 issues that we have talked about for the last several
6 months on which people of good will can have
7 significantly different opinions, you know, about
8 which we may not reach any sort of consensus in this
9 body, and I think the opinions expressed at both ends
10 here have been heard.
11 CHAIRMAN TEEFEY: I think--
12 DR. BLANCHARD: We shouldn't beat
13 that one into the ground any more.
14 CHAIRMAN TEEFEY: I agree with
15 you. We asked the Task Force, and we asked the public
16 to send in options after the last meeting, and we
17 have got some options to work with. And Mike
18 Worthington, do you want to go over and start with
19 the options, and then Michael Pyles will finish up?
20 MR. WORTHINGTON: Mr. Chairman,
21 Members of the Task Force, good morning.
22 I will briefly review --
23 CHAIRMAN TEEFEY: Now, before Mike
24 gets started, we still have one option on the floor,
25 and one option on the floor is still Senator Newman's

Page 52

1 option. And I want to make sure that we understand
2 that we still have Senator Newman's option on the
3 floor.
4 MR. WORTHINGTON: You should have
5 in front of you three pages, the first of which looks
6 like this: "Propositions To Be Considered By The
7 Special Task Force."
8 SENATOR NEWMAN: Do you have more
9 copies of this?
10 MR. WORTHINGTON: Do you have any
11 we can share with them?
12 DR. PYLES: I don't know if we
13 have any more.
14 CHAIRMAN TEEFEY: I have an extra.
15 MR. AYOTTE: Mike, this is what
16 you guys have put together?
17 MR. WORTHINGTON: It's what was
18 sent to us.
19 CHAIRMAN TEEFEY: That was sent to
20 us.
21 MR. AYOTTE: Can you identify it
22 for us, please?
23 MR. WORTHINGTON: For each one?
24 MR. AYOTTE: Yes.
25 MR. WORTHINGTON: Sure, as I go

Page 53

1 through it. Does everyone have a copy? That's it.
2 That's correct.
3 SENATOR NEWMAN: Mr. Chairman?
4 CHAIRMAN TEEFEY: Yes, sir.
5 SENATOR NEWMAN: Before we get
6 going, I do think we all need this in our hands.
7 But, if anybody in the audience needs this, could we
8 also have some available to interested people out
9 there? There are copy machines all over this
10 building that can run out as many as is necessary.
11 Can we have that?
12 CHAIRMAN TEEFEY: Here is an extra
13 one.
14 MR. WORTHINGTON: Would you like
15 to take a break and allow for that? Five minutes or
16 so?
17 CHAIRMAN TEEFEY: We'll be with
18 you in a minute.
19 MR. WORTHINGTON: Okay.
20 Are we ready? Yes, ma'am?
21 MS. POWELL: Could we ask Senator
22 Newman to review the option that he has on the floor
23 for us?
24 CHAIRMAN TEEFEY: Yes. Senator
25 Newman, can you remember it?

Page 54

1 SENATOR NEWMAN: Well, nobody
2 likes my option. But, my option is this: There is
3 an ongoing study out there to study the effects of
4 the core issue that we are talking about here, and
5 that is the Morgan Study looking at PBMs.
6 As I have reviewed the
7 information that's come in, we have a lot of
8 expertise here. I think I've gained new friends
9 here. But, a core issue is yet to be decided by that
10 group.
11 I believe that it may be of some
12 assistance to this committee to consider the option
13 of continuing this study, which would be a huge
14 change no matter what we recommended and the General
15 Assembly would have to approve almost all of the
16 changes we have come up with, until a full amount of
17 information can be provided by the other group that
18 studied it. The other side of it is that we simply
19 have gotten very little information. True empirical
20 data that we need has been told to us by staff is
21 simply not available and not out there.
22 I don't think that we can go into
23 the General Assembly very well and say we really
24 think that what you ought to do is this, but our
25 basis is that we don't have much basis. I think

Page 55

1 that's tough to recommend to the General Assembly.
2 So, my option is, if we can't come up with something
3 that is strongly supported by the data, then we
4 consider rolling this study over until next year, and
5 we can get a better holistic approach to be given to
6 the General Assembly.
7 It's not a motion yet, Mr.
8 Chairman, because I think we need to hear all of the
9 options that are in front of us.
10 MR. WORTHINGTON: Senator Newman
11 refers to the Harvey Morgan Study. It's technically
12 HJR 574. The School of pharmacy at the Medical
13 College of Virginia will be doing that study for the
14 Department, and it is due to us about this time next
15 year. That's the technical name for it.
16 I will briefly, very briefly,
17 simply review the six propositions, if you will, that
18 you have in front of you, and then I will turn it
19 over to Dr. Pyles who has three or four more that
20 have been submitted. You'll notice that the six that
21 are in front of you are pretty much dichotomized into
22 those that require legislative action and those that
23 require regulatory action by, I believe it's three
24 different State agencies.
25 Proposition Number 1, submitted

Page 56

1 by Mr. Ken McArthur.
2 MS. WARRINER: Mike, can I just
3 have point of clarification on these?
4 MR. WORTHINGTON: Yes.
5 MS. WARRINER: Those that were
6 submitted by Ken McArthur were also endorsed by the
7 Virginia Pharmacists Association.
8 MR. WORTHINGTON: Okay.
9 MS. WARRINER: I just didn't want
10 Ken, Ken, Ken, Ken, Ken.
11 MR. WORTHINGTON: Thank you.
12 MR. COUNCIL: I'm sorry to
13 interrupt, but what's the source of these
14 propositions?
15 MR. WORTHINGTON: I will do that
16 as I go through each one.
17 Okay, the first one?
18 MS. WARRINER: Yes.
19 MR. WORTHINGTON: All six, Cindy,
20 is that correct?
21 MS. WARRINER: Yes.
22 MR. WORTHINGTON: Well, they're
23 six submitted by Mr. McArthur and all endorsed by the
24 Virginia Pharmacy Association. I'll get that out of
25 the way right now.

Page 57

1 Proposition 1, "Outlaw
2 Therapeutic Interchange Based Upon Monetary
3 Incentives," e.g., Virginia Anti-Drug Switching
4 Patient Protection Act of 1997.
5 A regulatory proposition that
6 would involve the SCC Bureau of Insurance is
7 Proposition Number 2. "Prohibit Interchange To
8 Chemically Dissimilar Drugs For The Sole Reason"
9 appears to be due to formulary changes by the
10 patient's insurance plan or the patient changing from
11 one plan to another, either voluntary or
12 involuntary.
13 Number 3 would require
14 legislative action by the Assembly, and that would
15 require that all persons involved in any active
16 therapeutic interchange involving citizens of the
17 Commonwealth have a direct, personal relationship
18 with a patient and be licensed in the Commonwealth,
19 as required by law, to prescribe or dispense drugs.
20 To be unlawful to switch patients
21 to another drug under provisions of therapeutic
22 interchange without the patient's written approval
23 acknowledging full disclosure the reasons for the
24 switch.
25 Proposition 4, "A Legislative

Page 58

1 Proposition." All businesses in the Commonwealth
2 that develop and/or implement prescription benefits
3 plans and programs or that engage in therapeutic
4 interchange of chemically dissimilar drugs shall be
5 liable for any adverse health outcomes. This
6 liability shall extend to any and all entities
7 associated with the plan or program, including, but
8 not limited to, P and T committees, having oversight
9 for the company's formularies, and decisions related
10 to the therapeutic interchange of chemically
11 dissimilar drugs. Practitioners that are not
12 directly involved in the daily operations of the
13 company's business, but to transact business on the
14 part of their patients through contractual and other
15 means shall be held harmless.
16 Proposition 5, "Regulatory Action
17 by the Health Regulatory Board." Require all
18 persons/entities engaged in the development of
19 formularies or the implementation of prescription
20 plans and programs to be licensed by and registered
21 with the appropriate regulatory authority.
22 In particular, health
23 professional and practitioners that do business in
24 the Commonwealth on a regular basis, but who are not
25 residents of Virginia, shall be required to acquire a

Page 59

1 license to practice in Virginia or, in the case of a
2 business whose home office or parent company is not
3 located in the Commonwealth, required to be
4 registered with the appropriate board or agency to
5 conduct business in Virginia and required to document
6 all instances of interchange of chemically dissimilar
7 drugs.
8 The final, Number 6, "Regulatory
9 Action by the Virginia Formulary Board." It's
10 required that all prescription benefit plans and
11 programs operating in the Commonwealth be preapproved
12 or credited by the Formulary Board. Any
13 person/entity wishing to engage in the practice of
14 interchange must submit to the Board data necessary
15 to prove that each proposed act of interchange will
16 not place the patient at risk for an adverse health
17 outcome as a result of the interchange.
18 Dr. Pyles will now review with
19 you the three or four that he has.
20 DR. PYLES: Mr. Chairman and
21 Members of the Task Force, we received from Matt
22 Jenkins of Hunton & Williams some policy options to
23 be considered by the Task Force, and I shall go
24 through them, and we will have copies for everyone
25 just momentarily.

Page 60

1 CHAIRMAN TEEFEY: Yes.
2 MR. JENKINS: Yes, Mr. Chairman,
3 may I make a point of clarification? Those are not
4 offer as policy options of Matt Jenkins. There is a
5 list attached to the options that were offered up of
6 the entities that are in agreement with those as
7 options, and I would appreciate those being
8 identified.
9 DR. PYLES: I will read them--
10 MR. JENKINS: Thank you.
11 DR. PYLES: --at this time. These
12 four points that are made are endorsed by the
13 following entities: CVS, First Health Services
14 Corporation, Kaiser-Permanente, Merck & Company,
15 Merck-Medco Managed Care, NYL Care, PCS Health
16 Systems, Rite Aid Corporation, Trigon Blue Cross/Blue
17 Shield, Virginia Association of Health Maintenance
18 Organizations, Virginia Hospital and Health Care
19 Association, and the Academy of Managed Care
20 Pharmacists are the entities that have endorsed the
21 statements that I'm about to review with the Task
22 Force.
23 Their first statement refers to
24 the definition of the practice that this Task Force
25 developed in its earlier meetings, and they give what

Page 61

1 that definition is. And, since everyone in the
2 audience does not have one, I will read it at this
3 time, until they can get one.
4 The definition of the practice is
5 defined by the Task Force. "Therapeutic interchange
6 is the dispensing of a drug by any person authorized
7 by law to dispense drugs that is a chemically
8 dissimilar alternative for the drug initially
9 prescribed. The alternative drug is expected to have
10 the same clinical results and similar safety profile
11 when administered to patients at therapeutically
12 equivalent doses as the drug initially prescribed,
13 and is dispensed with the approval of the person who
14 prescribed the initial drug or their lawful
15 designee."
16 These entities make the statement
17 that this term is not intended to refer to dispensing
18 practices in licensed or State-operated hospitals
19 with respect to hospital inpatients. But, I would
20 like to add that in our discussions, however, that
21 was not stated. In fact, when we developed the
22 definition, I mean, it was stated that it could apply
23 in all settings, but, that, in the hospital or other
24 inpatient institutional settings, there was the more
25 formally-approved mechanism by which the switch could

Page 62

1 be made. And we were dealing, with the Task Force,
2 primarily, with this issue in the ambulatory patient
3 care setting. But, their statement is there.
4 The second of these is the
5 regulations of the practice, and they have reference
6 to the Code of Virginia, Chapter 54.1-34.10, and also
7 another Section 18 VAC-110-20-390. And this one
8 requires a regulatory kind of change, a
9 recommendation for some regulatory action, and they
10 state here that, "To the extent that the Board of
11 Pharmacy believes that no present law or regulation
12 adequately protects such interests," then the Board
13 of Pharmacy proceeding, in accordance with the
14 Virginia Administrative Process Act, should consider
15 promulgation of an appropriate amendment to existing
16 regulations. So this, indeed, would be a regulatory
17 change regarding the practice of therapeutic
18 interchange.
19 Number 3, "Out-of-State
20 Dispensing." They note here that there is already a
21 Subsection (a) 54.1-3434.4, and they here recommend
22 or suggest that legislative action be undertaken,
23 which would add a Subsection (b) to that section,
24 reading, "It is unlawful for any nonresident pharmacy
25 to dispense a drug that is chemically dissimilar from

Page 63

1 the drug initially prescribed without the approval of
2 the prescriber or his lawful designee." And that
3 would require legislative action.
4 And, then, finally, the fourth
5 point in their statements here, basically, I believe
6 is an endorsement of an option that we believe is on
7 the floor, and that is the continuation, Mr.
8 Chairman, of the Task Force. The Task Force
9 remembers that a resolution be adopted in the 1998
10 Session of the General Assembly to continue this Task
11 Force to coordinate with and provide input into the
12 Department of Medical Assistance Services, as
13 provided in House Joint Resolution 574, which is also
14 the Morgan Bill.
15 So, those are the remaining
16 options or suggestions that we have received, Mr.
17 Chairman, in addition to the ones we've gone over.
18 CHAIRMAN TEEFEY: All right. We
19 have the options that we requested last time. Let's
20 start off with option number one that Mike gave us,
21 and it's open for discussion.
22 DR. BLANCHARD: Mr. Chairman, if
23 what we are going to try to decide today is what sort
24 of report to bring forth from this Committee, I
25 wonder if it would be acceptable to have

Page 64

1 recommendations from anyone on the Task Force in
2 terms of tying some of these together in ways that
3 aren't exactly like the propositions here. We can
4 certainly go through every one of them and beat them
5 into the ground and then ask for our recommendations,
6 or we can do it in reverse order. It's at your
7 pleasure.
8 CHAIRMAN TEEFEY: No. I--
9 DR. BLANCHARD: But I feel like we
10 can spend a lot of time on every one of these
11 potentially flawed propositions and not necessarily
12 get the gist, if there is anybody here working, try
13 to get a consensus on them.
14 CHAIRMAN TEEFEY: I agree with
15 you, Doctor. Would you like to open up?
16 DR. BLANCHARD: Yes, with your
17 indulgence. The way I tried to express things last
18 time is that we ought to try to get these proposals
19 and that we ought to sit down and read them over the
20 last few weeks, and try to figure out which of them
21 makes some sort of sense and what ultimately that we
22 should propose to each other that we could come to in
23 the way of a consensus and a Task Force report.
24 I have to admit there have been
25 times that it is not clear to me that there was

Page 65

1 anything much that we could come to with consensus,
2 and acknowledging the copious quantities of material
3 that we've been presented with, that it still seems
4 be very confusing. Nevertheless, the more I have
5 thought about it over the last few days, I think
6 there really are some things that we can potentially
7 reach consensus on and support recommending to the
8 General Assembly when we give our report.
9 I'm going to hand out four
10 recommendations, and I have to admit that since I
11 didn't get Mr. Jenkins' proposals until late last
12 night, that there are a couple of those that I may
13 amend into this. I am actually going to make my
14 remarks sort of in the form of a draft Task Force
15 report, so that not only do you get an idea of what
16 the recommendations might be, but you need to kind of
17 have some handle on what it's going to sound like
18 when we actually make this presentation, because my
19 assumption is, you need to have some sort of
20 justification for the recommendations.
21 CHAIRMAN TEEFEY: Can we make
22 copies of that while you're--
23 DR. BLANCHARD: Yes. I actually
24 have the recommendations here. Save one for me.
25 In order to come to these

Page 66

1 conclusions, though, I think I had to assume that we
2 would agree on three or four points. In addition to
3 the ones that Senator Newman and I have been
4 discussing over here that we need to, preserving the
5 ethics of all practices involved here, that we tend
6 to want to involve ourselves--rely more heavily on
7 the free market system and less on legislative
8 solutions. I have to admit I'm very pessimistic
9 about the ability of a Task Force such as this,
10 either today or one year from today, being able to
11 micromanage this practice of therapeutic substitution
12 or therapeutic interchange.
13 I would hope that the basic
14 tenets, though, are that we would have to admit that,
15 although we have, as representatives of the
16 Commonwealth, a lot of disparate interests to protect
17 here, when push comes to shove, the final, absolute
18 responsibility we have is to our patients. But, we
19 need to acknowledge that there are other interests at
20 work.
21 Second, we need to admit that
22 when everyone switches drugs or starts a new course
23 of medication with a different medication or a new
24 medicine, there is some risk. It may be very small.
25 It may be very significant. But there is some risk.

Page 67

1 But, on the other hand, we've
2 heard testimony to the effect that there are
3 potentially many positive things that can happen with
4 the type of switches that can occur in a well-managed
5 formulary system, and those could include increased
6 quality, decreased side effects and, hopefully,
7 decreased costs.
8 I actually have read a huge
9 portion of the data presented to me, and I agree that
10 we're not going to be able to agree that those
11 studies show us the answer one way or the other, and
12 I am adamantly of the opinion that the Harvey Morgan
13 Study will shed some light on this, but it is not
14 likely to tell us everything we need to know to
15 either bless or condemn a practice in general. And I
16 think we need to get on with the realization that
17 there will be no magic study forthcoming, and that
18 we're being asked to proceed with honesty and
19 openness and a concern for the Commonwealth to come
20 out with some sort of a report.
21 I think we do have a few things
22 that we've reached a consensus on and would like to
23 be able to say the Task Force reached consensus on.
24 One was definition of therapeutic interchange, and
25 the other, as I've read through both sides'

Page 68

1 documents, I don't find any contention necessarily
2 with the managed care contention. I'm going to quote
3 from several of the documents, "A well-developed and
4 well-managed formulary may enhance quality of patient
5 care by encouraging physicians to prescribe
6 medications that are safe, effective, and likely to
7 produce the best possible outcomes. Such a formulary
8 may help patients and physicians to have access to
9 the best and most effective drugs on the market."
10 I would like to hope that we
11 could conclude that. Nevertheless, it seems to me
12 that the public seems worried about the process. Its
13 concern that it may affect patient outcomes; it may
14 increase patient inconvenience; it may undermine the
15 professional trust placed in doctors and pharmacists,
16 and I think we have debated at length the relative
17 values of those worries, and we may not agree on the
18 level that we should attach importance to those.
19 But, I think we need to make some sort of statement
20 about the practices in general without
21 micromanagement.
22 So, my recommendations are as
23 follows, and you should have them in front of
24 you: "Recommendation 1: Regulations should be adopted
25 by the Board of Pharmacy to make it unethical and

Page 69

1 inconsistent with the accepted practice of pharmacy
2 for a pharmacist to contact a physician to encourage
3 a therapeutic interchange." That's the purpose for
4 the contact. Unless the initially-prescribed drug is
5 not on the patient's formulary or there is a patient
6 safety issue involved, going on to say, "Supporting
7 legislation should be introduced, if necessary. The
8 regulations or legislation should also capture
9 out-of-state pharmacies, to the extent possible."
10 And, "Additionally, the regulations should apply to
11 chain pharmacies whose policies attempt to direct
12 their employee pharmacists to make unethical contacts
13 with physicians."
14 I should apologize from the very
15 beginning. This is written without the benefit of a
16 lawyer or legislative services. The purpose here is
17 to try to prohibit the types of kickbacks or
18 significant financial inducements for a pharmacist to
19 contact a physician.
20 It is, as we discussed last time
21 in testimony, it is unethical, in many cases illegal,
22 for a physician to accept significant monetary
23 inducements in order to prescribe one company's drug
24 over another, and I think the public very strongly is
25 in favor of that and would not want it any other

Page 70

1 way. It seems inconsistent with me that if there is
2 a soul left in the practice of pharmacy, that the
3 pharmacist would want to protect this ethical
4 relationship.
5 In all the discussions we've had,
6 the only person, other than the physician, who has an
7 "ethical relationship" with their patient as opposed
8 to a business relationship, is the pharmacist that
9 has been protected through a lengthy history from the
10 Board of Pharmacy. It seems to me that the Task Force
11 would want to find it, though, a preferable approach
12 compared to the bill last year that tried to define
13 what unacceptable behavior was and got into trouble,
14 quite frankly, because it is next to impossible to go
15 down the list and try to determine everything that
16 might be conceivably deemed to be objectionable. It
17 might be simpler for the Board of Pharmacy to handle
18 this instead of us, and for the Board of Pharmacy to
19 try to determine and define exactly what are
20 acceptable methods of contact.
21 Nothing in here would prohibit
22 anyone from contacting, for the purposes of generic
23 substitution. It would not place limitations on the
24 free speech of any of the pharmaceutical companies,
25 PBMs, HMOs or patients to contact me as a physician

Page 71

1 for any of these reasons.
2 I would know where those calls
3 are coming from, and would be expected to handle them
4 ethically and appropriately. The patient certainly
5 can contact me both for medical reasons and cost
6 reasons.
7 "Recommendation 2, the General
8 Assembly should request the Virginia Department of
9 Health... to include pharmacy issues, (including
10 therapeutic interchange issues.) in its proposed
11 areas of quality and access assessment of managed
12 care organizations under the directives of," I
13 believe it's called "HB 2785 from last year. Such a
14 standing body must possess the requisite power to
15 certify and decertify the health care delivering
16 systems overseen by it." As you may know, that
17 particular Bill authorized the Department of Health,
18 in conjunction with the Insurance Commission, to
19 begin a process whereby a standing regulatory body
20 would exist where appeals could be made and issues
21 like this could be resolved in a manner that both
22 protects patients and is consistent with allowing the
23 industry the flexibility to continue to change as the
24 marketplace changes and as scientific evidence
25 changes.

Page 72

1 In particular, we have heard
2 testimony on this subject. In the materials that were
3 provided in several situations, but, in particular,
4 in April, 1997, report from the United States Office
5 of the Inspector General, revealed to me a surprising
6 lack of oversight over PBMs, much more oversight over
7 the HMOs than there are over the PBMs. They clearly
8 say that the pharmacy benefit management companies
9 have emerged as significant players, and I did not
10 hear anybody refute their findings that, among other
11 things, the HMOs' biggest concern about PBMs is their
12 result in potential bias from their alliances with
13 pharmaceutical manufacturers.
14 The Inspector General this year
15 said that HMOs rely primarily on PBM supplied data
16 and reports for overseeing PBMs and HCFA and State
17 Medicaid agencies provide minimal oversight over
18 these services. They have gone on and recommended
19 for both Medicaid and HCFA that policies be adopted
20 Federally and Statewide to provide oversight over the
21 PBM portion of the health care they deliver and the
22 HMO contracts with respect to pharmacy benefits. It
23 seems consistent with that, that this Task Force
24 would find that there is a need for oversight but not
25 a need for statutory, point-by-point micromanagement

Page 73

1 recommendations coming out of this Task Force.
2 Such approach, to me, would
provide a reasonable level of citizen protection
4 again retaining the flexibility that might be lost
5 through some sort of legislative approach. Consistent
6 with the idea that we'd like to see the private
7 sector take on more of those problems and solve them
8 before we end up having to meet like this over and
9 over again, I've made Recommendation 3, which asks,
10 as an official request, I guess, from the Task Force,
11 that the Virginia Association of HMOs should consider
12 promptly adopting a strong and meaningful position
13 statement on the inappropriateness of unduly
14 encouraging therapeutic interchanges for patients
15 already on clinically effective drug therapies when
16 the patient is changed from one insurance company to
17 another or the formulary changes. And, as Dr. Hadley
18 was discussing before, we have heard testimony from
19 several high quality and financially successful HMOs
20 that allow such grandfathering and find such policies
21 to be both medically and economically supportable.
22 Not all of these plans, however,
23 have such a grandfathering clause in them, and those
24 that do not do not all make it convenient for either
25 the patient or the physician or realistic to expect

Page 74

1 grandfathering to be allowed. But, the Task Force
2 felt that the medical and public relations issues
3 involved here are fairly clear, and it would hope
4 that the Association could see this as the type of
5 issue about which it could get involved with
6 providing a private enterprise solution as is so
7 often recommended.
8 And, we would applaud the VAHMO
9 for its acceptance of this challenge to demonstrate
10 that it's newly-adopted national policy called
11 "Putting Patients First," is the meaningful type of
12 policy that the Task Force members assume that it is.
13 And the Task Force would encourage other parties to
14 take on more issues like this in a nonlegislative
15 arena.
16 And finally Recommendation 4,
17 which tries to tie all this together, suggests
18 that "Legislation should be introduced to attach
19 medical liability to those entities that provide
20 pharmacy benefits covering a list of drugs more
21 restrictive than the PDR. Now, PBMs operating outside
of Virginia would be appropriately captured by this
23 legislation." Now, obviously, any acting formularies
24 that we're talking about here provide benefits for
25 drugs, the drug list, less than PBM.

Page 75

1 The Task Force, though, is very
2 sympathetic. I've heard from all ends of the table
3 that the free market should be allowed to solve many
4 of these problems. Many Task Force members have
5 expressed the opinion that the free market will
6 ultimately come out with the right solution. People
7 won't buy their products if the solution is not of
8 the right quality. They won't buy them if they're not
9 of the right cost. But the Task Force should be of
10 the opinion, also, that to be valid, all of the major
11 forces that apply in normal checks and balances of
12 the free market system need to apply here.
13 Tort liability, as hard as this
14 is for a physician to say, tort liability in America
15 provides one of the essential checks and balances for
16 those persons making decisions in the marketplace.
17 Shielded from liability, people are likely to be
18 inappropriately cavalier in making decisions that
19 affect their fellow citizens. And no one would
20 suggest removing that liability from physicians.
21 Now the Physician's Desk
22 Reference, the PDR, represents a listing of virtually
23 every medicine available to physicians to treat human
24 diseases. It's a list. It's composed entirely of
25 those medicines carefully determined by the United

Page 76

1 States Food & Drug Administration to be both safe and
2 effective in the treatment of disease. Any formulary
3 system more restrictive than the PDR, would certainly
4 limit the options available to patients and
5 physicians. It's not necessarily bad, but it does,
6 you have to admit, it limits their options.
7 Now, multiple documents provided
8 to me and the Task Force indicate that no matter how
9 restrictive the formulary is, physicians will
10 acquiesce to the managed-care's directives and write
11 more than 95 percent of all prescriptions on the
12 formulary. One most conclude that the promulgation of
13 these restrictive formularies represents a de facto
14 practice of medicine and/or pharmacy that Ms. Russell
15 spoke about earlier.
16 If it does represent the de facto
17 practice of medicine, and you can conclude that these
18 promulgations by the PBMs, basically, affect and
19 determine the care of the drugs that a patient
20 receives, and, as such, it seems logical to the Task
21 Force that some appropriate amount of liability
22 should be incurred in making those decisions. Without
23 such legal exposure, the actions of the members and
24 members of the PBM committees could be
25 inappropriately cavalier with respect to the health

Page 77

1 of patients.
2 The Task Force, though, does
3 feel, should feel, that such liability exposure would
4 not burden inappropriately the managed-care firms
5 operating in Virginia for several reasons. You can't
6 argue with the fact that malpractice premiums would
7 add somewhat to the cost of doing business. That this
8 is a burden that is incurred by everybody who is
9 involved with the delivery of health care, everybody
10 else who is involved in the delivery of health care
11 in the State of Virginia. The Task Force felt it
12 unlikely that other health care providers would
13 successfully escape liability, simply by claiming
14 that it would add to the cost of health care.
15 The Task Force should acknowledge
16 that many of the decisions made in formularies are
17 actually based on safety issues and appropriate
18 issues regarding cost. And the Task Force does not
19 seek to impugn restrictive formularies. But, it's
20 important to remember that the HMO industry endorses
21 the statement that, and we quoted this earlier, a
22 well-designed and well-managed formulary enhances the
23 quality of patient care, et cetera. The Task Force
24 assumes that HMOs with their prodigious ability to
25 evaluate massive amounts of quality outcome data

Page 78

1 would be unlikely to create anything other than a
2 well-designed and a well-managed formulary. The
3 expected real liability exposure here resulting from
4 a quality formulary should be slight, predictable,
5 manageable and affordable.
6 Mr. Chairman, these
7 recommendations try to do several things. Maintain
8 the ethical relationship between pharmacists and
9 patients. They begin to provide reasonable oversight
10 and accountability to those systems orchestrating
11 health care in the Commonwealth. They try to engage
12 the managed-care industry in solving some of the
13 perceived problems outside of any legislative arena,
14 and they encourage the increased alliance in the free
15 market system as opposed to piecemeal legislative
16 solutions to health care debates.
17 I would suggest that the indented
18 portions of Mr. Jenkins' Recommendations Number 1 and
19 Number 3 would be very appropriate to attach to my
20 four recommendations. And, Mr. Chairman, I
21 respectfully submit these recommendations to the
22 committee as a formal recommendation.
23 CHAIRMAN TEEFEY: Are there any
24 discussion on the recommendations? That's a foolish
25 question.

Page 79

1 Senator Newman?
2 SENATOR NEWMAN: Well, I'll go
3 first. But, I think this amply represents one side
4 of the debate, quite honestly. I think this
5 represents what one side has been saying and that is
6 that the Bill that was introduced by Senator Hawkins,
7 basically, should, in some form, be adopted. But, we
8 go further than that, and we go into medical
9 liability, which I think has an interest. But, we
10 certainly haven't even discussed that point hardly at
11 all to come up with a recommendation that we move in
12 that direction. In my opinion, if we were to move
13 forward with this, we are moving forward with a much
14 more stringent request than that which came to us
15 from the General Assembly.
16 I think it's put forward in good
17 faith. I have become a friend of my seatmate over
18 the last few days and months, almost a year now, but
19 I think that it would be unfortunate if we were to
20 take the information that we have gotten thus far and
21 have this apply, as a result.
22 Let me give you an example. I am
23 deeply concerned that if you have an insurance change
24 in Number 1 -- Is it Number 1?
25 MS. PIGG: Number 3.

Page 80

1 SENATOR NEWMAN: Number 3. --if
2 you have the insurance change, you no longer could
3 have the opportunity, given what is going on in
4 Number 1, to call that doctor back and get the proper
5 coverage that's necessary. If we are going to have an
6 ability for a pharmacist at least to call the doctor,
7 make sure that they're having that option to call the
8 doctor and say, this medication is not going to be
9 covered, instead of leaving that patient out in the
10 dark, let us work on another, toward another goal or
11 another drug so that we can get a proper drug, this
12 will make that difficult.
13 And, the last point I will make
14 about this is there is some dismissal on the idea of
15 contracts. But, I think the General Assembly has
16 often struggled with the idea of having the best
17 practice of medicine versus the money that it will
18 require to do that.
19 We have, on a very limited basis,
20 said that the minimum drug standards that we're going
21 to impose or the minimum amount of insurance that
22 someone can provide has been raised very, very
23 carefully over the years. Every time we do that, the
24 fear always is, if we do that too much, the people
25 who are the poorest, the companies who are the

Page 81

1 poorest are going to drop off the bottom.
2 My concern is, if we go with the
3 approach that is presented here, I think it will
4 represent the largest change that the General
5 Assembly has ever requested and may very well have
6 the worst effect on the low incomes that are, and the
7 lower-end jobs that are right now teetering on
8 whether or not their insurance company, their
9 insurance is going to be continuing. So, I have,
10 specifically, a lot of other little concerns. But,
11 on a holistic basis, I think this is good argument
12 for considering continuation of the study.
13 CHAIRMAN TEEFEY: Mike, you have
14 some comments?
15 MR. AYOTTE: Yes. I have a
16 concern with Recommendation Number 1. As a
17 pharmacist, I think that, and with Dr. Dalton's
18 earlier conversation, the conversations between the
19 pharmacist and the doctor keep them in the loop.
20 When something occurs that, A, may save a patient
21 some money or may be beneficial to the patient is
22 completely taken out and "made in an unethical
23 contact," I think that the triangle of health care is
24 there. For eight, nine years now the pharmacist has
25 been one of the most respected professionals. I

Page 82

1 think you're making him, in the eyes of the world, a
2 criminal, a money grubber. I just think that if the
3 doctor has the ultimate control and can say yes or
4 no, and the pharmacist uses good decision-making
5 processes and doesn't just make that call, which I
6 don't think is happening, I really believe that we
7 can go with just the current Board of Pharmacy issues
8 that protect the patient and give the doctor that
9 control and make the pharmacist call the doctor, but
10 loop in those people that don't have current control
11 of the Board of Pharmacy.
12 I would think that the original
13 one that takes in out-of-state prescriptions would
14 help us more there because that seems to be the area
15 of the most concern.
16 CHAIRMAN TEEFEY: Any other
17 comments?
18 DR. HADLEY: Mr. Chairman. I
19 agree with Senator Newman. I think I would have a
20 very hard time supporting Recommendation Number 4,
21 the issue of medical liability to PBMs. I mean, we
2 haven't even discussed that issue, and I think it is
23 a complex one. And, to bring that up at the Eleventh
24 Hour seems to me to be inappropriate and it would be
25 difficult to support that.

Page 83

1 With regard to Recommendation 3,
2 again I would ask, and let me make two comments on
3 that. Is it really appropriate for this Task Force
4 to make recommendations to the General Assembly about
5 a private association? Now, having said that, this
6 issue is, in fact, being discussed. We had a
7 committee meeting just last week with the Medical
8 Directors and the Virginia HMO Association in which
9 this issue and all aspects of the therapeutic
10 substitution interchange was discussed. So, I think
11 that that issue is being appropriately dealt with.
12 We have presented a survey to show, in fact, that
13 those that have closed formularies have the
14 appropriate appeal mechanisms, and we think that this
15 issue will be appropriately handled there.
16 But, beyond that, I think the
17 other problem with making Recommendation Number 3,
18 again, as we've talked about in more than one
19 context, the managed formularies and, you know,
20 formulary benefits are not just coming from the HMOs.
21 We're probably in the minority of this, if you look
22 at the volume of drugs that are coming across on
23 that. Again, we talked about some of the
24 employer-specific plans. More and more -- I have
25 just got a survey that shows that the

Page 84

1 employer-specific plans are gradually increasing.
2 Many of the PBOs, what they call in certain indemnity
3 programs of which I have no idea how many millions of
4 people would be covered in the Commonwealth of
5 Virginia, many of them have managed formulary benefit
6 programs.
7 So, merely to single out the
8 Virginia HMO Association and say they're the only
9 ones that have to deal with this issue, what the
10 circumstances are under which you should allow, shall
11 we say, exceptions to the formulary and allow these
12 transition kinds of issues, just doesn't get at the
13 heart of the problem. Because, again, this problem,
14 this issue goes way beyond the Virginia HMO
15 Association. So, again, I think I'd have a very
16 difficult time supporting Recommendations 3 and 4 for
17 those reasons.
18 CHAIRMAN TEEFEY: Dr. Blanchard.
19 DR. BLANCHARD: My assumption was,
20 there would be more than two people taking pot shots
21 at this. But, if I can rebut them to some extent or
22 at least discuss them as they go along, it might
23 help. With respect to singling out the Virginia
24 Association HMO, I view this in a different light and
25 that is that there has been lots of lobbying, to me,

Page 85

1 that this whole process of therapeutic interchange on
2 people that are already on medications should be
3 legislated by this Committee, and I feel very
4 strongly that we should try to avoid that. And, I
5 would--I don't know about the appropriateness of how
6 you word a recommendation.
7 CHAIRMAN TEEFEY: Can we hold it
8 up for one second while she changes her paper.
9
10 NOTE: (Brief pause while the
11 Reporter adds paper to her machine.)
12
13 CHAIRMAN TEEFEY: Thank you, Dr.
14 Blanchard.
15 DR. BLANCHARD: Additionally, I'm
16 fully aware that the HMOs are not the only people
17 dealing with this issue, and I harbor no feeling, but
18 they're the worst offenders at all. The intent here
19 was to try to find a private sector association that
20 could set the standard of response to an issue that
21 is becoming increasingly prevalent in the public's
22 eye and see if they could come up with suggested
23 policies that they could try to get consensus among
24 their reputable members that might be used as an
25 example to follow by other deliverers of health care.

Page 86

1 Inasmuch as the HMOs could set
2 the standard of appropriateness for this, and
3 inasmuch as that could be found to be acceptable
4 whenever that policy is developed to people on the
5 other side, you have avoided legislation, and, you,
6 as a General Assembly, you have the ability to hold
7 over any other health care delivery systems of, you
8 know, at least the potential threat of legislation if
9 you don't get your act in gear and have a decent
10 policy. I see from my interactions with the VAHMO an
11 expressed sincere desire to be proactive on these
12 subjects and not to be waiting for things to blow up
13 in the public's perception, and waiting for people to
14 start bringing down to the legislature all sorts of
15 examples of patients that have been injured or
16 inconvenienced or hurt or whatever.
17 So I don't throw this out as a
18 tainted gauntlet. I would hope that you would see
19 this as an attempt to take some of these things out
20 of the legislative arena in good faith. I, with
21 respect to the stuff in Recommendation 1, I'm not a
22 pharmacist. I have my opinions on what ethics ought
23 to apply to pharmacists, and I also would like,
24 outside of this regulatory body, this legislative
25 body, to have the Board of Pharmacy decide how

Page 87

1 important ethics are and how to define that. This
2 whole issue of exactly what is an appropriate contact
3 and what is an appropriate reimbursement as opposed
4 to a kickback or whatever terms, we have a very
5 difficult time, depending on the needs to be dealt
6 with, which the pharmacist, first, if they don't do
7 it in a way that is appropriate and accepted by the
8 public, then there will be a degree of loss of trust,
9 public disgust and a demand for legislative
10 solutions.
11 By sending it to the Board of
12 Pharmacy as a recommendation, my assumption is they
13 do not have to adopt what we send them. There is
14 flexibility there, and it just expresses the opinion
15 that you need to come up with some way that allows
16 patients to communicate with doctors in the best
17 interest of their patients and that may include
18 costs, but in a way that the pharmacist and the
19 patient feels comfortable with and is not tainted by
20 inappropriate hidden financial agendas. And I don't
21 pretend to be able to define exactly what those
22 hidden ones are, but it seems not to be very
23 difficult for the public to decide what it is in my
24 case.
25 So, again, I'm trying to keep

Page 88

1 that from being legislated by us or defined by us. I
2 know that doesn't please the people who would like it
3 defined immediately.
4 MR. AYOTTE: And, if I may, Mr.
5 Chairman?
6 CHAIRMAN TEEFEY: Yes.
7 MR. AYOTTE: I agree. I think the
8 Board of Pharmacy has the ability to do that and can
9 set those standards. I just want to go back to the
10 point where, for the patients of Virginia that are
11 serviced out of pharmacies in Virginia, they have the
12 Board of Pharmacy that regulates the pharmacists of
13 Virginia and the doctor has the final say over any
14 therapeutic interchange in Virginia. You know what I
15 mean? There is that link. I think what we're
16 missing is what happens outside the borders of the
17 Commonwealth.
18 DR. BLANCHARD: And that's why I
19 suggested Number, whatever it is, 3 from Mr. Jenkins,
20 which tries to capture that as best as I have seen
21 that worded.
22 Now, with respect to
23 Recommendation 4, I think we have been talking around
24 the lines of, this is in the contract. We ought to be
25 able to use our responsible P and T committees to set

Page 89

1 these policies. We acknowledge that whether it's the
2 patient's choice or the doctor's choice, it
3 ultimately ends up determining the care that the
4 patient gets. But the following sentence is always,
5 but we don't really practice the medicine, the doctor
6 has the final say. It may be appropriate to change
7 Recommendation 4 to have the Legislature study the
8 appropriateness of any legislation regarding the
9 liability of it.
10 I have circulated an article in
11 Monday's Business Section of the Times-Dispatch by
12 Jane Bryant Quinn, I think, talking about the changes
13 across the Country with respect to managed care
14 occurring and some degree of liability. Threatening
15 somebody with liability is not the same as trying to
16 put people out of business. It's simply a question of
17 trying to keep people appropriately accountable. I
18 have also read in the past two weeks several legal
19 theses about the changing nature of the degree to
20 which this and the stuff determined by the Department
21 of Health, if they have a supervisory role, and its
22 relationship with ERISA plans.
23 There is a growing body of legal
24 case law that is beginning to apply general public
25 safety issues to what previously have been ERISA

Page 90

1 protected plans. I don't know which way that is
2 going to go, of course, in their own thing. But, to
3 simply say that we should not proceed in any path
4 because it is ludicrous because it won't cover
5 Medicaid, it won't cover Medicare and it won't cover
6 ERISA, fails to take into account that you've, at
7 least, set the stage appropriately for what we do
8 control and other forces will determine what other
9 programs are covered.
10 CHAIRMAN TEEFEY: But, I think we
11 still have to keep two things in mind. I think we
12 have got two pictures here. We have got one picture
13 that we're talking about switching drugs, therapeutic
14 drugs, because it's not on a formulary. And, if it
15 is on a formulary, we are talking about switching the
16 drugs. I think we're talking about two different
17 things. If it's not on the formulary and the
18 pharmacist calls back and that drug is not covered,
19 that's one thing. If it is on the formulary and the
20 pharmacist calls back and the drug is covered and he
21 wants it switched, that's another situation.
22 The problem is, I'm sure, and, in
23 the original Bill, if there was any type of financial
24 strings to that drug, I am sure, in every formulary,
25 that the HMOs, the PBMs deal with pharmaceutical

Page 91

1 companies and on their formularies they have drugs
2 that they get at a discount. Now, is that a kickback
3 or is that a discount?
4 The other thing is, if a drug is
5 on a formulary and the pharmacist tries to change
6 that drug because the pharmacist is getting a
7 kickback, that's another thing. But, the more I hear
8 in here, and I am talking from a layman's viewpoint,
9 now, I'm not talking as a pharmacist or a doctor, and
10 I think I'm probably the only layman up here, but I
11 have one lawyer up here. He's going to defend me. The
12 only thing I'm trying to say is, is the problem as
13 big as we think it is because are most of the
14 switches related, are most of the requests for
15 switches related, because the drug is not on the
16 formulary, and, therefore, they're trying to get a
17 drug for the patient that is on the formulary? I
18 think that's one case.
19 But, I think we've got to
20 separate those two things, because I have a feeling
21 that a small fraction of the switch requests are
22 requests that a person wants to switch a drug that's
23 already on the formulary. And, I think, when we look
24 into the final report, and I don't know, and I don't
25 think we're going to know that until after we get the

Page 92

1 study back that Senator Newman was talking about. I
2 think if we jump to conclusions and make
3 recommendations, I'm not sure that the
4 recommendations, when we get back to the General
5 Assembly and discuss this next year, if we do make a
6 recommendation, if it's going to hold any water, and
7 I think we will have wasted the whole time that we
8 have spent here by jumping to conclusions in making
9 recommendations.
10 I just, I keep hearing that and I
11 keep hearing the conflict, is it really switching
12 when it's not on the formulary and the person is
13 going to get nothing? And then when Jimmy said, it
14 shines a whole other light on this thing, that we
15 have businesses and we have businesses that have
16 their own formularies. They come up with their own
17 programs. And do we have any control over that
18 anyway? So I think we've got a bushel of a lot of
19 appeals here.
20 SENATOR NEWMAN: Mr. Chairman?
21 CHAIRMAN TEEFEY: Yes, Senator
22 Newman.
23 SENATOR NEWMAN: I'm sorry. I'm
24 wondering if, and this is somewhat of a proposal.
25 I'm glad to see at least we get proposals, even

Page 93

1 though I may disagree with the broad nature of this,
2 I'm wondering, Mr. Chairman, if we may hear from,
3 maybe in a five-minute form, the proponents and
4 opponents of this proposal that are out there. At
5 least, we get the benefit of their input on it, and
6 then we can discuss it. And let's vote and see what
7 we think about this so that we can move on.
8 CHAIRMAN TEEFEY: All right. We
9 have one person from each side. Do you want--
10 MS. PIGG: Can we take a break?
11 CHAIRMAN TEEFEY: Yes, can we take
12 a break and let me choose --
13 MR. COUNCIL: Could I ask Dr.
14 Blanchard one question, because I had to have heard
15 this wrong? I think you said, Dr. Blanchard,
16 something to the effect that the formulary de facto
17 became the prescription because of 90-some percent
18 acquiescence by the physician? I'm sure I didn't get
19 that right. What was the comment?
20 DR. BLANCHARD: That's pretty
21 close.
22 DR. PYLES: That's pretty close.
23 DR. BLANCHARD: The studies I have
24 seen show that whether formulary is minimally
25 restricted or tremendously restricted, doctors end up

Page 94

1 having their prescriptions okayed or originally
2 written 95 percent of the time on formulary. So,
3 whereas they may prefer to have some other drug,
4 because of the pressure of either the patient saying,
5 I don't have it covered or the pressure of HMOs
6 evaluating what percentage of the time you write on
7 formulary or off formulary, you end up writing,
8 according to the directive of the PBMs formulary
9 decision. And, in essence, that does determine the
10 drugs the patient ends up getting, because the doctor
11 is basically stuck in the position of picking from
12 the drugs from that company.
13 MR. COUNCIL: Isn't the corollary,
14 I mean, assuming the physician is doing his job,
15 isn't the corollary that in ten percent of the cases
16 it is very significant to the patient and those are
17 the ones where the doctor would not approve the
18 switch?
19 DR. MOFFATT: Five percent.
20 MR. COUNCIL: Five percent, okay.
21 DR. BLANCHARD: My only other
22 comment, Joe, from your comments was, that the
23 purpose of Recommendation 2 was to admit that we're
24 not going to solve the issue and somebody ought to be
25 able to look at it over time and determine whether

Page 95

1 these issues are very prevalent and as big as we're
2 making them out to be here, and it may not be.
3 CHAIRMAN TEEFEY: Yes. All right.
4 We're going to take a break.
5
6 NOTE: At this point, a recess was
7 had from 10:35 a.m. to 10:46 a.m., whereupon the
8 hearing proceeded, viz:
9
10 CHAIRMAN TEEFEY: All right. Let's
11 get started again, if we can. All right. We're going
12 to have Mr. McArthur and Mr. Jenkins respond to the
13 Doctor's proposals. And who wants to go first? Oh,
14 I'm sorry, Wyatt.
15 MR. JENKINS: I'll be happy to.
16 Thank you, Mr. Chairman and Members of the Task
17 Force. My name is Matt Jenkins, and I am retained by
18 Rite Aid. But, as many of you know, I have been
19 functioning somewhat as a coordinator for an ad hoc
20 coalition of persons and entities that are concerned,
21 and I want to be careful, as I make these remarks,
22 that I don't purport to speak for persons who haven't
23 authorized me to do so. But, in deference to the
24 Chair's wish that we try and do this one side to
25 another, I will ask the indulgence of those entities

Page 96

1 on whose behalf I have been communicating, and if
2 they disagree with what I say, they are free to
3 please note that.
4 I'm responding somewhat to Dr.
5 Blanchard's proposal on the fly, having only seen it
6 this morning. But, I have several concerns about the
7 appropriateness of these as recommendations to be
8 adopted by the Task Force, and I will tick them off
9 in numerical order.
10 I'll point out that the first
11 recommendation, if I read it right, would make it
12 unethical and inconsistent with accepted practice of
13 pharmacy for a pharmacist in Virginia to call a
14 physician and inform the physician that the drug he
15 has prescribed for the patient, cash-paying patient,
16 is much more expensive than a therapeutically
17 interchangeable alternative and would the physician
18 wish to know that, because the patient might
19 otherwise not elect to have the prescription filled.
20 And the Chair noted earlier that the one person about
21 whom we most wish to remain concerned is the right of
22 the individual.
23 It seems to me that this
24 recommendation, if adopted, is going to take away an
25 important element of communication that enables the

Page 97

1 customer, that patient, to make an informed decision
2 whether to acquire the drug or forego the drug
3 therapy, especially for those cash-paying patients
4 who aren't on a prescription benefit plan and for
5 whom the cost of the drug may determine whether they
6 take the drug. It seems to me that it ought not be a
7 crime, if you will, for a pharmacist to provide that
8 valuable information.
9 The second recommendation, it
10 seems to me that if the Virginia Department of Health
11 wants to look at pharmacy issues within the ambit of
12 their overall charge of looking at quality and access
13 issues, then that's fine. I'm not sure I agree with
14 the second sentence that indicates that that standing
15 body must possess the requisite power to certify or
16 decertify health care delivery systems. That seems to
17 be a rather extreme power, the right to put someone
18 out of business, and one that we would relegate to a
19 carefully structured and appropriately configured
20 body. Presently, it's my understanding that insurance
21 plans and HMOs that are regulated by the Bureau of
22 Insurance enjoy all sorts of procedural rights before
23 the State Corporation Commission, and I wouldn't want
24 to openly endorse a process of certification and
25 decertification in any sort of star chamber fashion.

Page 98

1 With respect to the third
2 recommendation, I think that Dr. Hadley's comments
3 and the comments of others have indicated that the
4 Virginia Association of HMOs is, as a body, on top of
5 this issue, and is, as a body, looking at best
6 practices within the industry, and, as a body, will
7 probably find that those who practice the best
8 practices are probably going to be the most
9 financially successful. And, I think, as in life, and
10 so is true in business, imitation is a sincere form
11 of flattery and it's also a way to fund profitable
12 behavior and emulate it. And, from what I understood
13 earlier, there are HMOs that are attacking this
14 problem, and they're finding it to their benefit and
15 the benefit of their members to deal with this.
16 With respect to the fourth
17 recommendation, I am astonished by this
18 recommendation in that what Mr. Council said earlier,
19 I think, rings very, very true. If we wish to see
20 entities running away from the provision of any type
21 of benefit, put them in the line of fire on
22 liability. If you wish to impose upon entities that
23 prescribe--that provide prescription drug benefit
24 plans, the liability for the way that plan works, the
25 employer is not going to provide that plan. They just

Page 99

1 won't. Why provide it? Why step into that line of
2 fire?
3 The PDR is a big and thick book.
4 The existence of formularies, particularly in
5 hospitals, particularly in well-established and
6 long-running HMOs, indicate that P and T committees
7 have determined that you don't need the entire PDR to
8 treat most decease states. There are always going to
9 be exceptions and a rational process should provide
10 for exceptions. But, if we are to indicate that you
11 have got to put a PDR on your prescription drug
12 benefit plan or you're going to be in the line of
13 fire for any alleged proximately caused adverse
14 outcome occasioned by the failure to dispense some
15 drug that was noncovered, those benefits are going to
16 vanish. I can't guarantee it. I can predict it as a
17 virtual certainty.
18 So, it seems to me that of the
19 recommendations that are out here, Number 1 is
20 antipatient and antichoice and anticonsumer.
21 Number 4 is antiVirginia business
22 and is going to lead to a diminution of prescription
23 drug benefits in the Commonwealth, if passed.
24 And, the second and the third are
25 not really recommendations that do much other than, I

Page 100

1 think, send a message that people ought to be
2 thinking about this in the private sector and, to my
3 knowledge, they are.
4 Thank you.
5 CHAIRMAN TEEFEY: Thank you, Mr.
6 Jenkins.
7 Mr. Durrette?
8 MR. DURRETTE: Thank you, Mr.
9 Chairman and Members of the Committee. My name is
10 Wyatt Durrette and, along with Ken McArthur, we
11 represent a group of independent pharmacies in
12 Virginia. I speak for them, and I think, in part,
13 for the Virginia Pharmacists Association. But, like
14 Mr. Jenkins, I am looking at these recommendations
15 for almost the first time. I was able to glance at
16 them last evening.
17 Ken McArthur has been covering
18 this hearing, as all of you know, and has spoken to
19 you on several occasions, and so I have talked with
20 him about this and want to make just a couple of
21 observations.
22 I am going to start inversely
23 from Mr. Jenkins and talk about the fourth
24 recommendation first, because ironically, I have been
25 spending most of my time over the last few weeks and

Page 101

1 will be for the next few weeks, representing a
2 Virginia business in a malpractice suit against a law
3 firm, and I am the trial attorney. So, the issue of
4 liability attached to making decisions that have
5 consequences for people's lives is one that needs to
6 be seriously considered, whether or not you adopt a
7 recommendation or a recommendation that it be
8 studied. Those who make decisions in the marketplace,
9 effectively de facto decisions, that have
10 consequences, need to be held accountable.
11 Now, they can be held accountable
12 by Government or they can be held accountable in the
13 private sector. But, part of being held accountable
14 in the private sector is being financially
15 responsible for those decisions if a Plaintiff can
16 prove, in a Court of law, that those decisions
17 proximally caused harm. Now, if it is correct that
18 physicians prescribe from the formulary in 95 plus
19 percent of the time, then the formulary becomes, de
20 facto, the controlling authority for the prescription
21 that's written. If the physician overrides it, nobody
22 has to worry about it. But, to the extent that that
23 has become the decision because the physician is
24 busy, the pharmacist is busy, the appeals process is
25 too protracted and too prolonged or for whatever

Page 102

1 reason, then, if there is harm to the consumer, to
2 the patient, why shouldn't the one who made the
3 decision be accountable? At least a recommendation
4 to look seriously at that ought to be made.
5 Now, Recommendation 1, to go back
6 to that, and to go to, first of all, to Matt's
7 comment regarding the cash-paying patient, I think
8 he's right. I think Recommendation 1, as written,
9 would affect a phone call that ought to be made and
10 would make that unethical. I don't think the Board of
11 Pharmacy would literally do that. So, I would suggest
12 that you look at Number 1 and that you either
13 consider broadening it or make its language more
14 general so that the Board of Pharmacy can look at the
15 practice of pharmacy from the standpoint of its
16 ethics and how appropriate conduct by pharmacists
17 would influence the communication between pharmacist
18 and physician.
19 Now, in that regard, let me say
20 that while we believe these proposals, to some
21 extent, move in the right direction, we believe they
22 have some shortcomings, and so we don't, I don't
23 necessarily bless them all enthusiastically. But I do
24 believe that this Task Force needs to come forward
25 with some kind of recommendations, if they can reach

Page 103

1 a consensus, on something. Remember, however, that
2 what motivated those of us who promoted this
3 legislation originally and accepted this Task Force
4 as a compromise was not because the individual
5 pharmacist in his or her store, whether it was a
6 chain store or a community pharmacy, was creating the
7 problem associated with therapeutic interchange or
8 drug switching. It was the corporate entities that
9 were driving the practice.
10 Whether they were PBMs, whether
11 they were HMOs, whether they were the new arrivals to
12 the drug-switching marketplace, chain drug stores, no
13 matter which corporate entity it was, it was those
14 corporate entities driven by the profit motive, which
15 all of us who believe in the free market endorse the
16 profit motive, but we know from a long series of
17 legislation from antitrust laws to preventing
18 drive-through mastectomies, we all know that
19 Government regulates the profit motive, to some
20 extent, when it's in the public interest to do so.
21 So, don't lose focus on the fact
22 that it's not the individual pharmacist standing
23 behind the counter that is driving this practice. It
24 is the corporate entities who stand to profit from
25 this practice that are driving it. And let that be

Page 104

1 part of your thought process.
2 Finally, with regard to the
3 Recommendation Number 2, I think that given the
4 changing nature of the marketplace, the moving target
5 that all of this has proven to be over time, the fact
6 that the marketplace, as we know it today, is not the
7 same marketplace that it was last year at this time,
8 and it won't be the same one next year at this time.
9 So, having the appropriate regulatory body look at
10 these practices with respect to governing them and
11 regulating them and licensing them seems to me to be
12 a step in the right direction.
13 With respect to the certification
14 and decertification, that's no different than
15 licenses that anybody has. If you're licensed by a
16 regulatory body, you're expected to conform with the
17 standards associated with your license, and, if you
18 don't, you lose it. And if you don't have that
19 enforcement mechanism, it's a toothless tiger. So, I
20 think Recommendation Number 2 is solid, and ought to
21 be passed.
22 Finally, Number 3, I would have
23 -- I would make it broader. I don't think there is
24 any -- The HMO Association probably is of less
25 concern to many of us than the pharmacy benefit

Page 105

1 management firms. They have an association. So I
2 would say for Number 3 that, perhaps, it needs to be
3 more generic, maybe naming no association in
4 particular, but encouraging all associations that
5 have for its, for their membership, companies who
6 engage in this practice to do what Recommendation
7 Number 3 anticipates or have the General Assembly
8 consider it.
9 So, Mr. Chairman, those are my
10 comments.
11 CHAIRMAN TEEFEY: Thank you, sir.
12 MR. COUNCIL: May I just ask Mr.
13 Durrette a couple of questions?
14 CHAIRMAN TEEFEY: Can I ask one
15 question on liability? And I know we have a lot of
16 lawyers in here. Let's say that I'm a company and I
17 set up a drug benefit for my employees, and I leave a
18 drug off of there. And what we're saying in here is,
19 if I leave that drug off, then I am liable? I could
20 be liable for leaving that drug off, because it's in
21 the PDR?
22 MR. DURRETTE: Well, the
23 question--
24 CHAIRMAN TEEFEY: Let me ask you--
25 MR. DURRETTE: Just one second,

Page 106

1 though.
2 CHAIRMAN TEEFEY: Yes.
3 MR. DURRETTE: The question, who
4 do you attach that liability to? I would not, when I
5 say I have mixed emotions about all this, I would not
6 attach it to the employer. I think all of us know
7 I think this is the real world. The real world is
8 that the employer contracts with the PBM or an HMO
9 and there may be formulary in existence at that
10 time. I don't think anybody for that employer knows
11 what drugs are on that formulary or off that
12 formulary. And that formulary is only going to last
13 for three months or six months until some
14 manufacturer gives that, whoever creates that
15 formulary a better deal, and then it's going to be a
16 different formulary than the manufacturer got at the
17 time of the contract, and he ain't going to have any
18 idea what the employer got at the time of the
19 contract. He doesn't have any idea what's on the
20 formulary. So, I would not extend the liability to
21 the employer, but to whoever makes the decision to
22 say you can have this drug, but you can't have that
23 one, unless you pay for it.
24 CHAIRMAN TEEFEY: All right. And
25 let me put one other picture out here. Suppose, I

Page 107

1 have an automobile and I have air bags on both sides
2 of my automobile. I have another automobile that has
3 air bags on one side and not on the other. If I have
4 an accident and the passenger in my car is killed, is
5 the manufacturer responsible? You're saying, no, the
6 manufacturer is not responsible. Well, I'd stop
7 selling that car if I was the auto dealer, because
8 what we are saying is, if I make a decision not to
9 have a drug on a plan, and I pass it off to the
10 person that's selling that product and handling that
11 product for me, then that person is liable for that
12 product. I think we've got to look at the air bags
13 on automobiles.
14 You know the person bought that
15 automobile, I don't think that the manufacturer is
16 responsible and I don't think the dealer is
17 responsible because that person bought that
18 automobile that only had an air bag on one side. I
19 think we're talking about the same thing here as
20 we're talking about automobiles, as we're talking
21 about drugs. And, Number 3 really worries me. And
22 that's why I want it, because I know Matt made an
23 inference to it.
24 MR. DURRETTE: Number 3?
25 CHAIRMAN TEEFEY: Number 4.

Page 108

1 MR. DURRETTE: Okay.
2 CHAIRMAN TEEFEY: The liability.
3 And, you know, I just wanted to bring that out about
4 the air bags, because I think we're talking about the
5 same thing.
6 MR. DURRETTE: Well, I don't, if
7 you want me to, I could talk for about ten minutes on
8 the difference between your hypothetical on the air
9 bags and the drug-switching program from the
10 standpoint of a lawyer, but I don't know that that's
11 profitable. They're not the same thing, and they
12 would not have the same liability consequences.
13 CHAIRMAN TEEFEY: It's both. It's
14 both health.
15 MS. WARRINER: Mr. Chairman, point
16 of question. I think you were, and maybe I'm wrong
17 and maybe Dr. Blanchard can clear it up, I don't
18 think it was talking about full liability, Joe. I
19 think they were talking about a shared liability.
20 Right now they hold no liability.
21 CHAIRMAN TEEFEY: No, I don't
22 think you're right, Cindy. I don't think you have
23 shared liability. I think the one that has--somebody
24 ends up with the full liability.
25 MR. DURRETTE: Well, in most

Page 109

1 instances it's shared. There is a concept called
2 joint and several liability and sometimes it applies
3 and sometimes it's doesn't. But, usually, anybody
4 that's-- It depends on all the facts and
5 circumstances of what you're talking about. But,
6 most of the time there is going to be more than, it
7 could be more than one person liable. And, in this
8 particular context, the pharmacist may have a
9 liability, individually, and his corporate employer
10 may have liability. The physician may have liability
11 and, under certain circumstances, depending on where
12 the Courts go, the corporate employer may have
13 liability. And the question is, should anyone else
14 have liability in this chain?
15 And, all Number 4 suggests is, is
16 that if the decision is initially driven by somebody
17 who chooses this drug on and this drug off, and, down
18 the chain, at the end, the patient suffers harm, why
19 should liability stop where the decision began in the
20 first place? Why shouldn't that decision-making
21 process be included in the liability chain?
22 CHAIRMAN TEEFEY: But you still go
23 back to my air bag. That's the same situation with my
24 air bag. I wear two hats. I have another hat that I
25 have 850,000 people uninsured, and we have been

Page 110

1 battling for years as to how to get 850,000 people
2 insured. I don't want to create a situation where
3 I'm going to have six million people uninsured. You
4 know, I have people right in this room that speak to
5 the people that are uninsured, that are speaking to
6 this with the possibility of putting more people on
7 the uninsured list, and hypocrisy is not real good.
8 You can't sit, you can't have it both ways, and
9 that's why I brought out the situation with the air
10 bags. I mean, I just don't want us to get into a
11 position where we force more people, where we force
12 companies to drop insurance or pharmacy benefits.
13 Because here are these same people that are fighting
14 for certain things in here always talking about
15 pharmacy benefits where there are not enough, they
16 need more, et cetera, and that's why I brought out my
17 air bag situation, because I think it is the same
18 thing we're talking about.
19 MR. COUNCIL: A couple comments,
20 if I may, Mr. Chairman.
21 CHAIRMAN TEEFEY: Yes, sir.
22 MR. COUNCIL: I know Mr. Durrette
23 said that he is just seeing this language, and he
24 would make modifications to it, also. But, that's
25 not what Recommendation 4 says as it's written. I

Page 111

1 mean, it clearly pulls in the plan sponsor. It would
2 make him liable. The sponsor is the one that's
3 providing the pharmacy benefits, and I reiterate what
4 I said earlier on this morning. I think any kind of
5 legislation like this can only reduce the number of
6 employers that are going to be willing to undertake
7 this liability and provide a benefit. I would,
8 secondly, say as to PBMs, for all that they're being
9 hammered about some of their practices here, the
10 general thought, as it was my impression, was that
11 PBMs, in fact, have done a lot of good in delivering
12 pharmacy benefits.
13 I cannot imagine that a PBM can
14 charge somebody six cents to process a claim and
15 undertake this kind of liability. I mean, it is going
16 to dramatically change the industry, and it's going
17 to have a negative long-term consumer impact.
18 MR. DURRETTE: Mr. Council, if
19 what you say is true, then there must be a horrible
20 risk to the public associated with drug switching,
21 because there would have to be a lot of injuries and
22 a lot of lawsuits and a lot of claims. So if you're
23 right that creating liability for the consequences of
24 drug switching would put PBMs out of business and
25 drive up the cost of health care and eliminate

Page 112

1 pharmacy benefit programs, then there are a lot of
2 injured people walking around out there because of
3 this practice who now don't have the right to sue.
4 MR. COUNCIL: Well, now you're
5 suggesting that intelligent companies don't look
6 around and try and waive risk before they're sued
7 themselves, and I don't think that's so.
8 MR. DURRETTE: I'm saying there
9 isn't the risk right now because there is no
10 liability for that practice.
11 MR. COUNCIL: Another comment I'd
12 just like to make, and this has been said a lot here.
13 I would agree that a plan sponsor may not know what
14 particular drugs are on or not on a formulary. But,
15 I think it's a real misperception to think that the
16 PBMs are undertaking these practices without the plan
17 sponsor's knowledge and consent. I'd just cite a
18 couple of examples. The last four State employee
19 plans that I have seen go out for request for
20 proposals, one of the first things in the cost
21 section they want to know is how much of the rebate
22 am I going to get? And what they're hoping you're
23 going to do is you're going to respond, we will give
24 you a hundred percent of the rebates. They are fully
25 aware of what's going on in this field. Medicaid,

Page 113

1 it's my understanding they get a hundred percent of
2 the rebates.
3 So, I can't tell you what's on my
4 plan's formulary in terms of one drug versus another.
5 But, the employers that are paying for those plans
6 have a good general idea about what's going on in
7 relation to formularies and rebates. In addition to
8 that, there have been recent cases interpreted in
9 Department of Labor Regulations that basically say,
10 the failure to disclose what rebates are received and
11 whether they're shared back with the plan sponsor can
12 have serious consequences. So, I can't give you
13 statistics. But I don't think it's accurate to
14 suggest that intelligent corporate employers who are
15 offering plans don't have a generally good
16 appreciation of what's going on in terms of the
17 administration of those pharmacy benefits.
18 MR. DURRETTE: I didn't intend to
19 say anything and, if I did, I misspoke, to suggest
20 that the employer would not generally know that there
21 was a formulary program and generally know that drugs
22 were on and off the formulary and that there were
23 price consequences associated with that. I think, of
24 course, they know that. I was only commenting on
25 whether they know the specific drugs that are on the

Page 114

1 formulary at any one time.
2 CHAIRMAN TEEFEY: Senator Newman?
3 SENATOR NEWMAN: That's fine. He
4 made the point.
5 MR. DURRETTE: Is that it?
6 CHAIRMAN TEEFEY: You know, I
7 lived through the original Bill, and I think we've
8 changed the original Bill now. From what I'm hearing
9 now, we are saying that you can't have formularies.
10 MS. PIGG: No.
11 MR. DURRETTE: Well, I don't think
12 I've said that. I didn't intend to say that.
13 CHAIRMAN TEEFEY: Well, either
14 what we're saying is if a drug is not on the
15 formulary, and you don't switch the drug, and you're
16 called in to switch the drug, and the doctor says,
17 no, you can't switch that drug and that formulary
18 doesn't--and that person doesn't fill that drug, then
19 I as the employer can be sued for that. I think we've
20 changed the whole road now. We were on 95; now we're
21 on 64.
2 MR. DURRETTE: Without air bags. I
23 guess, to some extent, we're speaking our personal
24 opinions here. Personally, I would not make the
25 employer incur liability for the reasons that I have

Page 115

1 stated. I don't think the employer is involved in
2 the decision as to which drug is available and which
3 drug isn't. So, to the extent that Proposal 4
4 extended to the employer, that would be one of the
5 things that I might disagree about. Because I don't
6 think the employer makes the decision. And, in order
7 to be accountable legally, I think you have to make
8 it, you have to consciously or carelessly do
9 something that causes harm to someone else. I don't
10 think the employer does that.
11 Now, Recommendation Number 1
12 contemplates a formulary, Joe.
13 CHAIRMAN TEEFEY: Before you go
14 there on that, let's say we take the employer out,
15 and we do leave the PBM in there, and they make a
16 decision that that's not on the formulary. Aren't
17 you still saying we're eliminating formularies?
18 MR. DURRETTE: No, I don't think
19 so. Recommendation Number 1 specifically allows and
20 approves, ethically, a contact by the pharmacist if
21 the drug is not on the formulary to generate the
22 change to a formulary drug. So, Recommendation Number
23 1 accepts formularies and accommodates them.
24 Recommendation Number 4 simply
25 recognizes, I think, whether you actually recommend

Page 116

1 it or whether you just recommend that it be studied,
2 it seems to me that it reflects the marketplace. The
3 marketplace already, in almost every instance that we
4 know of, doctors, pharmacists, automobile
5 manufacturers, automobile operators, chain drug
6 stores, everybody, if they do something carelessly or
7 negligently that injures another person, all of us
8 every day of our lives are accountable in the Courts
9 of America if we do that.
10 CHAIRMAN TEEFEY: Right. And I
11 understand that.
12 MR. DURRETTE: But what we have
13 here, in the present real world, are people who are
14 making those decisions that have those consequences
15 who do not share that accountability with others.
16 MR. COUNCIL: Does it make a
17 difference if really all they're saying is we will
18 not pay for it? Does that have any impact on your
19 position on that?
20 MR. DURRETTE: Uh-huh. That's all
21 they are saying.
22 DR. HADLEY: That's right.
23 MR. COUNCIL: That's right. And
24 yet they would still be liable.
25 DR. HADLEY: The PBMs or the HMOs

Page 117

1 do not make prescribing decisions; those are made by
2 the physicians. All these kinds of decisions are to
3 say this is the group of drugs that either are or
4 aren't covered. It's the physicians who make the
5 prescribing decisions.
6 MR. DURRETTE: But, we know--
7 CHAIRMAN TEEFEY: That's why I say
8 I think we've changed the game plan I thought we came
9 in here to talk about, and that's why I brought out a
10 little while ago, we're talking about two different
11 situations.
12 The first situation is, it's not
13 on the formulary, that's it. The other situation is,
14 it is on the formulary and the pharmacist calls in to
15 try to switch to a drug that's on the formulary. I
16 think we have a problem there.
17 MR. DURRETTE: And I agree with
18 you. I thought that that delineation was a good one,
19 and I agree with you that that situation is perhaps a
20 more serious situation than the formulary.
21 CHAIRMAN TEEFEY: Yes. And then I
22 go back to Senator Newman's recommendation that we
23 wait until the PBM study comes out, because I don't
24 know how many switches are one or how many switches
25 are the other. I think we don't know how many

Page 118

1 switches are because it's not on the formulary and
2 how many switches are on the formulary, and we have
3 got, and please take this with a grain of salt,
4 greedy pharmacists.
5 MR. AYOTTE: I don't take that
6 with a grain of salt.
7 MR. DURRETTE: Well, remember
8 again that Recommendation -- I think you have to look
9 at Dr. Blanchard's Recommendations in their
10 entirety. I would suggest, for heaven's sake, don't
11 get hung up on Recommendation 4. I mean, things with
12 regard to Recommendation 4 are going to come to the
13 General Assembly whether this Committee says or does
14 implement it or doesn't. There are other people who
15 have an interest in the area covered by
16 Recommendation Number 4, and you can bet your bottom
17 dollar that the Virginia General Assembly is going to
18 get legislation extending liability corporately to
19 HMOs and PBMs. That's coming. Everybody knows it's
20 coming. So, Number 4 is not the heart of this.
21 Number 1, Joe, contemplates the
22 existence of a formulary and says it's okay to make
23 the phone call. It's okay if the drug isn't on the
24 formulary. So, Number 1 tries to accommodate the real
25 world where formularies exist and where pharmacists

Page 119

1 are called upon to make those phone calls.
2 CHAIRMAN TEEFEY: Okay. I --
3 DR. BLANCHARD: Mr. Chairman?
4 CHAIRMAN TEEFEY: Yes.
5 DR. BLANCHARD: I'm a little
6 confused, having not sat in this position before,
7 about the process. But the spirit with which my
8 recommendations were given were the assumption this
9 was going to work in a situation where the Task Force
10 members will try to decide what, if any, parts of
11 recommendations are what they would like to
12 accomplish, can they be rewritten in a way that works
13 better, and in normal parliamentary procedure you may
14 extract proposals. You can extract single items out
15 of that. Perhaps, for purposes of discussion, we
16 might extract Number 4 and start getting some
17 feedback on the other proposals on what the Task
18 Force feeling is. Otherwise, we're never going to
19 get to vote on this up or down.
20 CHAIRMAN TEEFEY: All right. Well,
21 let's do this. Let's vote on the proposal to start
22 with.
23 SENATOR NEWMAN: The entire
24 proposal?
25 CHAIRMAN TEEFEY: The entire

Page 120

1 proposal to start with.
2 All of those in favor of the
3 proposal, say aye.
4 DR. BLANCHARD: Excuse me. We are
5 voting on the proposal without a chance to amend the
6 proposals in light of the comments?
7 CHAIRMAN TEEFEY: Well, then we're
8 going to bring the proposal up. We're going to bring
9 that up. You have presented a full proposal to us,
10 and I want to deal with the full proposal first.
11 All in favor of the full
12 proposal, say aye.
13
14 NOTE: (Affirmative response.)
15
16 CHAIRMAN TEEFEY: Raise your
17 hands, please. One, two, three, four.
18 All opposed. One, two, three,
19 four, five--
20 CHAIRMAN TEEFEY: The opposed have
21 it.
22 SENATOR NEWMAN: Mr. Chairman?
23 CHAIRMAN TEEFEY: Okay, Senator
24 Newman.
25 SENATOR NEWMAN: I don't want to

Page 121

1 limit the debate, and we'll go down whatever
2 processes this committee decides to do.
3 Wouldn't this have been a great
4 place to start in May, because now we're talking
5 about some things that have some relevance and some
6 proposals back and forth. I've looked at the
7 out-of-state dispensing idea, and maybe that's a good
8 idea, too. But, the discussion we just had on four,
9 we can have on one, two and three, and I may even
10 agree with part of them and disagree with other
11 parts, Mr. Chairman. But this is not in the last
12 meeting, at almost noon, on this last day, the type
13 of recommendations I think we want to give to the
14 General Assembly.
15 I believe that it might be of
16 some value to step back now and say, let us work in
17 conjunction with the Morgan Study. Let us come up
18 with some recommendations next year that we can have
19 confidence in, that we have thought through.
20 Mr. Chairman, on that basis, I'd
21 like to make a motion that we continue this study
22 until next year, ask the General Assembly to do so
23 with the current makeup of the study, and coordinate
24 our study with the Morgan Committee.
25 CHAIRMAN TEEFEY: Do I have a

Page 122

1 second for that motion?
2 MR. AYOTTE: Second.
3 CHAIRMAN TEEFEY: Is there any
4 discussion?
5 DR. DALTON: Yes, there is. I
6 think that we need to start somewhere, and I think
7 that the situation is a dynamic one. When the Morgan
8 data comes out, it's going to be dated. It's going to
9 be reflective of percentages and numbers as they are
10 right now. I think by our doing nothing, we're going
11 to influence those numbers because these practices
12 are going to change in the direction where abuses are
13 going to be increased, if there is that window of
14 opportunity that seems to be open to those who choose
15 to take advantage of it. I think we need to have
16 something concrete to come out, even if it's
17 something that is not completed. But, I think that
18 by our just saying, let's put it on the back burner,
19 again, is not what I have been contributing my time
20 for.
21 MR. COUNCIL: Mr. Chairman?
22 CHAIRMAN TEEFEY: Yes, sir.
23 MR. COUNCIL: If I may just make a
24 couple of comments in favor of the motion. When this
25 Task Force started, it struck me that I thought many

Page 123

1 people shared my view that, perhaps, the biggest
2 problem was out-of-state pharmacists switching drugs
3 without consulting with the physician. Now, we're at
4 the final hour here, and I haven't even seen that
5 issue addressed. If anything, Recommendation 1, while
6 it says that out-of-state pharmacists should be made
7 accountable to this regulation, would discourage them
8 from consulting the physician.
9 So, it seems to me we've gone
10 just about 360 from where I thought we were going to
11 address what everyone considered one of the major
12 deficiencies at the moment. So, I'm in favor of the
13 motion, if for no other reason, than to give us the
14 time to address the out-of-state pharmacy situation.
15 MS. PIGG: I just have a question
16 to make sure we still have a problem.
17 Mr. Durrette, I heard you say
18 that representing the independent pharmacists, that
19 they agree or endorse the whole formulary concept,
20 which has quality of care and financial
21 consequences. So, it was my understanding, and maybe
22 incorrectly so, that that was really the driver
23 behind the whole proposed legislation that the
24 pharmacist did not endorse the formulary concept if
25 there were financial components.

Page 124

1 MR. DURRETTE: If I said it the
2 way you just quoted me back, I didn't intend to say
3 that the pharmacists endorsed the whole formulary
4 concept. I did intend to say that these proposals
5 accepted the formulary in the marketplace and
6 approved it and allowed the pharmacist to make the
7 call if the drug wasn't on the formulary.
8 A formulary, the language that
9 Dr. Blanchard read when he was making his opening
10 remarks, about formulary having to be put together
11 with medical considerations to find the drugs that
12 will be most effective, that work best for the
13 patients and influence prescribing decisions along
14 that line, is my ideal of the way medicine should be
15 practiced.
16 But, to the extent that the
17 formulary deviates from that and substitutes the
18 profit motive of the decision maker, or the medical
19 considerations and the enforcement mechanisms which
20 are the switches to serve that motive, I don't think
21 it's the way to practice medicine or to deliver
22 health care.
23 CHAIRMAN TEEFEY: Any other
24 discussion?
25 DR. BLANCHARD: Yes, sir. My

Page 125

1 comments are in the nature of an amendment to the
2 motion. As I understand, the motion was to postpone
3 this until or to continue this Task Force and
4 reconvene when we have the results of the Morgan
5 Study.
6 In addition to that, then, I
7 would recommend that we adopt Mr. Jenkins' Proposal
8 Number 3 in my Recommendation Number 2. The
9 out-of-state dispensing issue is one that has come
10 before this committee and does suggest that there is
11 a practice going on in out-of-state pharmacies that
12 the Board of Pharmacy is unable to regulate and
13 requires legislative rectification, and it seems
14 reasonable to me that we do not want therapeutic
15 substitution, which is what this practice would be,
16 practiced by out-of-state pharmacists on patients in
17 Virginia.
18 In Recommendation 2, with or
19 without the last sentence, it's your preference,
20 would encourage the Department of Health in its
21 current evolving structure to begin considering
22 pharmacy issues. And, in doing so, they may actually
23 solve some problems that we might have before us this
24 time next year.
25 UNIDENTIFIED PANEL MEMBER: I

Page 126

1 second the amendment.
2 SENATOR NEWMAN: Mr. Chairman, I
3 have some parliamentary questions.
4 CHAIRMAN TEEFEY: Yes. We have to
5 vote on the first one first before we deal with the--
6 because we have a second to the-- Can we withdraw the
7 second and deal with the amended motion?
8 DR. BLANCHARD: Only if passage of
9 the one that says we will postpone the action of this
10 committee immediately doesn't end the meeting, by
11 itself. I feel a little under the gun if we have to
12 sneak something in here.
13 SENATOR NEWMAN: That's a
14 reasonable concern. And I say that we can vote on
15 the measure that's in front of the table, and let's
16 continue to have some discussion. Today was a good
17 day. We talked about some things and partly because
18 of what you brought to the table and what the other
19 side brought to the table, we talked about some
20 things that made a difference today. I don't agree
21 with all of them, and maybe we've broadened it too
22 far, but I think we can vote on the proposal that is
23 on the table and then continue to have a discussion,
24 because we're going to be here, I hope, long enough
25 to help invent some cures to this.

Page 127

1 I don't know if you want to vote.
2 DR. BLANCHARD: All right. In that
3 atmosphere, I withdraw my motion.
4 CHAIRMAN TEEFEY: Okay. Do I call
5 for the question? All in favor say aye?
6
7 NOTE: (Unanimous affirmative
8 response.)
9
10 CHAIRMAN TEEFEY: All opposed.
11
12 NOTE: (No response.)
13
14 CHAIRMAN TEEFEY: Okay. The ayes
15 have it. We will make a -- We will do up our paper to
16 the General Assembly. We will use the information
17 that we have talked about today as some guidelines.
18 We will deal with the study that the Pharmacy School
19 is doing with the PBMs, and I would like to work with
20 the Bureau of Insurance, also, I mean the Pharmacy
21 Board, also, in our deliberations of these things, if
22 we could work pretty closely together with you-all it
23 would really help us. And, we will carry it over to
24 next year.
25 DR. BLANCHARD: Mr. Chairman,

Page 128

1 obviously, in my discussions with my colleague over
2 here, misinterpreted both your ruling and his
3 interpretation, dramatically. His assumption or his
4 statement that we would continue to have discussions
5 on this implied today.
6 CHAIRMAN TEEFEY: Oh, okay.
7 DR. BLANCHARD: It also implied
8 that motions for acceptance of additional items by
9 the Task Force were not precluded.
10 CHAIRMAN TEEFEY: Okay.
11 DR. BLANCHARD: If for no other
12 reason than being on the public record that this
13 committee felt that way about some of these
14 proposals.
15 CHAIRMAN TEEFEY: Well, I told
16 you-all I wasn't a lawyer.
17 SENATOR NEWMAN: Mr. Chairman, in
18 fairness to the gentleman, I think that my motion did
19 include that as not only in the sense but also in
20 words, that we would continue, since today has been a
21 good day, to continue to discuss some of these items
22 within the Committee, and this may be the first
23 meeting of next year's continuing study, would not,
24 anyway, do harm to the motion that was voted on
25 unanimously.

Page 129

1 CHAIRMAN TEEFEY: That's fine. I
2 didn't understand that. But, --
3 MR. COUNCIL: Is the expectation
4 that we will periodically continue to meet? Is that
5 what we're saying or not?
6 DR. BLANCHARD: No. My expectation
7 is that we would vote on the motion that I proposed
8 in the midst of his motion, having been advised that
9 it was necessary to separate the two.
10 SENATOR NEWMAN: I'm confused,
11 now.
12 DR. BLANCHARD: I attempted to
13 make a motion that, included in our Task Force
14 Report, would be a recommendation that legislation be
15 adopted by the General Assembly that accomplishes
16 what Mr. Jenkins has so eloquently pointed out in 3
17 Number B on Page 2 of his letter: "It is unlawful for
18 any nonresident pharmacy to dispense a drug that is
19 chemically dissimilar, without the prior approval of
20 the prescriber or his lawful designee." I think this
21 is something that this Task Force agrees on.
22 SENATOR NEWMAN: Which one?
23 DR. BLANCHARD: 3.
24 CHAIRMAN TEEFEY: Number 3.
25 DR. HADLEY: 3-B.

Page 130

1 SENATOR NEWMAN: Mr. Chairman, may
2 I?
3 CHAIRMAN TEEFEY: Yes, sir.
4 SENATOR NEWMAN: I like the
5 proposal, too, and it's something that the Doctor and
6 I agree on, which is movement. I am still your
7 friend and all those good things. But, I don't know
8 if we do want a bifurcated statement going to the
9 General Assembly now. But, if there is a, if we
10 don't stop here, I think we're going to go down the
11 rest of the list, is that the-- Are we going to go
12 that far?
13 DR. BLANCHARD: Two. Two things.
14 Move on and discuss them.
15 SENATOR NEWMAN: Well, Mr.
16 Chairman, the will of the Committee. I don't mind
17 Number 3, but I don't want to go down the list of the
18 rest of them, either, because we have agreed that we
19 are going to look at this holistically. So, I guess
20 the will of the Committee, if they want to take up
21 these items.
22 I hope that we don't get into a
23 situation where we say we're going to roll it over,
24 and we're going to offer a bifurcated message to the
25 General Assembly, also.

Page 131

1 MR. AYOTTE: Mr. Chairman, can I
2 ask a question?
3 CHAIRMAN TEEFEY: Yes, sir.
4 MR. AYOTTE: Scotti, is it the
5 intent of the Board to look at this regulation for
6 out-of-state dispensing one way or another? Or, are
7 you looking for us to direct that?
8 MS. RUSSELL: Mike, this is not
9 a -- It's not a regulation. It's a statute. The
10 problem with the existing statute, not just this, is
11 that the existing statute requires nonresident
12 pharmacies to comply with the laws and regulations of
13 their residence state. And I think that maybe better
14 than this particular language might be the language,
15 at least for the nonresident pharmacy portion of the
16 draft we submitted last year, where what we do is
17 require nonresident pharmacies to comply with the
18 laws and regulations of Virginia, specifically. And
19 that would take care of this and anything else that
20 they happen to do that was a violation of Virginia
21 laws or regulations.
22 So I would go with the more
23 general approach than just this.
24 MR. AYOTTE: Would that be
25 something that you would look to find, no matter

Page 132

1 what? Or is this --
2 MS. RUSSELL: Well, we've already
3 submitted our administrative proposals for this
4 Bill. And we, the Board of Pharmacy, would not be
5 looking at this change for this particular
6 legislative session. It's a little late. But that
7 doesn't mean you couldn't recommend that.
8 CHAIRMAN TEEFEY: I think we're
9 going to have a motion.
10 DR. BLANCHARD: My motion is
11 dependent, though, on the answer to that question, to
12 some extent, and that is, if we make such a
13 recommendation to approve or to recommend a change
14 such as what was just recommended, would the
15 legislature be able to act on that this year or does
16 it still have to go through your process first? Are
17 you precluded from supporting it because you have
18 already sent in your other stuff?
19 MS. RUSSELL: No, we're not
20 precluded from supporting it. It just would not go
21 in as an Administration Bill.
22 SENATOR NEWMAN: Mr. Chairman?
23 CHAIRMAN TEEFEY: Yes.
24 SENATOR NEWMAN: Could we then
25 consider an amendment? I think you have agreed that

Page 133

1 we will only consider Number 3 of Mr. Jenkins'
2 document as saying, we want to continue this study
3 until next year, however, let us now-- We all agree.
4 I don't think there is any disagreement. We can
5 disagree on Number 2 of the other document. But,
6 there is no disagreement on Number 3 of this one.
7 However, we asked the General Assembly to deal with
8 these out-of-state issues as embedded in Number 3. Is
9 that reasonable?
10 CHAIRMAN TEEFEY: I think the Task
11 Force can ask that in our report, and it can come up
12 in General Assembly and support what they are doing
13 as the Board of Pharmacy.
14 DR. BLANCHARD: I'd second that
15 motion.
16 CHAIRMAN TEEFEY: Any discussion?
17
18 NOTE: (No response.)
19
20 CHAIRMAN TEEFEY: Call for the
21 question. All in favor--
22 DR. HADLEY: Just a
23 clarification.
24 CHAIRMAN TEEFEY: Yes.
25 DR. HADLEY: So, we'd only be

Page 134

1 voting for the Amendment 3-B of Mr. Jenkins', not
2 Recommendation 2? Is that correct?
3 DR. BLANCHARD: Not Recommendation
4 2.
5 My recommendation to 3-B is sort
6 of amended by Mr. Ayotte to include what Scotti
7 Russell suggested.
8 CHAIRMAN TEEFEY: Right.
9 DR. HADLEY: Okay. I think we can
10 support that.
11 CHAIRMAN TEEFEY: All right. All
12 in favor, say aye.
13
14 NOTE: (Unanimous affirmative
15 response.)
16
17 CHAIRMAN TEEFEY: All opposed?
18
19 NOTE: (No response.)
20
21 CHAIRMAN TEEFEY: Do we all know
22 where we are now?
23 DR. BLANCHARD: We all know where
24 we stand.
25 CHAIRMAN TEEFEY: Yes, sir?

Page 135

1 DR. PYLES: I just wanted to, as
2 the Facilitator, make sure that we understand. I
3 wanted to review real quickly what we'll be thinking
4 about as we carry this over.
5 One of the things that was
6 included in HJR 630 was that the Task Force would
7 identify the components of the cost of this
8 practice. So we need to be thinking about, as we
9 carry this over, how we're going to go about
10 identifying the components of cost and be able to
11 make recommendations on those. And the other part of
12 it was, to determine the impact of the practice on
13 the health care and the affected professions and the
14 overall cost of health products and services. So I
15 think that, as we go forward and think about it, we
16 need to be thinking about how we're going to do that,
17 because that was a part of the resolution, as well.
18 CHAIRMAN TEEFEY: I think that's a
19 good idea, Mike, and I think we're better prepared
20 going into next year than we were coming into this
21 year. It's a very, very complicated and convoluted
22 problem.
23 I want to thank everybody on the
24 Task Force. This has really been very, very
25 difficult. And, I want to thank everybody on the

Page 136

1 Task Force.
2 Scotti, I just want to thank you
3 and your staff for helping us out on this, and I want
4 to thank the people in the audience, because I think
5 now that we have really a beacon that we can follow.
6 And, Scotti, I think you helped form this beacon.
7 I just want to thank everybody
8 for the time they've put into this.
9 MR. SZALWINSKI: Mr. Chairman, if
10 I might.
11 CHAIRMAN TEEFEY: Yes, sir.
12 MR. SZALWINSKI: One of the things
13 that I would also suggest is that we began to
14 characterize data as to how managed care prescription
15 programs benefit the public, the way that they are
16 currently administered. Because, again, I point to
17 the IMS data. There is significant data out there to
18 suggest that people with managed care get more
19 prescription drug coverage than other folks, and
20 that's a good thing. We need to keep that in mind.
21 MS. PIGG: I just have a question
22 on how the governmental process works. So, we've
23 recommended that the Task Force be continued to
24 continue studying this. Does that preclude or is
25 there the potential that folks that may not agree

Page 137

1 with that that were not on this Task Force could
2 submit legislation to this General Assembly?
3 CHAIRMAN TEEFEY: That can happen
4 at any time.
5 MS. PIGG: Any time? And, of
6 course, then, I guess you can come back and say there
7 is already a study studying this?
8 CHAIRMAN TEEFEY: What we're going
9 to recommend to the General Assembly is, we discussed
10 this, and we didn't come to a conclusion and we think
11 another year of study is important.
12 DR. BLANCHARD: Mr. Chairman, will
13 we see the draft before it hits?
14 DR. PYLES: Absolutely.
15 CHAIRMAN TEEFEY: Yes.
16 DR. BLANCHARD: And, the second
17 thing, Dr. Pyles, will you be addressing some of your
18 cost issues or referring some of those to Delegate
19 Morgan's Committees?
20 DR. PYLES: Well, that is one of
21 the other things I think we have to clarify. We need
22 to look at exactly what that study is going to do. As
23 I recall, it looks at various aspects of PBMs, but
24 not so much in the context of what we've talked
25 about. So I think that, in the interim, before the

Page 138

1 report goes out and we get a draft to you, perhaps we
2 need to clarify and get to you what that study is
3 expected to produce, and then we can go from there
4 and get your comments in terms of how we can go about
5 that, if that's okay, Mr. Chairman.
6 CHAIRMAN TEEFEY: That's fine.
7 Thank you all for coming.
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9
10 NOTE: The hearing was concluded
11 at 11:43 a.m.
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14 * * * * * * * * * *
15 HEARING CONCLUDED.
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Page 139

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6 CERTIFICATE OF COURT REPORTER
7
8
9 I, PATRICIA PRICE WHITE, hereby certify that
10 I was the Court Reporter in the foregoing Hearing,
11 when heard on the 17th day of September, 1997.
12 I further certify that the foregoing
13 transcript is a true and accurate record of the
14 HEARING herein.
15 Given under my hand this 22nd day of
16 September, 1997.
17
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19
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21 PATRICIA PRICE WHITE, RPR, CP
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