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GOVERNMENT **SUBSTITUTE PRESCRIPTION DRUG ACT**  
**AMENDMENTS**

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**HEARINGS**

BEFORE THE

**SUBCOMMITTEE ON CONSUMER PROTECTION  
AND FINANCE**

OF THE

**COMMITTEE ON  
INTERSTATE AND FOREIGN COMMERCE  
HOUSE OF REPRESENTATIVES**

**NINETY-FIFTH CONGRESS**

**SECOND SESSION**

**ON**

**H.R. 1963**

**A BILL TO PERMIT PHARMACISTS, IN CERTAIN CIRCUM-  
STANCES, TO USE SUBSTITUTE DRUGS IN THE FILLING OR  
REFILLING OF PRESCRIPTIONS MADE BY PHYSICIANS**

**JUNE 22 AND JULY 27, 1978**

**Serial No. 95-155**

**Printed for the use of the  
Committee on Interstate and Foreign Commerce**



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## SUBSTITUTE PRESCRIPTION DRUG ACT

THURSDAY, JUNE 22, 1978

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The subcommittee met at 9:30 a.m., pursuant to notice, in room 2218, Rayburn House Office Building, Hon. Bob Eckhardt, chairman, presiding.

Mr. ECKHARDT. The Subcommittee on Consumer Protection and Finance will commence its hearings on legislation to allow pharmacists to substitute equivalent, or generic drugs, for drugs prescribed by trade name. The subcommittee held hearings on similar proposals in the 94th Congress. At that time, witnesses testified that only 15 States had repealed laws which prohibit pharmacists from substituting chemically equivalent drugs for drugs prescribed by trade name and which were enacted throughout the States in the 1950's.

Motivated by the large anticipated cost saving consumers could enjoy by not paying promotional costs associated with trade name drugs, consumer groups, professional associations and legislators combined efforts to urge State legislatures to enact laws allowing substitution of equivalent drugs. The work of these groups has been impressive—today some 39 States have laws providing for some form of substitution.

Today we begin a reexamination of the issue from a Federal perspective. Are current State laws adequate, or is a Federal law necessary to assure that consumers in fact enjoy the potential economic benefits of substitution and in a manner that is consistent with the protection of human health? Laws vary from State to State—for example, some States utilize lists of drugs which can be substituted for other drugs, that is, a "positive formulary"; other States utilize lists of drugs which cannot be substituted, that is, a "negative formulary," while the remaining States rely on the professional judgment of the pharmacist to select a drug which should be substituted. State laws differ in other respects, such as whether substitution is required or voluntary. Are the differences so great that there is a need for a consistent program of drug substitution throughout the United States? If so, how should that program work?

Our first witness is my distinguished colleague, Congressman John Murphy of New York, who is the sponsor of H.R. 1963. He served as chairman of this subcommittee in the 94th Congress, and during that time he held several days of hearings on drug substitution legislation. We will hear Congressman Murphy's testimony, then, due to the markup in full committee on health cost contain-



ment, will recess the hearing until 2 p.m. We will continue in this room.

John, we welcome you back to the subcommittee, and certainly will be most interested in your views on this, since you are so familiar with the issues both as subcommittee chairman and as author of the bill.

Without objection the text of H.R. 1963 will be printed in the record at this point.

[Testimony resumes on p. 9.]

[The text of H.R. 1963 follows:]



95TH CONGRESS  
1ST SESSION

# H. R. 1963

## IN THE HOUSE OF REPRESENTATIVES

JANUARY 17, 1977

Mr. MURPHY of New York introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

## A BILL

To permit pharmacists, in certain circumstances, to use substitute drugs in the filling or refilling of prescriptions made by physicians.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 SHORT TITLE

4 SECTION 1. This Act may be cited as the "Substitute  
5 Prescription Drug Act".

6 FILLING OR REFILLING OF PRESCRIPTIONS

7 SEC. 2. (a) (1) Except as provided in paragraph (2), if  
8 a drug to be dispensed pursuant to a prescription of a physi-  
9 cian licensed by law to administer the drug is identified in the  
10 prescription by a proprietary name or designation, any phar-



1   macist may fill or refill the prescription with a substitute drug  
2   if—

3           (A) the physician does not specify in the pre-  
4       scription (in the case of a written prescription) or  
5       in transmitting the prescription to the pharmacist (in  
6       the case of an oral prescription) that such prescription  
7       is to be filled or refilled with only the drug so identified;  
8       and

9           (B) the cost of the substitute drug to the patient  
10      for whom the prescription is made is less than the cost  
11      to such patient of (i) the drug so identified; and (ii)  
12      any other substitute drug in the inventory of the phar-  
13      macist at the time such pharmacist fills or refills the  
14      prescription involved.

15    (2) A pharmacist may not select a substitute drug to  
16    be used to fill or refill a prescription under paragraph (1)  
17    if the patient for whom the prescription is made requests  
18    such pharmacist to fill or refill such prescription with a drug  
19    other than the substitute drug selected by such pharmacist.

20       (b) (1) Except as provided in paragraph (2), if a drug  
21    to be dispensed pursuant to a prescription of a physician  
22    licensed by law to administer the drug is identified in the  
23    prescription by its established name, any pharmacist who  
24    fills or refills the prescription shall fill or refill it with the



1 substitute drug whose cost to the patient for whom the  
2 prescription is made is less than the cost to such patient of  
3 any other substitute drug in the inventory of the pharmacist  
4 at the time such pharmacist fills or refills the prescription  
5 involved.

6 (2) The provisions of paragraph (1) shall not apply  
7 if—

8 (A) the physician involved specifies in the prescrip-  
9 tion involved (in the case of a written prescription)  
10 or in transmitting the prescription to the pharmacist  
11 involved (in the case of an oral prescription) that the  
12 prescription is to be filled or refilled with a drug other  
13 than the substitute drug which would be required under  
14 paragraph (1), except that, in any case in which more  
15 than one substitute drug conforms to the specification  
16 made by the physician, the pharmacist shall fill or refill  
17 the prescription with a substitute drug (i) which con-  
18 forms to such specification; and (ii) whose cost to the  
19 patient for whom the prescription is made is less than  
20 the cost to such patient of any other substitute drug  
21 which would conform to such specification and which  
22 is in the inventory of the pharmacist at the time such  
23 pharmacist fills or refills the prescription involved; or  
24 (B) the patient for whom the prescription is made



1     ... requests the pharmacist to fill or refill such prescription  
 2     ... with a drug other than the substitute drug which would  
 3     ... be required under paragraph (1).

4     (c) Any substitute drug used to fill or refill a prescrip-  
 5     tion under subsection (a) or subsection (b) shall be in the  
 6     same quantity and dosage form as specified in such pre-  
 7     scription.

8     (d) For purposes of this section, a drug is a substitute  
 9     drug for a drug identified in a prescription (either by a  
 10    proprietary name or designation or by the established name  
 11    of such drug, if any) if such drug has the same established  
 12    name as the drug so identified.

#### 13                   EXEMPT TRANSACTIONS

14    SEC. 3. In the case of any individual participating in  
 15    the insurance program under part B of title XVIII of the  
 16    Social Security Act, the filling or refilling of any prescrip-  
 17    tion for such individual, with respect to which benefits are  
 18    payable under part B of title XVIII of the Social Security  
 19    Act, shall not be subject to the provisions of section 2.

#### 20                   EFFECT ON STATE LAW

21    SEC. 4. No State or political subdivision of a State may  
 22    establish or enforce any law or practice which prohibits a  
 23    pharmacist from taking any action authorized by section  
 24    2 (a) (1), or any action required by section 2 (b) (1), in  
 25    connection with the filling or refilling of a prescription for



1 a drug by a physician licensed by law to administer such  
2 drug.

### 3 ENFORCEMENT

4 SEC. 5. (a) Any violation of any provision of this Act,  
5 or any regulation prescribed to carry out this Act, shall  
6 constitute a violation of section 5(a) (1) of the Federal  
7 Trade Commission Act (15 U.S.C. 45(a) (1)) and shall  
8 be subject to enforcement under the Federal Trade Com-  
9 mission Act.

10 (b) Nothing contained in this Act shall be construed  
11 (1) to prevent or interfere with the enforcement of the pro-  
12 visions of any antitrust Act or any Act to regulate com-  
13 merce; or (2) to alter, modify, or repeal any antitrust Act  
14 or any Act to regulate commerce.

### 15 DEFINITIONS

16 SEC. 6. For purposes of this Act—

17 (1) the term "Act to regulate commerce" has the  
18 meaning given it by section 4 of the Federal Trade  
19 Commission Act (15 U.S.C. 44);

20 (2) the term "antitrust Act" has the meaning  
21 given it by section 4 of the Federal Trade Commission  
22 Act (15 U.S.C. 44);

23 (3) the term "drug" has the meaning given it by  
24 section 201(g) (1) of the Federal Food, Drug, and  
25 Cosmetic Act (21 U.S.C. 321(g) (1));



1 (4) the term "established name" has the meaning  
 2 given it by section 502 (e) (2) of the Federal Food,  
 3 Drug, and Cosmetic Act (21 U.S.C. 352 (e) (2) );  
 4 and  
 5 (5) the term "State" means any State or territory  
 6 of the United States, the District of Columbia, and the  
 7 Commonwealth of Puerto Rico.

8 EFFECTIVE DATES

9 SEC. 7. (a) Except as provided in subsection (b), the  
 10 provisions of this Act shall take effect six months after the  
 11 date of the enactment of this Act.

12 (b) The authority of the Federal Trade Commission to  
 13 prescribe regulations to carry out the provisions of this Act  
 14 shall take effect on the date of the enactment of this Act.



STATEMENT OF HON. JOHN M. MURPHY, A REPRESENTATIVE  
IN CONGRESS FROM THE STATE OF NEW YORK

Mr. MURPHY. Thank you very much for the opportunity to testify on a serious problem facing virtually every person in the Nation: The costs of medication. H.R. 1963 would permit pharmacists, under certain circumstances, to substitute lower cost drugs and medicines in the filling or refilling of prescriptions made by physicians.

Prescription drugs form an immense part of the American consumer's medical costs—\$8 billion last year alone, of which it has been estimated that up to \$2 billion—fully 25 percent—is being paid by the patient in unnecessary and excessive charges. This in itself is an extraordinary figure, and is compounded by the fact that this hardship falls most heavily on those who can least afford the expense: families with young children, and on the elderly, for whom nearly 25 percent of their total medical expenditures go to pay for prescription drugs.

It is clear that drug prices are a major problem, with the industry itself leading the battle to maintain high prices—and high profits—by disallowing generic substitution. The bringing down of these unnecessary and excessive medical costs should be a primary effort of the Congress.

What goes to make up these extra costs? The answer can be found in two separate areas.

First, and most important, is an intensively high level of brand name promotion, particularly within the medical profession. The industry's own figures show that about 25 percent of every sales dollar goes to pay for product promotion of some sort. Yet, while theoretically, a generic drug, by definition, is a particular chemical compound unprotected by a patent or trademark, many times the trade or brand name drugs are simply generic drugs which have been repackaged and relabeled, with little or no significant change in chemical substance.

The second area which can account for a great deal of these extra costs to the consumer is a contributory ignorance by both the consumer and the physician. The industry spends an average of \$5,000 per year in product promotion for each of the Nation's 200,000 physicians, to generally convince the doctors or the patient to continue to prescribe or to ask for the drug names with which they are most familiar. Each relies on his exposure to and experience with brand names, due largely to the fact that the doctor's training is barely minimal in pharmacology, and the patient's is even less—most medical schools require only a single course in the subject, except, of course, for those who wish to go on to become pharmacists.

In addition, most consumers are totally unaware that drugs identical to their prescribed brand name compounds may be purchased at a lower price under their generic names.

Having said all this, the question remains whether the system itself can be changed—and, of course, whether generic drugs can be safely substituted without endangering the health of the patient.

This safety issue has caused an understandable amount of concern. But I think it is an exaggerated one, basically a red herring in a sea of corporate profit.



There are two aspects to this controversy. One is whether the same drug made by different manufacturers can confidently be said to have the same therapeutic effect on the patient. The other is whether companies which manufacture generic products are able to maintain adequate quality controls throughout their manufacturing process.

As to their therapeutic equivalence—whether drugs are or can be manufactured so that they have the same effect in the patient—most scientists conclude that only a very small number of drugs pose any such problems. These include the most famous example, the heart drug digoxin, in which the Food and Drug Administration spent 3 years working with the drug manufacturers to insure an industrywide uniform product. The FDA has already published a list of those theoretical “problem drugs” which cannot be substituted until certain manufacturing irregularities can be resolved.

The therapeutic equivalence issue is so well controlled now that the FDA has based its “maximum allowable cost” (MAC) formula under medicare on the presumption that, with very few exceptions, drugs can indeed be substituted without difficulty.

All veterans’ and other Government-operated hospitals, as well as about 90 percent of all private hospitals, have been using generic products for many years. And the city of New York had its own MAC program operating for several years.

The quality control controversy also appears to be highly overblown. The industry which claims to be the hallmark of quality control cannot be allowed to refuse substitution based on the alleged lack of such quality in their own industry.

I presume that, as in any industry, there are some few companies which do not meet the highest standards. But the Federal Food and Drug Administration monitors all companies, not just the major manufacturers; so that product standards in this industry are considerably higher than the average corporate norm.

The FDA conducted a recent survey which indicates there is no significant difference in the number of “recalls” which have been ordered for brand name drugs or for their generic equivalents.

Having laid the quality control myth to rest, legislation which permits generic drug substitution goes a very long way beyond just encouraging use of generic house drugs. It is important to note that the bill would allow, not require, the pharmacist to make such generic substitutions. It would be up to the discretion of the pharmacist, who has been specifically trained in this highly specialized field, to make the generic substitutions if and when they can be safely done with no significant difference to the patient except in his wallet.

When the prescription is limited to the trade name drug only, however, the pharmacist could then fill the prescription only with the brand name drug. Thus, the argument which contends that control of the administration of drugs is taken out of the hands of the physician is groundless. It would simply require the presence of such limiting instructions on the prescription for the doctor to limit generic substitution. But at that point, the doctor is answerable to his patient as to why he has chosen to burden the patient with the most expensive of all the available alternatives.



Another argument raised by the drug manufacturers claims that their "extensive" research and development programs would suffer and be stifled if the industry is not permitted to maintain their virtually unchallenged monopoly. Frankly, if this is true, then it certainly deserves attention. However, the industry's own statistics are quite to the contrary, indicating that only 6 percent of sales goes to research and development, while 25 percent goes to product promotion. If the industry's interest is in research, or the lack thereof, the industry has developed an odd ordering of their priorities. In a study of over 800 "new" drugs introduced in the United States, over two-thirds were found to represent little or no therapeutic gain over existing drugs. If such drug industry "research" amounts to little more than a proliferation of similar products under different labels and packages, I can see very little reason to accord such a public relations function any favorable legislative treatment. The need for research should not be the justification for maintaining an anticompetitive market structure. If prices must remain at high levels to support significant research and development costs, then so be it. But this is simply not the case in an industry which spends at a 4½ to 1 ratio for promotion over research.

Finally, I feel that Federal, not State, legislation is necessary. Most drug companies, as well as many major chain stores, cross State lines. Additionally, today's mobile society means that many travelers find the need to fill a prescription in another city on short notice. State laws do not take into account such problems as shipping costs, particularly for specialized drugs requiring refrigeration, short-term shelf life of many drugs, controlled conditions necessary for storage, regional trends in epidemiology, et cetera.

Passage of this drug substitution legislation represents a potential savings to drug users—that is, every man, woman, and child, old and young, rich and poor—savings of as much as 1,000 percent in some identifiable cases where the brand name markup is 10 times the cost of identical generic compounds.

For example:

Penicillin VK, \$1.85 generic—Lilly V-Cillin-K, \$8.32—plus 449 percent.

Penicillin G, \$1.20—Squibb Pentids, \$8.36—plus 696 percent.

Oxytetracycline, \$1.90—Pfizer Terramycin, \$18.43—plus 970 percent.

Ampicillin, \$4.40—Bristol Polycillin, \$13.81—plus 314 percent.

Erythromycin, \$5.70—Abbott Erythrocin, \$12.96—plus 227 percent.

Chloramphenicol, \$8.00—Parke-Davis Chloromycetin, \$23.71—plus 296 percent.

These are not necessarily instances of conscious abuse of what amounts to a monopoly situation. They do represent, however, a system which is obviously open to a new approach.

In some cases, the industry has priced itself right out of its own market: many sick and elderly people can no longer afford their expensive drugs on an extremely limited fixed income, so they simply do without, and die earlier.

While we cannot legislatively require these companies to lower their profit margins, we can certainly provide the means by which



the competitive marketplace can once again be opened up to those who need drug products the most.

Substitution of generic drugs is not the final answer: it is the first step.

Mr. ECKHARDT. Thank you very much for your very able testimony.

Since a good number of States have passed laws in those States, what would be your comment with respect to the argument that the State ought to control this?

Mr. MURPHY. I think I would probably use the same argument the very able chairman of this subcommittee used in passing a recently famous insurance bill called no-fault.

The problem is a Federal problem, and I think it should be addressed at a Federal level. I think the States themselves are more susceptible to lack of uniformity in legislation and do not have the ability to address the problem on as comprehensive a basis as the Federal Congress can.

Mr. ECKHARDT. What about the question of whether a law should be fashioned in a way in which the pharmacist makes the ultimate judgment about whether or not the drug is substitutable or there is some kind of formulation of what may be substituted or, on the contrary, a formulation of in what area substitution should not be required?

Mr. MURPHY. The pharmacist is trained, and properly trained, in this field, and probably is trained, as I indicated, in a much superior manner to the physician.

The problem of the physician, of course, is when he makes out a prescription, if he fills out the generic drug, it must be filled in the generic name; if a brand name, it should be filled in a brand name.

The pharmacist should fill in the generic if there is that option, or if the physician permits an option.

Mr. ECKHARDT. Frequently the physician may not even know about the option.

Mr. MURPHY. The physician, of course, has been campaigned and lobbied by the drug salesman for the brand name drug. This is where the problem of habit comes from. The pharmacist should certainly make the substitution where the option is there.

Mr. ECKHARDT. I certainly do know that to be true. My father was a physician, and I remember, he used to get some of these beautiful advertisements of drugs which also included very detailed and highly colored illustrations of organs of the body and the effect of the drug, rather detailed material. Of course, they did not say anything about that drug having generic substitutes which would do the same thing.

Certainly a great amount of the cost that you detail here, the difference of costs, must go into that somewhat fancy advertising.

Mr. MURPHY. Promotion, as well as advertising.

Mr. ECKHARDT. Yes.

Mr. MURPHY. You will get some interesting testimony from the industry as well as from many consumer organizations which have gone into this issue for many, many years in an effort to try to reduce costs.

Mr. ECKHARDT. Thank you very much for your testimony.



This meeting was not only to commence the hearing on the generic drug bill, but also to mark up and act upon H.R. 12563. Are there any persons here amongst the public who are here for H.R. 12563? I just wanted to notify you the full committee is meeting in 5 minutes in room 2123. For that reason, it is very difficult for members of this subcommittee to come to this meeting at this time. The markup of that bill will be in open meeting, and anyone who is interested in attending such open meeting may be admitted to the cloakroom in room 2123, downstairs. We will merely recess this meeting and go to that place and continue with this process.

I would say this: It is a rather smallish room, and if you are just interested in the question of generic drugs, nothing will be done on that. The bill I am referring to merely has to do with a study relating to the Magnuson-Moss Warranty-FTC Improvement Act, on which hearings have already been held. Nothing remains to be done but to pass the bill on to the full committee. So the subcommittee will recess and reconvene in this hearing at 2 o'clock this afternoon in this room.

[Whereupon, at 9:50 a.m., the subcommittee was recessed, to reconvene at 2 p.m., the same day.]

#### AFTER RECESS

[The subcommittee recovered at 2 p.m., Hon. Bob Eckhardt, presiding.]

Mr. ECKHARDT. Dr. Goldberg. Will you please identify yourself for the record.

**STATEMENT OF THEODORE GOLDBERG, PH. D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF COMMUNITY MEDICINE, WAYNE STATE UNIVERSITY SCHOOL OF MEDICINE, ACCOMPANIED BY MICHAEL DICKSON, PH. D., ASSISTANT PROFESSOR, UNIVERSITY OF WISCONSIN**

Dr. GOLDBERG. Thank you very much. My name is Theodore Goldberg. With me is Dr. Michael Dickson of the University of Wisconsin who is a coparticipant in the research we are undertaking in drug products selection legislation. I am professor and chairman of the department of community medicine of the Wayne State University School of Medicine, which is in Detroit, Mich. In addition to that and perhaps of more relevance to the interests of these hearings, for the past 4 years I have been principal investigator of a research project to study the impact of drug product selection legislation. The study was initially funded by the Michigan Association of Regional Medical Programs, and for the past 2 years and currently we are supported financially by the National Center for Health Services Research of the Department of Health, Education, and Welfare.

I should mention, Mr. Chairman, that we have prepared fairly lengthy testimony which we have submitted for the consideration of your committee.

Mr. ECKHARDT. If you would like, Dr. Goldberg, you may ask unanimous consent to place that in the record and you may summarize.



Dr. GOLDBERG. I would like very much to make that request, Mr. Chairman.

Mr. ECKHARDT. Without objection, it will be so ordered.

Dr. GOLDBERG. Before proceeding with the details of my testimony, however, I would like to make a couple of preliminary remarks. The first is that while we obviously are interested in seeking answers to various questions regarding the impact of what we consider very important social legislation—and this is particularly true during the period when there is widespread concern with issues of health care cost containment as well as increased sensitivity to consumer interests and to consumer protection—but at the same time we make every effort to maintain academic objectivity and scientific impartiality. We have absolutely no ax to grind nor any vested interest to protect. We can and have viewed the data that have been produced with as an unbiased perspective as we believe it is possible to achieve.

My second preliminary remark is to indicate that the members of our research team represent various academic and professional interests including substantial representation from the profession of pharmacy. My own particular academic background is in the fields of political science and economics. Dr. Willis E. Moore, the coprincipal investigator, is a professor of pharmacy at Wayne State University. Dr. Michael Dickson is an assistant professor and assistant dean in the School of Pharmacy of the University of Wisconsin. Mr. Jerry Vidis is a registered pharmacist licensed in the States of Michigan and Iowa. Ms. Carolee DeVito is a registered pharmacist in Connecticut and Michigan and currently is a Ph. D. student in medical care organization at the University of Michigan.

Mr. David Smith and Mr. Kenneth Guire are trained biostatisticians, Mr. Smith on our faculty and Mr. Guire on the staff of the statistics research laboratory of the University of Michigan. In addition, we have been fortunate to have had valuable consultations from a wide variety of people including Dr. Paul Stolley, now of the University of Pennsylvania, Dr. T. Donald Rucker, of Ohio State University, Dr. Allen Dyer of the Ontario Ministry of Health, Prof. Sylvester Berki of the University of Michigan, Dr. Myron Stano of Oakland University in Michigan, and others.

To date, our research has produced 21 papers incorporating various aspects of the research and our findings. Some of these have been published in various professional journals including the Journal of the American Pharmaceutical Association and Medicare Care, the official journal of the medical care section of the American Public Health Association. A number of the more recent papers are to be published as part of the proceedings of the recent invitational dissemination workshop on drug product selection legislation held in Detroit, Mich., on April 13 and 14, 1978, and jointly sponsored by the National Center for Health Services Research of HEW and our drug study research team in the department of community medicine at Wayne State University.

I have copies of all of these papers which I will leave for the committee's review. We also will be most happy to make copies of additional papers from our study available to your committee as soon as they are produced.



Mr. ECKHARDT. The papers will be accepted without objection for the file of the committee.

Dr. GOLDBERG. We would also be happy to make additional papers, as they become available, available to your committee as soon as they are produced.

What I would like to do today is keep our formal remarks as brief as possible in order to allow a maximum time to respond to questions that you may have. We would like to summarize the conclusions reached in various reports we have produced to date. While my oral remarks will not cite all the evidence on which the conclusions are based, nor will they provide the detail of the methods by which the conclusions were reached, I am sure that such detail can be gathered from the written testimony that we have presented plus the prepared papers which have been submitted to the committee.

Our research has dealt specifically with the issue of the impact of drug product selection legislation. Thus we have considered many of the questions with which this committee is concerned. However, some of the questions which were raised in your letter of invitation really are matters of individual opinion and cannot be determined from the data we have collected, nor from any other evidence with which we are familiar.

We would be most happy to give our opinions on many or most of these questions, but I am afraid that we will be unable to justify our opinions on the basis of the information we have gained from our research. Thus we will be very careful to distinguish between conclusions drawn from our data and our opinions about some of the important issues you have outlined in your letter.

We believe that our written testimony, including the background papers, provides the kind of detail about our research which is of interest to your committee. Our oral testimony will simply draw attention to some of the conclusions which we consider more far reaching.

I would like to review these conclusions with you. The first, Mr. Chairman, is that over half of all prescriptions written are for drug entities for which there are two or more generically equivalent drug products which may be used to fill the prescription. This means that the potential impact of drug product selection legislation—or the term used in H.R. 1963 is drug substitution legislation—is very great indeed. That is a very substantial conclusion, and I think an important one, arrived at on the basis of solid and strong facts to support that conclusion, that over half of all prescriptions are for entities for which there are two or more products which may be used to fill the prescription.

Mr. ECKHARDT. This conclusion would be true only if the two products—I say two, there might be more—if the products involved were of substantially different cost.

Dr. GOLDBERG. That is another conclusion that I will draw to your attention further on in my testimony, sir. Yes, that is correct.

The second major conclusion we would like to draw to your attention is that in excess of 20 percent of prescriptions for multiple-source drug entities; that is, for drug entities for which there are two or more products, over 20 percent of all prescriptions are written generically; that is, they are written in a way that specifies



the active ingredients without indicating a proprietary or brand name product.

This is important. This means that in all of these cases pharmacists already had, before the law was passed, the right, in fact the obligation, to drug product select, to choose a product among various products to be used to fill the prescription written. Whenever a prescription is written generically for a multiple-source entity, the pharmacist must choose between various possible products, to choose the one to dispense. Over 20 percent of all prescriptions for multiple-source entities are written generically.

The third major point I would like to draw to your attention is that there is a very substantial variation in the prices charged for various drug products within the same drug entity. Our data show that for Michigan there is an average difference of \$1.15 per prescription, or approximately 20 percent, between the prices of the drug prescribed and the price of the drug dispensed for those prescriptions in which substitution took place.

This does not take into account that potentially lower priced products could have been chosen to be dispensed. The \$1.15 or the 20 percent simply reports the difference in prices which actually occurred rather than those savings that were potentially possible. There is a very substantial difference in the price of products prescribed and dispensed when substitution takes place. In our study the difference was \$1.15 or approximately 20 percent difference in price.

Mr. ECKHARDT. In your study was the cost saving passed on to the customer?

Dr. GOLDBERG. In our State it is required to be passed to the consumer. I should perhaps elaborate on that. Our State requires that for other than third-party prescriptions, in other words, other than prescriptions paid for by an insurance company or third-party payer. But for people who pay directly for the prescription, any savings must be directly passed on to them. So this \$1.15 for the first party paid prescriptions was passed on to the consumer, yes, sir.

The fourth conclusion that I would like to draw to your attention is that in both Michigan and Wisconsin, both of which permit physicians to require that the specific product prescription be dispensed as written—in other words, the legislation says that if a physician feels strongly enough to want to advise the pharmacist not to make a change, he must take an affirmative action in so writing on the prescription “dispense as written” or “D.A.W.” In Michigan and in Wisconsin they are required to take affirmative action by writing DAW. This is different from the procedure used in other States where physicians are required to check boxes which permit or deny substitution or to indicate by signing on one of two lines whether substitution is either allowed or forbidden. In our State the prescriber has to take affirmative action in order to forbid drug product selection.

In both Michigan and Wisconsin fewer than 4 percent of prescriptions require the pharmacist to dispense the product as written. In jurisdictions where physicians simply check boxes or initial lines to allow or not to allow drug product selection, the literature



has reported a substantially higher proportion of dispensed as written prescriptions, in some cases amounting to 25 percent or more.

I think the importance of this observation is that in Michigan and Wisconsin the legislation specifically allows a physician to prohibit substitution, but in order to prohibit substitution the physician must take the initiative of saying on the prescription to the pharmacist, in his own handwriting, to dispense the prescription of the drug product that he has prescribed precisely as written. He has to take that initiative. When this kind of provision is included in the legislation, our experience—and I must tell you it has not changed very greatly over the 3 years we have been studying the effects of the legislation—is that fewer than 4 percent of prescriptions carry the legend to dispense as written.

The fifth conclusion I want to bring to your attention is that all our evidence seems to indicate that because of the high proportion of multiple-source drugs; that is, over half of all drugs of multiple source, because of the wide range in the drug prices among product and the same drug entity; that is, 20 percent or perhaps more, and because of the low rate of prescriber prohibitions, because of all these facts there is a very substantial potential for savings from drug product selection legislation.

In Michigan alone we estimate the potential savings to be between \$18 million and \$21 million a year. I must point out there is a substantial gap between the potential savings from drug product selection and the amount that has been indicated as having occurred. The difference is between \$18 million and \$21 million that we identify as potential savings and the amount we have estimated to be actual savings during the same period of between \$200,000 and \$300,000 a year.

We do not underestimate the importance of \$300,000 of savings, but there is a substantial gap between that amount and the potential amount of savings of \$18 million and \$21 million.

The gap between the potential for savings and the actual amount of savings is and continues to be substantial. The evidence from the first 2 years of experience in Michigan indicates that the rate of substitution in the first year was only 1.49 percent of all multiple-source prescriptions, and increased only 1.50 percent the second year.

The experience in the first 6 months of the Wisconsin legislation was only slightly better, being approximately 3 percent of substitutions for multiple-source products during the first 6 months of operation. We had been inclined to conclude that time alone would not substantially alter the pattern of drug product selection utilization and that some more definite social action would be required. However, since having come to that conclusion, we have now had an opportunity to look at some of the early data from this year's operation. These data represent the third year of operation of the legislation in Michigan and the second year of operation of the legislation in Wisconsin.

While I want to emphasize and draw to the committee's attention the preliminary nature of our observations about the current data, however we have been struck by what seems to be a substantial increase in the light of drug substitutions.



We have not yet made the kind of careful analysis which is required and which we will make as soon as possible, but our early impressions are that rates of substitutions may have jumped to as much as between 20 and 15 percent of multiple-source drug products. Obviously we will check this initial impression very carefully. It may very well be that the effects of drug product selection legislation will be felt earlier than we had previously thought. Further analysis is needed to make this determination.

One final remark, Mr. Chairman, is that it seems to us that in order to make drug product selection legislation more effective there have to be greater encouragements to have pharmacists engage in this. These encouragements can be either in the form of incentives, which are provided to encourage pharmacists to select among various drug products, or they could be in the form of more specific conditions providing direction for pharmacists' action.

As examples of the provisions which would provide greater incentives for pharmacists to practice drug product selection I would suggest the following:

1. By providing legal protection against any additional liability resulting from the practice of drug product selection, might overcome this area of possible concern and thus provide greater incentive for pharmacists to exercise this option more frequently.

2. By minimizing in every way the difference in administrative requirements between practicing drug product selection or by dispensing the prescription as written. This would apply to such things as reducing extra labeling requirements or extra record-keeping or extra requirements for receipt provisions when drug product selection takes place. That is to say, reduce the differential between what the pharmacist has to do when he exercises drug product selection compared to what he would have to do when he simply dispensed the prescription as written. This would be further encouragements to have pharmacists exercise their professional prerogative in choosing among various products.

Other examples are to look carefully at who can advise individuals or inform the purchaser about drug products selection, whether this requires the activity of a pharmacist or could be done by someone else who works in the pharmacy. I think this should be considered.

A very important aspect of this seems to us to be to assure that pharmacists will not stand to lose financially from exercising the option of drug product selection. In fact, it may very well be that the legislation should provide the incentive to share in the savings so as to encourage the practice of drug product selection. These are all examples, Mr. Chairman. There is an additional one I might point out to you.

Blue Cross-Blue Shield in Michigan now provides a pharmacy incentive program. They have estimated the amount of saving to Blue Cross-Blue Shield of Michigan for a year through exercising the choice of less costly generically equivalent products to be approximately \$4 million. They have developed a plan where they say they will share these savings with the participating pharmacists by returning to the pharmacist an average of 20 cents a prescription. They estimate that over the course of the year this will amount to approximately \$2 million.



So they say that of the \$4 million they stand to save from drug product selection, we will share this amount between the prepayment agency, Blue Cross-Blue Shield, and the participating pharmacists. That seems to be a method designed to provide greater incentives for pharmacists to exercise their professional prerogatives.

On the other hand, there are examples of conditions which would require drug product selection. Two examples that I would give to you is: first the maximum allowable cost or MAC program which simply says to the pharmacist: You can dispense whatever you want but we will reimburse you to a specified, maximum amount.

The incentive is that the pharmacist will probably dispense a product at or below the maximum allowable cost which shall be reimbursed. A second program similar to MAC is the Parcost program which operates in Ontario, Canada, which also identifies maximum amounts of reimbursements to participating pharmacists, which encourages them to dispense products at or below the price which the program will reimburse.

It seems to me that perhaps the committee would be concerned with considering both the various incentive programs as well as the provisions of the MAC or the Parcost program in designing its legislation.

There are a number of other points contained in our written testimony. We would be most happy to answer any questions you may have about anything that we have said in our testimony or about anything we have presented orally. We would also be happy to send you copies of further papers and other information as they become available.

[Testimony resumes on p. 55.]

[Dr. Goldberg's prepared statement follows:]



STATEMENT OF THEODORE GOLDBERG, PH. D., PROFESSOR AND CHAIRMAN, DEPARTMENT  
OF COMMUNITY MEDICINE, WAYNE STATE UNIVERSITY SCHOOL OF MEDICINE

Mr. Chairman and Members of the Committee:

My name is Theodore Goldberg. I am Professor and Chairman of the Department of Community Medicine of the Wayne State University School of Medicine in Detroit, Michigan. In addition, and perhaps of more relevance to the interests of these particular hearings, for the past four years I have been Principal Investigator of a research project to study the impact of drug product selection legislation. The study was initially funded by the Michigan Association of Regional Medical Programs and for the past two years, and currently, we are funded by the National Center for Health Services Research of the Department of Health, Education and Welfare.

Before proceeding with the details of my testimony, I should like to make a couple of preliminary remarks. The first is that while we obviously are interested in seeking answers to various questions regarding the impact of important social legislation, particularly during a period when there is widespread concern with issues of health care cost containment as well as increased sensitivity to consumer protection, we have made every effort to maintain academic objectivity and scientific impartiality. We have absolutely no axe to grind, nor any vested interest to protect. We can and have viewed the data that have been produced with as an unbiased perspective as we believe it is possible to achieve.

My second preliminary remark is to indicate that the members of our research team represent various academic and professional interests including substantial representation from the profession of pharmacy. My own particular academic background is in the fields of political science and economics. Dr. Willis E. Moore, the Co-Principal Investigator, is a Professor of Pharmacy at Wayne State University. Dr. Michael Dickson is an Assistant Professor and



Assistant Dean in the School of Pharmacy of the University of Wisconsin. Mr. Jerry Vidis is a registered pharmacist licensed in the states of Michigan and Iowa. Ms. Carolee DeVito is a registered pharmacist in Connecticut and Michigan and currently is a Ph.D. student in Medical Care Organization at the University of Michigan. Mr. David Smith and Mr. Kenneth Guire are trained biostatisticians, Mr. Smith on our faculty and Mr. Guire on the staff of the Statistics Research Laboratory of the University of Michigan. In addition, we have been fortunate to have had valuable consultations from a wide variety of people including Dr. Paul Stolley, now of the University of Pennsylvania, Dr. T. Donald Rucker, of Ohio State University, Dr. Allen Dyer of the Ontario Ministry of Health, Professor Sylvester Berky of the University of Michigan, Dr. Myron Stano of Oakland University in Michigan, and many others.

To date, our research has produced 21 papers incorporating various aspects of the research and our findings. Some of these have been published in various professional journals including the Journal of the American Pharmaceutical Association and Medical Care, the official journal of the Medical Care section of the American Public Health Association. A number of the more recent papers are to be published as part of the Proceedings of the recent Invitational Dissemination Workshop on Drug Product Selection Legislation held in Detroit, Michigan on April 13 and 14, 1978 and jointly sponsored by the National Center for Health Services Research of H.E.W. and our drug study research team in the Department of Community Medicine at Wayne State University.

I have copies of all of these papers which I will leave for the Committee's review. We also will be most happy to make copies of additional papers from our study available to your Committee as soon as they are produced.



What I would like to do today is to describe the background of our research, trace the development of state enacted drug product selection legislation, define some of the terms and concepts involved in this subject, report on some of our major findings, and to make some observations about what we have learned and the direction we believe our research is taking.

We began our research in the summer of 1974 when the Michigan state legislature was debating an amendment to the state's pharmacy act which would repeal the anti-substitution provision of the state law and would allow the state's pharmacists, under certain specified conditions, to select the particular drug product to be dispensed, even though the product may be different from the one specifically prescribed by the physician. The Michigan amendment was one of the first in the country to repeal the anti-substitution restrictions of state pharmacy acts. Only Massachusetts and perhaps one other state had repealed the anti-substitution provisions earlier. All the other states had continued to enforce the anti-substitution provisions of their acts which were adopted almost universally in the United States during the period of the early 1950's as protection of consumers against the allegedly widespread distribution of inexpensive "counterfeit" drug products which resembled, in appearance at least, the genuine branded products. The anti-substitution laws thus made it illegal for the pharmacist to dispense anything other than the specific brand product prescribed by the physician. However, I should point out that even during this period of concern for protecting against inferior products, if the physician wrote the prescription for the drug in generic terms, the pharmacist always had the legal right, indeed the responsibility to choose the product to be used to fill the prescription. This is an important point to be remembered for our later consideration.



Quality of the counterfeits was called into question because manufacturing standards were ill-defined and inadequately enforced. Many observers believed that some small manufacturers had no incentive to product quality products since they were trading upon the established image of branded products. These "irreputable" manufacturers were characterized as appealing to pharmacists and wholesalers strictly on the basis of profit maximization. The nature of their products and clientele permitted these small firms to enter the market intermittently under different names, with different address, and without being subjected to the same regulatory scrutiny as the established pharmaceutical manufacturers. Their method of operation was thought to provide significant profits.

Counterfeiting was not a problem during earlier years (i.e., prewar period) because a large percentage of prescriptions were compounded. Many of the manufactured products available were only moderately effective and/or could be purchased without a prescription. Thus, there was little incentive for producing or using counterfeit products.

The immediate post-second World War period saw major developments in drug therapy. Potent new drugs were synthesized and gained high visibility among health professionals and the public. There was an understandable concern among health professions that these new agents be of high quality. Prescribers and pharmacists alike recognized that these new chemicals required sophisticated manufacturing techniques far beyond what was needed for their predecessors. Thus, in 1953 the major drug manufacturers founded the National Pharmaceutical Council (NPC) to, "promote optimum standards and assure the public of high quality pharmaceutical products." They designed secret or difficult to counterfeit identifications into their products and began shopping pharmacies in search of counterfeits. As the substituting pharmacists were discovered and revealed,



factions in support of ant substitution laws began to coalesce. Almost every state enacted a law or pharmacy board regulations prohibiting brand substitution. Government action enjoyed widespread support from physicians, pharmacists, manufacturers, and consumers. The more recent controversy over substitution indicates that neither the prevalence nor the therapeutic consequences of brand name substitution were carefully documented when ant substitution laws were enacted in the 1950's.

When Michigan repealed its ant substitution provision in 1974, it was only the second or third state in the U.S. to do so. Today, well over half the states (38) with a very substantial majority of all people in this country have either repealed the prohibition (35) or are in the process of doing so (3).

A chart we have developed shows the provisions contained in the 35 laws now in effect. I am happy to make a copy of this chart available to the committee with the explanation that it is based upon our interpretation of the provisions of the amended acts and regulations and has not in all cases been checked with responsible agencies in each of the states. We are now in the process of doing just that and will send this Committee a copy of the revised comparisons as soon as it becomes available.

A fairly detailed analysis of the major provisions of the various state laws is contained in the paper by Dr. Michael Dickson which I have also made available to the Committee and from which I have borrowed generally in my earlier remarks. I don't intend to review that paper in detail at this point except to point out that each of the state laws falls into one of these general patterns.

The first allows substitutions only within a predetermined list of drugs or formulary. A typical provision incorporating this approach is that contained



within the Maryland Act which provides --

"The provisions of this section shall only apply to those drug products included in the Maryland Medical Assistance Formulary determined by the Maryland Department of Health and Mental Hygiene on the basis of scientific evidence to be clinically equivalent."

The second pattern allows substitution of any drug which is not specifically forbidden. This, in a sense, provides for a "negative formulary" of all drugs for which substitution is not allowed.

Typical of provisions with this approach is that from the state of California --

"The Director of Health shall establish by regulation a formulary of generic drug types and drug products which the Director of Health determines demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted under Section 4047.6, would pose a threat to the health and safety of patients receiving prescription medication.

....No pharmacist shall dispense a generically equivalent drug product pursuant to Section 4047.6 if the drug product and its generic drug type is included in the formulary."

The third pattern is that adopted by the Michigan legislature which allows for substitution of any drug without any reference to a formulary either positive or negative. Each pharmacist is allowed to use his professional judgment in selecting whatever drug he feels is best to dispense, provided that --

1. The prescribing physician has not forbidden the pharmacist to exercise his judgment by writing "Dispense as Written" or "D.A.W." in his own handwriting on the face of the prescription; and



2. Substitution is requested by the patient; and
3. The pharmacist substitutes a "lower cost" drug and passes along the savings to the patient.

To understand the operation of the Michigan law it is necessary to keep in mind the key operative provisions of the Act which are as follows:

1. When a pharmacist receives a prescription for a brand name drug product, the pharmacist may dispense a lower cost but not higher cost generically equivalent drug product if available in the pharmacy, except as provided in subsection (3)...
2. If the pharmacist dispenses a generically equivalent drug product, unless the prescription purchase is covered by a "third-party pay contract," the pharmacist shall pass on the savings in cost to the consumer. The savings in cost is the difference between the wholesale cost to the pharmacist of the two drug products.
3. The pharmacist shall not dispense a generically equivalent drug product under subsection (1) of this section if ...
  - (a) the prescriber, in the case of a prescription in writing signed by the prescriber, writes in his own handwriting "dispense as written" or "D.A.W." on the prescription, or



(b) the prescriber, having preprinted on his prescription blanks the statement "another brand of a generically equivalent product identical in dosage, form and content of active ingredients, may be dispensed unless initialed "D.A.W.", writes the initials "D.A.W. in a space, box or square adjacent to such statement, or

(c) the prescriber, in the case of a prescription other than one in writing signed by the prescriber, expressly indicates the prescription is to be dispensed as indicated.

In addition, the Act requires the pharmacist to provide certain information on a customer receipt (or on the label); provides penalties for violation of the Act; defines terms, and includes a requirement that each pharmacy post a list of the prices charged in the pharmacy for the 100 most frequently prescribed drugs as designated by the Michigan State Board of Pharmacy.

Early in our work on drug product selection it became obvious that nomenclature was a problem. The terms in common use often lacked precision and more frequently, had numerous definitions as the result of common usage over the years. In an effort to reduce misunderstanding and improve communication among ourselves, we attempted to define key words in the drug product selection (DPS) vocabulary. In addition to defining existing terminology, we also found it necessary to create new words. In this spirit, the following glossary of terms is presented in an effort to forestall possible misunderstandings and a more complete list of definitions is found in a paper entitled "Impact of Drug Substitution Legislation: A Report of the First Year's Experience," a copy of which I have made available to the Committee.



|                         |   |                                                                                                                                                                                                                                                            |
|-------------------------|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Distributor             | - | The company responsible for selling a given product to the ultimate vendor. This firm may also be the labeler and/or manufacturer.                                                                                                                         |
| Drug Entity             | - | Identification of a drug specifying generic code, strength, and dosage form.                                                                                                                                                                               |
| Drug Product            | - | Identification of a drug specifying generic code, strength, dosage, form, and labeler.                                                                                                                                                                     |
| Generically Equivalent  | - | Drug products which have as active ingredients chemical entities in the same salt form and in the same proportions. These products have been identified with the same generic code number. This level of coding does NOT refer to strength or dosage form. |
| Labeler                 | - | The company name under which a given drug product is ultimately marketed. This firm may also be the manufacturer and/or distributor.                                                                                                                       |
| Manufacturer            | - | The company responsible for the production of a given drug product. This firm may also be the labeler and/or distributor.                                                                                                                                  |
| Multiple Source Product | - | A given drug entity that is available from more than one labeler at a specified point in time. Labeler refers to ultimate labeler regardless of manufacturer or distributor.                                                                               |
| Price                   | - | The total amount of money collected for the prescription dispensed. Price refers to retail/selling price NOT acquisition cost.                                                                                                                             |
| Single Source Product   | - | A given drug entity that is available from only one labeler at a specified point in time.                                                                                                                                                                  |
| Substitution            | - | The dispensing of a drug product different from but generically equivalent to the product prescribed.                                                                                                                                                      |

When we began our research in the summer of 1974 we had in mind a variety of objectives to be achieved, including the following:

1. Survey physicians and pharmacists about their attitudes about and intended behavior under the drug product selection legislation.
2. Collect and analyze a sample of dispensed prescriptions, both in Michigan and in a comparison state, from the year immediately



prior to and the year immediately following the effective date of the law.

3. Initiate a three-year longitudinal study of the effects of the legislation.

In addition to these general objectives, there were a number of more specific questions for which we sought answers. These included:

1. What proportion of prescriptions were for single-source and what proportion for multiple-source entities?

2. What proportion of prescriptions are written generically? In these cases, drug product selection is absolutely required since no specific product is identified. Of course, if there is only one product in an entity, that is, a single source entity, then the pharmacists can only dispense that product even if the prescription is written generically.

3. To what extent does substitution take place within multiple-source entities?

4. What are the potential and actual savings resulting from drug product selection?

5. To what extent does the rate of substitution change over time?

6. What is the overall impact of changes in the marketplace on prescription drug prices as the result of the enactment of drug product selection legislation?



For some of these questions we have fairly definite answers, for others we have tentative answers, and for some additional data are required before any conclusion can be drawn with confidence.

Our first study was of the attitude of physicians and pharmacists toward drug product selection legislation. This produced a number of very interesting observations, including the following:

In their attitudes toward the legislation 34 percent of the physicians either strongly or mildly favored its enactment, while just slightly over 50 percent of the pharmacists were strongly or mildly in favor of the repeal of the "antissubstitution" provisions of the Pharmacy Act. More physicians than pharmacists were neutral about its enactment (21.5 percent compared to 11.8 percent) while the percentage strongly or mildly opposed was roughly the same. Only a small percentage of physicians or pharmacists was actively involved in either supporting or opposing the legislation - 3.6 percent of physicians actively supporting, 9 percent opposing; 11.3 percent of pharmacists actively favoring, 11.8 percent actively opposing.

The attitudes of physicians and pharmacists regarding the financial impact of the Act were remarkably similar. Over 60 percent of both groups felt the provisions of the Act would result in moderate or substantial savings for all consumer age groups; a very small proportion felt the Act would result in an increase in costs, while about 25 percent of both groups felt that there would be no cost savings involved.

A number of questions was directed to whether or not the physicians and pharmacists considered generic equivalency to be "generally synonymous" to therapeutic equivalency. Two specific questions were asked. The first



question was whether they felt that brands of drug products which were generically equivalent were essentially equivalent in therapeutic effect.

The second question was whether they felt that differences between generically equivalent drug products were significant enough to preclude freely interchanging brands.

Interestingly, more physicians than pharmacists felt that there were no significant differences in generically equivalent drugs, while more pharmacists than physicians felt there was a significant difference for many drug products. There was no marked difference of opinion between the two groups in their feelings that there was a significant difference for a few drugs or that there was no significant difference for most drug products.

Of particular interest is the difference in attitudes of physicians and pharmacists regarding whether pharmacists possess the technical knowledge to safely substitute one brand of drug product for another of the same generic name. This is the essential underlying assumption of the Act which makes it both theoretically as well as operationally effective. It is not surprising that pharmacists overwhelmingly (82.5 percent) agree either moderately or strongly with this assertion. However, as many as 16 percent of pharmacists either moderately or strongly disagreed that pharmacists were technically prepared to safely substitute one brand for another.

Over 60 percent of physicians felt that pharmacists were technically qualified to exercise judgment on safely substituting drug products while over 34 percent either moderately or strongly disagreed with this contention. This attitude on the part of physicians is particularly significant in that the decision to allow substitution (that is, by not writing "D.A.W." on the prescription order)



will be influenced by the physician's knowledge of the pharmacy or the pharmacist who will dispense the prescription or of the pharmacy profession in general. Almost 26 percent of physicians indicated that they will definitely be influenced, 34 percent will be influenced to some extent, while 32 percent responded they will not or probably will not be influenced by their knowledge of the pharmacy or pharmacist who will dispense the prescription order.

The two most direct influences on the effectiveness of the legislation will be -- (1) the practice of physicians in allowing or forbidding substitution and (2) the practice of pharmacists in actually substituting as well as in encouraging patients to request substitution.

To what extent will physicians encourage or discourage substitution and what are the characteristics associated with each type of physician?

Almost 56 percent of physicians will encourage substitution, either selectively or generally. Twenty-seven and a half percent will not encourage substitution and almost nine percent will actively discourage the practice.

If a prescription is written by the nonproprietary (generic) name of the drug, the pharmacist is free to dispense the prescription with any product which meets the generic definition; thus the Michigan law has no effect on prescriptions that are written generically.

Physicians in the sample, when asked whether their practice requires substantial prescribing of drugs, 38 percent of the respondents indicated that they issue "one or more prescriptions for practically every patient." An additional 41 percent said they prescribe frequently but not for all or most patients. Fewer than 20 percent of physicians replied that they prescribe infrequently or practically never. This confirms our assumption, which also is supported in the literature, that prescribing more than one drug to many if



not to all patients has become a common practice for most physicians.

A more surprising fact was that a substantial portion of physicians reported they prescribe generically either "whenever possible" or "sometimes." Over 23 percent indicated the former and an additional 38 percent the latter. This means that the current legislation will have very little effect on their generic prescriptions, since there is no requirement that a "less costly" generic drug product be dispensed to the consumer.

Two other series of questions are of particular interest. One set was to determine how well physicians and pharmacists could identify "generically equivalent possible substitutes" for seven identified drugs. For each of seven drugs listed as the "Prescribed Drugs," a second list of "Possible Substitutes" was provided. The physicians and pharmacists were asked to identify those drugs in the "Possible Substitute" list which were "generically equivalent" to the designated "Prescribed Drug."

The average proportion of those physicians correctly identifying drugs which were in fact "generic equivalents" was below 30 percent. An average of 36.3 percent incorrectly identified as "possible substitutes" those drugs which were definitely not generically equivalent and therefore not substitutable.

The pharmacists' record was somewhat better. The average correct identification of the drugs which were generic equivalents was about 57 percent. The average percentage of pharmacists who identified as "generically equivalent" those drugs which definitely were not equivalents was 36 percent.

Our subsequent research involved an analysis of a sample of actually prescribed and dispensed drugs. The method by which the sample was drawn, the



determinants of sample size, and the actual operation of the multi-stage equal probability sampling are described in detail in a paper on "Probability Sampling of Prescription Order Forms" presented at the 1977 Annual Meeting of the American Pharmaceutical Association. A copy of this paper has also been made available to the Committee.

In the interest of conserving time, I will not review the details of the sampling methodology but rather will summarize by saying that the data upon which we base our conclusions were derived from a stratified probability sample of about 31,000 prescriptions in the State of Michigan for the year immediately prior to and 33,000 and 22,000 in each of the two years following the implementation of the legislation in Michigan. A comparable data base was developed in Wisconsin with a slightly smaller sample of 25,000 prescriptions in the first and second years, and 18,000 in the third year of the study. These numbers are the sample sizes for the completely recorded sample, and do not include additional scanned prescriptions, which constitute approximately an additional half a million prescriptions per year in each of the states.

Thus, we have generated and have computerized a data base from which to analyze and answer questions related to drug product selections covering a three-year period and containing completely recorded information regarding over 154,000 prescriptions. We believe this is the largest, most carefully compiled and most useful data set available anywhere in this country. Most important, however, is the fact that these data have allowed calculations to be made on actual prescribing and dispensing information, not merely on the basis of some arbitrary schedule of prices which may or may not accurately reflect what is actually charged.

I should also point out that in collecting and recording the data we had a great deal of difficulty in finding an existing drug identification system which would allow us to capture the key characteristics of the drug product or



drug entity which had shown up in our sample. Thus we had to develop our own drug product coding system, the details of which are contained in a paper, Development of a Comprehensive Drug Product Coding System, which is included with those made available to the Committee.

We now are in a position to analyze the process of drug product choice and to answer questions about the effectiveness of drug product selection legislation to date. The specific questions which flow from the description of the process by which savings ensue from drug product selection legislation are as follows:

1. What proportion of prescriptions fall into the category of "multiple source drug entities?" The answer to this question determines the perimeter of the area in which product selection can be effective.
2. Is there a significant differential in the prices of products within the same drug entity? The answer to this question determines whether there is the potential for significant savings to be achieved even if the number of multiple source drug entities is large.
3. Based on the answers to questions 1 and 2, what is the range of potential savings from drug product selection, assuming a number of possible alternatives, such as substitution of the lowest priced generically equivalent product; or substitution of the median priced product, or various other alternatives?



4. To what extent is the option to substitute foreclosed by the actions of prescribers in requiring the pharmacist to dispense the specific product which was identified in the prescriptions? The answer to this question will disclose the extent and degree of restriction imposed upon the dispensing pharmacist and thus will identify the area in which the pharmacists may exercise discretion.
5. To what extent do pharmacists actually exercise the option to select less costly products within the scope of prescriptions for multiple source entities and for prescriptions which do not contain any prohibition? A subsidiary question relates to the choice of products selected when substitution does occur. The answer to these questions produces the final answer to the question of the extent of actual savings and allows a determination to be made of the size of the gap between potential and actual savings.
6. Is there a change over time of any of the following conditions:  
The proportion of prescriptions for multiple source drug entities;  
the price range of products within drug entities; the proportion of prescriptions which are written generically; the extent to which physicians require that drugs be "dispensed as written";  
the rate of drug product selection exercised by pharmacists?

I am sure that there are many other questions which could be asked; some even for which we have the data to answer. But the questions listed here are the ones which we believe most directly affect the process of drug substitution and



thus the resulting savings impact.

Now to answer the questions that were raised:

There are a very substantial number of entities for which there are two or more generically equivalent products. In each of the years studied, the proportion of multiple source drugs was over 51% in Michigan and 52% in Wisconsin. Thus, the answer to the first question of whether there are enough prescriptions for multiple source entities to provide the opportunity for savings from drug product selection -- the answer is definitely and emphatically yes.

Knowing that many products exist from which choices can be made is one thing. Knowing whether there are price variations among the products which could result in savings is quite another.

The fact of the matter is that there is a substantial variation of the prices of products within many entities. Our analysis looked at the difference in prices between the drug product actually prescribed and the price of the drug product actually dispensed. Thus, our estimates show the minimum amount of savings. There may very well have been lower priced products which could have been dispensed in substitution for the product prescribed. However, we calculated the prices of the products actually dispensed. But we also have the data which would allow further analysis to determine whether any additional savings could have occurred if a less costly product had been dispensed instead of the one actually selected.

For the first year after the Michigan law became effective, there was approximately a 21 percent savings (or \$1.14 savings per prescription) when substitution occurred. The second year's savings were remarkably close being



approximately 20 percent or \$1.15 per prescription. The amount of savings in Wisconsin for the six month period of the second year (which was the first six months of allowable substitution in Wisconsin) was \$.87 a prescription, or 17 percent.

Savings from substituting a lower priced generically equivalent drug product for a higher priced prescribed one within the same drug entity is directly attributable to the introduction of the drug product selection legislation.

But an important and related issue is the question of price differential, or price savings, as a result of drug product selection which has been practiced for years before the recent acts became effective and which has never really been thought of as drug product selection -- that is, what happens when prescriptions are written generically. In these cases -- and our findings that between 20 and 25% of prescriptions are written generically is much more than had previously been thought -- a choice has to be made by the pharmacist as to which product to dispense. Thus in more than one out of five of all prescriptions for drug entities in which there is more than one product, pharmacists must make a choice among two or more products to be dispensed. The importance of this practice to cost savings is in terms of the choice of the product to be dispensed -- is it the most expensive, the average priced or the lowest priced, of products which could be dispensed? Whichever the choice, it will have a substantial impact on drug costs, particularly since we now know that generically written prescriptions account for a very substantial proportion of all multiple source entity prescriptions.



Interestingly enough, the Michigan law is silent when it comes to generically written prescriptions. The Michigan law states that:

"When a pharmacist receives a prescription for a brand name drug product..." (emphasis added) and then proceeds to define what is to happen, totally ignoring the cases of generic prescribing."

The Wisconsin law, on the other hand, directly deals with the issue of generic prescribing by requiring that:

"If a drug product listed in the formulary is prescribed generically, the prescription should be filled with one of its drug product equivalents having a cost not higher than the average wholesale cost of all its drug product equivalents."

The key issue, though, is how the price of the product actually dispensed compares with the average price of products within the same drug entity, any one of which legally could have been dispensed in filling the prescription.

Our results provide very satisfying evidence to demonstrate that pharmacists filling generically written prescriptions do, in fact, choose products whose price is below the median price and thus are lower priced than would be the case of a prescription in the same drug entity which was dispensed as written. However, the difference in price between the price of the product dispensed and the average price of the products in that drug entity is not as great as the difference between the price of the drug dispensed and the price of the drug prescribed when substitution takes place.



The comparisons in Michigan are: \$.65 "saved" per prescription for generically written prescriptions during the first year compared to \$1.14 actual savings when substitution was involved. Comparable figures for the second year in Michigan are \$.68 "saved" for generically written prescriptions and \$1.15 actually saved by substitution. This means that while lower than median priced drug products are dispensed when prescriptions are written generically, this does not result in as great a savings as when the process of substitution is actually involved and a drug product different from the one specifically prescribed is dispensed.

The pattern of savings from generic prescribing also prevails in Wisconsin. The cost of the products selected to fill generically written prescriptions is below the average price of drug products within the same drug entity. However, an interesting finding is that the amount of difference in the price of products dispensed and the average price of products within that entity was much smaller in Wisconsin than in Michigan. For the first six months of the Wisconsin legislation, \$.14 was "saved" in dispensing generic prescriptions compared to \$.74 for the corresponding year in Michigan.

The two conditions necessary to achieve savings from drug product selection obviously are present to the extent that the potentials for savings not only exists but is substantial.

The next question to be asked is what possible barriers exist to achieving the maximum potential savings.

One possible impediment to achieving potential savings is if prescribers frequently exercised their option to require the pharmacist to dispense the specific product ordered in the prescription. Such a restriction would only be



meaningful for multiple source prescriptions. An order to "dispense as written" for a single source product would have little meaning since there would only be the one product which could be dispensed.

Both in Michigan and Wisconsin, as in almost all other jurisdictions, physicians specifically retain the right to order that the specified drug be dispensed as written (or some other terminology having the same effective meaning). And yet, the option to exercise this restraint is practiced very infrequently. Whether or not this comes as a surprise reflects one's preconceived notions. But the facts are that in the first year of the operation of the legislation in Michigan only 6.4 percent of prescriptions bore the handwritten order that the prescription be dispensed as written and the following year the proportion had dropped to 4.0 percent. (As an aside, it's interesting to note that the requirement that the prescription be "dispensed as written" was applied just as frequently to single source prescriptions for which no substitution was possible, let alone whether it was advisable, and even to generically written prescriptions which in no way could be "dispensed as written.")

The experience in Wisconsin followed the same general pattern with 3.6 percent of the prescriptions requiring that there be "no substitution" during the one year in which the legislation was effective.

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Based on the foregoing process of analysis it is possible to now calculate the potentials for savings from drug product selection. In other words, the information we now have allows us to project accurately and precisely the area of possible savings and to measure the projection of actual savings against the potential.



In order to calculate the savings from substitution, as well as the potential savings from substitution, it is necessary to know the price of the product dispensed as well as the price that would have been charged if the product that was prescribed had been dispensed. When a substitution takes place, however, only the price of the dispensed product is known. Therefore, a method had to be designed which would allow an estimate of the price of the prescribed product to be made.

The comparison thus would be between the actually known price of the product dispensed and the price of a comparable, randomly selected prescription that was dispensed as written. If each substitution is matched with another prescription which was dispensed as written randomly sampled from a group similar to the substituted prescription, then the average price differences can be computed for all the resulting matched pairs to obtain an estimate of the average savings due to substitution.

This technique requires that the "matched" prescription must be reasonably comparable to the substituted prescription. Three characteristics have been identified as important for comparability. The "matched" prescription should be from the same time period, it should be for approximately the same quantity, and it should be from the same pharmacy or from a pharmacy with similar characteristics. (Any of these matching characteristics could be relaxed, or other criteria could be introduced. However, any such criteria affect only the strength of the statistical test for a difference in prices; the validity of the test flows from the random selection of the substituted or generically written prescriptions, and their matches).



The question of whether the prices of dispensed and prescribed products differ when substitution takes place can be answered by matching each actually substituted prescription with a comparable prescription for the same product that was dispensed as written and then comparing the prices of the matched pairs.

To answer the question of whether the price of the product dispensed was lower than the average price of all products within that entity, it is necessary to match each actually substituted prescription with a randomly selected comparable prescription for any product within that entity, and then compare the prices of the two.

A third important question relates to the price of the products that are selected in filling generically written prescriptions. This can be examined by matching each generically written prescription with a randomly selected comparable prescription for any product within that entity, and then comparing the prices of the two.

Comparisons have been made to answer all three of these questions. This was done in two different ways: First, by matching prescriptions within the dispensing pharmacy where such matches could be found, and second, by matching substituted prescriptions with those randomly selected, which had been "dispensed as written" in any pharmacy in the sample.

The latter method yields the largest number of matched prescriptions and thus the method we used for our calculations. Tables A, B, and C show the prices and their differences, using this method and the t-tests of the hypotheses that the differences are zero. (Comparison of these prices with those found by matching within pharmacies showed no meaningful differences between the two methods.)



TABLE A

Prices of Substituted vs Non-Substituted Prescriptions,  
Michigan Years 2 & 3 (First Two Years of Allowable Substitution),  
Comparing Similar Prescribed Products

|        | Number of<br>Matched<br>Prescriptions | Average<br>Price of<br>Dispensed<br>Product | Average<br>Price of<br>Matched<br>Prescriptions | Average<br>Price<br>Difference | Standard<br>Deviation<br>of the<br>Difference | Paired<br>t-<br>Statistic |
|--------|---------------------------------------|---------------------------------------------|-------------------------------------------------|--------------------------------|-----------------------------------------------|---------------------------|
| Year 2 | 463                                   | \$4.37                                      | \$5.51                                          | \$-1.14                        | 2.41                                          | -9.92*                    |
| Year 3 | 521                                   | 4.72                                        | 5.87                                            | -1.15                          | 2.54                                          | -10.34*                   |

\*Significant at  $P < .00005$

TABLE B

Prices of Substituted vs Non-Substituted Prescriptions,  
Michigan Years 2 & 3 (First Two Years of Allowable Substitution),  
Comparing Similar Prescribed Products

|        | Number of<br>Matched<br>Prescriptions | Average<br>Price of<br>Dispensed<br>Product | Average<br>Price of<br>Matched<br>Prescriptions | Average<br>Price<br>Difference | Standard<br>Deviation<br>of the<br>Difference | Paired<br>t-<br>Statistic |
|--------|---------------------------------------|---------------------------------------------|-------------------------------------------------|--------------------------------|-----------------------------------------------|---------------------------|
| Year 2 | 565                                   | \$4.56                                      | \$5.49                                          | \$-.92                         | 2.21                                          | -9.94*                    |
| Year 3 | 653                                   | 4.79                                        | 5.75                                            | -.96                           | 2.46                                          | -9.93*                    |

\*Significant at  $P < .00005$

TABLE C

Prices of Generically Prescribed Entities Compared to  
Prices of Products Within That Same Entity,  
Michigan Years 1, 2, & 3

|        | Number of<br>Matched<br>Prescriptions | Average<br>Price of<br>Dispensed<br>Product | Average<br>Price of<br>Matched<br>Prescriptions | Average<br>Price<br>Difference | Standard<br>Deviation<br>of the<br>Difference | Paired<br>t-<br>Statistic |
|--------|---------------------------------------|---------------------------------------------|-------------------------------------------------|--------------------------------|-----------------------------------------------|---------------------------|
| Year 1 | 708                                   | \$3.83                                      | \$4.43                                          | \$-.60                         | 1.97                                          | 8.05*                     |
| Year 2 | 615                                   | 3.90                                        | 4.53                                            | -.64                           | 2.05                                          | 7.65*                     |
| Year 3 | 404                                   | 4.07                                        | 4.81                                            | -.74                           | 2.25                                          |                           |

\* Significant at  $P < .00005$



The results displayed in the tables show that a statistically significant price reduction was obtained by substitution. The price of the substituted item also was significantly below the average price for all drug products dispensed for the same entity. The average price reduction for a matched substitution pair within the state was \$1.14 (or 21%). This shows that substantial savings were realized by substitution.

The price of the substituted product dispensed was \$.92 (17%) less than the price of other products within the same entity for matched pairs within the state. This shows that pharmacists do dispense lower priced products (i.e., products in the lower half of the price range for the entity) when substituting one product for another.

For generically written prescriptions, the price of the product dispensed was \$.64 (14%) and \$.72 (15%) less than the price of prescriptions for all products within the same entity, dispensed in the state during three years. This demonstrates that when filling a generically written prescription pharmacists dispense a product in the lower half of the price range for products in that entity. Savings incurred when prescriptions are written generically, however, were not as great as the savings resulting from substitution.

To calculate the potential savings from substitution reliable estimates of the following information is required:

1. The total number of prescriptions dispensed during the year.
2. The proportion of this number which involve multiple source drugs.
3. The average savings if substitution was exercised.



The calculation would thus utilize the following formula:

$$\text{Total Potential Savings} = \text{No. of Substitutable Prescriptions} \\ \times \text{Estimate of Average Savings}$$

The estimate of the number of prescriptions dispensed in Michigan during the year ranges between 26 and 34 million. If the proportion of these which involve multiple source drugs is approximately 51 percent, this means that the prescriptions which are susceptible to drug product selection are between 13.3 and 17.3 million prescriptions per year.

Our findings indicate the approximately 20 percent of these prescriptions for multiple source drug entities are written generically and even though these may be influenced by drug product selection legislation, for our present purposes these generically written prescriptions will be considered separately.

If we further reduce the number of the pool of prescriptions for which potential savings are possible by the proportion of them for which the prescriber forbids substitution, then the total must be reduced by a further 4 percent (the current rate of D.A.W.'s).

The final range thus becomes between 10.2 and 13.3 million prescriptions per year.

The average savings from substitution amounts to approximately \$1.15 per prescription, and if we assume that this average savings is reflective of the average savings on all substitutable prescriptions, then the total potential annual savings in Michigan is between \$11,730,000 and \$15,295,000. If to this were added the savings from dispensing lower priced products when filling generically written prescriptions, then the total potential annual savings would amount to



between \$13,538,800 and \$17,647,800. This, of course, is just for Michigan. Comparable data could be developed for each of the other states, whether or not drug product selection law exist.

It should also be emphasized that no actual or potential savings from refilled prescriptions has been taken into account. Thus, the estimates of both actual and potential savings has been substantially underestimated, probably more than offsetting any over-estimate of savings resulting from the assumption that average savings of actually substituted prescriptions is reflective of the average potential savings of all substitutable prescriptions.

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But, just because savings, and very substantial savings at that, are potentially available does not mean that they necessarily will be realized. The final element in the process which must be satisfied before potential savings become actual savings is that substitution must occur or that prescriptions must be written generically and filled with "lower" cost products. The potential for savings may be substantial but may never be realized if the actual process of substitution does not occur.

The experience in Michigan does not provide the basis for any degree of confidence that the potential for savings is being realized to anywhere near the extent which is possible. Nor does the evidence indicate that the trend toward achieving a greater degree of the potential is increasing at anything other than a snailspace even though admittedly the legislation has only been in operation for three years which is a relatively short period on which to base projections.



All the evidence we have gathered and received, and which we have already summarized in this report, seems to indicate that pharmacists have a substantial, largely unkindered, opportunity to choose among generically equivalent products. Reports by the professional association of Michigan pharmacists seem to indicate that pharmacists look forward to the opportunity to exercise their professional judgment in selecting a less costly product to dispense when given the opportunity. In fact, a recent survey conducted by the Michigan Pharmacists Association of Michigan pharmacists indicated that:

"Fifty-five percent of community pharmacists responding to a membership opinion survey ... report that they practice drug product selection 'frequently' of 'whenever possible.'"

But, despite these indications that the process of drug product selection should be occurring frequently, and thus generating substantial savings for consumers, the facts do not support this conclusion.

During the first year of the operation of the legislation in Michigan, only 1.49% of all prescriptions for multiple source entities (.67% of all prescription orders written) were actually substituted. During the second year of the legislation only 1.50% of all prescriptions for multiple source entities were substituted. Thus, during this first two-year period, not only was there little use of the opportunity to substitute but there is no indication that the rate of substitution increased very rapidly, if at all.

One reason given for the low rate of substitution in Michigan was that the original act required a "purchaser request" before the pharmacist could exercise his/her option to select a product to dispense different from the one prescribed. There was considerable controversy over the meaning of this requirement, which was argued as being ambiguous at best, but the issue was brought to a



head by a declaration of the State's Attorney General who found that the language of the act clearly required the prior request of the purchaser before the pharmacist could exercise any option. As a result of this decision, a campaign was waged to amend the legislation in order to allow pharmacists the option to initiate the process of drug product selection. This was accomplished by an amendment, which became effective on January 11, 1977, and eliminated the requirement that "... the purchaser request..." The amended version of the law states: "When a pharmacist received a prescription for a brand name drug product, the pharmacist may, or when a purchaser requests a lower cost generically equivalent drug product, the pharmacist shall dispense a lower cost but not a higher cost generically equivalent drug product..."

We have attempted to measure the effect of removing the requirement for the purchaser's request on the rate of substitution. During the period covered by the data collected for the second year there were only four months when the amended law applied. Thus, it may be too early to measure the impact of removing this condition. Nevertheless, we applied what is known as a "time series" analysis to the data to see whether any difference occurred at or after the point in time when the amendment became effective. Our analysis failed to indicate any effect on the rate of substitution other than that which could be explained by the very slight increase in the rate of substitution over time.

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What we have tried to do in this paper is to present the picture of the potential impact of drug product selection legislation and to compare it with the actual record of performance. Obviously there is a wide gap between the two. However, it would be both inaccurate and misleading not to acknowledge the extent



of savings which has resulted from the operation of this legislation.

Based on the range of estimates of the volume of prescribing in Michigan as being between 26 and 34 million prescriptions per year, applying the difference in prices actually found between the prescribed and dispensed products and applying the actual rate of substitution experienced in Michigan, we calculate that the actual reduction in the cost of prescribed drugs, as the result of drug product selection, falls somewhere within the range of \$200,000 and \$300,000 a year.

We don't suggest that this amount of savings isn't significant. It is and should be acknowledged to be. However, when one compares this amount to the amount of potential savings, which we have calculated to be between 16 and 21 million dollars a year in Michigan, one is left with the uneasy feeling that time alone may not achieve the desired goals. However, I should tell you that while we have not yet completed our collection and analysis of data from our third field survey, which will provide us with a fourth year of data from which to project trends, our very sketchy and preliminary observation of the data as they are coming in seems to indicate that there is a very substantial increase in the extent of drug product substitution, our impression being that it may even be as high as 10 to 15 percent of multiple source entity prescriptions. If this impression is confirmed when we analyze the complete data, then it may be that the low rate of drug product selection during the first couple of years may be only a temporary phenomenon until the provisions of the law become better known. We certainly will make this analysis available as soon as it is completed.

On the other hand, if we continue to observe substantial and continuing and only very slowly diminishing gap between actual and potential savings



resulting from the low rate of utilization of the opportunities afforded by the legislation, it may be necessary to consider changes in the legislation which would encourage greater utilization of the process of drug product selection in order to assure that its potential benefits are to be realized. Encouragement probably can take many forms. The two most obvious ones can be characterized as incentives or directives. The legislation can build in greater incentives for pharmacists to exercise the option to dispense less costly products more frequently, or the legislation can build in provisions that pharmacists are required to dispense in conformity with certain conditions specified in the legislation. There are examples of variations and combinations of both these approaches which could be considered.

As examples of provisions which would provide greater incentives for pharmacists to practice drug product selection would be the following:

1. By providing legal protection against additional liability for practicing drug product selection.
2. By minimizing in every way the difference in administrative requirements between practicing drug product selection and not practicing it:
  - (a) Reduce extra labeling, recordkeeping, and receipt provision requirements to a minimum, when drug product selection occurs. It would seem appropriate (when not specifically forbidden by the prescriber) to label the product dispensed with its generic name, and the name of the manufacturer (or distributor).



- (b) Any dispenser of drug products to the public must meet all requirements of drug product selection as does a dispensing pharmacist.
  - (c) A non-pharmacist can be the individual who informs the purchaser that drug product selection can occur, as well as the options available.
3. By assuring the pharmacist that he will not stand to lose financially from exercising drug product selection. In fact, the legislation should provide the incentive to share in the savings so as to encourage the practice of drug product selection. The dispenser should not be expected to financially underwrite any aspect of drug product selection, and any increase in work associated with drug product selection should have the work's associated cost paid by the person (or third-party payor) for whom the service is provided.

Examples of possible regulatory provisions are much more difficult to find, but two fairly recent illustrations come to mind. The first is of the PAR COST program in Ontario which establishes maximum reimbursable costs for the drug entities contained within the PAR COST Manual. This provincial government program applies mainly to prescription drugs dispensed to persons covered for benefits under the provincial welfare program or programs for the elderly, but the agreements to participate in the program extend to most retail pharmacies in the province.

The other example of a regulatory program is the Maximum Allowable Cost ("MAC") program operating at both the federal and state levels in the United States.



The significance of these programs is that they provide a schedule of maximum payments to pharmacists for specifically identified drug entities dispensed under programs covered by the MAC regulations. The federal MAC program has identified a number of multiple source drug entities for which it will pay a maximum ingredient cost plus dispensing fee when a product within this entity is dispensed. The incentive is thus for the pharmacists to dispense a product within the entity which has a cost at or below the limit paid by the MAC program.

The state MAC programs are similar to the federal program except that they also include maximum reimbursable costs for single source as well as multiple source drug entities.

Since I understand that representatives from the agency which has the responsibility for administering the MAC program will appear before this Committee, I will leave it to them to describe in greater detail the details and operations of that program.

Before closing, however, I should like to comment briefly on a number of additional papers which have been produced by members of our research team or by others in association with our activities. Copies of each of these papers are being made available to the Committee.

Three additional papers were prepared for presentation at the recent Invitational Dissemination Workshop on Drug Product Selection Legislation held in Detroit, Michigan on April 13 and 14, 1978. The Workshop was jointly sponsored by the National Center for Health Services Research of H.E.W. and the drug study group of the Department of Community Medicine of the School of Medicine of Wayne State University.



These three papers were:

- "Issues and Alternatives Involved in Achieving Maximum Public Benefit" (from Drug Product Selection Legislation) by Carolee A. DeVito;
- "Implementation and Implications of Applying Drug Product Selection to Selected Populations" by Dr. Allan E. Dyer of the Ontario Ministry of Health;
- "Alternatives for Public Policy Decisions" by Dr. Albert I. Wertheimer of the University of Minnesota.

Nine additional papers were presented at the recent Annual Meeting of the American Pharmaceutical Association in Montreal, Quebec on May 17, 1978. The papers, all prepared by the members of the drug study research team, were the following:

- "Cost Patterns for those Drugs With A MAC Ceiling in the State of Michigan"
- "Incentives for Drug Product Selection"
- "Actual and Potential Savings from Drug Product Selection: A Comparison of Two Approaches"
- "Effect of Removing 'Consumer Request' Requirement from Drug Product Selection Legislation"
- "Relationships Among Pharmacy Characteristics and Inventories for Common Multiple Source Entities"
- "Drug Product Selection Legislation: How Can the Public Gain Most from this Kind of Legislation?"
- "Analysis of Actually Substituted Prescriptions"
- "Bioavailability Issues in Drug Product Selection Legislation"
- "Product Choices of Pharmacists When Filling Generically Written Prescriptions"

We would be most happy to answer any questions that members of the Committee may wish to ask. We would also provide any additional information that the Committee may desire.

Thank you very much for your attention.



Mr. ECKHARDT. Doctor, you said in your testimony here that the proportion of physicians correctly identifying drugs which were in fact generic equivalents to the seven brand name drugs was below 30 percent, and that the proportion of direct identification for pharmacists was only 57 percent. Although the pharmacists rate better, I think one may assume that the physician, in prescribing the particular drug, would know what the drug did, so, even though he might not know that other drugs were generic substitutes, the danger of an error would be relatively slight if he were in fact familiar with the drug prescribed.

On the other hand, if the pharmacist is incorrect by a measure of 57 to 43 percent, in that ratio, his making a mistake and substituting something that was not a generic equivalent could be quite disastrous or at least an unfortunate mistake. Would that militate in favor of establishing by some authority a list of equivalent generic drugs?

Dr. GOLDBERG. I think there are at least two aspects of an answer to your question, Mr. Chairman.

The first is the results of a study we did of attitudes of physicians and pharmacists before the legislation was effective. We wanted to know the attitudes of the two professions were about this legislation that was being debated, which was just in the process of being passed and which would become effective in a few months. So we asked them a lot of questions about their attitudes.

In addition to that, we simply wanted to test how much both physicians and pharmacists knew about a range of generically equivalent drugs. The results showed that physicians were simply unaware of all the drugs that were generically equivalent or not equivalent, which probably explains some of the testimony that was provided earlier in the day saying physicians simply are not as well trained as pharmacists are in terms of knowing what drugs are available on the market and all the details on the drugs.

However, it does not mean that the pharmacist not knowing it simply restricts the range of the product with which the pharmacist is familiar.

Mr. ECKHARDT. I understand. What that would probably do is cause him to substitute to only 57 percent of his potential. He would not be guessing in the other 43 percent.

Dr. GOLDBERG. Exactly. He would probably restrict his substitution to that range of drugs with which he was familiar. This is made plain what we pointed out earlier, that the amount of savings that we identified was of the drug prescribed and the drug dispensed. There may have been ones the pharmacist did not know about that were even lower priced, but it is beyond his range of knowledge of experience. That is true. I think that would be true whether you had a positive formula or negative formula or no formula, there would still be drugs with which physicians or pharmacists are similarly unfamiliar. I do not think it has an important impact on legislation.

Mr. ECKHARDT. I think we could probably presume a responsible, well-trained pharmacist would only operate within the range of his actual knowledge, just as the doctor making the original prescription would also operate.

Dr. GOLDBERG. I think so.



Mr. ECKHARDT. I am interested in your summary of the Michigan law on page 7 of your testimony. In the first place, the law does not seem to go quite as far as the proposed bill here with respect to what kind of generic drug substitute would be used. It requires that it not be of higher cost than the drug prescribed, but it does not provide that it should be the lowest cost amongst the generic substitutes. It appears to me that the bill before us requires that it be the lowest cost. It says the prescription can be filled with a substitute drug if:

The cost of the substitute drug to the patient for whom the prescription is made is less than the cost to the patient of (1) drug identified and (2) of any other substitute drug in the inventory of the pharmacist at the time such pharmacist fills or refills the prescription involved.

I have some question in my own mind, and I would like to have your opinion on it, as to whether once the pharmacist decides to make the substitution, he should be required to pick the lowest in the inventory. There may be some range of judgment with respect to the quality or the dependability of the drug. Since in the first place he does not have to veer from a specific prescription, I see no reason why, once he decides to do it, he should be bound necessarily to the lowest cost generic substitute. I do not find that at least in your summary of the Michigan law. Of course, I do not have the act before me. Whatever the law provides we do have these two possible choices.

Dr. GOLDBERG. I think you have raised a question that leads to a fairly complicated subject. To answer most directly, in our analysis of the Michigan law we were talking about the lack of provision dealing with prescriptions that are written generically. With a drug that is written generically in Michigan, the pharmacist has no guidance whatsoever from the legislation as to whether he should dispense the medium or the highest or the lowest priced product. The Michigan law is completely silent on prescriptions that are written generically. That is different than, for example, the Oregon legislation which says that when a prescription is written generically the pharmacist will fill that prescription with the lowest priced drug product in his inventory which in his professional opinion is substitutable. So it gives the pharmacist the protection of exercising his professional judgment but indicates the public policy that the lowest price one should be dispensed that meets his professional standards.

The Michigan law, as I say, is silent when it comes to generically written prescriptions. Michigan law is not silent when it comes to nongenerically written prescriptions. If a physician writes a prescription for a brand named drug and a pharmacist substitutes, he must substitute a lower priced drug product.

Mr. ECKHARDT. That is the same as the Federal proposal except the Federal goes farther and says if he makes a selection it must be the lowest price. I do not think that is the case in the Michigan law.

Dr. GOLDBERG. It is not.

Mr. ECKHARDT. Maybe the Michigan law is more desirable for the Federal proposal. It is hard for me to see, if he is not compelled to substitute a drug, why, once he decides to do so, he should then be compelled to use the lowest price. Besides that, you bring into the



question what his professional judgment was, and whenever we bring in such subjective questions we raise different questions, I think, of enforcement.

Dr. GOLDBERG. I think, Mr. Chairman, our experience in both Michigan and Wisconsin, which simply says dispense a lower priced drug, has led us to conclude that pharmacists do dispense a substantially lower priced drug product when substitution occurs. As a matter of fact, they go further than that.

Mr. ECKHARDT. The Michigan law is more specific and is more protective of the consumer in this respect, as I read your analysis here. It provides a standard of lower cost to the customer, whereas the Federal proposal here merely says that the cost of the substitute drug to the patient for whom the prescription is made is less than the cost to such patient of the drug identified. That can be a penny less to the patient, but to the pharmacist it could be a dollar less, so he could put the 99 cents in his pocket and there would be a considerable incentive for him to use the generic drug that is cheaper but it would not necessarily benefit the patient. It would seem to me the highest price would end to be the magnet toward which price would flow under this proposed Federal language, whereas that is not true in Michigan.

Dr. GOLDBERG. That is right.

Mr. ECKHARDT. But, on the other hand, in the Michigan language since it appears that there is a very rigid standard, it might also tend to be a little too rigid. A person might find himself in violation because they did not make a precise calculation, which might be a little difficult to make off the cuff, and it might make him tend not to use a substitution in the first place. So it seems to me, that we have here again a question of balancing incentives, and I would like to have your comment as to what we ought to do about that.

Dr. GOLDBERG. I think your observation, Mr. Chairman, is very correct. If you simply say as the Federal law apparently does of passing on some savings to the consumer, it may be very minimal. On the other hand, the Michigan law provides that all savings must be passed on to the consumer, which minimizes the incentive for pharmacists to engage in drug product selection. I think some sort of median point should be reached whereby a substantial portion of the savings is passed on to the consumer, which I think should be the intent of the legislation, but some incentives should remain—financial incentives—for pharmacists to engage in drug product selection.

So I think that the law should somehow provide that either a set portion of savings be passed on to the consumer or written in such a way to indicate that the majority of savings should accrue to the consumer. But I think it should specify the consumer's interest should be protected by requiring the passing on of savings.

Mr. ECKHARDT. Dr. Lower, do you have any questions?

Dr. LOWER. You just, in the last few minutes, reiterated the fact that something over 20 percent of prescriptions in Michigan were written generically. Just as a matter of curiosity, that contrasts sharply with the national generic prescription ratio that is found in the national prescription audit.

Dr. DICKSON. That is 20 percent of multiple-source prescriptions.



Dr. LOWER. Let me clarify that for the record. I note that only 11.7 percent in the national audit were generic prescriptions. So you are saying the difference is in the base. Your 20 percent is of multiple-source drugs only.

Dr. GOLDBERG. Yes.

Mr. ECKHARDT. Mr. Greene, do you have any questions?

Mr. GREENE. How many States have enacted drug substitution legislation that either allows or requires substitution of drugs?

Dr. GOLDBERG. I will ask Dr. Dickson to comment further, but we have provided you with an analysis of the 35 laws which have, as of the time we did it, allowed drug substitution to take place. Since then, 5 additional States have enacted legislation, so there is at latest count approximately 40. They are going very fast. It may be 41 or 42 or 43 as of the moment. But we know of a minimum of 40 jurisdictions including the District of Columbia that have enacted the legislation, and we have provided details of 35 of those laws.

Dr. DICKSON. We would only disagree on the number, I suppose. I know the testimony later today will say 39. It is in a state of flux but the number is going up steadily.

Mr. GREENE. The Federal proposal, H.R. 1963, in the case of a prescription that is written generically, requires, mandates, that the pharmacist substitute a drug whose cost to the patient is less than the cost to the patient than any other substitute drug in the inventory of the pharmacist at the time the pharmacist fills or refills the prescription. There have been continuing expressions of concern that our health system is not fully and properly utilizing the educational training and experience and knowledge of our Nation's pharmacists, and numerous suggestions have been made as to how we could more properly utilize the pharmacist's talents in the selection of drugs.

Do you think a requirement such as this may run counter to any efforts to give more latitude to pharmacists to use their educational training and background and skills in the selection and filling of prescriptions, a mandate such as this, that the only consideration you take into account is the cost of the drug?

Dr. GOLDBERG. My immediate reaction is that I would suggest that you take a look at the Oregon legislation which says to the pharmacist when a prescription is written generically: Dispense the lowest priced product you have in stock commensurate with your professional judgment as to the quality of the product.

You safeguard the professional integrity of the pharmacist while still encouraging the dispensing of the lowest priced product that he professionally thinks is of high quality.

Dr. DICKSON. I would like to leave the pharmacist with as much professional judgment as possible. The evidence that we have seen in Michigan and Wisconsin is when he does have the opportunity to choose a product for dispensing on a generically written prescription, in fact he chooses one from the lower half of the cost distribution, that he is acting in good faith, and I would hate to see legislation that tied him into things like the lowest priced item.

Mr. GREENE. You made a passing comment about the liability of the pharmacist. Shouldn't we insulate him from further liability if we are going by law to require him to make a selection only on the basis of cost? Why would exposure to liability be greater? We have



addressed the question of bioequivalence, but there seems to be an assumption underlying the legislation that there is a pretty uniform bioequivalence among drugs and there is evidence at times there is not. Is that what the fear of a greater exposure to liability is based on?

Dr. GOLDBERG. My personal opinion on this is that there is very little liability encountered by the pharmacist in exercising drug product selection. But I think to provide the kind of psychological protection to the pharmacist it would be a good idea to include in the legislation legal protection that he incurs no greater liability when he drug product selects than he does when he dispenses a generically written prescription.

I think that protection should be inserted in the legislation for the pharmacist in that regard. It would be of tremendous psychological importance at very little cost.

Mr. ECKHARDT. If you are establishing through some agency what does constitute equivalent, but when you are giving him authority to make that choice, I think it would be a bad thing from the standpoint of the person who might be injured if he makes a mistake to protect him absolutely on his choice merely because he thought it was equivalent. As a matter of fact, I do not know how you would draft it unless you established some authority to determine what are, in fact, bioequivalents or within the generic family.

Dr. GOLDBERG. My answer, Mr. Chairman, is this: That the pharmacist should be protected against any greater liability than he now has when he dispenses a generically written prescription. Every pharmacist now is legally entitled, in fact is required to choose a product to fill a generically written prescription. Whatever legal liability he incurs when he makes that choice would continue.

What I am saying is that when you write legislation to encourage pharmacists to exercise drug product selection, you should say to that pharmacist: You don't incur any greater liability than you have when you fill a generically written prescription.

It makes perfectly good sense. There has been very little, if any, liability incurred by pharmacists from dispensing generically written prescriptions. I do not know of any case where a pharmacist has incurred a liability from dispensing a generically written prescription. I think we overcome this fear—and I think it is really fear of the unknown or the uncertain—by providing that component in the legislation.

In Ontario that provision is included in the legislation which protects the pharmacist against incurring any greater liability from drug product selection than he otherwise had. It has caused no problems whatsoever.

Mr. ECKHARDT. Doctor, would you be available to answer some questions from the committee in writing at a later time?

Dr. GOLDBERG. Certainly.

[Testimony resumes on p. 70.]

[The following was received for the record:]





## WAYNE STATE UNIVERSITY

SCHOOL OF MEDICINE

MAILING ADDRESS:  
GORDON H. SCOTT HALL  
OF BASIC MEDICAL SCIENCES  
840 EAST CANFIELD AVENUE  
DETROIT, MICHIGAN 48201

DEPARTMENT OF COMMUNITY MEDICINE  
1400 CHRYSLER FREEWAY

July 24, 1978

The Honorable Bob Eckhardt, Chairman  
Subcommittee on Consumer Protection and Finance  
Committee on Interstate and Foreign Commerce  
House of Representatives  
Room 3275  
House Office Building Annex No. 2  
Washington, D.C. 20515

Dear Mr. Eckhardt:

Thank you for the opportunity to respond to the comment of Mr. Nicholas Ruggieri regarding the methodology and conclusions of the research studies referred to in my testimony before your Committee on June 22, 1978. I think it is important for the record to include the discussion of the accuracy and validity of the data which were presented for the Committee's information.

Mr. Ruggieri's comments contain observations based upon two different sources of analyses. The first is that provided by Mr. Thomas Olsen, Manager of Corporate Affairs Research for Eli Lilly and Company, contained in a letter to Mr. Ruggieri dated June 30, 1978. The second is Mr. Ruggieri's own comments with references to PMA research as well as to other research conducted by Rx OTC Research.

I should like to comment on both these documents, but in reverse order.

Response to Mr. Ruggieri's comments:

Mr. Ruggieri is quite right that Tables B contained in the prepared testimony submitted to your committee was mislabelled. I apologize for this unfortunate mistake, which occurred as a result of the undue haste with which the testimony was typed in order for it to be available on time for your committee. I probably would feel much more concerned about this error if it were not for two factors. The first is that Mr. Ruggieri found little difficulty in determining that there probably was a misprint in the labelling of the title of Table B and made the necessary correction without any great difficulty. The second is that after, quite properly, calling attention to our mistake in labelling our Table, the PMA then had to send a follow-up letter to their commentary correcting two relatively important errors in their own submission. Thus it would seem that even the purest among us sometimes make mistakes which require later correction.



To deal with the more substantive issues in Mr. Ruggieri's letter: Mr. Ruggieri and I may use the term "self-selection", when referring to the drawing of a sample, differently but he is absolutely wrong when he applies the term "self selection" to criticize the sample from which we draw our conclusions. Our sample is the most carefully and accurately drawn sample of any study of drug product selection done anywhere or by anyone in the United States. Our sample accurately reflects the universe of prescriptions and substitutions of all prescriptions written and dispensed in the states of Michigan and Wisconsin during each of the years of our study. We are confident that our data represent the best information available anywhere about drug product selection and its economic effects.

It is true that we found substitution in only about 1½% of all prescriptions for multiple-source drug entities during the first two years of the operation of the law in Michigan. Our testimony suggests that the following year's data may show a substantial increase as new forces and increased awareness of the law come into effect. To cite a 1973 study of "illegal" drug substitution based on an analysis of two drugs, which our study also indicates are the high volume drugs for product selection, is patently ridiculous. Ampicillin and erythromycin represent a substantial proportion of all substitutions which perhaps best illustrates the importance of sampling all-prescriptions rather than concentrating on any preconceived list of specific drugs. One further comment on the survey referred to in the PMA commentary, its conclusion that the price of a substituted drug was identical to or higher than the price of the prescribed product may have been the reason for both the Michigan and Wisconsin laws, as well as the terms of HR 1963, to provide that the pharmacist must dispense a less costly product when drug product selection occurs. It would not be legal to "substitute" an equal priced or higher priced product in Michigan and Wisconsin, and our data confirm that this is not done. If Mr. Ruggieri or the PMA know that illegal activity is occurring, which did not show up in our study, they have a social as well as moral obligation to present their evidence.

The paragraph on the bottom of page 2 of Mr. Ruggieri's letter refers to the fact of our mislabeling of Table titles, which even they consider of minor importance, but then point out what they find to be a discrepancy in our findings citing a 34% savings figure which they say we reported in our study and compared this to a 21% savings which they say we reported in another study. The difference between 34% and 21% might be a serious defect in our reporting except in the follow-up letter they point out that the figure of 34% which they cited really should have read 24% and they apologized for the error. The fact that the 24% and 21% and even the 16.8% which they also cite are reasonably close and the differences can be accounted for by the fact that they are based on different comparisons which are fully described in the texts. There are different results when we match prescriptions within pharmacies or between pharmacies, and it is a matter of a statistical trade-off, between the precision of intra-store comparisons but with fewer cases as opposed to the greater accuracy of more prescriptions but with lesser precision in cross-store comparisons. This is discussed more fully later in the response to Mr. Olson's comments.



The second paragraph of pg.3 of Mr. Ruggieri's letter contains a couple of observations which are almost incredible. First of all, he says that the PMA's own research has disclosed that there are "only two drugs -- both relatively minor -- in which a generic product would offer as much as 50% in savings over the brand name product." This wording was later corrected in their follow-up letter to read ".....in which a generic prescription offers, on the average, as much as 50% in savings over a brand-specified prescription." I'm sure that the correction was meant to clarify the wording in the original commentary. However, I'm afraid that it does not do so. For example, I have no idea of what "on the average" means in this context. It must be intended to mean something since it was not in the original wording but added later. But the words don't seem to make any sense in the context in which they are used. But the more important point is that what Mr. Ruggieri seems to be implying is that the PMA research indicated that there are only two drugs for which there is as much as a 50% savings among products in the same drug entity. Without knowing what the PMA's own research amounts to it is impossible to know whether their research is inadequate or whether their conclusions are poorly drawn. But what I can tell Mr. Ruggieri is that our data show many more than two drug entities within which there is one drug product whose prices is as much as two times or more the price of another product in the same entity. I would be happy to make examples available to him or to the committee if it so desires.

Later in the same paragraph there is reference to the fact that in an IMS America study there were 8 out of 37 major multisource drugs where the average unit price of the drug when prescribed by brand was the same as or lower than when prescribed generically. The implication, as I would read it, is that for the other 29 major multisource drugs, or over 78%, the price was lower when prescribed generically rather than by brand name.

The penultimate paragraph on the same page also contains another strange comment. Mr. Ruggieri suggests that because the few Michigan pharmacists who substituted knew that the study was being conducted that they would have every reason to demonstrate a high average rate of saving per substituted prescription. He then adds the incredible comment that: "The law was, after all, designed to meet the goals of pharmacists as much as the interests of consumers." First of all, I don't know how Mr. Ruggieri knows that only a "few" Michigan pharmacists substituted. We have never reported on the number or percentage of pharmacies which engaged in drug product selection. All our reporting has been about the number and proportion of prescriptions for which a product different from the one prescribed was dispensed. Therefore, it would be impossible for Mr. Ruggieri to know, from our data, the number of pharmacists who practice drug product selection. Second, all the pharmacies which participated in our study know that the survey was being conducted. Why would the "few" who substituted be influenced by knowledge that the study was being conducted to show a high rate of savings from substitution while the "many" who supposedly did not substitute were uninfluenced by the knowledge that the study was being conducted. And third, if the law "after all" was designed to meet the goals of pharmacists as well as consumers, why isn't there a higher rate of drug product selection. Perhaps Mr. Ruggieri is anticipating what he expects to happen.



Mr. Ruggieri's point in the last paragraph on pg.3 is that our study shows a lower "savings rate" when prescriptions are written generically than when written by brand name or substituted. He suggests that this should have "alerted" us to a bias in our sample. Not at all. The answer is much simpler and straight forward than that. Under the Michigan law when a prescription for a multiple-source entity is written generically, and the pharmacist thus has the responsibility to select the product to be dispensed, the law is silent on any direction to the pharmacist to choose the least expensive product, the product at the median price in the range, or even the most expensive product to dispense. But when pharmacists do dispense generically written prescriptions our data show that they select products whose price is below the median price for products within that drug entity. But when a pharmacist makes a conscious decision to substitute one product for the one prescribed, his conscious decision apparently directs him to a lower priced product in the range of prices, for our data show a greater savings when substitution occurs than when generically written prescriptions are filled.

One final response to Mr. Ruggieri's comments -- the final sentence of his letter contains a prediction that the continuation of our study in Michigan will demonstrate a decline in the "savings rate" if the rate of substitution in Michigan increases. I have no idea as to what our future analysis will show but I will promise Mr. Ruggieri and the committee that we will make new reports available to them as soon as they become available.

- We do appreciate the confidence which the PMA places on the objectivity and impartiality in our study which they believe will confirm their predictions.

I should point out to you, Mr. Eckhardt, that there is one point raised by Mr. Ruggieri, and also by Mr. Olsen, which contains some substance but really is not very damaging to our presentations. They suggest, although it is really more by implication than by statement, that it is highly speculative to try to extrapolate the total amount of potential savings from the limited information about actual savings which has been produced by the analysis of actual substitution occurring so far.

While it is perfectly true, and we thought perfectly obvious, that such projections were highly speculative, we were very careful to identify the fact that we were speculating on projected savings and qualified our statements accordingly. It may be, as the PMA predicts, that as the rate of substitution increases, the average savings per substituted prescription will decrease. Thus, the total potential savings will likewise decrease. On the other hand, as our data seem to indicate (see our paper "Analysis of Actually Substituted Prescriptions") that of the first group of substituted drugs a substantial proportion were for entities which produced relatively little savings. Thus future savings may, in fact, be greater than the average produced so far. Moreover, if refills are taken into account, which we have not done, then even larger potential savings may be anticipated. Only time will tell which of these speculations will turn out to be correct.



The point is that even accepting the speculative nature of the projections of potential future savings does not invalidate whatsoever the accuracy of any of our findings about the number and rate of actual substitution and the calculation of cost savings. Nor does the speculative nature of forecasting potential savings invalidate any of our research or statistical methodologies.

#### Response to Mr. Olsen's Comments

The information contained in Mr. Olsen's letter to Mr. Ruggieri is almost identical to those contained in a document entitled "Comments on Theodore Goldberg Studies Advocating(sic) Drug Substitution in Michigan" with Mr. Thomas F. Olsen, Corporate Affairs Research, Eli Lilly and Company identified as author and dated April, 1978. Therefore the comment regarding limited time to respond to the information which I presented to the Committee would seem to be suggesting that Mr. Olsen and his staff have not had the opportunity to review our research in detail. This is obviously untrue since they have produced, and circulated, extensively detailed commentary on our research and publications.

Let me start by pointing out that the drug manufacturing industry apparently has a hard time understanding that objective, scientific research can be conducted without having an ulterior motive. Thus the fact that our research is characterized as "advocating drug substitution" or suggesting "additionally mandated substitution" is not only an inaccurate "cheap shot" but probably reflects how sensitive the industry is to any research which might tend to produce results which are not comfortable or convenient for their own self-interest. As we pointed out in our testimony, we are an academic institution and our research is established on an objective, scientific model. If our findings and conclusions are uncomfortable for them, that is their problem, not ours.

To deal now with the specifics of Mr. Olsen's comments.

The two conclusions presented on the first page of the letter are both unsubstantiated and unrelated to the detailed comments which follow in the letter. The first point is totally unfounded and untrue. The second point is misdirected, also, for it is not insufficient data that Mr. Olsen may be complaining about but rather what he might consider incomplete analysis or insufficient time to measure the full impact of the legislation.

In regard to his criticism of "insufficient basis" and "insufficient data", let me say that we know of no prescription survey other than our own which has been conducted with such high standards of quality control from beginning to end: in the initial selection using proven survey sampling techniques, in the data collection and coding, and in the analysis. Our response rates (over 80%) are considered satisfactory, if not high, for a survey with completely random selection of participants. Quality control mechanisms in collecting and coding data show that such errors occur in less than  $\frac{1}{2}\%$  of the observations.



In view of this degree of quality control, the conclusions of "insufficient data" and "an insufficient basis" for our conclusions requires substantial evidence of inadequacies and inproprieties and careful reasoning to establish the two stated conclusions. We found no such evidence or reasoning in Olsen's criticism. On the contrary, Mr. Olsen's criticism exhibits considerable ignorance regarding Michigan's drug product selection law. The law requires that when a pharmacist chooses to dispense a substitute product, the retail price must be lower. Therefore, no study is necessary to conclude that substitutions actually save money. Studies are needed to measure the extent and amount of savings. Olsen's conclusion merely implies that the profession is violating the law, an implication which is never supported. In addition, the Michigan law does not "additionally mandate" substitution (Conclusion 2), it only permits substitution, requiring that any savings be passed along to the consumer. Both conclusions are predicated on a misunderstanding of Michigan's law.

#### Specific Comments and Questions

1. "The inclusion of pharmacy fee in the measured cost of each prescription introduces an unquantified, but substantial, source of variability."

We did not assume that price changes were "a direct consequence of ingredient price differences." The purpose of our paper was to measure the change in retail price when a substitution occurs. While it would be useful to know what the components of the price change are, that was not our objective; therefore, pharmacy fee, no matter how variable, should be properly included in our price comparisons. We have not tried to ".....conclude that the ingredient price differential assertion' (sic) is proved."

2. "Even if ingredient price differentials were real, the 'prior approval' clause in Michigan's substitution (law) virtually ensures a biased sample of substituted prescriptions."

Our sample was randomly chosen with equal probability of selection for each prescription written in the State of Michigan. Prescriptions were systematically selected from pharmacies with a random starting value. Pharmacies were randomly selected from groups which were stratified using several criteria. Therefore, our sample is a stratified, clustered sample of elements. The sampling scheme permits unbiased estimates of means and conservative estimates of variances to be computed. Therefore, the conclusions that "prior approval.....virtually ensures a biased sample of prescriptions" is incorrect. Further, Olsen's assertion that "even if the sample is valid, the results are not generalizable" is patently incorrect.

The "prior approval" clause, as well as the low rate of substitution suggests that substituted prescriptions are different from all prescriptions for multiple-source drugs. Examination of the substitutions verified this fact.



Nonetheless, our sample of substitutions is unbiased, as is our sample of other prescriptions. On the basis of the sample we have computed our unbiased estimate of the actual savings due to substitution as well as the potential savings which might be realized if all multiple-source prescriptions were actually substituted. These two estimates naturally depend, for the accuracy, on different assumptions. The former requires only that the sample selection be done correctly, the latter assumes both that the sample is done correctly, and that the savings due to actual substitution can be extended to all prescriptions for multiple-source products. We deliberately chose not to include the savings attributable to refilled prescriptions (at about a 1.1 to 1 ratio) in order to make our estimate of potential savings more conservative. The fact that substituted prescriptions are usually written for the most common, lowest priced entities also minimizes our estimate of potential savings.

3. "Possible shortcomings in sample design and data collection."

- 3a. "By ignoring errors-of-measurement (in at least quantity and time dimensions) they have understated variance."

By instituting careful quality control procedures, we have minimized the errors-of-measurement. We have estimated that collection and coding errors occur in less than 1/2% of the data. Furthermore, prescriptions are a legal record whose custodians, pharmacists and physicians, are subject to stringent requirements regarding their recording, storage, and maintenance, as well as their writing and dispensing. Violation of these requirements carry criminal penalties. The vast majority of physicians and pharmacists are conscientious professionals who take their responsibilities seriously. We must conclude that while errors can occur in recording and maintaining prescriptions, there are very few. This essentially error-free situation must be contrasted with the typical social research interview where individual responses to items requesting annual income, political behavior, and social attitudes may be subject to random error, consistent under-reporting, and substantial misunderstanding as to the intent of the question. Consider the following example: Q: Do you own any stock? A: Yes, I have two cows and a horse.

- 3b. "The t-test statistical methods used depend on equal probability sampling but the study protocol does not assure that."

The distribution of a t-statistic has not been shown to depend on equal probability sampling. In fact, its distribution is unknown for multi-stage samples of finite populations. At least one study using a simulation approach (Frankel, Martin R., Inference From Survey Samples an Empirical Investigation, p. 104) has concluded that complex statistics from a multi-stage sample still have a distribution close to that which follows from more stringent hypotheses, such as independent, normally distributed random variables. Our sample of prescriptions, and substitutions, is an equal probability sample for each type. Substitutions were deliberately over sampled at a rate of eleven to one.

We have, in order to validate practically our use of a statistical technique whose mathematical properties are unknown under the sampling methods used, examined the matched pairs empirically. We found that price differences were approximately



normally distributed with no unusual outliers, and that the observed differences were not related to differences in quantity or date dispensed. Where clustering effects could be estimated, for the matches within the pharmacy, intraclass correlations were computed. These indicated a moderate degree of clustering in the first year, and none in the second year, of substitution. We believe that the proper focus of this study is the actual population of substitutions which occurred, not the hypothetical population of all possible pairs of matches that could occur. In any event, we know no way to design an equal probability sample of the hypothetical population of matches, unless that population is precisely defined. Furthermore, even if an equal probability sampling scheme is possible, it may not be the most useful for making valid inferences.

- 3c. "In much the same way that "matched" prescriptions probably have unequal likelihood of being sampled, smaller pharmacies and lower-incidence therapeutic classes and drug entities are probably under-represented in the sample."

Since our sample was planned as a sample of prescriptions, we planned it to include each prescription written in Michigan with a fixed probability. Substitutions were deliberately oversampled with a fixed probability eleven times as great by scanning ten prescriptions for each one selected in the primary sample. Therefore "lower-incidence therapeutic classes and drug entities" are represented in proportion to their existence in the population of all prescriptions or in the population of substitutions.

Pharmacies, which were not the focus of our study, were selected with probability proportional to their estimated size. When combined with equal probabilities of selection of prescriptions, this reduces the variance of estimators by reducing the variability in sample size among pharmacies. Therefore, while smaller pharmacies were selected with reduced probability, the prescriptions occurring in them were selected with probability equal to prescriptions occurring elsewhere.

Because substitutions are rare, we oversampled them by a ratio of eleven to one, in order to increase the usefulness of our sample. Out of about 31,000 recorded prescriptions, and 310,000 scanned prescriptions, about 1200 were actually substituted. Initially, we matched within pharmacies, to obtain a more precise price comparison with a smaller frequency. The smaller frequency implied only greater sampling variation of our estimated difference. We also matched across pharmacies to obtain almost 500 matches out of the 1200 possible. This introduces a greater degree of sampling variability in the estimated differences, against the greater precision possible with a larger sample. This characteristic was reflected by the standard deviations: which we reported. Both methods are random, therefore statistically valid; the difference lies in the tradeoff between more controlled sampling variation obtained by the more precise match within pharmacies, and the greater sample sizes obtained by the match between pharmacies. Similarity of the conclusions from both procedures reinforce the correctness of the estimate.



4. "The variance of the differences between means (these differences being the basis for the projected 'savings' from substitution) is probably incorrect."

The variance of the differences between means was computed using the formula:

$$s^2 = \frac{\sum_{j=1}^n d_j^2}{n-1}$$

This formula ignores the effects of stratification, clustering, and the correction for finite population sampling. Stratification and a finite population both reduce the sampling variation of the differences, clustering usually, but not always, increases it.

The exact formula to estimate the variance for a post-hoc analysis of a complex sample, such as ours, are not generally known. Conservative estimates (overestimates) are usually used, where they can be computed. At least one author (Frankel, Martin R., Inference From Survey Samples an Empirical Investigation) has found empirically, that the ordinary variance estimate, as above, works well in practice when "higher order" statistical analysis is performed on a finite sample.

5. "The regression analysis, which purports to functionally express the prescription price-per-unit for all possible quantities, includes too few variables and presents poor variance-explained and goodness-of-fit measures."

The regression equation is not designed to explain the determinants of retail prescription prices, although it can be easily extended in that direction by including additional regressors. The example illustrates a technique for investigating quantity and product effects on unit prices.

From the intercept term and the coefficient of "Dispensed Quantity" the significantly inverse unit price-quantity relationship can be computed for the base product, Eli Lilly and Company in this case. The remaining product coefficients indicate the logarithm of the difference in the unit price between the product in question and Lilly. There is no a priori reason to expect all or any of these coefficients to be statistically significant. Here, four drug products have a significantly (at the 5 percent level) lower price than Lilly, while there is no significant difference in the price of any of the remaining products and Lilly.

There is also no reason to believe that any relevant excluded variable in an extended study of the determinants of prescription prices would be correlated with the included variables (namely quantity and product dummies), in which case, the regression coefficients would be unbiased. We would, of course,



prefer to estimate product price differences from a more complete regression equation and are working on such a model.

Finally, when quantity and product effects alone explain 65 percent of the total variation in unit prices over a sample of 560 observations, we interpret this as strong support for the methodology which was adopted.

I hope the information provided herein is useful to you and to your Committee. If I can be of any further assistance, please let me know.

Yours sincerely,

*Theodore Goldberg/mg*

Theodore Goldberg, Ph.D.  
Professor and Chairman

Enclosure

TABLE B

Prices of Substituted vs Non-Substituted Prescriptions,  
Michigan Years 2 & 3 (First Two Years of Allowable Substitution),  
Comparing Prescriptions within Entity Classes

|        | Number of<br>Matched<br>Prescriptions | Average<br>Price of<br>Dispensed<br>Product | Average<br>Price of<br>Matched<br>Prescriptions | Average<br>Price<br>Difference | Standard<br>Deviation<br>of the<br>Difference | Paired<br>t-<br>Statistic |
|--------|---------------------------------------|---------------------------------------------|-------------------------------------------------|--------------------------------|-----------------------------------------------|---------------------------|
| Year 2 | 565                                   | \$4.56                                      | \$5.49                                          | \$-.92                         | 2.21                                          | -9.94*                    |
| Year 3 | 653                                   | 4.79                                        | 5.75                                            | -.96                           | 2.46                                          | -9.93*                    |

\*Significant at  $P < .00005$



Mr. ECKHARDT. We thank you very much, gentlemen, for your testimony here. It has been very useful to the committee.

The committee will recess long enough to catch the vote. Then we will resume.

[Brief recess.]

Mr. ECKHARDT. I want to apologize. I didn't think we would be so long, but we were in a series of votes and would have been interrupted every few minutes.

Thank you for your patience.

Mr. Wegner, will you identify yourself for the record and proceed in the manner you see fit?

**STATEMENT OF FRED WEGNER, LEGISLATIVE REPRESENTATIVE, NATIONAL RETIRED TEACHERS ASSOCIATION AND THE AMERICAN ASSOCIATION OF RETIRED PERSONS**

Mr. WEGNER. Thank you. My name is Fred Wegner, and I am a legislative representative for the National Retired Teachers Association and the American Association of Retired Persons. I would like to observe that Dr. Goldberg always gives a fine presentation. He does have access to graduate students, however, which I don't, so what my own presentation lacks in academic brilliance, I hope to make up in brevity.

Most of our 12 million members are in the over-65 age segment which—although only 11 percent of the U.S. population—accounts for some 25 percent of the total national prescription drug market and an incidence of chronic illness which is twice that of the middle-age group.

Because medicare offers no outpatient prescription drug coverage for the elderly and few of them can afford the premium for private drug insurance, some 86 percent of their drug costs are paid out-of-pocket, constituting their second highest personal health care expenditure.

Nearly every advanced nation in the world has a system for providing its elderly with prescription drugs and a system for controlling the costs of prescription drugs. Not so here. Older Americans are without a drug benefit program and are forced to pay the highest prescription drug prices in the world.

In the face of continued congressional inaction on either a drug benefit or a drug cost containment program, NRTA and AARP 5 years ago embarked upon a legislative action plan to enact State generic drug substitution laws in an effort to stimulate price competition and thereby lower drug prices. The result is one of the remarkable success stories of the consumer movement. Today 39 States, the District of Columbia and Puerto Rico have enacted substitution laws, and we have efforts underway in nearly all the remaining 11 States.

Why, then, are we here in support of a Federal generic drug substitution law? For several very important reasons:

First, to solidify our gains in the 39 States with substitution laws by assuring through Federal preemption that they will not again enact discriminatory and anticompetitive antisubstitution laws.

Second, to overturn those unfair antisubstitution laws still on the books in the remaining 11 States and to keep them off the statute books.



Third, to achieve a national minimum level of uniformity in substitution among all of the States. This is necessary, we believe, to clarify ambiguities in certain of the State laws. A recent editorial in the American Druggist magazine of June 1978, by Dan Kushner makes this statement:

We have three dozen laws that saddle pharmacists, prescribers, patients, and manufacturers with a bewildering variety of requirements—formularies, negative, positive and none at all; unclear savings-passalong rules; confusing substitution authorization and prevention procedures; ill-defined liability rules.

Mr. Kushner also makes the point in this editorial, as you are well aware, that HEW, FDA, FTC, and I don't know who else, is in the business these days of putting together a model generic drug substitution law, and Mr. Kushner goes on to suggest that he thinks this is the proper business of Congress, and I couldn't agree more.

With your permission, Mr. Chairman, I would like to have this editorial inserted in the record.

Mr. ECKHARDT. Without objection, it will be so ordered.

[The following information was received for the record:]



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# EDITORIAL

BY DAN KUSHNER



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## If U.S. Needs A Policy On Substitution, Congress, Not FDA, Should Make It

HEW Secretary Califano has called on the governors of all 50 states to "take all necessary steps to promote the substitution of generic drugs for more expensive brand name drugs." He has offered the governors "technical assistance" by FDA; in fact, he has instructed FDA to prepare a "model generic drug law." Presumably, the model is for use not only by the 15 or so states that don't yet have generic drug laws, but also by states with laws that don't match FDA's notion of what a generic drug law should be like.

What's wrong with all this is that it amounts to an HEW/FDA attempt to establish a national substitution policy—without the bother of subjecting it to scrutiny and debate. National policy, on any subject, should be made through the national legislative process, not by regulatory agencies.

Aside from the need for preventing FDA from getting away with an end run around Congress, the case for Congressional action on substitution/generic dispensing/drug-product selection rests on these considerations:

(1) Five years of state-level action have produced a mess. We have three dozen laws that saddle pharmacists, prescribers, patients, and manufacturers with a bewildering variety of requirements—formularies, negative, positive and none at all; unclear savings-pass-along rules; confusing substitution authorization and prevention procedures; ill-defined liability rules. If further evidence is needed that the states have mishandled the matter, look at just one feature of the newest law, New York's: if the prescriber signs on the "substitution permissible" line, the pharmacist *must* substitute—even if the patient insists on the prescribed product and is willing to pay for it.

(2) However one feels about the matter, it is by now probably impossible to revert to the rigid antisubstitution laws of recent decades. The perception, among the public and lawmakers, that some degree of substitution can achieve some reduction in prices is too strongly entrenched for that.

(3) Congress is right now engaged in deciding how research, approval, and distribution of drugs should be regulated. Congress is doing so because these are matters of national concern. They are matters of national concern only because, once a drug is allowed on the market, physicians prescribe it, pharmacists dispense it—and patients take it. But if the actual "it" the patient takes is to depend on rules governing prescribing and dispensing, then Congress ought to have a hand in making those rules; otherwise, the benefits of Congress' attention to approval, distribution and promotion may be dissipated when the drug reaches the point of all this concern—the patient.

This is not a call for Congress to outlaw substitution—or to allow unrestricted substitution. It is a call for Congress to recognize that allowing each state to make its own rules for substitution creates senseless confusion and inconsistency; and that HEW/FDA, in attempting to eliminate these shortcomings by promoting a model law of their own, are bypassing Congress on an aspect of drug regulation every bit as important as research, approval and marketing. If drug-product-selection is to be controlled, only Congress has the national perspective and the information-gathering resources needed to produce controls that accommodate the legitimate interests of all parties—pharmacy, medicine, industry, government, and the public.



Mr. WEGNER. We further need a Federal drug substitution law to accommodate the mobility of physicians, pharmacists and, particularly, consumers who reside or travel among the several States; and to assure that the rights and responsibilities of health professionals, consumers and drug manufacturers and distributors are equitable on both sides of State borders.

Fourth, and most important, to make drug substitution work more effectively.

State legislators by overwhelming majorities in nearly four-fifths of the States have firmly established the principle of drug substitution. That principle, expressed as the lowest common denominator of every State substitution law, is that absent prohibition by the prescriber, the pharmacist may substitute an equivalent drug product. Beyond this basic provision of all the State substitution laws, however, the guidelines for physicians, pharmacists, and patients vary widely in application and effect.

The prime objective of a Federal substitution law must be to achieve the greatest potential in drug cost savings for the patient among drug products of equivalent safety, effectiveness and quality. In order to do so, Federal law must combine those elements of State laws which have proved to be most workable and most effective.

Accordingly, NRTA and AARP believe a good Federal drug substitution law should contain these basic and essential provisions:

First, a pharmacist shall select and dispense a lower priced equivalent drug product whenever a prescription order is written for a brand name drug available from two or more manufacturers or distributors except when (a) the prescriber personally indicates either orally or in his or her own handwriting on the prescription order "Dispense As Written," "D.A.W." or words of similar meaning, or (b) the patient requests either the brand name drug or another equivalent drug product.

Second, a pharmacist shall select and dispense, consistent with professional judgment, the equivalent drug product in stock with the lowest retail price whenever a prescription order is written for a drug by its established or generic name.

Third, the pharmacist shall pass on to the patient the savings in the usual and customary prices between the drug product prescribed and the drug product dispensed. This takes care of the profit incentive for the pharmacist that was mentioned earlier to get him to stock and dispense generic drugs.

Fourth, a substitute drug must be a pharmacologically equivalent drug of the same strength, dosage form and salts and appear in the most recent edition of the list of therapeutically equivalent drugs published by the Food and Drug Administration.

This NRTA-AARP model Federal drug substitution law is, we believe, a considerable improvement over most existing State laws as well as H.R. 1963.

It updates this other legislation by recognizing the imminent publication of the FDA's recently announced list of therapeutically equivalent drugs. We would add that it is the hope of our associations that in time the FDA list will be melded with the Guide to Prescription Drug Prices soon to be published—as an element of the maximum allowable costs (MAC) program by the Office of



Pharmaceutical Reimbursement in the Department of Health, Education, and Welfare.

The combined list and guide would become the first national formulary of the United States. By indicating the relative costs of drug products and therapy among therapeutically equivalent drugs, this national formulary would help overcome one of the most difficult problems with the present drug delivery system; namely, the economic waste from overpayments for brand name drugs.

With publication of a national formulary of interchangeable drug products and their prices, no longer will any reason exist for a physician to prescribe, a pharmacist to dispense, or a patient to pay for any but the lowest priced drug product.

We estimate that a potential one-half billion dollars could be saved by individuals and the Federal and State Governments in the first year after implementation of an effective system of mandatory drug substitution. The savings potential should be expected to rise for at least another decade as more of the frequently prescribed drugs come off patent.

Drug substitution is one of the easiest, quickest, and most effective means of helping to combat the rising inflation in our country. State legislatures have made the initial response to consumers seeking increased competition and lower drug prices. Congress now has the opportunity to help make drug substitution effectively fulfill its huge potential.

Thank you.

Mr. ECKHARDT. You suggest that the pharmacist should pass on to the customer the difference in "the usual and customary prices between the drug product prescribed and the drug product dispensed."

The Michigan act provides that the savings should be the difference between the wholesale cost to the pharmacist of the two products. The act before us provides that the cost of the substitute drug to the patient must be less than the cost to such patient of the drug identified.

Certainly in the bill we have before us it seems to me there is no assurance that the cost be anything but some finite amount less than the other drug, which, of course, would permit the pharmacist to enjoy virtually all of the advantages, and I would think that the other two approaches from your testimony would be the preferable approach, from your standpoint.

Do I correctly interpret you on that?

Mr. WEGNER. Yes. To begin with, you understand we make a distinction between prescriptions which are written by brand name and prescriptions which are written generically. If they are written by brand name and the physician permits substitution, then we say that the pharmacist should substitute a lower priced drug than the brand name, that is, the brand name price being the—

Mr. ECKHARDT. The lower price or lowest price?

Mr. WEGNER. A lower price, we say.

In the case of a generic prescription I think because the physician has written that prescription generically, that is an indication to the patient and to the pharmacist that he wants that patient



given a break in the price. That is why he wrote the prescription generically to begin with.

Mr. ECKHARDT. So that would be the lowest price, right?

Mr. WEGNER. Right.

Mr. ECKHARDT. But you make the exception within the professional judgment of the pharmacist?

Mr. WEGNER. Right.

Mr. ECKHARDT. When would there ever be something other than the lowest price generic drug because of the professional judgment of the pharmacist?

Mr. WEGNER. Pharmacists have given me reasons why they might have a drug in stock that they don't like to dispense. I don't entirely buy that argument, myself. In my opinion, the professional judgment of the pharmacist is reflected in his inventory of drugs. He shouldn't have any drugs in there that he doesn't want to dispense, that he has any doubts about whatsoever.

Therefore, that is the first step: The pharmacist determining which generic drugs he wants to stock. After that, he ought to be dispensing the lowest price. I see no reason why he should not be dispensing the lowest price drug.

Mr. ECKHARDT. I suppose you would not consider in the same classification a drug that was in, say, capsule form or in liquid form. Would you consider those generic equivalents?

Mr. WEGNER. No; those are not equivalents.

Mr. ECKHARDT. What about a drug which is pulverized in a finer form than another drug? I could conceive of a situation in which the manner in which the drug was prepared might have some effect on the intake into the system.

Mr. WEGNER. We are talking about equivalent drugs which are the same strength, dosage forms, salts, everything, and the further caveat that has now been added that is new, is that the FDA says it is going to give us a list of these therapeutically equivalent drugs. All we need is that list now in this country, and there is no excuse for not substituting. In other words, the FDA is assuring that these drugs are chemically bioequivalent and therapeutically equivalent. Therefore, the only remaining difference between these drugs is one of price.

Mr. ECKHARDT. And the FDA is assuring us that there is the same quality control?

Mr. WEGNER. That is right. They are saying that all of these drugs on this list will have performed bioequivalent tests.

Mr. ECKHARDT. Is this that positively ascertainable, in your view?

Mr. WEGNER. Yes.

Mr. ECKHARDT. I mean to the extent that there might not be a reasonable judgment on the part of a medical man that one of the bioequivalent drugs or one of the drugs within the generic classification was not more effective than another? I mean, do you feel that this is totally within the competence of the FDA?

Mr. WEGNER. Absolutely. I think a large problem that exists, that has existed in generic drug substitutions and that continues to exist, is that certain parties in this controversy are living in the past.

Mr. ECKHARDT. Well, but if that be true, then you don't need the qualification of professional judgment. You simply should, it seems



to me, require that the drug within the generic classification which is cheapest should be dispensed.

Mr. WEGNER. Well, I am saying this: That the FDA has the capacity—and is doing and will do—to require bioavailability tests for drugs, and in 95 percent of the drugs, such tests are performable.

Obviously in those drugs which cannot meet bioavailability tests, either because they failed them or because we don't even have the sophisticated instrumentation to measure them, they are not going to be listed as bioequivalent drugs and will not be substitutable.

Mr. ECKHARDT. I see no reason for your putting in here the qualification, "within the professional judgment of the pharmacist." It seems to me that you could just simply say that that drug within the generic classification which is cheapest shall be dispensed. Where is any room, under the facts that you set out, for professional judgment? You say at the lowest cost consistent with professional judgment.

Mr. WEGNER. Let me explain it this way: After the FDA has put together this list of equivalent drugs, say, for drug X we will have perhaps 26 manufacturers. Then we leave it up to the pharmacist to select which of those manufacturers' products he wants. I don't want to force the pharmacists to stock any particular drug in his inventory, so what we are talking about is his professional judgment in selecting the manufacturer's product.

Mr. ECKHARDT. I see, but then you don't need that qualification. All you need to say is, he shall select the drug within his inventory within that generic classification which is cheapest.

Mr. WEGNER. Right. In the world of reality, I would think—I mean this is a great help to the pharmacist. Now he can stock one drug rather than several brand names and several generics. He can stock one inexpensive drug so he doesn't have to carry—I don't know why he would want to carry other drugs.

Mr. ECKHARDT. Unless he wanted to be equipped to satisfy the prescription which specifically referred to the particular drug.

Mr. WEGNER. Right.

Mr. ECKHARDT. If he wanted to be able to serve that customer and fill that doctor's prescription, he would have to have that drug available.

Mr. WEGNER. Right. Frankly, I think we are in a transition stage right now. I don't offer this as the ideal world that we would like to see come about. In time, I am hopeful that we will see a drug benefit for this country, for the elderly, and for all Americans under national health insurance. Then when the Government is paying for drugs, perhaps we can implement an effective drug cost containment program which will take advantage of substitution but which will put into effect some more sophisticated guidelines, such as the maximum allowable cost program.

I think then when the Government establishes a ceiling for each multiple source drug product, then the pharmacist knows what he is going to get reimbursed for that particular drug, and if he is smart, he will try to buy a less expensive drug product so he can make a little profit.

Mr. ECKHARDT. Now, I would like to go back to a question I think I predicated a minute ago. You used the difference between the



usual and customary prices of the drug listed on the prescription and the generic equivalent.

Isn't it easier to determine, and wouldn't it be more readily available to the pharmacist, to use the approach the Michigan statute uses: The difference between the wholesale cost to the pharmacist of the two drug products? How does he really know what the usual and customary price of each is? Doesn't he have to then look to other factors besides those that are within his immediate reach?

Mr. WEGNER. Because he established the usual and customary price.

Mr. ECKHARDT. If that is what is meant, he can take the whole profit. In other words, he can establish the usual and customary price of the cheaper generic drug at a penny less than the named equivalent.

Mr. WEGNER. Five years ago almost no State in this country allowed substitution. We have had to fight the pharmaceutical manufacturers and the doctors and the pharmacists very often to try to get these laws passed. We are trying to save consumers money. We are getting opposition everywhere along the line. We have to be realistic about this and try to implement something that is going to work.

Dr. Goldberg has explained that Michigan is far, far from realizing its potential in savings. One of the good reasons for that is just that provision you read. What incentive does a pharmacist have to stock a generic drug if he is not going to make any more money than he is on the brand name drug? We are willing to go along with pharmacists getting a little more money if he will stock the generic drugs to begin with.

Our people cannot get generic drugs unless the pharmacist stocks them. You are going to hear the American Pharmaceutical Association say they have been great supporters for drug substitution in this country for years. I am telling you we are having a big problem with pharmacists stocking generic drugs and dispensing them.

Mr. ECKHARDT. But this language could cause either a greater or lesser spread, it seems to me. You are just interpreting the language to the effect that the pharmacist could simply put the price on the substitute at anything he wants to. If that is true, there is no use putting in a requirement that the pharmacist pass on to the consumer the difference, because he could make the difference anything from a penny to a dollar.

Mr. WEGNER. That is right.

Mr. ECKHARDT. But I had not read this to mean the usual and customary price between the drug product prescribed and drug product dispensed but as meaning that which was usual and customary among druggists generally in the marketplace.

Mr. WEGNER. No. I think the first thing we have to do is to get the pharmacists to inventory some generic drugs. Then we have to depend upon competition amongst the pharmacists to get the price down from there.

Mr. ECKHARDT. In that case you would be just as satisfied, I assume, with the language of the bill. It says pharmacists may fill or refill prescription with a substitute drug if (a) there is no other



specification otherwise; and (b) the cost of the substitute drug to the patient for whom the prescription is made is less than the cost to such patient of the drug identified.

Mr. WEGNER. That is correct.

Mr. ECKHARDT. That would be essentially what you would argue for?

Mr. WEGNER. Right. It may be advisable, however, to specify what the pass-along savings is because as you have just quoted from the Michigan law, that is not to us an acceptable one. That mitigates substitution. Unfortunately, the State laws are filled with provisions like that.

Mr. ECKHARDT. We had our discussion with Dr. Goldberg and I think he agreed that perhaps something between the authority of the pharmacist to take all the difference and the requirement passing on all the difference might be desirable. That might require some language different from what exists in H.R. 1963 and in the Michigan act.

Mr. WEGNER. I think maybe I can give you an example. When we got substitution passed in the District of Columbia, I believe Giant was the first to come out with a full-page ad saying: Buy the generic equivalent for 50-percent savings.

I believe I am correct. Peoples came out next and said they have generics for 50 percent less. And then Dart or Drug Fair came out and said the same thing, 50 percent. So they established at least on those particular drugs a certain percentage of savings.

I am hopeful that if a pharmacist is going to Mickey Mouse around and say, "We will save you 2 cents under the brand-name drug," he is going to lose his business to the pharmacist who is passing most of the savings along to the consumer.

Mr. ECKHARDT. Any bill which does not say anything about the pass-on will nevertheless, once it provides the generic substitution, protect the customer on the basis of competition with respect to price. At the same time, it will encourage the druggist because he can take some of the difference and still compete effectively with those who do not commonly substitute the generic drug. Is that what you are saying?

Mr. WEGNER. Yes.

I was in the State of Alabama talking to pharmacists there a few months ago. They were very excited about drug substitution. These are the community pharmacists, the local retail druggists. They felt this was a weapon that they could use to compete against the chains by astute buying of generic drugs and establishing lower prices. They can at one and the same time increase their professional stature, save the consumer money, and increase their competitive positions.

Mr. ECKHARDT. Thank you very much. It has been very helpful testimony.

Next we have a panel—Mr. Nicholas Ruggieri and Mr. George Schneller.



**STATEMENT OF NICHOLAS RUGGIERI, ASSISTANT GENERAL COUNSEL, PHARMACEUTICAL MANUFACTURERS ASSOCIATION; ACCOMPANIED BY GEORGE SCHNELLER, VICE PRESIDENT, WYETH LABORATORIES**

Mr. RUGGIERI. I am Nicholas Ruggieri, assistant general counsel of the Pharmaceutical Manufacturers Association and director of State government relations. I am accompanied by Dr. George Schneller, vice president for quality assurance for Wyeth Laboratories, Philadelphia, Pa. Wyeth is a member company of the PMA. We appreciate the opportunity to appear before this subcommittee to express our views on H.R. 1963.

I would like to point out we have some reservations about this proposal. I have a prepared statement here which I will try to summarize. The statement is itself a summary of a full statement we submitted for the record. In the interest of time. I will try to highlight what I have in our prepared remarks.

Mr. ECKHARDT. Without objection we will accept into the record your statement and let you summarize [see p. 85].

Mr. RUGGIERI. Thank you.

Mr. Chairman, H.R. 1963 would authorize a pharmacist to override a doctor's request for a prescription drug product made by a particular manufacturer. The pharmacist would be authorized to substitute another product having the same generic name without consulting with the prescriber. If a substitution takes place the bill would require that the pharmacist select only the least expensive version.

Our concern with this proposal is based on the firm belief that it is the professional responsibility of the physician to select appropriate and high-quality medicine for a patient. In the physician's discretion that responsibility may be, and often is, delegated to the pharmacist. However, by allowing the pharmacist to substitute a brand of drug other than the product specified by the doctor without the prescriber's prior knowledge or concurrence, this proposal would, in our view, erode this important medical responsibility. Moreover, in forcing the pharmacist to select a product entirely on the basis of lowest price, it denies the value of the pharmacist's own special training and ability.

Traditional pharmacy practice laws and standards on drug product substitution generally require communication between the pharmacist and the physician before any modification could be made in the original prescription. We feel that this approach makes use of the special knowledge and talents of each profession jointly in the patient's best interest. On the other hand, proposals like H.R. 1963 would drastically modify dispensing practices so that the prescriber would never have the opportunity of concurring in the change in products or of knowing precisely what product the patient received.

Effective prescription drug therapy requires a knowledge of the drug and a familiarity with the patient who is to be treated with the drug. Only the physician has both these essential qualifications. Because a change in the prescribed source of a prescription drug can make a serious difference in the patient's response to treatment we strongly believe that the physician should continue to have primary control over that decision.



In 1976, testifying on a similar proposal before this subcommittee PMA witnesses observed that neither manufacturers nor the Food and Drug Administration can guarantee that prescription products with identical generic names will perform in the same manner. We believe this is still true. Consumers cannot be assured today that a substituted product will perform as well as the prescribed item. Despite advances in technology, the question of comparative drug product quality and performance still remains troublesome.

Four years ago this issue was addressed by the Congress in response to a proposal by the Secretary of Health, Education, and Welfare that reimbursement for prescription drugs for medicaid and medicare patients be limited to the "lowest cost" drug products generally available. Noting the relationship of that proposal to the question of therapeutic inequivalence, the Health Subcommittee of the Senate Labor and Public Welfare Committee referred the issue to the Office of Technology Assessment—the scientific advisory arm of the Congress. The OTA, in turn, commissioned a panel of leading scientists to study the question.

In July 1974, the OTA released a comprehensive report containing 11 principal findings and recommendations. Even though the report is now 4 years old, we consider it to be an authoritative statement of the conditions that generally prevail in the U.S. drug market today.

Two of the major findings of the OTA panel are particularly significant: First, the panel concluded that current standards and regulatory practices do not assure drug bioequivalence. Second, the panel found that compendial standards and guidelines for current good manufacturing practices do not insure quality and uniform bioavailability for drug products.

These findings mean that it is not possible to assure that two drug products having the same ingredients, but made by different manufacturers, will perform the same within the human body. Drug products that are apparently identical can and do vary significantly in quality and performance.

Although there is agreement that drug product inequivalence is an important health issue, there is disagreement as to the extent of the problem. On this point, the OTA report is not definitive, primarily because for many products the art of measuring therapeutic failure, or differences through bioavailability testing is relatively new and has not yet been perfected. Proponents of substitution feel that the question of equivalence is not serious and should not preclude conferring on the pharmacist unilateral authority to substitute. We disagree.

I would now like to summarize the main points in our formal response to the questions posed in the chairman's letter.

I would like to skip some of the points we cover in the remainder of our statement. On the need for Federal legislation, I will refer to the main statement we have submitted. We feel the States have been so active in this area it would be premature, given the degree of interest, for Congress to intervene with its own standards. We think that the jury is still out, if you will, on the question of what laws are the most effective and on that basis we would urge you not to approve H.R. 1963.



Let me move to the question of cost savings. We have often read about savings estimates of tens of millions of dollars annually per state whenever a substitution proposal is under consideration. Virtually all of these bloated estimates are prepared by taking wholesale catalog prices and multiplying the price differences by the number of annual prescriptions for a particular product. None of these estimates reflect actual transaction prices at retail.

Mr. ECKHARDT. May I interrupt you there just a moment. I believe you could certainly not figure the savings that way if both Mr. Wegner's and Dr. Goldberg's suggestions, that there be certain flexibility with respect to the cost giving the pharmacist an incentive to substitute, were in effect. The difference would not be the precise difference, either of the wholesale price nor of the common prices in the market which now exist. So I suppose we really do have a variable there which is a little difficult to judge.

Mr. RUGGIERI. You have a very difficult job. If you want to fine tune the proposal to such an extent where you can almost predict with certainty that certain savings will accrue and certain will not, we think it will take a lot of time and effort to construct such a legality that will not have countervailing influences. You do not want to make it too attractive to substitute willy-nilly; at the same time not creating disincentives that are not necessary—what about a physician who wants to insist upon a particular product; what about a patient who does not want a substitute under any condition. The variables are so numerous we think it is very difficult to come up with an idea.

Mr. ECKHARDT. But we certainly are sure, are we not, that such a program would reduce the total cost in some amount?

Mr. RUGGIERI. We are not prepared to agree that a substitution program in any State so far has actually produced measurable impact on the consumer's pocketbook.

Mr. ECKHARDT. You may proceed.

Mr. RUGGIERI. Thank you sir.

On the issue of mandatory versus permissive substitution we can only express a view in this particular context. Given our preference for legislation that neither allows nor requires unilateral substitution, we can only express a view on which we consider the lesser of two evils. We would assert that allowing substitution is less oppressive or hazardous than requiring it.

A mandatory substitution law would completely extinguish the value of any contribution the pharmacist can add to prescription drug source selection. One of the major reasons some pharmacists advocate substitution is that the ability of the pharmacist to utilize long years of education and training would be enhanced. The object is, in their view, to remove any barriers to the exercise of professional discretion. Even though the effect is to second guess the prescriber's judgment, some pharmacists firmly believe in their competence to do so.

Some pharmacy spokesmen have challenged our opinion that a change in product source without the knowledge of the prescriber could make a difference in therapy. They felt that the quality of the Nation's drug supply is such that, generally, there are no important differences among various suppliers, but if there were



any, the pharmacist would be perfectly able to manage the problem by selecting an appropriate high-quality source.

Ironically, and predictably, consumer groups in some States seized on that argument as the reason for seeking mandatory substitution. If everything is the same, why not mandate the switch? If there is any problem, the prescriber can always make a special effort to avoid or prohibit the change.

In fact, the consumer lobby has not only taken over the main argument in support of substitution but has moved the effort further along toward the virtual extinction of professional judgment by endorsing drug lists, such as New York's, from which the pharmacist must substitute, without regard to the welfare or consideration of the patient. We think pharmacists universally agree that such mandatory programs are a very poor way to practice medicine or pharmacy.

The key issue is control over patient therapy and control over selecting the source of prescription medicine. Who should exercise this control? We think the physician should, and where this authority has been consciously delegated to the pharmacist, then the pharmacist should select the best source available, taking quality and price into account. We cannot think of a single reason for assigning this important responsibility to the legislature or to a State bureaucracy.

I would like to move to the subject of drug lists. No single issue has created more controversy and confusion than the effort by State legislatures to minimize any problems that might arise from substitution. The danger that the States have sought to avoid is the possible adverse consequence of filling a prescription with a product that is not equivalent to the one named in the prescription.

Thus, 22 State laws include special provisions establishing a body of experts charged with the duty of making up a drug list. These lists, often called formularies, are of two varieties: The first is the so-called positive formulary, which purports to list the products that can safely be interchanged with one another. The other type is a negative formulary, which attempts to list only those products that may not be substituted because of known or suspected equivalence problems. The differences between the two are substantial, and overall results have been unsatisfactory.

Given the poor results of these State efforts to attack the problem of nonequivalence, we do not endorse the creation of special drug lists, positive or negative, for purposes of substitution. The individual pharmacist can make as good a judgment, or guess, as the best of the State formulary committees.

I would like to mention the activities by the New York Department of Health since they have received a great deal of attention. We think the drug list propagated by this agency is about the worst example of confusion and misconception that we can find. To no one's surprise, it is now the subject of two lawsuits in Federal district court.

Essentially, the New York Department of Health would have the public believe that mere approval by the Food and Drug Administration makes a drug product safe, effective, and interchangeable. No other State program makes this convenient assumption.



Without repeating the long history of the New York list and the difficulties experienced by the authors, it is sufficient to observe that the Federal Food, Drug, and Cosmetic Act was never designed to produce a guarantee, or even an assurance, of drug product equivalence. We have already mentioned the inability of the Food and Drug Administration to assure uniform performance among the Nation's drug manufacturers. Consequently we have challenged FDA's concurrence with New York's interpretation of its list as a guide to therapeutically equivalent drug products.

The capabilities and function of the FDA are at the heart of the debate over the value of drug lists or formularies. Until Dr. Kennedy assumed office at FDA no Commissioner claimed such effective monitoring abilities that there can be complete confidence about the uniform high quality of every drug manufacturer. Yet, the Commissioner has made this claim time and time again. He made this claim so often, and in such strident tones, that we were convinced of the need to look again at the information that would either substantiate or discredit his view.

Members of our staff, aided by experts from PMA member companies, spent the last 6 months combing through product recall data, laboratory studies comparing various products, and FDA's own records on the quality performance of firms that FDA inspects. After reviewing the material we concluded that FDA's own data thoroughly refute the public positions the Agency has taken.

Mr. Chairman, in that connection one of our member companies did a very special study on comparative performance on the industry. Lilly will release an analysis of documents from the Food and Drug Administration plus independent market research data in the form of a study that measures the relative incidence of FDA enforcement activities involving companies most heavily engaged in research as contrasted with those that do little or no research. We have never claimed a superiority of big over small, generic over brand name, but this particular report—and we offer it for the record, if and when it becomes available, as soon as it becomes available.

It shows that firms not devoting a great deal of attention and effort to research tend to have seven times more FDA recalls. They have 43 times more FDA-initiated court actions and 1½ times more FDA drug problem reports than those in the research-intensive category.

We think those findings are relevant. We think they are very important and we think they show another bit of evidence that the FDA is not the guarantor of quality that it would like to hold itself out to be. Neither can it produce a fair assurance. It does the best job it possibly can but it is not perfect and it is far from being as effective as some of its advocates would claim it is.

Mr. Chairman, I have one final point to make. On June 7, an event occurred that we think lends added strength to the views we hold on the value of drug lists. It was a little-noticed announcement of an agreement between FDA and the State of New York. Under this agreement FDA will provide New York with separate quality compliance information, on request, which evaluate an individual firm's ability to supply a product that meets all standards and is in conformity with all applicable laws and regulations. This



special program was needed because the State government purchases for its own use large quantities of medicine on a low-bid basis, and is now looking for assurance that it can safely purchase from the lowest bidder.

After praising the general uniform high quality of all the Nation's manufacturers for 1½ years since the development of the legislation, New York and the FDA are now getting down to the business of identifying whose products are acceptable and whose are not. After spending large amounts of money developing the so-called New York list of safe, effective and therapeutically equivalent drug products, these agencies are busily engaged in checking on the performance of the very same firms whose products appear on this list of so-called equivalents. The \$64 question is obvious: If the New York list is reliable, why is a special program necessary to assure the quality of the very same firms?

We cannot answer that question, we do not think the FDA can answer it. In their high enthusiasm for generic drug substitution programs, the FDA and the State of New York have hopelessly entangled themselves in confusion and contradiction.

I will spare you the conclusion. It is in the record.

[Testimony resumes on p. 102.]

[Mr. Ruggieri's prepared statement follows:]



STATEMENT OF THE  
PHARMACEUTICAL MANUFACTURERS ASSOCIATION  
BEFORE THE SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE  
OF THE  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE  
CONCERNING H.R. 1963, 95th CONGRESS  
June 22, 1978

The Pharmaceutical Manufacturers Association is a scientific and professional trade association representing 127 manufacturers of prescription drugs and medical devices. Many of these firms manufacture the products that would be affected by H.R. 1963, if enacted.

This bill would authorize the pharmacist to override a doctor's request for a prescription drug product made by a particular manufacturer. The pharmacist would be authorized to substitute another product having the same generic name without consulting the prescriber. If a substitution takes place, the bill would require that the pharmacist select only the least expensive product. In the case of a generically written prescription, where the prescriber leaves the source selection to the pharmacist, the bill would require, again, that the pharmacist dispense the least expensive version.

Our concern with this proposal is based on the firm belief that it is the professional responsibility of the physician to select appropriate and high quality medicine for a patient. In the physician's discretion that responsibility may be, and often is delegated to the pharmacist. However, by allowing the pharmacist to substitute a brand of drug other than the product specified by the doctor without the prescriber's knowledge or concurrence,



this proposal would, in our view, erode this important medical responsibility. Moreover, in forcing the pharmacist to select a product entirely on the basis of price, it denies the value of the pharmacist's own special training and ability.

Traditional state pharmacy laws on drug product substitution generally require communication between the pharmacist and the physician before any modification could be made in the original prescription. This approach makes use of the special knowledge and talents of each profession jointly in the patient's best interest. On the other hand proposals like H.R. 1963 would drastically modify dispensing practices so that the prescriber would never have the opportunity of concurring in the change in products or of knowing precisely what product the patient received.

In 1972 state legislatures began to consider the issue of substitution mainly in the context of purported economic advantages to the patient. Aside from any medical considerations, could patients save money if pharmacists were allowed to substitute freely? Today, six years and 37 state laws later, this question still lacks a good answer.

Although we understand that the primary object of measures such as H.R. 1963 is consumer savings, we do not believe that the medical and scientific considerations can be ignored. Just as the economic questions have not been settled in 6 years, neither have the medical issues been resolved satisfactorily. In the majority of states where changes in the law have been adopted, a genuine concern for these medical issues has been expressed, to a greater or lesser degree.

#### DRUG PRODUCT EQUIVALENCE

In 1976, testifying on a similar proposal before this Subcommittee, PMA



witnesses observed that neither manufacturers nor the Food and Drug Administration can guarantee that prescription products with identical generic names will perform in the same manner. We believe this is still true and is a fact which goes to the heart of the issue. Consumers cannot be assured today that a substituted product will perform as well as the prescribed item. Despite advances in technology, the question of comparative drug product quality and performance still remains troublesome.

Four years ago this issue was addressed by the Congress in response to a proposal by the Secretary of Health, Education, and Welfare that reimbursement for prescription drugs for Medicaid and Medicare patients be limited to the "lowest cost" drug products generally available. This proposal subsequently became known as the HEW Maximum Allowable Cost Program. Noting the relationship of that proposal to the issue of therapeutic inequivalence, the Health Subcommittee of the Senate Labor and Public Welfare Committee asked the Office of Technology Assessment, the scientific advisory arm of the Congress, to study the subject. The OTA, in turn, commissioned a panel of leading scientists to investigate the facts and present findings.

In July 1974, the OTA released a comprehensive report containing the panel's eleven principal findings and recommendations. Even though the report is now four years old, we consider it to be an authoritative statement of the conditions that generally prevail in the U.S. drug market today.

Two of the major findings of the OTA panel are particularly significant with regard to drug substitution: First, the panel concluded that current standards and regulatory practices do not assure drug bioequivalence. Second, the panel found that compendial standards and guidelines for current good manufacturing practices do not ensure quality and uniform bioavailability for drug products.



To the lay person these findings mean that it is not possible to assure that two drug products having the same active ingredients, but made by different manufacturers, will perform the same within the human body. Drug products that are apparently identical can and do vary significantly in quality and performance.

Although everyone seems to agree that drug product inequivalence is an important health issue, there is disagreement as to the extent of the problem. On this point, the OTA report is not definitive, primarily because for many products the art of measuring therapeutic failure through bioavailability testing is relatively new and has not yet been perfected. Proponents of substitution feel that the question of equivalence is not serious and should not preclude conferring on the pharmacist unilateral authority to substitute. We disagree.

With that background, we now offer our responses to the particular questions raised in the Chairman's letter of June 9:

#### THE NEED FOR FEDERAL LEGISLATION

The first question asks, "Is federal legislation to allow substitution needed, or are existing state laws adequate?"

There are two issues in this question that are not necessarily related. On the need for federal legislation, we would answer in the negative. We would also question the adequacy of state laws, regardless how one defines "adequate."

Are the state laws adequate to assure financial savings for consumers? Probably not. Are they adequate to protect against any possible adverse consequence arising from a substitution? As a whole, probably not, although they differ greatly in this respect. Do they adequately serve the consumer's right



to be informed of what is taking place in the pharmacy and in the doctor's office? Again, probably not, with some exceptions.

We are not enthusiastic about the overall adequacy of state laws on substitution. In fact it is well known that our industry has consistently questioned the wisdom of such legislation, state or federal. So, although we are not able to describe a good substitution law, we can distinguish between a bad law and one that is worse.

That should explain our reluctance to endorse a federal law on this subject. However there are other reasons, apart from the medical and scientific problems we perceive. For instance the record shows that the states have been very active in pursuit of a legislative policy on substitution. Thirty-seven state laws were adopted in the relatively short span of 6 years, and the majority of these were enacted between 1975 and 1978. By next year, all but a few states probably will have adopted a law.

Also, although they have the same thrust the state laws differ widely. Over time this will allow better measurement of relative impact. From a standpoint of encouraging economy, experience may show that the South Dakota or Delaware laws have proved relatively effective, while from a standpoint of patient health, experience may show that the laws in Florida and New York are among the least attractive. After a period of study, whatever law emerges as the most promising and, of course, least harmful might become the standard for future revision, the model law so to speak. In short, this is a subject on which the states are vigorously experimenting, or, as we would prefer to style it, venturing into the unknown. Accordingly, a supervening federal standard would be premature at this time.



Finally, insofar as the entire subject of drug product dispensing has always been regulated effectively by local pharmacy boards in the states, along with other aspects of professional practice, this policy of local control should continue. Placing the federal government in charge of such an everyday detail as source selection would not produce any different results than are attainable by the state governments acting individually.

#### BRAND vs. GENERIC

"Are trade name drugs better than generic drugs and, therefore, no substitutions should be allowed?"

Trade name products are not inherently superior to generically labeled products. Drug nomenclature has absolutely nothing to do with the quality of the product inside the container. Proponents of substitution have attempted to cast our position as one of claiming automatic superiority for larger companies or trade name drugs. We make no such claims, but we do emphatically state that no two manufacturers perform their roles in identical ways. The plain fact is that some manufacturers have consistently better records of performance than others and thus, by inference, make a superior product. This is true whether or not a manufacturer is a member of the PMA.

Also, we maintain that scientific evidence supports our view that products made by different manufacturers, although chemically identical, can produce differing results in the human body even though they meet FDA or compendial standards. Finally, we assert that information recorded by the FDA itself distinctly confirms the disparity of performance among manufacturers.

#### COST SAVINGS

"What is the potential cost savings to consumers if substitution legislation is enacted?"



This is a question that elicits the most extreme optimism from supporters of drug substitution. The correct figures will probably never be uncovered, but it is not uncommon to read about savings estimates approaching tens of millions of dollars annually per state. Virtually all of these bloated estimates are prepared by taking wholesale catalogue prices and multiplying the price differences by the number of annual prescriptions for a particular product. None of these estimates reflect actual transaction prices at retail.

The truth is that if there are any savings to be gained from a substitution policy, the order of magnitude is a tiny fraction of commonly quoted estimates. Furthermore, whatever the actual price impact on the consumer, it is obscured by two emerging trends that have their own effect on retail prices:

- a steady increase in competition among suppliers of multisource products, and
- a trend toward greater disclosure of actual retail prescription prices.

The best example of a widely known "generic" policy that produced little or nothing by way of savings is HEW's so-called Maximum Allowable Cost program for Medicaid prescription drugs, which we mentioned earlier. After hearing HEW Secretary Weinberger announce an estimated 40 million dollar annual savings to American taxpayers in December 1973, proponents of the program must now concede, five years later, that hardly a small fraction of the estimate can be positively identified as having been saved in four years of operation. The program has cost taxpayers over one million dollars in administrative expense.



"Should the legislation require that any savings be passed on to consumers?"

There is no doubt that supporters of substitution intend that savings be passed on to consumers, and some state laws are very strongly worded in that respect. The PMA has no position for or against any such mandate.

It is not possible to legislate savings at the prescription counter in complete disregard of the pharmacists professional and business judgment. Otherwise, the state must be prepared to send out an army of inspectors and auditors. All the state laws on this particular point, therefore, merely articulate an obligation to pass on the economies realized by switching products. Only detailed economic studies will tell whether states that have legislated on savings fare better than the ones who did not. Our impression is that there is no difference in average prescription prices that is attributable to mandated savings pass-on.

MANDATORY vs. PERMISSIVE SUBSTITUTION

"Should legislation allow or require substitution?"

Given our preference for legislation that neither allows nor requires substitution, we can only express a view on which we consider the lesser of two evils. We would assert that allowing substitution is less oppressive or hazardous than requiring it.

Only 7 state laws force a substitution whether or not the pharmacist concurs in the change of products. However, 5 of the 7 mandate the switch only if the prescriber specifically indicated on the prescription that a substitution is permissible.

Mandatory substitution laws completely extinguish the value of any contribution the pharmacist can add to prescription drug source selection. One of the reasons why some pharmacists advocate substitution is that the ability of the pharmacist to utilize long years of education and training would be enhanced.



The object is, in their view, to remove any barriers to the exercise of professional discretion. Even though the effect is to second guess the prescriber's judgment, some pharmacists firmly believe in their competence to do so.

In the course of generating support for substitution laws, some pharmacy spokesmen have challenged our assertion that a change in product source without the knowledge of the prescriber could make a difference in therapy. They feel that the quality of the nation's drug supply is such that, generally, there are no important differences among various suppliers, but if there were any, the pharmacist would be perfectly able to manage the problem by selecting an appropriate high quality source.

Ironically, and predictably, consumer groups in some states seized on that argument as the reason for supporting mandatory substitution. If everything is the same, why not mandate the switch, and if there is any problem, the prescriber can make a special effort to avoid or prohibit the change.

In fact, the consumer lobby has not only taken over the main argument in support of substitution but has moved the program further along toward the complete extinction of professional judgment by endorsing drug lists, like New York's, from which the pharmacist must substitute, without regard to the welfare of the patient. We think pharmacists now universally agree that such mandatory programs are a very poor way to practice medicine or pharmacy.

The key issue is control over patient therapy and control over selecting the source of prescription medicine. Who should exercise this control? We think the physician should, and where this authority has been consciously delegated to the pharmacist, then the pharmacist should select the best source available, taking quality and price into account. We cannot think of a single



reason for assigning this important responsibility to the legislature or to a state bureaucracy.

#### PRESCRIBER PREROGATIVES

"Should provision be made for practitioners to require that a prescription be filled with a trade name drug; if so, how should this be done?"

We would answer yes to the first part of this question--the practitioner must have that authority. Practitioners need the authority to prohibit substitution when, in their best medical judgment, it would not be in their patients' interest. For particular drugs and certain patients--such as a heart disease patient who has been titrated on a specific drug product, practitioners must have the authority to prohibit substituting another drug product, regardless of whether it's more or less expensive than the one prescribed.

Even the most ardent proponents of the substitution concept usually agree that medical practitioners should retain the authority and responsibility to require that a prescription be filled with a specific drug product. This is evidenced by the fact that all of the 37 state substitution laws contain provisions which give practitioners that opportunity.

How should practitioners exercise the authority to specify a particular product?

One approach is to allow a pharmacist to dispense a different product, unless a practitioner prevents it by remembering to write "Dispense as Written", or words of similar meaning, in his or her own handwriting on a prescription. Such a procedure, in our opinion, is deliberately intended to make it difficult for physicians to specify a particular drug product. Those who propose such a requirement know full well that most medical practitioners are human creatures of habit who've been writing prescriptions and getting exactly what they ordered for years. They know just as well that by instituting a totally new procedure



that imposes an uncustomary prescribing method on practitioners the result may be "substitution by default."

We believe that this approach increases the risk of inadvertent failure by practitioners to specify a particular drug product when they believe it should be in the best interest of the patient. It increases the chances of medically unwise or even unsafe substitution.

A less dangerous approach to substitution was offered by the Drug Research Board of the National Academy of Sciences in 1975. Its report contained the following statement and recommendation:

"The physician must have the ultimate responsibility and authority in drug product selection, since he has the fullest knowledge of the patient's needs and responses... the physician, having selected the chemical entity to be used for therapy, should be required to make a choice, each time a drug is prescribed, either to delegate to the pharmacist, or explicitly to retain to himself, selection of the particular drug product to be dispensed and received by the patient."

In many states the mechanism used to implement this recommendation has been the two-signature line prescription form. This requires prescriptions to contain two signature lines, one authorizing substitution and one preventing it. A practitioner must sign one of the lines in order to make the prescription valid. Such a procedure requires doctors to make a conscious choice, depending on the particular drug and individual patient involved. It also allows them a more customary procedure for communicating their dispensing instructions on a prescription, just as is done now for labeling and refill instructions.



Seventeen of the 26 state substitution laws enacted in the last 3 years, since the study and recommendations of the Drug Research Board were published, contain the two-signature line prescription form provision.

#### PROFESSIONAL LIABILITY

"Should a provision delineating the liabilities of pharmacists be included?"

Some state laws have included special provisions that attempt to immunize a pharmacist from liability for making a substitution, while other laws immunize the physician from liability for failing to insist on the prescribed source. We do not endorse any of these laws inasmuch as they attempt to restrict the consumer's remedy for any injury that might occur. There are also questions about their constitutionality.

Their very existence is testimony to the concern the legislatures have shown for potential adverse consequences arising out of substitution. It is true that no litigation has yet been brought alleging death or injury because of a substitute product, but it is clear that some legislatures have acted in anticipation of such claims.

When a pharmacist is authorized to substitute a drug brand without conferring with the prescriber, professional liability becomes complicated and subject to some speculation. If the law authorizes substitution, and the physician is given no power to prevent it, then the physician probably cannot be held liable if injury occurs. However, since H.R. 1963 and most state laws contain a provision that would preclude substitution if certain additional acts are performed by the prescriber, liability actually may be increased. Physicians could conceivably be held responsible for an injury attributable to substitution if they did not take the necessary steps to prevent it. Whether such a failure would result in a recovery of damages would depend in part on other



legal questions, such as negligence, standard medical procedures, proximate cause, patient consent, negligence of the pharmacist and others. Nonetheless, we believe the malpractice vulnerability of the physician and the pharmacist, as a result of such provisions, would be considerably increased.

#### ENFORCEMENT

"Should the Federal Trade Commission or the Food and Drug Administration enforce the Act?"

We are not able to offer any opinion, since we do not endorse a federal law on this subject. The question of enforcing substitution laws has not been given much attention in the states, and we cannot correlate whatever enforcement experience there is with the degree of substitution or the level of prices. Adopting substitution programs gives rise to various expenses: general regulatory oversight, formulary commission expenses, duplication, mailing, creation of new staff positions, and, at least in New York, advertising campaigns to promote substitution. If policing and enforcement are to be added, the public expense could be high enough to embarrass many proponents. It is possible to spend 99 dollars to save 100, but the 99 dollars is far more visible and meaningful to taxpayers than the elusive 100.

#### DRUG LISTS

"Should the selection of the drug to substitute be left entirely to the discretion of the pharmacist, or should a list of drugs that can be substituted be established? Alternatively, should a list of drugs which cannot be substituted be established?"

No single issue has created more controversy and confusion than the effort by state legislatures to minimize any problems that might arise from drug product



substitution. The danger that the states have sought to avoid is the possible adverse consequence of filling a prescription with a product that is not therapeutically equivalent to the one named in the prescription.

Thus, 22 state laws include special provisions establishing a body of experts charged with the duty of making up a drug list. These lists, often called formularies, are of two varieties: The first is the so-called positive formulary, which purports to list the products that can safely be interchanged with one another. The other is a negative formulary, which attempts to list only those products that may not be substituted because of known or suspected equivalence problems. The differences between the two, therefore, are substantial, and, more importantly, the message they convey is flatly contradictory.

States with a positive formulary claim that only certain products are safely interchangeable, while those with a negative list claim that everything is interchangeable unless otherwise noted. Actually there is no such thing as a perfectly safe substitution no matter what approach is followed.

Given the results of the state efforts to attack the problem of non-equivalence, we do not endorse the creation of special drug lists, positive or negative, for purposes of substitution. The individual pharmacist can make as good a judgment, or guess, as the best of the state formulary committees.

To highlight the immense difficulties one encounters in the realm of drug lists, the recent activities by the New York Department of Health should be mentioned. The drug list propagated by this agency is about the worst example of confusion and misconception that we can find. To no one's surprise, it is now the subject of two lawsuits in federal district court.

On its face, there is nothing unique about the New York Generic Drug Law. It is not the first two-line prescription law, or the first mandatory substitution law, or the first positive formulary.



The New York law and its accompanying drug list, however, does enjoy the highest exposure level among all its 36 counterparts, largely because of the list itself and the sweeping assumptions that its advocates make for it. Essentially, the New York Department of Health would have the public believe that mere approval by the Food and Drug Administration makes a drug product safe, effective and interchangeable. No other state program makes this convenient assumption.

Without repeating the long history of the New York list and the difficulties experienced by the authors, it is sufficient to observe that the federal Food, Drug and Cosmetic Act was never designed to produce a guarantee, or even an assurance, of drug product equivalence. We have already mentioned the inability of the Food and Drug Administration to assure uniform performance among the nation's drug manufacturers. Consequently, we have challenged FDA's concurrence with New York's interpretation of its list as a guide to therapeutically equivalent drug products.

The capabilities and function of the FDA are at the heart of the debate over the value of drug lists or formularies. Until Dr. Donald Kennedy assumed office at FDA no Commissioner claimed such effective monitoring abilities that there can be complete confidence about the uniform high quality of every drug manufacturer. Yet, the present Commissioner has made this claim time and time again. He made this claim so often, and in such strident tones, that we were convinced of the need to look again at the information that would either substantiate or discredit his view.

Members of our staff, aided by experts from PMA member companies, spent the last 6 months combing through product recall data, laboratory studies comparing various products, and FDA's own records on the quality performance of



firms that FDA inspects. After reviewing the material we concluded that FDA's own data thoroughly refute the public positions the agency has taken.

On June 7 an event occurred that we think gives added strength to the views we hold. It was a little-noticed announcement of an agreement between FDA and the State of New York. Under this agreement FDA will provide New York with separate quality compliance information, on request, which evaluates an individual firm's ability to supply a product that meets all standards and is in conformity with all applicable laws or regulations. This special program was needed because the state government purchases for its own use large quantities of medicine on a low-bid basis, and is now looking for assurance that it can safely purchase from the lowest bidder.

After praising the general uniform high quality of all the nation's manufacturers, New York and FDA are now getting down to the business of identifying whose products are acceptable and whose are not. After spending large amounts of time and money developing the so-called New York List of Safe, Effective and Therapeutically Equivalent Drug products, these agencies are busily engaged in checking on the performance of the very same firms whose products appear on this list of so-called equivalents. The \$64 dollar question is obvious: if the New York List is reliable why is a special program necessary to assure the credentials and performance of the very same firms?

We cannot answer that question, we do not think the FDA can answer it. In their high enthusiasm for so-called generic drug programs the FDA and the state of New York have hopelessly entangled themselves in confusion and contradiction.

#### CONCLUSION

To summarize, because an assurance of uniform drug product equivalence



and performance is still lacking today, we believe that physicians should continue to have the primary responsibility for selecting the drug products their patients will receive. The physician, although not in a position to know everything about product formulation and all the possible variations in performance that may occur among different products, is the only person who can make a judgment based on experience with a particular product, and on knowledge of the individual patient. We believe that the pharmacist can contribute to the product selection decision, but only by acting with the physician, not unilaterally.

Under H.R 1963, control over the prescription would be taken away from the prescribing physician, unless there was a special effort to avoid it. The pharmacist, in turn, would be required to dispense only the cheapest substitute drug available. This amounts to a complete denial of the value of professional discretion. It thwarts the medical judgment of the physician and accords nothing in the way of professional discretion to the pharmacist. We feel strongly that such a drastic change in the prescription drug dispensing system is not warranted or desirable.

Although the rationale behind the bill is a reduction in the cost of an important health care item, we believe the economic evidence necessary to support such an approach is lacking. The proponents of substitution can offer only unsubstantiated opinions that legislation such as this will help reduce the cost of a prescription. Yet, wherever this approach has been adopted, there has been no evidence of any significant savings at all.



Mr. ECKHARDT. Mr. Ruggieri, in looking over the testimony here and Dr. Goldberg's, I find his results were based upon actual transactions rather than theoretical transactions based on price. For instance, on page 24:

The question of whether the prices of dispensed and prescribed products differ when substitution takes place can be answered by matching each actually substituted prescription with a comparable prescription for the same product that was dispensed as written and then comparing the prices of the matched pairs.

He lists some questions and, he says comparisons have been made to answer all three:

To answer the question of whether the price of the product dispensed was lower than the average price of all products within that entity, it is necessary to match each actually substituted prescription with a randomly selected comparable prescription for any product within that entity, and then compare the prices of the two.

A third important question relates to the price of the products that are selected in filling generically written prescriptions. This can be examined by matching each generically written prescription with a randomly selected comparable prescription for any product within that entity, and then comparing the prices of the two.

Comparisons have been made to answer all three of these questions. This was done in two different ways: First, by matching prescriptions within the dispensing pharmacy where such matches could be found, and second, by matching substituted prescriptions with those randomly selected, which had been "dispensed as written" in any pharmacy in the sample.

Then his table A shows average price of dispensed products in Michigan—and this seems to be a real life experiment and observation—and he shows that to be \$4.37. The average price of matched prescriptions was \$5.51. Therefore, he shows an average price difference of \$1.14. So I think your general criticism of some of the prognostications of saving, which may indeed be a proper criticism, would not apply to Dr. Goldberg's examinations. They do quite definitely, it seems to me, show savings.

Mr. RUGGIERI. If I may, Mr. Chairman, I am not a statistician but I have read Dr. Goldberg's paper and I was struck with the very small sample that was used to develop the \$1.15 figure that he eventually wound up with. The number of prescriptions actually compared numbered 50. To get a matched pair Dr. Goldberg could go through a number of gyrations that statisticians I suppose normally go through, but I was impressed with the various ways in which there could be some overstatement or understatement as you go through. He did not take actual transactions. He did not take a prescription that was dispensed as written and that very same product where that instruction was omitted, everything being the same—he took a composite.

Mr. ECKHARDT. I thought he did. But maybe—he is still here—we ought to ask him.

Dr. GOLDBERG. The answer is we did precisely what you said. We actually matched prescriptions that were actually dispensed as written compared to those that were substituted.

Mr. ECKHARDT. I understand you were concerned about a possible inaccuracy by comparing apples and oranges if you simply used the whole universe and you tried to select within a given pharmacy what had happened.

Dr. GOLDBERG. Yes, sir.

Mr. ECKHARDT. You collected some of your data in that way. I do recognize Mr. Ruggieri is probably justified in his criticism of some of the prognostications of savings, because I think some of those



were probably done on a rather gross basis that might have shown the outside possible savings. But, I do not see that to be the case in your examination. Of course, Mr. Ruggieri points out that necessarily this was a sampling of relatively small size with respect to the whole universe.

I know when I am making an opinion poll to find out how I stand in a political election, about 400 telephone calls properly selected will be a reasonably good statistical evidence of about how the electorate stands at that time, although the persons voting may be in the neighborhood of 50,000.

Dr. GOLDBERG. I note the actual evasion, "I am not a statistician, but \* \* \*" The fact of the matter is a randomization is very important. A total number is not nearly as relevant as how the sample is drawn. If a sample is drawn carefully and randomly, conclusions can be drawn from a reasonably small total number. As a matter of fact, if you look at the proportion of our estimates in determining amounts of unemployment throughout the United States, in the sample we use to draw conclusions it is a relatively small one but very carefully drawn. So the point is how random the sample is. In your case I think you will find it to be very carefully randomized.

Mr. ECKHARDT. I think this subcommittee needs to look into this question and be assured about what experiences occurred. I am sure you, Mr. Ruggieri, would perhaps like us to keep the record open for introduction of some evidence with respect to the failure of these programs to result in substantial savings. The record will be kept open for that purpose, but we would like it not to be kept open too long, say 2 weeks.

Mr. RUGGIERI. I think that will be acceptable, Mr. Chairman.

Mr. ECKHARDT. Without objection, the record will be kept open for that period of time. You may have some further comments.

[Testimony resumes on p. 125.]

[The following information was received for the record:]



## PHARMACEUTICAL MANUFACTURERS

*Association*

NICHOLAS L. RUGGIERI  
ASSISTANT GENERAL COUNSEL

1155 FIFTEENTH STREET, N.W.  
WASHINGTON, D.C. 20005  
AREA CODE 202-296-2440

July 7, 1978

The Honorable Bob Eckhardt, Chairman  
Subcommittee on Consumer Protection  
and Finance  
Committee on Interstate and Foreign  
Commerce  
House of Representatives  
House Office Building Annex No. 2  
Room 3275  
Washington, DC 20515

Dear Congressman Eckhardt:

I appreciate this opportunity to comment further on the testimony presented by Dr. Theodore Goldberg at the June 22, 1978 hearing on H.R. 1963, 95th Congress. In his statement Dr. Goldberg described studies concerning the economic effects of the drug substitution law adopted in Michigan in 1974.

Mr. Thomas F. Olsen, Manager of Corporate Affairs Research for Eli Lilly & Company has been closely following the Michigan law and the successive studies on the subject by Dr. Goldberg and his colleagues at Wayne State University. Enclosed is a letter dated 6/30/78 to me from Mr. Olsen discussing some of the statistical deficiencies which, in his opinion, render Dr. Goldberg's study inadequate as a basis for projecting potential savings to the universe.

At the bottom of page 18 Dr. Goldberg's testimony states:

"For the first year after the Michigan law became effective, there was approximately a 21 percent saving (or \$1.14 per prescription) when substitution occurred. The second year's savings were remarkably close, being approximately 20 percent or \$1.15 per prescription. The amount of savings in Wisconsin for the six months of the second year (which was the first six months of allowable substitution in Wisconsin) was \$.87 a prescription, or 17 percent".

Representing manufacturers of prescription pharmaceuticals,  
medical devices and diagnostic products



We believe that the Michigan sample from which Dr. Goldberg draws his conclusions suffers from "self-selection" and hence the results do not provide a proper basis from which to estimate the potential savings to be achieved from drug substitution.

It is not until page 31 of his statement that we learn what a very low proportion of prescriptions for multiple-source drugs in Michigan were found to have been substituted--just 1.49% for the first year and 1.50% for the second year. As a share of all prescriptions (including those for sole-source drugs) the proportion was even lower--0.67% for first year.

Frankly, we are surprised that the percentage was so low. We have seen a survey (enclosed) of 1000 prescriptions each for ampicillin and erythromycin in twelve major cities which showed that close to 30% of the brand-specified prescriptions in each case were substituted, with only one out of four substitutions authorized by the prescriber. In that study, which was conducted before the repeal of many state antisubstitution laws, the price of the substituted prescriptions for ampicillin was practically identical to those dispensed as written, while the price of the substituted erythromycins was, on the average, 3% higher.

Dr. Goldberg's study presents a further complication in trying to reconcile Tables A and B, which have identical captions but different figures on savings. These tables are also difficult to reconcile with Table A of the earlier Goldberg study presented on October 31, 1977 to the American Public Health Association. According to this earlier table, for the second year of the study Dr. Goldberg found a saving of \$1.23, or almost 24%, from an average of 55 truly matched pairs (i.e., comparing dispensed as written with substituted in the same pharmacies for the same drug entity). Table A of his June 22nd statement shows an average saving of \$1.14, or 21%, on an average of 463 "matched pairs" also for year 2. But Table B shows a saving of \$.92, or 16.8%, also for matched pairs in year 2, but this time with 565 matched prescriptions. Not only are the captions identical, but the text on page 28 leads us to understand that in both cases he is discussing "matched pairs" within the state--which we understand from his earlier report to mean that he is comparing prices between substituted and non-substituted prescriptions at different stores. From his October 1977 study it is clear that when he compares matched pairs at different stores the saving is substantially less (i.e. 15.9% for year 2) than with the much smaller sample of matched pairs from the same pharmacies.

Mr. Olsen, in his June 30 letter, points to the hazards of comparing prescriptions at different stores, given the evidence of very wide divergences in retail charges for the same drug product in the same prescription size from different pharmacies. There may be an even more serious flaw in trying to extrapolate from the savings found in matched pairs at the same store. (We are assuming that there is a misprint in the caption on Table A of Dr. Goldberg's testimony and that it does refer to matched pairs in the same pharmacy, while Table B refers to matched pairs in different pharmacies).



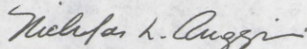
There are relatively few drugs which offer large savings. From our own research at PMA we know of only two drugs--both relatively minor--in which a generic product would offer as much as 50% in savings over the brand name product. At the other extreme there are some very important drugs where the potential saving is relatively inconsequential. In one study of IMS America invoice data of 1976, we found that for 8 out of 37 major multisource drugs the average unit price at retail when prescribed by brand was the same as, or lower than when prescribed generically.

Given this spectrum of differentials between brand and generic versions of multi-source drugs, the pharmacist's natural self-interest as well as a professional concern for the patron's welfare would cause him to substitute primarily when it involved a drug with a substantial price differential. This fact would skew the sample in Dr. Goldberg's study towards those drugs with high savings potential, and would be one factor contributing to the low number of recorded substitutions.

Also, the few Michigan pharmacists who substituted knew that a survey was being conducted and would have every reason to demonstrate a high average rate of saving per substituted prescription. The law was, after all, designed to meet the goals of pharmacists as much as the interests of consumers.

The fact that the savings rate on generic prescriptions was so much lower than those on substituted prescriptions should have alerted Dr. Goldberg to the bias in his sample. There is really no reason why the savings rate should be different for the two types. In the case of the generically written prescriptions, the doctor expressly authorizes "product selection", while in other cases the pharmacist can exercise that authority under Michigan law irrespective of any express authorization from the prescriber. As a basis for extrapolation, the savings rate shown for generic prescribing would be much more reliable as an indicator of potential savings assuming substitution were truly cost free. In any case, we predict that if the substitution rate in Michigan rises, as Dr. Goldberg foresees, then the savings rate will decline, and we believe that any continuation of Dr. Goldberg's study will confirm our prediction.

Sincerely,



Nicholas L. Ruggieri

Enclosure



## ELI LILLY AND COMPANY

INDIANAPOLIS, INDIANA 46206 • TELEPHONE (317) 636-2211

June 30, 1978

Nicholas L. Ruggieri, Esq.  
Assistant General Counsel and  
Director of State Government  
Relations  
Pharmaceutical Manufacturers Association  
1155 -- 15th Street, N.W.  
Washington, DC 20005

Dear Nick:

We read with considerable concern the recent testimony of Dr. Theodore Goldberg before the House Subcommittee on Consumer Protection and Finance.

Although the time available to respond to such complicated testimony, especially considering the proximity of the holiday weekend, is quite limited, we feel it is very important to point out to the Subcommittee that Dr. Goldberg's study technique is so deeply flawed that he is left with:

1. An insufficient basis for concluding that substituted prescriptions are less costly than prescriptions dispensed as written by the physician, and
2. Insufficient data for defining and estimating any incrementally lower consumer expenditures for drugs in the whole State of Michigan (or any larger jurisdiction) as a consequence of additionally-mandated substitution.

What strikes us as singularly dubious in the recent testimony is the basing of "savings" estimates on inter-pharmacy prescription "pairs." The analytical literature (see especially footnotes one through nine) is rich with documentation of the very large inter-pharmacy price differentials for exactly the same product, manufacturer, strength, form and quantity. For the reasons described below, there is no basis we can imagine for concluding that the "differentials" Dr. Goldberg measured were due solely to ingredient cost differences.



If his methodology were even to have an outside chance of definitively answering the questions posed, it would have to depend on the prescription pairs within the same pharmacy--and even then, major increases in sample size and improved sampling techniques are still needed.

We have followed with interest Dr. Goldberg's statements over recent months regarding his study series, and have waited for some form of publication of "final" numbers so that we could make formal comments. The numbers he cited in his June 22, 1978 testimony are different from those in his previous presentations of his draft results--but similar enough in magnitude to apparently be based upon the methodology he described before the American Pharmaceutical Association meeting last fall.

Please find below our detailed thoughts about Dr. Goldberg's methodology described in that October, 1977 draft.

We would appreciate it greatly if you would attempt to convey our comments to the Subcommittee despite the rushed schedule.

#### Specific Comments and Questions

1. The inclusion of pharmacy fee in the measured cost of each prescription introduces an unquantified, but substantial, source of variability.

Berki, Richards and Weeks in a study of more than 13,000 Michigan prescriptions, collected within a two-week period, document inter-pharmacy variations as high as two hundred percent and intra-pharmacy variations as high as 130 percent--for exactly the same drug product and quantity.<sup>1</sup> Similar significant price variations within, and between, pharmacies have been widely documented in the literature.<sup>1-9</sup> In a study of northern California pharmacies, Busath<sup>2</sup> concluded, "A pharmacist's choice of a pricing schedule is generally arbitrary and does not take into account the cost to the pharmacist of filling the prescription." Some



studies have even demonstrated prescription price variation as a function of the quality of the customer's clothing<sup>3</sup> or the customer's race.<sup>8</sup>

How can we be sure that the price variations measured in the study sample are not pharmacist-fee or pharmacy-price-policy related rather than, as the researchers did assume, a direct consequence of ingredient price differences? Since there was no mention of this effect in the study, the reader is left in doubt on this point and cannot conclude that the ingredient price differential assertion is proved.

2. Even if ingredient price differentials were real, the "prior approval" clause in Michigan's substitution virtually ensures a biased sample of substituted prescriptions.

For all but four months of the study period the substitution law in Michigan required the consumer's consent before each instance of substitution could occur. Knowing that this prior-approval process had the potential for initiating a time-consuming (and, therefore, expensive) conversation with the customer, was it not likely that the pharmacist would only attempt to recommend substitution on those prescriptions where the savings opportunity was the greatest? Given whatever savings potential might otherwise have existed (and this critique documents the insufficient basis for the basic claim of savings), it seems unlikely that a sample of prescriptions produced by such a system as was in place in Michigan would be representative of the gross possible savings if all substitutable prescriptions were indeed substituted. In other words, even if the sample is valid, the results are not generalizable.

3. Possible shortcomings in sample design and data collection.
- 3a. By ignoring errors-of-measurement (in at least quantity and time dimensions), they have understated variance.



Even if we ignore the inappropriate inclusion of the pharmacy fee in the sampled prices, the conclusion that average differences between "matched" substituted and non-substituted prescription prices are statistically significant depends on the t-test values, which are degraded by higher variances. The study, by assuming errors-of-measurement to be zero, arbitrarily and unrealistically understates variance and overstates t-test values. Are these t-values so overstated that, if realistically computed, the conclusion of the study that "substitution saves money" would be reversed? The study does not treat this question nor give us the necessary detail to be able to estimate it.

- 3b. The t-test statistical methods used depend on equal probability sampling, but the study protocol does not assure that.

While the study's sampling methodology may have assured an equal probability of selecting any single prescription from the sampling frame, the assertion that this satisfies the equal-probability-sampling prerequisite of the methodology is incorrect. What must have the equal-sampling-probability are the "matches" (substituted and non-substituted prescriptions, for the same entity, within the same store). The consequences of this sampling oversight include errors of indeterminate magnitude and direction in the point estimators (the sample means). This casts further doubt on the study's assertion that substituted prescriptions are less costly.

- 3c. In much the same way that "matched" prescriptions probably have unequal likelihood of being sampled, smaller pharmacies and lower-incidence therapeutic classes and drug entities are probably under-represented in the sample.

The essential need in this study design, as we have observed, is to find the "matched" prescription pairs within the same store. Given the low incidence of overall substitution (only about 1.5% of substitution opportunities were exercised),



large samples of "matches" were certainly difficult to obtain. Indeed, the study indicates that "clustering" and "caliper-sampling" techniques were instituted solely to increase the sample "matches."

And yet only about fifty "matches" were obtained out of total prescription sample of approximately twenty thousand.

Simple common sense, to say nothing of more arcane sampling technicalities, should make the reader skeptical that all sizes of stores and all frequency-of-use therapeutical classes and entities are proportionately represented in a sample of only about fifty prescriptions.

And what if they are not proportionally represented? There is certainly no evidence presented that price differential ratios (even if they existed and were computed correctly) are even similar for all entities, therapeutic classes and pharmacy sizes. And yet, the study projects the "savings" anticipated through mandated substitution for the whole Michigan multiple-source prescription market-- a market the study estimated in 1974 was between thirteen and seventeen million prescriptions!

Reference should be made here, since we are critical of the small sample sizes of prescriptions matched within stores, to the other "match" sample the researchers defined: "matches" by entity between stores. Given the evidence of very substantial inter-pharmacy price variation,<sup>1-9</sup> this sample should be presumed meaningless for determining substitution "savings" and the burden of proof to establish the credibility of this technique is clearly on the researchers.

4. The variance of the differences between means (these differences being the basis for the projected "savings" from substitution) is probably incorrectly calculated.

With a complicated sampling plan such as this, the variance estimators are



quite difficult to compute.<sup>10</sup> Generally, precision is enhanced by stratification, a technique which was apparently used in this sampling design. However, the clustering technique also employed in this sampling design customarily degrades precision in variance estimators.

In personal conversations with some of the researchers, they inform us that variance of differences were computed using standard procedures available under the "MIDAS" software package. It is unlikely that the variance formulae employed are appropriate for the study's sample design.

5. The regression analysis, which purports to functionally express the prescription price-per-unit for all possible quantities, includes too few variables and presents poor variance-explained and goodness-of-fit measures.

In the Pen-VK example presented by the researchers, the only variables that entered the multiple regression equation with any statistical "clout" are the base constant, the script quantity, the time counter and a "company factor" for two of the nine manufacturers considered. Especially in comparison to the breadth of variables defined by Gosselin and colleagues,<sup>11</sup> the study's approach seems singularly limited. The amount of variance explained ( $R^2 = .65$  in the Pen-VK example) also makes the reader suspect that the nominated causative variable list is probably incomplete. The Gosselin study identified thirty-six variables whose inclusion in a "prescription price" model was statistically significant at the .05 level:

- I. External factors

1. Regional adjustment (state grouping)
2. Urbanization and income level
  - a. Avg. per capita income
  - b. Trading area served ( $\text{mi}^2$ )



- c. No. competing pharmacies in area
- d. Avg. hourly wage of RPH.
- e. Avg. hourly wage non-pharm.

3. Store characteristics

- a. Single ownership?
- b. Years in present location
- c. Store size (ft<sup>2</sup>)
- d. Rental expense
- e. Shopping Center or not?
- f. Hours open per week
- g. Daily Rx volume
- h. Health/Beauty Aid discount policy

4. Third party reimbursement involvement

- a. Fed/State Rx's as pct. total Rx's
- b. Private, third-pty Rx as pct. of total
- c. Usual waiting period for reimbursement of third-party Rx's

II. Internal Factors

1. Special customer services

- a. Pct. Rx's charged
- b. Usual waiting time for payment of charge accounts
- c. Rx sales as pct. of total store sales
- d. Free delivery?
- e. Patient/family records?
- f. Customer waiting area?

2. Sources of drugs purchased

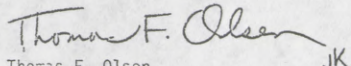
- a. Pct. direct
- b. Pct. through wholesaler



- c. Pct. from central warehouse
- 3. Personnel deployment
  - a. Pct. time typing labels by R.Ph.
  - b. Pct. time count and pour by R.Ph.
  - c. Pct. time handling recalls and returns by R.Ph.
  - d. Pct. time preparing and sending bills by R.Ph.
  - e. Pct. time non-Rx drugs and supplies sold by R.Ph.
  - f. Pct. time customers are instructed in Rx use by R.Ph.
- 4. Community relations and professional development
  - a. Hrs/week in prof. mtngs. and seminars
  - b. Hrs/week reading prof. journals
  - c. Hrs/week reading pharm. co. literature
  - d. Hrs/week instructing patients in drug and health care information

Not having considered most of these variables, Dr. Goldberg and his colleagues have considerable refinement to do on their regression studies before they even attain the level of precision already available in the literature.

Sincerely,

  
Thomas F. Olsen JK  
Manager  
Corporate Affairs Research

TF0:jk

Footnotes

1. Berki, Richards and Weeks, "The Mysteries of Prescription Pricing in Retail Pharmacies," Medical Care Vol. XV, No. 3, March, 1977.



2. Busath, "Prescriptions, Pricing and Profits: Do Pharmacists Really Want to Make Money?," Pharmacy West, May, 1977.
3. "Clothes Make the Customer?," Pharmacy West, May, 1977.
4. McGowan, "Pharmacy Drug Prices Can Vary 1,200 Percent," William Smith College, School of Economics (Syracuse New York) in Herald Tribune, February 20, 1978.
5. Jackson and Smith, "Relations Between Price and Quality in Community Pharmacy," Med. Care, XII, No. 1, January, 1974.
6. Gagnon and Rodowskas, "A Study of the Relationships of Drug Dosage Form, Therapeutic Class and Pharmaceutical Services with the Gross Margins on Prescription Drugs," Med. Care, XII, No. 1, January, 1974.
7. Wertheimer, "Pricing Pharmaceutical Service--Art, Science or Whim," J. Am. Pharm Assn., NS13, No. 1, January, 1973.
8. Kotzan and Braucher, "A multivariate Analysis of Retail Prescription Prices," J. Mktng. Res., VII, November, 1970.
9. Hastings and Kunnes, "Predicting Prescription Prices," New Eng. J. Med., 227, No. 12, September 21, 1967.
10. Cochran, Sampling Technique, Second Edition, John Wiley, New York, copyright 1963, Chapter 11.
11. Gosselin et al, "Pharmacy Charges for Prescription Drugs Under Third Party Programs," R.A. Gosselin and Company, Inc., Dedham, Mass., Copyright 1971.



IX. SUBSTITUTION SURVEY

Each year there appears to be a greater incidence of retail pharmacists substituting heavily stocked brands in place of the brands specified by physicians in filling prescriptions. However, there is very little evidence that this wave of substitution helps the consumer in any way or lowers his prices. In many cases, substitution has had the opposite effect---the retail pharmacist substitutes a higher-priced brand for the lower-priced brand specified by the physician.

To determine the extent of substitution, a survey was conducted by Rx OTC Research, an independent market research company, using professional shoppers who presented identical prescriptions to retail pharmacies in twelve metropolitan areas during June 1973. The cities were New York, Washington, D.C., Detroit, Chicago, San Francisco, Los Angeles, Boston, Philadelphia, Baltimore, Louisville, St. Louis, and Dallas. The shoppers presented one prescription per store, for a total of 1,000 prescriptions for various brands of ampicillin, 1,000 prescriptions for various brands of erythromycin, 400 prescriptions for penicillin VK, and 110 each for brands of tetracycline and oxytetracycline. In addition, 100 generic prescriptions each for ampicillin and erythromycin were also presented to retail pharmacists.

The survey showed that 33.1 percent of all ampicillin prescriptions were substituted, 29.6 percent of all erythromycin prescriptions were substituted, as were 26.1 percent of all penicillin VK prescriptions. Moreover, for four of the nine brands of ampicillin and five of the nine brands of erythromycin, the average prescription price was the same or higher if the retail pharmacist substituted another brand for the one specified on the prescription. In three out of every four cases where substitution did occur, the physician was not notified of the switch.

SUBSTITUTIONSAmpicillin Substitution

| <u>Rx for:</u> | <u>Average Price<br/>If Filled with<br/>Specified Brand</u> | <u>Average Price<br/>If Filled with<br/>Substituted<br/>Brand</u> |
|----------------|-------------------------------------------------------------|-------------------------------------------------------------------|
| Pen A          | \$4.17                                                      | \$4.56                                                            |
| Penbritin      | 4.94                                                        | 5.14                                                              |
| Principen      | 4.69                                                        | 4.69                                                              |
| Totacillin     | 4.30                                                        | 5.03                                                              |
| 4 Other brands | 4.97                                                        | 4.56                                                              |

Erythromycin Substitution

| <u>Rx for:</u>  | <u>Average Price<br/>If Filled with<br/>Specified Brand</u> | <u>Average Price<br/>If Filled with<br/>Substituted<br/>Brand</u> |
|-----------------|-------------------------------------------------------------|-------------------------------------------------------------------|
| Pfizer E        | \$4.28                                                      | \$4.70                                                            |
| SK-Erythromycin | 4.28                                                        | 4.45                                                              |
| Ethril          | 4.32                                                        | 4.44                                                              |
| Erythrocin      | 5.30                                                        | 5.36                                                              |
| E-Mycin         | 4.77                                                        | 5.45                                                              |
| 3 Other brands  | 4.96                                                        | 4.72                                                              |

Source: Rx/OTC Inc., 1973



Moreover, the big differential in prescription prices is not between generically written prescriptions and brand-name prescriptions but between stores in the same cities:

Average and Range of Consumer Rx Prices  
for 250 mg. of Erythromycin/20 tablets

| <u>Cost of Rx to<br/>Consumer If<br/>Filled<br/>As specified:</u> | <u>E-Mycin</u> | <u>Ilosone</u> | <u>Pfizer E</u> | <u>Erythrocin</u> |
|-------------------------------------------------------------------|----------------|----------------|-----------------|-------------------|
| Lowest Price                                                      | \$3.03         | \$3.60         | \$2.20          | \$3.23            |
| Average Price                                                     | 4.77           | 5.64           | 4.28            | 5.30              |
| Highest Price                                                     | 9.00           | 7.20           | 8.95            | 7.00              |

Cost of Rx to Consumer:

|                                    |        |        |        |        |
|------------------------------------|--------|--------|--------|--------|
| If used to fill<br>generic Rx      | \$5.07 | \$4.62 | \$4.98 | \$5.11 |
| If specified on<br>Rx              | 4.77   | 5.64   | 4.28   | 5.30   |
| If another brand<br>is substituted | 5.45   | 5.30   | 4.70   | 5.30   |

Average and Range of Consumer Rx Prices  
for 250 mg. of Ampicillin/20 Tablets

| <u>Cost of Rx to<br/>Consumer If<br/>Filled<br/>As specified:</u> | <u>Polycillin</u> | <u>Principen</u> | <u>Penbritin</u> | <u>Pea A</u> |
|-------------------------------------------------------------------|-------------------|------------------|------------------|--------------|
| Lowest Price                                                      | \$2.80            | \$2.59           | \$2.65           | \$2.60       |
| Average Price                                                     | 5.05              | 4.69             | 4.94             | 4.17         |
| Highest Price                                                     | 9.90              | 7.50             | 9.50             | 7.50         |

Cost of Rx to Consumer:

|                                    |                         |        |        |        |
|------------------------------------|-------------------------|--------|--------|--------|
| If used to fill<br>generic Rx      | \$4.72                  | \$4.93 | \$4.26 | \$4.02 |
| If specified on<br>Rx              | 5.05<br><del>3.05</del> | 4.69   | 4.94   | 4.17   |
| If another brand<br>is substituted | 4.44                    | 4.69   | 5.14   | 4.56   |



Lastly, the survey revealed that six percent of the retail pharmacists substituted drugs other than oxytetracycline in filling the oxytetracycline prescriptions and approximately one percent of the stores were substituting drugs other than erythromycin in filling the erythromycin prescriptions.

The conclusions to be drawn from the survey are as follows:

1. Allowing pharmacists to substitute multi-source drugs will not necessarily lower the price of drugs to consumers and in some cases will actually raise the cost of prescriptions to consumers.
2. The public runs the risk that a small percentage of retail pharmacists will illegally substitute different classes of drugs for the therapeutic agents specified by physicians. Any scheme of reimbursement that is based primarily on "lowest available price" would inevitably tend to accentuate this illegal and dangerous trend and would have deleterious effects on health care in the U.S. in the long run. (See section IX.)



Questions to the Pharmaceutical Manufacturers Association submitted  
by Congressman Matthew J. Rinaldo and response thereto

1. If FDA approves a drug product for marketing, doesn't such approval assure that the product is interchangeable with other versions of the same drug?
2. You stated that FDA's own information shows a difference in performance among manufacturer. On what data do you base that judgment?
3. It is my understanding that pharmacists receive more education about drugs than doctors. If that's the case, why do you believe physicians are in a better position than pharmacists to select a drug product for patients?
4. Wouldn't a law that mandates a pharmacist to substitute have a negative impact on physicians?
5. What are the major trends in state substitution laws passed in recent years?
6. There are several major research-oriented pharmaceutical companies in my state. Will such legislation, which requires that only the cheapest drug products be used, have an impact on pharmaceutical research?



1. No. FDA evaluates only the safety and effectiveness of drug products for their approved uses. That is done under distinctly different standards for different manufacturers. The company that discovers a new drug must conduct exhaustive tests, including clinical evaluation of the product in patients. The standards applied to follow-on producers range from limited testing to simple promises to conform to Good Manufacturing Practices regulations. So the knowledge FDA has of the actual safety and effectiveness of different drug products varies widely. For generations FDA and the scientific community has considered actual clinical comparisons necessary to judge equivalence. For instance, both the HEW Task Force on Prescription Drugs, and the OTA Drug Bioequivalence Study Panel issued reports in 1969 and 1974 respectively clinical comparisons are the only accurate measure of relative equivalence. FDA has only recently unilaterally changed that accepted scientific principle by declaring that all approved drug products of a given entity can be considered therapeutically equivalent if certain standards are met. (i.e., identical dosage form, specifications, and manufacturing standards). Even FDA scientists disagree with that position, as indicated by internal agency efforts to create a task force to upgrade compendial standards for better quality assurance. The Agency has purposefully declined to use the word "interchangeability" when referring to two allegedly equivalent products. In addition to differences in the quality of products made by different manufacturers, even FDA knows that two products of comparable quality may still not be interchangeable because of formulation variations, individual patient characteristics, and types of disease conditions. FDA has been repeatedly asked to certify the medical interchangeability of drug products, but wisely refuses to do so.



2. Company performance differences have been documented using two FDA sources. Quality Assurance Profiles (Form FD 2855 9/76) are maintained on each drug company under FDA's jurisdiction. They include a record of establishment inspections and the results thereof, the results of tests conducted on product samples, recalls, and a regulatory profile which notes other compliance actions (regulatory letters, seizures, court actions, etc.). Sample QAP's show that some companies have continuing problems that result in defective products reaching consumers in spite of FDA's efforts to correct the situation. FDA "Enforcement Reports" are published weekly and include a tabulation by company of the most recent compliance actions. These reports were used in a recent analysis showing that companies that are not heavily engaged in medical research have seven times more recalls and 43 times more serious FDA court actions against them than do the research-intensive companies. A further evaluation of FDA's documents also demonstrates that research-intensive companies do not have larger recalls than other companies. In 1977 the research companies had less than one million units recalled (tablets, capsules, etc.), while the other companies had over 15 million units recalled. The point is that some companies do a better job than others. FDA data show that the research-intensive companies have consistently better records of performance than do companies not heavily engaged in research.



3. The medical evaluation of an individual's specific disease condition is the most important part of drug product selection. Individual patient characteristics are very important in selecting a product that may have unique properties. A person's weight, age, sex, level of stress, biotransformation efficiency, gastrointestinal acidity, and many other factors may call for a unique formulation of a certain drug. A continuing evaluation of the progress of medical treatment, including drug therapy, is also necessary for optimum patient care. Only the attending physician can monitor all of these critical factors. The physician therefore makes a decision when prescribing a drug. The doctor may decide that conditions are such that any manufacturer's product will do in a particular patient's case, and write the prescription generically. The same doctor may also decide that a specific manufacturer's product is necessary for another patient with the same disease because of the factors listed above or other considerations such as extent of side effects, possible interactions with other medications, and the like. In that case, a brand name may be prescribed (identifying both the drug and a particular manufacturer's formulation), or the drug's generic name with the manufacturer identified. In seeing patients regularly and monitoring their progress, doctors also come to know which products do a better job. These are all medical decisions that must be made by the person who has considered the patient's medical history, diagnosed the disease, and understands the patient's characteristics and the conditions under which therapy is being prescribed. That person is the doctor. Pharmacists have a critical and invaluable role in selecting medical products under certain circumstances. But the initial decision must be made by the physician responsible for the patient's care.



4. Mandatory substitution laws have a negative impact on physicians, but on consumers and pharmacists as well. A doctor's patient who returns with complaints of a therapeutic failure is unnecessarily denied efficient treatment, and creates unnecessary additional problems for the doctor. A further diagnosis may be required to find out why the patient is not progressing adequately, and may even result in alternate and less effective courses of treatment when a quality drug product could have had the desired effect in the first place. By the same token, mandatory laws may require pharmacists to dispense products in which they have less confidence than the prescribed brand. If substitution is to take place, pharmacists must be free to dispense the product originally prescribed if that is what is considered best for his or her customer. Mandatory substitution laws are an attempt to meet political and economic objectives without giving proper consideration to the medical and scientific issues involved.
5. For trends in state legislation, please refer to the attached chart.



6. Yes. The costs of discovering a new drug and bringing it to market are staggering. The estimated cost now stands at \$54 million for each new drug. Some 8,000 drugs are tested for every one that makes it to the pharmacy. The process takes from 8 to 10 years, and sometimes generations. It is important to remember that the 17 year patent protection afforded to innovators throughout industry does not really apply to drug manufacturers. The patent clock starts running at the time the chemical entity is discovered in the laboratory. That is long before it is developed into a useable product form, before the clinical trials begin, and before the company even submits an application to FDA for approval to market the drug. Drug companies have an average of 7 to 9 years of patent protection for new discoveries. The costs of discovery must therefore be recovered in a much shorter time than is the case for other products. While innovative firms can survive in an open and competitive market, the arbitrary requirement to dispense the cheapest version of a drug is a direct threat to the ability of pharmaceutical companies to recover research and development costs and continue to discover new medicines. These mandatory provisions must also be considered in the context of the existing climate for innovation, which is not good. It is becoming increasingly difficult for any industry to engage in basic research.

As more and more tests are required, more research is going overseas where standards are high but reasonable. During the past ten years the number of patents originating in the U.S. has declined by 20%. Fewer scientists are entering the fields of basic research because too much research is now defensive and not truly innovative. If pharmaceutical research is further threatened by legislative mandates to use only the cheapest products, we may very well deny future generations the new medicines we need so much, to say nothing of the inevitable sacrifice in quality consumers would suffer today.



Mr. RUGGIERI. I merely wish to observe quickly that Dr. Goldberg is prepared to announce to the world that for 1978, tentatively speaking, there may be an order of magnitude of 15 percent, whereas up until now he was able to detect only 0.75 and 1.5. We would very politely suggest there may be some methodological considerations involved in moving from a 1.5 to a 10 to a 15.

We could design a study, as I am sure you could imagine, that would not produce anywhere near the orders of magnitude that have been mentioned today and would be perfectly valid from a statistical and scientific standpoint. There have been other studies, particularly in Delaware, where methods are different and conclusions are therefore different and inferences therefore are different. But we would call that to your attention.

In view of your kind invitation for supplemental evidence, we would be happy to devote some time to clarifying at least what we think are some pitfalls.

Mr. ECKHARDT. I wonder if you would like to comment on some of the questions I had asked previous witnesses. It would seem to me that though it might be possible to find somewhat general equivalency with respect to the content of the particular drug and its gross effect, there might be considerable difference having to do with the manner in which it was prepared and the manner in which it was dissolved or pulverized.

I suppose if it were in a pill form or capsule form it would not be considered within a single generic classification for the purposes of this act. I do not know. But it does seem to me there would be certain areas of effectiveness or certain ranges of effectiveness that would be rather settled and difficult to come about without very extensive experimentation.

Mr. RUGGIERI. Could I ask Dr. Schneller to comment on that? He is a scientist by training, if you don't object.

Mr. ECKHARDT. Sure.

Dr. SCHNELLER. Sir, that is a very valid observation that you made, and that is a subject of concern which I and my peers in the industry and also in academia, specifically within the membership of the academy of Pharmaceutical Scientists, have considered and wrestled with for a long time.

Some of these facts you mentioned were contained in a committee report published by the academy 9 years ago, which are still valid today. I have a copy of the statement, which treats that and other aspects of drug quality.

The differences in the effect of a drug in the body, its rate of absorption and availability for action, which is referred to as bioavailability, are subtle and difficult to solve and are still, in very large part, with respect to any drugs, unsolved.

A current example of this difficulty is that between the October issue and the April 1, 1978 issue of the New York Formulary, there are tremendous differences. The October issue had on the cover "These drugs present no known issue as to interchangeability," but 19 of these drugs have disappeared from the April 1978 issue. They are simply not there. These are not obscure drugs gathering dust in the corner of the pharmacy. These each, on an average, were listed with 20 suppliers in that previous issue.



When I look at that list which I prepared simply by comparing the two books, I find most of these 19 are drug substances which have for years been suspected or known of having difficulty with bioavailability.

It is true, as one previous witness said, that the FDA has issued regulations on bioavailability. Those regulations took them 3 years just to develop and to pass through several phases of draft, but by no means are they yet fully implemented.

Most of the drugs in this book and in the April book have not been subjected to the kind of individual study, and the only way a drug can be evaluated in the true, full sense is by studies in people.

It is recognized that these studies are very expensive and time consuming and for some drugs perhaps that is not justified.

But as a compromise or interim measure for establishing at least part of the way this equivalence, there is a laboratory test of dissolution. This is simply a rate at which a tablet or capsule goes into solution, the theory being it has to be into solution before it is absorbed. But even that method of determining the dissolution is far from being established for many drugs. The "U.S. Pharmacopeia," which is the book of standards—and if anyone wants to see it, I have one in my bag—adopted a policy that favors or would like to see a dissolution test for every tablet and capsule product in the book. Yesterday, I looked at 250 monographs in the state of preparation and have reached the stage of common proof where a large number of the committee members, totaling nearly 100, get in circulation and comment and get it back. These monographs have to go to the printer by the end of the year, but of the 250 monographs, 15 have a dissolution test. Fourteen or fifteen others say dissolution test to be provided. And the remainder say nothing about a dissolution test.

Mr. ECKHARDT. Are some drugs perishable, depending on how they are maintained?

Dr. SCHNELLER. Yes; they are perishable in general; that is, with regard to deterioration and the lowering of the content of the active ingredient, and this is unpredictable from a single test made at the time of manufacture. It can only be determined by prolonged studies and is not subject to any particular control by FDA. You cannot pick up a sample on the market or in the market and predict what the shelf life will be.

Mr. ECKHARDT. Does this have anything to do with the manner of suspension of the drug, even assuming that the same ingredients are contained in it, or the manner of packaging or other mechanical means of preserving or packaging of the drug?

Dr. SCHNELLER. Yes; and it has to do largely with the formulation. The formula is not a matter of public knowledge. The formula of a tablet and capsule does not have to be disclosed and is not stipulated in any—

Mr. ECKHARDT. Yes; but we are talking about generic drugs, so aren't we assured the formula is essentially the same?

Dr. SCHNELLER. No; there is no assurance that the formula is the same. Nobody ever made that claim. The formula actually is different. Any company which starts out to formulate a product is apt to start with a difference. There is no guidebook, no standard, no



encyclopedia providing a formula telling what ingredients to use or prepare for the product.

Mr. ECKHARDT. Yet there are, I think you would admit, many drugs that have the same active ingredients and really are quite substitutable. For instance, various types of aspirin, various types of relatively simple drugs that may be put out under quite fancy names that may differ widely, contain precisely the same ingredient, do they not?

Dr. SCHNELLER. The same active ingredients, not the same inactive ingredients. Until 10 years ago, the pharmaceutical world, including people like myself in industry, the pharmacological experts, the academic world, assumed that if the same amount of active ingredient was present in the tablet and it met the chemical test for the presence of that active ingredient, that it was interchangeable. That was a general assumption.

But about 10 years ago, a revolution took place in the thinking of the scientists and the technologists, both in the companies and in the field, and that is no longer the case. What brought that to a head was some very drastic events which illustrated this was not true and these events are still accumulating.

Mr. ECKHARDT. Why shouldn't you operate, then, on a substitution program that provided a positive formulary of drugs safe to substitute? Why not identify those drugs which are "safe to substitute." That may be too narrow a term perhaps "safe and expedient" to substitute? Why wouldn't that be a desirable objective? Why should the public pay much more for the same thing in those cases in which the active ingredients are the same and there is no substantial difference in the efficaciousness of the drugs. Many drugs are of that nature, are they not?

Dr. SCHNELLER. No; that is the question. What is the difference in efficaciousness? That can only be determined by testing each drug in comparison with the standards.

Mr. ECKHARDT. Well, you can't tell me that St. Joseph's Aspirin and Bayer's is really any different as far as its effectiveness. It contains the same thing. It might melt in your mouth slightly differently, but can you really tell me those are different, and that it would be more desirable to use the one than the other? I am not asking you which is best.

Dr. SCHNELLER. That is an extreme example. The factor of potential difference might be minimal. If you have a headache and you take an aspirin and it doesn't work in 20 minutes, you may take another one. But not many drugs are in that category. For example, if you have a high blood pressure drug and it is consistently working and available at a 20 percent level lower than the one you had been taking before, you would not get the therapeutic effect. You are not going to drop dead from a stroke, but I think reasons of economy are not sufficient to justify allowing that type of product on the market.

The Food and Drug Administration tends to concentrate on what they call lifesaving drugs, critical drugs. However, those are not the only ones. If we are talking about dollars and cents and 10 cents a prescription incentive, then I think we should not just regard differences in lifesaving drugs or drugs where there have been drastic or catastrophic effects from switching products.



Mr. ECKHARDT. Then why not a negative formulary with respect to those that are lifesaving drugs and are not safe to substitute?

Dr. SCHNELLER. It depends on its scope. There are some people who would put 10 drugs on there, which would mean that everything else is all right, but that would not be justified scientifically unless the other drugs have been tested and other products have been tested. This book has many products which have never been tested. I think it is safe to say most of the individual products, not the single source, but multiple-source products in this book, have never been tested for bioavailability.

Mr. ECKHARDT. Thank you.

Are there further persons on the panel that have further statements?

Mr. RUGGIERI. We are finished.

Mr. ECKHARDT. Mr. Schwartz, I must answer this vote.

We will recess briefly and then resume with your statement.

[Brief recess.]

Mr. ECKHARDT. Mr. Schwartz, please proceed.

**STATEMENT OF GEORGE SCHWARTZ, EXECUTIVE DIRECTOR,  
NATIONAL ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS (NAPM)**

Mr. SCHWARTZ. Mr. Chairman, I am George Schwartz, executive director of the National Association of Pharmaceutical Manufacturers, NAPM.

The National Association of Pharmaceutical Manufacturers is a trade association of manufacturers and distributors who are engaged in the manufacture and sale of drug products to wholesalers, retail pharmacies, physicians, hospitals, and bona fide recipients of pharmaceutical commodities.

I would like to thank you and the members of your subcommittee for the opportunity to appear here today to offer comments and views on this important legislation.

I would also like to apologize, my presentation is not comprehensive, as requested in the letter which I received quite late, as I was out of town for a while.

I also would appreciate the fact this statement be inserted in the record.

We wish to express our support for H.R. 1963.

The high cost of prescription drugs is a major problem for the elderly. This bill will result in lower cost for drugs, which is a problem for all elderly, low-income and middle-income people through this Nation. The bill will result in lower costs for the Nation. This bill will also help the small pharmaceutical manufacturer to compete in the marketplace.

We suggest that section 4 be amended as follows:

No State or political subdivision of a State may establish any requirement which is different from, or addition to, any requirement of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. section 301 et seq., with respect to a drug, drug entity, or drug product.

This amendment will help to prevent unnecessary interference with the sale and distribution of generic drug products in interstate commerce.

Thank you for the opportunity to testify.



I am also prepared, if there are any questions, to elaborate on this as to the reason why we are requesting this, if you so desire.

Mr. ECKHARDT. Have you completed your statement?

Mr. SCHWARTZ. This is the extent of my testimony; yes, sir.

Mr. ECKHARDT. Mr. Schwartz, some of the testimony here was to the effect that it is difficult to determine drugs that might be considered a category of substitute drugs.

You have heard the discussion here immediately before your testimony.

Do you have any comments on it?

Mr. SCHWARTZ. Yes; I do. We have an arm within our Government, the Food and Drug Administration, one of the most highly funded organizations in this Nation, one of the most competent groups of individuals that has been put together, with access to some of the finest brains and availability of the finest technology within this Nation.

It is about time, sir, that industry, consumers, and everybody in this Nation, drop this thing to a point and decide now what are we going to do. This is 1978.

We should have one standard in this Nation of drugs regardless of who manufactures that drug, and that is the highest standard.

We must have a monitoring agent such as the FDA.

We must give this to an impartial group. This impartial group is FDA, and if FDA publishes a list there should not be a single drug entity in this marketplace if it is not purported to do what it will or is supposed to do.

I think it is about time we have taken this into consideration. We have now a situation with our formulary system which we are discussing at great length here, where each and every State is setting up a little FDA within the State.

Whose money is going into this little FDA in each State outside of taxpayer money, consumer money, my money, and everybody else's money? If we have one central agency, there is not a State in this country that can say we have come to the FDA and we found a problem with a drug and the FDA did not act on.

I don't know of any such thing. They will move and move rapidly.

Let us take and put this power where it belongs, within one agency. If industry does not recognize that the day has come, they will be faced at some very, very near future date with a fixed formulary concept, so the supply of drugs in this Nation at a point where it can be afforded by all of the people in the country.

Mr. ECKHARDT. Now, H.R. 1963 gives authority to the pharmacist to substitute a drug which is considered a generic drug and suitable for a particular drug on a prescription, but it does not seem to me to give any guidance or limitations based upon any formulary.

Do you recommend that there be any such formulary?

Mr. SCHWARTZ. I recommend if we must have a formulary that the formulary be a negative formulary. In other words, if there is a product in the marketplace, first of all that product should not be in the marketplace in the first place, but if we must have a negative formulary or it should be a negative one.

In other words, if there is a product that may or may not be efficacious and the product use is of such nature at that particular



time where the agency feels that they must of necessity leave it within the marketplace until such time that it is proven either efficacious or nonefficacious, then we have a situation where the product may remain in the marketplace and it may go on the negative formulary based on the physician's desire to have that particular product.

Mr. ECKHARDT. But don't you have the question of efficacious for what?

Mr. SCHWARTZ. For whatever the purported recommended dosage and for the particular disease state or particular condition that it is being used for. In other words, there are many drugs in the marketplace where they don't even know how they work, why they work, but yet they work.

We had folklore medicine going back many, many years. Nobody could explain how or why. Today some of these folklore medicines have become sophisticated medications, but this is a problem.

In other words, we must have one agency, one law, one method of governing what is going on. As far as the pharmacy is concerned, generic products or generic substitution, I cannot address myself. You have a marketing situation which is regional, you have small manufacturers in various parts of the country that are purveying their products just in a particular small area.

Now, those products are available at a more reasonable price from the smaller manufacturer in that particular marketing area.

Now, invariably I think while it is going to be a lower priced drug when dispensed, the fact also remains that the pharmacist will, in many cases, being subjected to competitive forces within the area in which he is dispensing, and this will be part and parcel of the so-called normal reaction of what happens in the marketplace and, in other words, in a competitive situation.

Mr. ECKHARDT. I note that the bill says that as a general proposition, a drug to be dispensed pursuant to a prescription of a physician, which is identified in the prescription by a proprietary name or designation, may be filled by the pharmacist with a substitute drug in the inventory of the pharmacist at the time such pharmacist fills or refills the prescription involved.

Now, I am not quite sure within what range of drugs substitutes may be applied.

Mr. SCHWARTZ. Sir, we are having a generic conference which will commence tomorrow.

Mr. ECKHARDT. Now, the Act also provides that the established name as the meaning given in the Federal Food, Drug, and Cosmetic Act, and that provides:

The term "established name," with respect to a drug or ingredient thereof, means (A) the applicable official name designated pursuant to section 508; or (B), if there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof in such compendium, or (C), if neither clause (A) nor clause (B) of this subparagraph applies, then the common and usual name, if any, of such drug or of such ingredient,

And then there is a proviso.

I assume what this means is that only those drugs might be substituted which are within the designation of the established category of drugs that are the same as that under the generic name.



Mr. SCHWARTZ. We are talking about active ingredients now.  
Mr. ECKHARDT. Yes. But I just wondered how much judgment is permissible in substituting one drug for another.

I am just raising that question here.

Mr. SCHWARTZ. It's a very, very good question.

I think we have two distinct problems. One is the state of the art, the other is current technology. I don't think there is anybody in the room that can deny there are many products in the marketplace where the formulation has changed drastically as compared to 5 years ago or 3 years ago and sometimes 2 years ago, which is the state of the art or as technology develops where there is a problem that we are faced with and a problem is involved.

I think we are going to live with this as long as we are around. But I do believe that we do have an agency that should be monitoring this, it should not be industry, it should be an impartial agency such as the Food and Drug Administration.

I also believe that this should be addressed to the problem agency within our Government; I do believe there should be industry input, yes, but I think the final decision should come from an impartial point.

Mr. ECKHARDT. The language of the act may answer the questions I am raising here, and I raise these questions with a bit of trepidation with you people who are familiar with drugs and the manner in which they are handled.

I agree with you that we do have an agency that has a capability of accomplishing these objectives, and the only question I am raising is whether or not the scope of judgment of the pharmacist under this act may not be overly expansive, overly broad. In a sense we have got the question of who is going to make the determination of what constitutes a reasonable substitution.

Of course, the doctor may say there shall be no substitution, so he has the ultimate decision if he wants to make it. But, if he does not say there shall be no substitution, then there may be a substitution within some range, and I am not sure how that range is defined.

Mr. SCHWARTZ. Let's put it this way: This man you speak of as a pharmacist has gone to school; we must put our faith someplace, and we must assume this man has integrity.

I do feel they do have integrity. I will purchase a generic drug based upon what is available in his marketing area. It may be something that he is buying in Alabama that is nowhere available in New York because it is distributed in the State of Alabama and maybe one or two States nearby by a local manufacturer or distributor, who is a very, very small manufacturer or a small distributor. But he trusts these people.

Now, these people are producing and manufacturing and shipping a product which is in compliance with the food and drug laws of this Nation. Now, if it's in compliance we must assume that this particular drug is going to do what it should be doing.

Mr. ECKHARDT. I think we need to explore a bit what the Food and Drug Administration describes as "a drug within the same category for substitution." I suppose perhaps we had better explore this a little later with the pharmacist.



Mr. SCHWARTZ. I think there is an excellent program that is going to be put on which is called the generic conference, which is going to take place tomorrow afternoon, starting tomorrow afternoon, and one of the panelists that is going, or one of the panels being convened is, "Are Generic Drugs Equivalent."

I think possibly if you had someone of your staff come down it might be very, very revealing, because we are going to have some very, very fine people and very knowledgeable people there from the Food and Drug Administration as well as from industry.

I believe Dr. Marvin Zief, who is head of the Generic Drug staff of the Food and Drug Administration is scheduled and Dr. Steve Carson, who is, I think, in my opinion, a very well-versed individual when it comes to bioavailability and biostudy availability studies, and I believe he is the one that developed the initial concept with the Canadian Ministry of Health on bioavailability, and it should be an interesting program.

Mr. ECKHARDT. That is a good suggestion.

Thank you very much, Mr. Schwartz.

Mr. SCHWARTZ. Thank you.

Mr. ECKHARDT. Thank you all.

Mr. William S. Apple, if you gentlemen will submit to questions in writing, we will leave the record open for that purpose.

**STATEMENTS OF WILLIAM S. APPLE, EXECUTIVE DIRECTOR, AMERICAN PHARMACEUTICAL ASSOCIATION, ACCOMPANIED BY EDWARD G. FELDMANN, ASSOCIATE EXECUTIVE DIRECTOR; AND CARL ROBERTS, ASSOCIATE GENERAL COUNSEL**

Dr. APPLE. Thank you, Mr. Chairman.

Mr. Chairman, I am Dr. William S. Apple, executive director of APhA, the National Professional Society of Pharmacists.

I am accompanied by Mr. Carl Roberts, APhA associate general counsel, and Dr. Edward G. Feldmann, APhA associate executive director.

We are pleased to accept your invitation to testify on H.R. 1963, the Substitute Prescription Drug Act.

With your permission, sir, I would like to have our entire statement inserted into the record.

Mr. ECKHARDT. Without objection, it will be so ordered.

Dr. APPLE. Mr. Chairman, as you know, APhA testified almost 2 years ago on H.R. 882, the Prescription Drug Labeling Act, which contained provisions similar to those in the bill you are considering today. At that time, APhA opposed the enactment of those provisions of H.R. 882 which would have preempted State antisubstitution laws. The association's position remains the same today, and we believe it is reinforced by the experience of the past 2 years.

Mr. Chairman, it might be helpful to put into the record the fact that when the American Pharmaceutical Association started its effort to change the State antisubstitution laws back in April of 1970 the State laws generally read:

No person shall dispense or cause to be dispensed a different drug or brand of drug in lieu of that ordered or prescribed without the express permission in each case of the person ordering or prescribing such drug.

The thrust of our effort at the State level was to amend those antisubstitution laws to omit or delete the four words "or brand of



drug." Earlier the witnesses were discussing the question of selecting a generic drug for a brand drug.

APhA's position is that drug product selection involves the selection of one brand for another brand, as well as a nonbranded drug product for a particular branded drug product that has been prescribed.

I think this might be helpful for the committee to keep this in mind as you continue to explore the necessity for H.R. 1963.

Mr. Chairman, in the interest of conserving the committee's time, if I may just turn to a few of the questions that were asked and comment on them.

The first being question 1: Is Federal legislation to allow substitutions needed or are existing State laws adequate?

In July 1976, APhA took the position that the States should be left to deal appropriately with their existing ant substitution laws. At that time we pointed out that 21 States had already taken action toward that end; 2 years later, we can now report that 39 States have amended their ant substitution laws in one form or another. We believe that in another few years virtually all States will have accomplished this task.

We do not wish to leave the impression that APhA is entirely satisfied with the action taken by all States to date. In fact, a few current State drug product selection laws are totally unsatisfactory.

However, we must also note that several States which have made what we regard as mistakes in enacting drug product selection legislation have already undertaken the amendment of those laws. These amendments offer the opportunity for pharmacists to exercise drug product selection authority in a fashion which will benefit both the profession and the public.

In sum, we adhere to our earlier position that matters regarding the control of professional practice should be left to the States and are not an appropriate subject for Federal legislation.

If we can turn to question 3, please, what are the potential cost savings to consumers if substitution legislation is enacted?

The candid answer to this question is that we do not know. However, we do not believe that proponents of drug product selection legislation should be sidetracked by unrealistic cost savings projections. We believe that substantial cost savings will be realized with the passage of time as pharmacists and the public become acclimated to drug product selection authority.

The policy key is that whatever cost savings may be achieved, they are justified and worthwhile. Moreover, returning to pharmacists, their drug product selection authority is right from both a professional and public interest standpoint.

I might supplement my formal testimony by commenting that when we first initiated this effort to amend the State ant substitution laws there was a particular drug entity which was being marketed as a different product by two firms, one at \$17.95 and the other at \$17.95, both under brand names, and by two other firms at \$2.25 and \$2.27, both also under brand names.

I would submit that the potential savings represented in such a case by the pharmacist being able to select one brand in place of another, from \$17.95 to \$2.25, is rather substantial.



Unfortunately, at the time when those particular market prices for those products existed, the pharmacist did not have such authority. It was shortly thereafter that through legislative action at the State level he began to acquire this authority and, eventually, the price of most products of that particular drug entity are now clustered down around the \$2 level.

So that, in itself, is indicative of why we feel it is important to have this authority restored to the professional who can best exercise it, without regard to projections of future financial savings.

We are convinced savings will occur.

With regard to question 4, should the legislation require that any savings be passed on to consumers?

APhA has opposed this type of provision in any drug product selection law, since it will psychologically discourage drug product selection when pharmacists are subject to legislation which states implicitly that they cannot be trusted.

This type of provision is a blatant insult to the pharmacy profession and as such will work against the drug product selection goals of APhA, State legislatures, and the sponsors of H.R. 1963.

For many years, it has been APhA's position that pharmacists should utilize a professional fee method of determining charges for pharmaceutical service. This method reimburses pharmacists a professional fee and is independent of the drug product cost and, therefore, eliminates any economic incentives for pharmacists to dispense high cost drug products.

In fact, competitive considerations encourage pharmacists to dispense lower cost drug products when possible. The professional fee concept is utilized by the vast majority of the Nation's pharmacies.

Question 5, should legislation allow or require substitution?

This point also was addressed in our earlier testimony. H.R. 882 contained a provision which would have required the dispensing of the least expensive drug product if the pharmacist were to exercise drug product selection authority. Although the current bill takes into account the technical problems we raised earlier with regard to the least expensive drug requirement, our statement with regard to that provision applies with equal force to the question we are now considering.

If we can turn to question 6:

Should the selection of the drug to substitute be left entirely to the discretion of the pharmacist, or should a list of drugs that can be substituted be established? Alternatively, should a list of drugs which cannot be substituted be established?

Mr. Chairman, we are confident that if pharmacists are permitted to fully exercise their professional judgment and discretion in drug product selection, that the public health would be benefited.

We believe that pharmacists who, after all, possess more information about factors relating to drug product quality than any other health care professionals, would not go widely about dispensing different drug products when factors arguing against drug product selection in a given situation are known.

Based on our observation, all such lists act as an impediment to workable drug product selection.

Could we turn then to question 9:



Should the Federal Trade Commission or the Food and Drug Administration enforce the act?

Again, we have made clear APhA opposition to Federal jurisdiction in the control of professional health care practices and our position is that drug product selection should be permissive, not mandatory. That could be the simple answer to this last question. However, we will again quote from our testimony of 2 years ago on this point:

Even if an enforcement mechanism were specified in the bill, it would represent an unrealistic and undesirable additional burden on Federal officials who presently are alleged to have too much to do.

We know of no Federal agency which would welcome the enforcement responsibility that would have to be created by this bill to make this a meaningful Federal requirement.

We urge that Congress strenuously avoid the enactment of laws which, in practice, become nothing more than words on paper. To do so heightens disrespect for our Federal system and for the responsibility and function of our Federal Government.

Mr. Chairman, members of the subcommittee, as we did 2 years ago, we acknowledge and applaud your continuing attention to the subject of drug product selection.

We believe that continuing Federal interest in the subject has been a major factor in moving the 39 States which have done so to reexamine and take appropriate action with regard to their existing antisubstitution laws.

Nonetheless, we believe that developments during these 2 years have reinforced our position that this is not an appropriate subject for Federal legislation and that it should be left to the States to resolve for the benefit of their respective citizens.

Thank you, Mr. Chairman.

[Testimony resumes on p. 146.]

[Dr. Apple's prepared statement follows:]



**Statement  
of the  
American  
Pharmaceutical  
Association**

*The National Professional Society of Pharmacists*

BEFORE THE  
SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE  
THE HOUSE COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE  
U.S. HOUSE OF REPRESENTATIVES  
WASHINGTON, D.C.  
JUNE 22, 1978



American Pharmaceutical Association  
2215 Constitution Avenue, N.W.  
Washington, D.C. 20037

(202) 628-4410



MR. CHAIRMAN, MEMBERS OF THE SUBCOMMITTEE, I AM DR. WILLIAM S. APPLE, EXECUTIVE DIRECTOR OF APHA, THE NATIONAL PROFESSIONAL SOCIETY OF PHARMACISTS. I AM ACCOMPANIED BY MR. CARL ROBERTS, APHA ASSOCIATE GENERAL COUNSEL AND DR. EDWARD G. FELDMANN, APHA ASSOCIATE EXECUTIVE DIRECTOR. WE ARE PLEASED TO ACCEPT YOUR INVITATION TO TESTIFY THIS MORNING ON H.R. 1963, THE "SUBSTITUTE PRESCRIPTION DRUG ACT."

AS YOU KNOW, APHA TESTIFIED ALMOST TWO YEARS AGO ON H.R. 882, THE "PRESCRIPTION DRUG LABELING ACT," WHICH CONTAINED PROVISIONS SIMILAR TO THOSE IN THE BILL YOU ARE CONSIDERING TODAY. AT THAT TIME, APHA OPPOSED THE ENACTMENT OF THOSE PROVISIONS OF H.R. 882 WHICH WOULD HAVE PREEMPTED STATE ANTISUBSTITUTION LAWS. THE ASSOCIATION'S POSITION REMAINS THE SAME TODAY, AND WE BELIEVE IT IS REINFORCED BY THE EXPERIENCE OF THE PAST TWO YEARS.

WE DO NOTE, HOWEVER, THAT THE CURRENT BILL SEEKS TO RESOLVE SOME OF THE TECHNICAL PROBLEMS WE HAD RAISED WITH THE EARLIER BILL. UNFORTUNATELY, AS WE WILL POINT OUT, THE EFFORT HAS NOT BEEN ENTIRELY SUCCESSFUL. AS REQUESTED, WE WILL NOW ADDRESS EACH OF THE QUESTIONS SET FORTH IN YOUR LETTER OF INVITATION TO TESTIFY.

QUESTION 1 - IS FEDERAL LEGISLATION TO ALLOW SUBSTITUTION NEEDED, OR ARE EXISTING STATE LAWS ADEQUATE?

IN JULY, 1976, APHA TOOK THE POSITION THAT THE STATES SHOULD BE LEFT TO DEAL APPROPRIATELY WITH THEIR EXISTING ANTISUBSTITUTION



LAWS. AT THAT TIME WE POINTED OUT THAT 21 STATES HAD ALREADY TAKEN ACTION TOWARD THAT END. TWO YEARS LATER, WE CAN NOW REPORT THAT 39 STATES HAVE AMENDED THEIR ANTISUBSTITUTION LAWS IN ONE FORM OR ANOTHER. WE BELIEVE THAT IN ANOTHER FEW YEARS VIRTUALLY ALL STATES WILL HAVE ACCOMPLISHED THIS TASK.

WE DO NOT WISH TO LEAVE THE IMPRESSION THAT APhA IS ENTIRELY SATISFIED WITH THE ACTION TAKEN BY ALL STATES TO DATE. IN FACT, A FEW CURRENT STATE DRUG PRODUCT SELECTION LAWS ARE TOTALLY UNSATISFACTORY. HOWEVER, WE MUST ALSO NOTE THAT SEVERAL STATES WHICH HAVE MADE WHAT WE REGARD AS MISTAKES IN ENACTING DRUG PRODUCT SELECTION LEGISLATION HAVE ALREADY UNDERTAKEN THE AMENDMENT OF THOSE LAWS. THESE AMENDMENTS OFFER THE OPPORTUNITY FOR PHARMACISTS TO EXERCISE DRUG PRODUCT SELECTION AUTHORITY IN A FASHION WHICH WILL BENEFIT BOTH THE PROFESSION AND THE PUBLIC.

IN SUM, WE ADHERE TO OUR EARLIER POSITION THAT MATTERS REGARDING THE CONTROL OF PROFESSIONAL PRACTICE SHOULD BE LEFT TO THE STATES AND ARE NOT AN APPROPRIATE SUBJECT FOR FEDERAL LEGISLATION.

QUESTION 2 - ARE TRADE NAME DRUGS BETTER THAN GENERIC DRUGS AND THEREFORE NO SUBSTITUTIONS SHOULD BE ALLOWED?

THE SHORT ANSWER TO THIS QUESTION IS, NO. EVEN THE PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WHICH HAS BEEN THE MOST VIGOROUS OPPONENT OF ELIMINATING TRADITIONAL STATE ANTI-SUBSTITUTION LAWS, HAS ITSELF CONCEDED THAT THIS MATTER DOES NOT INVOLVE A "BRAND" VERSUS "GENERIC" ISSUE. WE HAVE PREVIOUSLY



POINTED OUT ON NUMEROUS OCCASIONS THAT THERE IS A SUBSTANTIAL AND GENERAL MISUNDERSTANDING ABOUT THE USE OF THE TERM "GENERIC" DRUGS. THE FACT IS THAT SPECIFIC DRUG PRODUCTS WHICH YOU MIGHT CLASS EITHER AS BRAND (TRADE NAME) DRUG PRODUCTS OR GENERIC DRUG PRODUCTS HAVE EXPERIENCED QUALITY PROBLEMS. FINALLY, MOST DRUG PRODUCTS FOUND IN EACH OF THE CLASSIFICATIONS ARE FULLY ACCEPTABLE AS TO QUALITY. OUR EARLIER TESTIMONY DEALT IN GREAT DETAIL WITH THE DRUG PRODUCT QUALITY ISSUE. CONSEQUENTLY, WE WILL NOT REPEAT THE POINTS MADE IN OUR 1976 TESTIMONY BUT WILL SIMPLY STATE THAT WE HAVE NO CURRENT REASON TO CHANGE THE VIEWS THEN EXPRESSED.

WE NOTE THAT ON JUNE 7TH, FDA COMMISSIONER KENNEDY DECLARED: "IF THERE IS ANY CONFUSION IN ANYONE'S MIND ABOUT FDA'S POSITION ON THE GENERIC-BRAND NAME ISSUE, LET ME DISPEL IT NOW. FDA ENFORCES A SINGLE STANDARD OF QUALITY FOR ALL DRUGS SOLD IN THIS COUNTRY. WE REGULARLY INSPECT ALL DRUG PROCESSING PLANTS TO BE SURE THEY MEET THESE STRICT STANDARDS. WE ANALYZE THOUSANDS OF DRUGS EACH YEAR AND WE MAINTAIN COMPREHENSIVE INFORMATION ABOUT RECALLS AND COMPLAINTS. WE FIND NO EVIDENCE OF WIDESPREAD DIFFERENCES IN DRUG QUALITY ON THE BASIS OF A COMPANY'S SIZE OR ITS STATUS AS A 'BRAND-NAME' MANUFACTURER."

QUESTION 3 - WHAT ARE THE POTENTIAL COST SAVINGS TO CONSUMERS IF SUBSTITUTION LEGISLATION IS ENACTED?

THE CANDID ANSWER TO THIS QUESTION IS THAT WE DO NOT KNOW. HOWEVER, WE DO NOT BELIEVE THAT PROPONENTS OF DRUG PRODUCT SELECTION LEGISLATION SHOULD BE SIDETRACKED BY UNREALISTIC COST SAVINGS PROJECTIONS. WE BELIEVE THAT SUBSTANTIAL COST SAVINGS WILL BE



REALIZED WITH THE PASSAGE OF TIME AS PHARMACISTS AND THE PUBLIC BECOME ACCLIMATED TO DRUG PRODUCT SELECTION AUTHORITY. THE POLICY KEY IS THAT WHATEVER COST SAVINGS MAY BE ACHIEVED, THEY ARE JUSTIFIED AND WORTHWHILE. MOREOVER, RETURNING TO PHARMACISTS THEIR DRUG PRODUCT SELECTION AUTHORITY IS "RIGHT" FROM BOTH A PROFESSIONAL AND PUBLIC INTEREST STANDPOINT.

QUESTION 4 - SHOULD THE LEGISLATION REQUIRE THAT ANY SAVINGS BE PASSED ON TO CONSUMERS?

APhA HAS OPPOSED THIS TYPE OF PROVISION IN ANY DRUG PRODUCT SELECTION LAW, SINCE IT WILL PSYCHOLOGICALLY DISCOURAGE DRUG PRODUCT SELECTION WHEN PHARMACISTS ARE SUBJECT TO LEGISLATION WHICH STATES IMPLICITLY THAT THEY CAN'T BE TRUSTED. THIS TYPE OF PROVISION IS A BLATANT INSULT TO THE PHARMACY PROFESSION AND AS SUCH WILL WORK AGAINST THE DRUG PRODUCT SELECTION GOALS OF APhA, STATE LEGISLATURES, AND THE SPONSORS OF H.R. 1963.

FOR MANY YEARS, IT HAS BEEN APhA POSITION THAT PHARMACISTS SHOULD UTILIZE A PROFESSIONAL FEE METHOD OF DETERMINING CHARGES FOR PHARMACEUTICAL SERVICE. THIS METHOD REIMBURSES PHARMACISTS A PROFESSIONAL FEE AND IS INDEPENDENT OF THE DRUG PRODUCT COST AND, THEREFORE, ELIMINATES ANY ECONOMIC INCENTIVES FOR PHARMACISTS TO DISPENSE HIGH COST DRUG PRODUCTS. IN FACT, COMPETITIVE CONSIDERATIONS ENCOURAGE PHARMACISTS TO DISPENSE LOWER COST DRUG PRODUCTS WHEN POSSIBLE. THE PROFESSIONAL FEE CONCEPT IS UTILIZED BY THE VAST MAJORITY OF THE NATION'S PHARMACIES.



QUESTION 5 - SHOULD LEGISLATION ALLOW OR REQUIRE SUBSTITUTION?

THIS POINT ALSO WAS ADDRESSED IN OUR EARLIER TESTIMONY, H.R. 882 CONTAINED A PROVISION WHICH WOULD HAVE REQUIRED THE DISPENSING OF THE "LEAST EXPENSIVE" DRUG PRODUCT IF THE PHARMACIST WERE TO EXERCISE DRUG PRODUCT SELECTION AUTHORITY. ALTHOUGH THE CURRENT BILL TAKES INTO ACCOUNT THE TECHNICAL PROBLEMS WE RAISED EARLIER WITH REGARD TO THE "LEAST EXPENSIVE" DRUG REQUIREMENT, OUR STATEMENT WITH REGARD TO THAT PROVISION APPLIES WITH EQUAL FORCE TO THE QUESTION WE ARE NOW CONSIDERING. LET ME REPEAT A PORTION OF THAT TESTIMONY:

AS WE HAVE POINTED OUT, ALTHOUGH IN THE MAJORITY OF CASES THERE MAY BE NO REASON NOT TO DISPENSE THE LEAST EXPENSIVE DRUG PRODUCT AVAILABLE, THERE ARE SOME INSTANCES IN WHICH THAT CLEARLY SHOULD NOT BE DONE. THESE INSTANCES ARE KNOWN TO PRESCRIBERS AND PHARMACISTS WHO MUST BRING TO BEAR THEIR PROFESSIONAL EXPERTISE IN MAKING RATIONAL AND BENEFICIAL THERAPEUTIC DECISIONS ON BEHALF OF PATIENTS. IN THE CASE OF SOME DRUG PRODUCTS, ALLERGIC REACTIONS AND RELATED PROBLEMS FOR A PATIENT MAY RESULT FROM PARTICULAR INACTIVE INGREDIENTS WHICH ARE NOT PRESENT IN ANOTHER PREPARATION OF THE SAME DRUG. SUCH FACTORS ARE NOT KNOWN TO CONSUMERS OR TO CONGRESS. IT IS FOR THIS KNOWLEDGE AND SURVEILLANCE, AS WELL AS FOR THE EXERCISE OF OTHER PROFESSIONAL JUDGMENTS BY THE PHARMACIST, THAT THE PATIENT PAYS WHEN OBTAINING



PHARMACEUTICAL SERVICE. PHARMACISTS ARE NOT MERELY MEN AND WOMEN WHO "SELL DRUGS." IF THEY WERE, THERE IS NO WAY IN WHICH THE EXISTENCE OF THE PROFESSION OF PHARMACY COULD BE JUSTIFIED OR, INDEED, DEFENDED BY APHA. CONSEQUENTLY, THIS ASSOCIATION WILL ALWAYS VIGOROUSLY OPPOSE ANY EFFORT TO REDUCE EITHER THE PROFESSIONAL EXPERTISE OR EXERCISE OF PROFESSIONAL DISCRETION BY ANY OF THE NATION'S PHARMACISTS.

QUESTION 6 - SHOULD THE SELECTION OF THE DRUG TO SUBSTITUTE BE LEFT ENTIRELY TO THE DISCRETION OF THE PHARMACIST, OR SHOULD A LIST OF DRUGS THAT CAN BE SUBSTITUTED BE ESTABLISHED? ALTERNATIVELY, SHOULD A LIST OF DRUGS WHICH CANNOT BE SUBSTITUTED BE ESTABLISHED?

MR. CHAIRMAN, WE ARE CONFIDENT THAT IF PHARMACISTS ARE PERMITTED TO FULLY EXERCISE THEIR PROFESSIONAL JUDGMENT AND DISCRETION IN DRUG PRODUCT SELECTION, THAT THE PUBLIC HEALTH WOULD BE BENEFITED. WE BELIEVE THAT PHARMACISTS WHO, AFTER ALL, POSSESS MORE INFORMATION ABOUT FACTORS RELATING TO DRUG PRODUCT QUALITY THAN ANY OTHER HEALTH CARE PROFESSIONALS, WOULD NOT GO WILDLY ABOUT DISPENSING DIFFERENT DRUG PRODUCTS WHEN FACTORS ARGUING AGAINST DRUG PRODUCT SELECTION IN A GIVEN SITUATION ARE KNOWN. BASED ON OUR OBSERVATION, ALL SUCH LISTS ACT AS AN IMPEDIMENT TO WORKABLE DRUG PRODUCT SELECTION. NONETHELESS, WE RECOGNIZE THAT, BECAUSE OF THE "SMOKESCREEN" DRUG PRODUCT QUALITY ISSUES RAISED PRIMARILY BY MANY DRUG MANUFACTURERS, IT IS PROBABLY NOT POLITICALLY FEASIBLE TO AVOID



SOME TYPE OF "LIST" WHICH WOULD SET A PERIMETER FOR PHARMACIST DRUG PRODUCT SELECTION AUTHORITY.

OUR CHOICE, IF ONE NEED BE MADE, IS FOR A WHAT WE CHARACTERIZE AS A "NEGATIVE FORMULARY," A LIST OF DRUG ENTITIES AMONG WHICH THE PHARMACIST SHOULD NOT EXERCISE DRUG PRODUCT SELECTION AUTHORITY. WE BELIEVE THAT THE NEGATIVE FORMULARY APPROACH ENTAILS FAR LESS INVESTMENT OF TIME AND MONEY THAN THE PREPARATION OF A POSITIVE FORMULARY, A LIST OF DRUGS FROM AMONG WHICH THE PHARMACIST MAY EXERCISE DRUG PRODUCT SELECTION AUTHORITY. A NEGATIVE FORMULARY CONTAINING ONLY A HANDFUL OF DRUGS, IS MUCH EASIER TO MANAGE FROM AN ADMINISTRATIVE AND PROFESSIONAL PRACTICE STANDPOINT AND, IN THE LONG RUN, EXACTLY THE SAME OBJECTIVE IS SERVED. THEREFORE, IF SOME FORM OF LIST IS TO BE REQUIRED BY ANY DRUG PRODUCT SELECTION LEGISLATION, WE GIVE OUR SUPPORT TO THE NEGATIVE FORMULARY CONCEPT.

QUESTION 7 - SHOULD PROVISION BE MADE FOR PRESCRIBING PRACTITIONER TO REQUIRE THAT A PRESCRIPTION BE FILLED WITH A TRADE NAME DRUG, AND IF SO, HOW SHOULD THIS BE DONE?

APHA DOES NOT BELIEVE THAT SUCH A PROVISION IS NECESSARY. IN ITS "WHITE PAPER" ON "THE PHARMACIST'S ROLE IN PRODUCT SELECTION" PUBLISHED IN MARCH, 1971, THE ASSOCIATION STATED: "UNDER THE MODIFICATIONS WE SEEK IN THE ANTISUBSTITUTION LAWS, THE PHYSICIAN WHO WISHES UNEQUIVOCALLY TO SPECIFY THE SOURCE OF A DRUG PRODUCT NEED ONLY DESIGNATE THE MANUFACTURER BY NAME. DOING SO WOULD REPRESENT A CLEAR THERAPEUTIC JUDGMENT THAT NO



COMPETENT PHARMACIST WOULD IGNORE." WE HOLD TO THESE VIEWS TODAY,

WE SHOULD POINT OUT, THAT IN STATES WHICH HAVE ENACTED PHARMACIST DRUG PRODUCT SELECTION AUTHORITY AND WHICH HAVE MAINTAINED PHYSICIAN "DISPENSE AS WRITTEN" AUTHORITY, THERE ARE VERY FEW INSTANCES IN WHICH THE PHYSICIAN IS OBJECTING TO THE PHARMACIST'S EXERCISE OF DRUG PRODUCT SELECTION AUTHORITY. WE REGARD THIS AS POTENT SUPPORT FOR APHA'S POSITION.

QUESTION 8 - SHOULD A PROVISION DELINEATING THE LIABILITIES OF PHARMACISTS BE INCLUDED?

IT WOULD SEEM CLEAR THAT ANY PROVISION WHICH REDUCES THE PHARMACIST'S LIABILITY EXPOSURE IN DRUG PRODUCT SELECTION WOULD SERVE TO ENCOURAGE PHARMACISTS TO EXERCISE THAT AUTHORITY. THE QUESTION IS WHETHER THE PUBLIC IS WILLING TO TRADE SOME PROTECTION IN THE LIABILITY AREA FOR THE EXPECTED BENEFITS OF DRUG PRODUCT SELECTION. THIS IS A POLICY DECISION ON WHICH WE DO NOT BELIEVE WE CAN BE EXTREMELY HELPFUL.

WE CAN SAY, HOWEVER, THAT IF ANY DRUG PRODUCT SELECTION LEGISLATION WERE TO BE MANDATORY IN FORM, IN OTHER WORDS WERE TO REQUIRE PHARMACISTS TO ENGAGE IN DRUG PRODUCT SELECTION, THEN CLEARLY THE PHARMACIST MUST NOT BE SUBJECTED TO POTENTIAL LIABILITY FOR HAVING COMPLIED WITH THE EXPLICIT MANDATORY REQUIREMENTS OF THE STATUTE. WE BELIEVE WE HAVE MADE OURSELVES CLEAR THAT APHA WILL VIGOROUSLY OPPOSE ANY MANDATORY FORM OF DRUG PRODUCT SELECTION LEGISLATION. MANDATORY DRUG PRODUCT



SELECTION WILL DESTROY NOT ONLY THE PHARMACY PROFESSION, BUT ALSO THE PUBLIC HEALTH PROTECTION FUNCTION WHICH THE PHARMACIST IS INTENDED TO SERVE.

QUESTION 9 - SHOULD THE FEDERAL TRADE COMMISSION OR THE FOOD AND DRUG ADMINISTRATION ENFORCE THE ACT?

AGAIN, WE HAVE MADE CLEAR APhA OPPOSITION TO FEDERAL JURISDICTION IN THE CONTROL OF PROFESSIONAL HEALTH CARE PRACTICES AND OUR POSITION IS THAT DRUG PRODUCT SELECTION SHOULD BE PERMISSIVE, NOT MANDATORY. THAT COULD BE THE SIMPLE ANSWER TO THIS LAST QUESTION. HOWEVER, WE WILL AGAIN QUOTE FROM OUR TESTIMONY OF TWO YEARS AGO ON THIS POINT:

EVEN IF AN ENFORCEMENT MECHANISM WERE SPECIFIED IN THE BILL, IT WOULD REPRESENT AN UNREALISTIC AND UNDESIRABLE ADDITIONAL BURDEN ON FEDERAL OFFICIALS WHO PRESENTLY ARE ALLEGED TO HAVE TOO MUCH TO DO. WE KNOW OF NO FEDERAL AGENCY WHICH WOULD WELCOME THE ENFORCEMENT RESPONSIBILITY THAT WOULD HAVE TO BE CREATED BY THIS BILL TO MAKE THIS A MEANINGFUL FEDERAL REQUIREMENT. WE URGE THAT CONGRESS STRENUOUSLY AVOID THE ENACTMENT OF LAWS WHICH, IN PRACTICE, BECOME NOTHING MORE THAN WORDS ON PAPER. TO DO SO HEIGHTENS DISRESPECT FOR OUR FEDERAL SYSTEM AND FOR THE RESPONSIBILITY AND FUNCTION OF OUR FEDERAL GOVERNMENT.



MR. CHAIRMAN, MEMBERS OF THE SUBCOMMITTEE, AS WE DID TWO YEARS AGO, WE ACKNOWLEDGE AND APPLAUD YOUR CONTINUING ATTENTION TO THE SUBJECT OF DRUG PRODUCT SELECTION. WE BELIEVE THAT CONTINUING FEDERAL INTEREST IN THE SUBJECT HAS BEEN A MAJOR FACTOR IN MOVING THE 39 STATES WHICH HAVE DONE SO TO REEXAMINE AND TAKE APPROPRIATE ACTION WITH REGARD TO THEIR EXISTING ANTISUBSTITUTION LAWS. NONETHELESS, WE BELIEVE THAT DEVELOPMENTS DURING THESE TWO YEARS HAVE REINFORCED OUR POSITION THAT THIS IS NOT AN APPROPRIATE SUBJECT FOR FEDERAL LEGISLATION AND THAT IT SHOULD BE LEFT TO THE STATES TO RESOLVE FOR THE BENEFIT OF THEIR RESPECTIVE CITIZENS.

MR. ECKHARDT. Let us consider the Federal act recognizing, of course, your preference to States. Let's consider the act and try to consider what would be desirable. In looking it over, it seems to me in section 2 it provides for substitution, and of course it provides substitution only where the doctor has not specifically prohibited substitution. It provides that substitution shall occur where it is of less cost to the patient, but it does not set out any formula for reducing or setting the price of the substitute drug.

We have had some discussion here about that and perhaps we are coming toward a consensus that the market ought to take care of the price question. Would you agree with that? Assume you were drafting a model State law.

DR. APPLE. If we were drafting a model State law, we would certainly leave that out.

MR. ECKHARDT. You would leave out the Michigan-type approach?

DR. APPLE. That is correct. We would leave out any reference to prices charged because we have long recognized what you astutely observed earlier this afternoon: It is the competitive forces of the marketplace that will take care of that situation.

MR. ECKHARDT. I think perhaps its not unreasonable to say that the substitution should be one of a drug involving a cost to the patient of less than the cost of the drug identified. It does not say how much less, but there would certainly be no reason why if we can rely on the fact that the drugs are all reliable drugs within the category, a substitution would be made for the identified drug that was more expensive.

DR. APPLE. Mr. Chairman, I do not think any pharmacist would engage in drug product selection unless there was some advantage to the patient in the process. The purpose of the selection process is to bring into play an action that will result in savings to the patient.

MR. ECKHARDT. Then why not say so? I am not saying we should provide, as in the Michigan act, that there be a standard of so much less cost. All this act says, as it is written, is that the substitute drug shall be at a cost to the consumer which is less



than that for which the substitute is offered. It can be any amount less. But as you point out, there would be no valid reason for pharmacists to substitute a higher priced drug.

Dr. APPLE. There will be an occasion actually in the patient's interest when a pharmacist, given the authority to engage in drug product selection, will not do so.

Mr. ECKHARDT. If you did not have a provision that the cost shall be less than the drug identified, some pharmacists might simply get the highest priced drug and then have only one drug in their stock and simply sell all the highest priced drug.

Dr. APPLE. I do not think that pharmacist would be in practice very long, sir.

Mr. ECKHARDT. I do not know. I know of some institutions that last for a long time which charge very high prices, particularly in connection with women's clothes. Some even advertise it is a little higher but far better. I cannot see any justification at any time for a pharmacist substituting his judgment with respect to a substitute drug where the cost is actually higher than that in the doctor's prescription.

Dr. APPLE. I realize that the incidence of that occurring is very infrequent and is not a major factor under consideration, but there are specific examples. I can give you a concrete one. I have two children, one 9 and one 10. One of them will take an antibiotic in a liquid form if it is green, and the other one won't touch the green one; she happens to prefer the red one.

I can probably attempt to explain to my children that both medicines are the same because they contain the same active ingredients, but it so happens that my son likes one flavor and my daughter likes the other flavor. The point is that I am interested in having them take the medication. There may be a cost differential of 15 or 25 cents, and I am not going to—

Mr. ECKHARDT. That is a customer preference. If the customer comes in and asks for the drug, I suppose under the prescription he would have to get that authority from the doctor.

Dr. APPLE. In my example, the physician had prescribed the green one for both children, yet the one child prefers the red one. If I know this as the patient's parent—that one child does not like the red one but prefers the green one—then why shouldn't the pharmacist be able to accommodate the patient on that basis?

Mr. ECKHARDT. He can. It says here a pharmacist may not select a substitute drug used to fill or refill a prescription if the patient for whom the prescription is made requests such pharmacist to fill or refill such prescription with the identified drug.

All I am saying is I do not think the pharmacist should be permitted on his own to select a substitute for the doctor's prescription, and perhaps initially the patient's choice, a drug which is higher priced. I cannot see any excuse for that.

Dr. APPLE. We agree with you.

Mr. ECKHARDT. Then the act provides on page 4 that "Any substitute drug used to fill or refill a prescription under subsection (a) or subsection (b) shall be in the same quantity and dosage form as specified in such prescription," which seems to be a desirable provision. Then, "(d) For purposes of this section, a drug is a substitute drug for a drug identified in the prescription \* \* \* if such drug has



the same established name as the drug so identified." Then there is a reference on page 6 to established name. This should be section 502(e) (3) instead of (2) of the Federal Drug and Cosmetic Act which establishes the established name, and that established name would be the generic name covering the various trade names.

This seems to be a rather workable piece of legislation if it were considered from your standpoint as a pattern for State legislation. Do you have any objection to the legislation as such, except that you feel this should be done at the State level?

Mr. ROBERTS. There is a specific problem, Mr. Chairman, with regard to the provision which would require the pharmacist to dispense the least expensive drug which was in inventory. It is a practical problem.

Mr. ECKHARDT. I agree with you on that and I have had some discussion on that. It seems to me that that item, section 2(a)(1)(B)(ii), addresses that question. I frankly cannot see any reason why the pharmacist would be permitted to use the higher priced initially prescribed drug. But he could not, once he decides to substitute it, substitute anything but the least expensive in his inventory. There might be legitimate reasons, it seems to me, why he might substitute another.

Mr. ROBERTS. Let me try to explain a specific situation which pharmacists have told me they run into with patients as a matter of patient psychology. The cost of drug products to the pharmacist is continually changing. One product may be at this level today and then another product goes and exceeds it or goes to a lower price.

The price structure in the industry is changing constantly. In a situation where a pharmacist has dispensed an original prescription to a patient and the dosage form is a pink capsule, you have a problem situation when the patient comes back for a renewal of that prescription, the pharmacist is faced with having the same established name drug at a lower price, the same drug in the same dosage form, a capsule, but it is now a green and black capsule instead of the pink capsule which the patient received in the original prescription. The patient is very likely to announce rather loudly, "You have made a mistake in my prescription."

Then the pharmacist of course gets involved in all kinds of explanations that this is really the same drug, et cetera, et cetera. Patients do not react very well to that kind of situation. The pharmacist in those circumstances might choose to dispense the same pink capsule to the patient on a renewal even though the cost might now be slightly higher than a product which was otherwise in inventory. That is a very practical problem.

Mr. ECKHARDT. Thank you very much for your contribution.

That concludes our witnesses and our hearing on this subject. As I previously said, if you will be so kind as to respond to written questions, we may desire to send you some.

Dr. APPLE. We will be glad to do that.

Mr. ECKHARDT. The record will be kept open for that purpose.

The committee is adjourned until the call of the Chair.

[Whereupon, at 6:30 p.m., the subcommittee adjourned, to reconvene at the call of the Chair.]



# SUBSTITUTE PRESCRIPTION DRUG ACT

THURSDAY, JULY 27, 1978

HOUSE OF REPRESENTATIVES,  
SUBCOMMITTEE ON CONSUMER PROTECTION AND FINANCE,  
COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE,  
*Washington, D.C.*

The subcommittee met at 2:15 p.m., pursuant to notice, in room 2218, Rayburn House Office Building, Hon. Bob Eckhardt, chairman, presiding.

Mr. ECKHARDT. The Subcommittee on Consumer Protection and Finance will commence its hearings.

Today the Subcommittee on Consumer Protection and Finance continues its hearings regarding H.R. 1963. H.R. 1963 permits a pharmacist to substitute an equivalent drug for a drug prescribed by trade name unless the doctor or the consumer prohibits such a substitution.

The subcommittee has heard testimony that the potential cost savings to consumers is substantial. Today, we will continue to explore the potential benefits to consumers, as well as the problem of assuring that such benefits are not enjoyed at a risk to human health.

Further, in the past few years, there has been a strong movement in the States to repeal antisubstitution laws. A variety of laws have been enacted establishing the proper conditions under which substitution should or must take place.

Consequently, a decision on the substantive merits of allowing substitution must be made in conjunction with an assessment of State legislative enactments. We welcome today's witnesses who will assess these various considerations.

It is a pleasure to have appear before the subcommittee as our first witness Chairman Mike Pertschuk of the Federal Trade Commission.

## STATEMENT OF HON. MICHAEL PERTSCHUK, CHAIRMAN, FEDERAL TRADE COMMISSION

Mr. PERTSCHUK. Thank you, Mr. Chairman.

My statement is relatively short so I will read it, but I will spare you the footnotes.

I am pleased to have this opportunity to discuss the deregulation of generic drug substitution. Consumers have an enormous stake in this issue, and for that reason the Federal Trade Commission has taken an active interest in it.

Within the next few months—and we think now October—our Bureau of Consumer Protection will release a staff report present-



ing the results of its nearly 2-year investigation of generic drug substitution. The staff is working closely with its counterparts in the Food and Drug Administration and the Department of Health, Education, and Welfare.

In addition to collecting and analyzing published articles, dissertations, and surveys, the staff has solicited comments and supporting documentation from representatives of brand name and generic manufacturers, consumers, pharmacists, and physicians.

Consultants were hired to estimate the economic impact of substitution laws, and an independent market-research firm conducted a multistate survey of pharmacists' attitudes and behavior to determine the types of provisions that can most effectively encourage pharmacists to substitute low-cost generics. As a result of this investigation, we hope to develop for the States a model substitution law—one that will succeed in bringing prices down.

Although the staff report is not yet completed, we have learned a great deal about both the problem of substitution—or lack of substitution, to be more precise—and the pros and cons of various solutions to it.

First, let me say a few words about the problem.

Consumers spent over \$8 billion for prescription drugs in 1977, and the figure will undoubtedly be up in 1978. A considerable portion of this expenditure—amounting to hundreds of millions of dollars—could be saved if the market fostered the purchase of the lowest-cost equivalent drugs.

Unfortunately, as you know, the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay.

Generically equivalent drugs are frequently sold at grossly disparate prices. Yet it has been demonstrated that physicians often have little knowledge of drug prices.

One recent study showed that of 144 physicians responding to a survey, 32 percent said they had "no idea" of the prices of prescription drugs.

And when the remaining 68 percent of physicians were asked to rank themselves as to their degree of knowledge of drug prices on a scale of 1 (very informed) to 5 (uninformed), 64 percent assessed themselves at a 4 or 5.

The reason is simple: There is little incentive for a physician to shop around for the least expensive drug products.

First, patients do not choose their physicians on the basis of the cost of the drugs the physician prescribes. Indeed, probably only a small percentage of patients currently know enough about comparative drug prices or the availability of less expensive generic equivalents to ask the doctor to prescribe low-cost generic drugs.

Second, it is time-consuming, and therefore costly, for physicians to acquire comparative price information.

Drug manufacturers are aware that they would not gain physician loyalty on the basis of price competition. Instead, they spend millions of dollars promoting their brand name products.

A 1977 Federal Trade Commission staff report notes that, in 1970, 30 of the largest marketers of prescription drugs spent \$682 million on drug promotion, an amount representing 21 percent of the firms'



total sales in the United States or an outlay of more than \$2,400 per practicing physician.

Not surprisingly, physicians as a group tend to prescribe by these heavily promoted, easily remembered brand names: Nearly 90 percent of all new prescriptions are written by the brand name of the drug. The FTC staff report revealed further that physicians demonstrated a strong preference for the brands that were the first of their kind to enter the market, and were persuaded to prescribe late-entering brands only if they offered some specific therapeutic gain.

The report states, and I quote:

Physicians' preferences for a relatively small number of trademarked, brand-name drugs are probably rational responses to the proliferation of trademarked drugs in the industry as a whole. For just one dosage strength of one generic chemical, 20 mg. PETN, the physician faces a bewildering array of alternatives. In 1971, 61 firms offered PETN, 32 under a brand name. To weigh the quality and price alternatives presented by such an array of drugs would involve a notable feat of research and memory. As one pharmacologist has noted, doctors are human beings, not computers \* \* \*.

While pharmacists are no less human, they have the capacity to be more efficient in selecting drug products.

First, of course, the pharmacist is aware of price differences. Moreover, the pharmacist is intensively trained in drug pharmacology, and is considered technically qualified to dispense generic drug products safely.

Indeed, pharmacists have long been allowed to select drug sources for generically written prescriptions. Yet, in some States ant substitution laws prevent the pharmacist from using his or her expertise to select a less expensive equivalent product to fill a brand-name prescription.

One way to promote price competition, then, would be enactment of less restrictive State laws. About 40 States do now permit some form of pharmacist selection. The State laws, however, vary greatly in their potential effectiveness; indeed, as I will explain in a few moments, some "substitution" laws impose so many burdens and restrictions on the substituting pharmacist that substitution simply does not take place.

Nevertheless, the most sensible role for the Federal Government at this stage may not be enactment of preemptive legislation. Because the States are currently in a period of transition—some are beginning to seek actively to make their substitution laws effective—it may be more appropriate to continue to monitor closely the impact of the various State laws, and reserve judgment as to whether Federal intervention is warranted.

As I mentioned earlier, our staff is currently analyzing the State laws and attempting to determine which approaches work best to encourage pharmacists to substitute low-cost generics.

Our report will be finished and made public this fall, but we intend to continue our scrutiny of competition in the prescription drug market as the various State laws make their mark.

Furthermore, there is a serious drawback to enacting Federal legislation before we have definitive evidence that it is needed: The difficulty and cost of Federal enforcement. An attempt by the FTC—or, probably, any Federal agency—to police every sale of a prescription drug would undoubtedly be burdensome.



A better approach, at this stage, would be to observe and evaluate the States' efforts to enforce their laws through the pharmaceutical regulatory bodies and mechanisms already at their disposal.

We do, however, have some specific comments about H.R. 1963, the bill now before the subcommittee. This bill contains what we believe, based on our studies to date, to be some of the most essential features of a good substitution law. At the same time, we recommend that certain revisions be made, if a determination is made that legislation should be enacted by Congress at this time.

H.R. 1963 permits, rather than requires, substitution of a lower-priced generic drug for a drug prescribed by brand name. That is a wise approach. A pharmacist who is allowed to substitute lower-cost drugs has an economic incentive to substitute and to pass on cost savings to consumers in order to compete with other pharmacists for the consumer dollar. And competition at the retail level is likely to be enhanced by the recently recognized right of pharmacists to advertise drug prices. If pharmacist substitution does occur, the manufacturers selling higher-priced drugs to the pharmacists will be motivated to lower their prices in order to compete with the substitutes. Thus, competition at these two levels of drug distribution should produce lower prices for consumers.

In short, this is an instance where, according to information available at this time, the market is likely to work well enough by itself that a regulatory mandate is not required.

For the same reason, the best approach to substitution would not attempt to force pharmacists to pass on to consumers all cost savings. H.R. 1963 does not attempt to do this. In those States that have mandatory pass-ons, the pharmacist cannot profit by so much as a penny for costs incurred in using his or her skills to search for, stock and dispense lower-cost generics. Rather than encourage competition, then, mandatory pass-ons provide an economic disincentive for substitution by the pharmacist.

A good substitution program should allow the pharmacist to bill at his or her usual retail price for a lower cost generic equivalent, since the marketplace should work to insure that pharmacists pass on to consumers a healthy portion of the cost savings. Only if the market fails should more restrictive actions be considered.

While H.R. 1963 does not have a mandatory pass-on, it permits a pharmacist to select only the lowest cost product in stock, whether the drug was prescribed by brand name (section 2(a)(1)(B)) or by established name (section (2)(b)(1)). This restriction is probably neither necessary nor workable. It is unnecessary because, as I have outlined, the market is likely to accomplish the same end unassisted.

It is not workable because, first, the pharmacist could technically comply by pricing the least expensive product in stock only 1 cent below the brand name drug prescribed.

Second, a pharmacist who did not wish to be forced to sell the substitute at the price of the least expensive drug in inventory could refuse to stock the lowest cost products at all—so that the effect would be to raise overall retail drug prices.

Indeed, with respect to generically written prescriptions, there is evidence that this type of restriction on the pharmacist does not save consumers money. One study showed that greater savings



have been generated in Michigan, which has no such provision, than in Wisconsin, which does have one.

Moreover, to determine whether a violation of the lowest price-in-stock provision has occurred, the Commission would need to ascertain the various prices of drugs in a pharmacist's inventory at the time a particular substitution took place.

This determination might be impossible; it would certainly be costly. Especially in light of this enforcement problem, it makes more sense to test the forces of competition in an unfettered market before authorizing or mandating substitution of only the lowest priced drug in stock. We therefore recommend that H.R. 1963 be revised to permit pharmacist substitution of any lower cost equivalent drug product.

Mr. ECKHARDT. Mr. Chairman, we will have to recess for a moment to go and vote. You do understand.

Mr. PERTSCHUK. I do.

[Brief recess.]

Mr. ECKHARDT. Please resume.

Mr. PERTSCHUK. Mr. Chairman, I would be pleased to put the rest of my statement in the record with one comment and then respond to your question.

Mr. ECKHARDT. We would be glad to hear it if you would like to summarize or whatever.

Mr. PERTSCHUK. Why not. I made some comments on the provisions which I think the committee can peruse at its leisure.

[Testimony resumes on p. 167.]

[Mr. Pertschuk's prepared statement follows:]



## STATEMENT OF MICHAEL PERTSCHUK, CHAIRMAN, FEDERAL TRADE COMMISSION

Mr. Chairman, members of the Subcommittee, I am pleased to have this opportunity to discuss the deregulation of generic drug substitution. Consumers have an enormous stake in this issue, and for that reason the Federal Trade Commission has taken an active interest in it.

Within the next few months, our Bureau of Consumer Protection will release a staff report presenting the results of its nearly two-year investigation of generic drug substitution. The staff is working closely with its counterparts in the Food and Drug Administration and the Department of Health, Education and Welfare. In addition to collecting and analyzing published articles, dissertations and surveys, the staff has solicited comments and supporting documentation from representatives of brand-name and generic manufacturers, consumers, pharmacists and physicians. Consultants were hired to estimate the economic impact of substitution laws, and an independent market-research firm conducted a multistate survey of pharmacists' attitudes and behavior to determine the types of provisions that can most effectively encourage pharmacists to substitute low-cost generics. As a result of this investigation, we hope to develop for the states a model substitution law--one that will succeed in bringing prices down.

Although the staff report is not yet completed, we have learned a great deal about both the problem of



substitution--or lack of substitution, to be more precise--and the pros and cons of various solutions to it. First, let me say a few words about the problem.

Consumers spent over \$8 billion for prescription drugs in 1977, and the figure will undoubtedly be up in 1978. 1/ A considerable portion of this expenditure--amounting to hundreds of millions of dollars 2/--could be saved if the market fostered the purchase of the lowest-cost equivalent drugs. Unfortunately, as you know, the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay.

Generically equivalent drugs are frequently sold at grossly disparate prices. 3/ Yet it has been demonstrated that physicians often have little knowledge of drug prices. One recent study showed that of 144 physicians responding to a survey, 32% said they had "no idea" of the prices of prescription drugs. 4/

And when the same physicians were asked to rank themselves as to their degree of knowledge of drug prices on a scale of 1 (very informed) to 5 (uninformed), 64% assessed themselves at a 4 or 5.



The reason is simple: there is little incentive for a physician to shop around for the least expensive drug products. First, patients do not choose their physicians on the basis of the cost of the drugs the physician prescribes. Indeed, probably only a small percentage of patients currently know enough about comparative drug prices or the availability of less expensive generic equivalents to ask the doctor to prescribe low-cost generic drugs. Second, it is time-consuming, and therefore costly, for physicians to acquire comparative price information.

Drug manufacturers are aware that they would not gain physician loyalty on the basis of price competition. Instead, they spend millions of dollars promoting their brand name products. A 1977 Federal Trade Commission staff report notes that, in 1970, 30 of the largest marketers of prescription drugs spent \$682 million on drug promotion, an amount representing 21% of the firms' total sales in the United States or an outlay of more than \$2400 per practicing physician. 5/ Not surprisingly, physicians as a group tend to prescribe by these heavily-promoted, easily-remembered brand names: nearly 90 percent of all new prescriptions are written by the brand name of the drug. 6/ The FTC staff report revealed further that physicians



demonstrated a strong preference for the brands that were the first of their kind to enter the market, and were persuaded to prescribe late-entering brands only if they offered some specific therapeutic gain. 7/

The report states,

Physicians' preferences for a relatively small number of trademarked, brand-name drugs are probably rational responses to the proliferation of trademarked drugs in the industry as a whole. For just one dosage strength of one generic chemical, 20 mg. PETN, the physician faces a bewildering array of alternatives. In 1971, 61 firms offered PETN, 32 under a brand name. To weigh the quality and price alternatives presented by such an array of drugs would involve a notable feat of research and memory. As one pharmacologist has noted, doctors are human beings, not computers . . . . 8/

While pharmacists are no less human, they have the capacity to be more efficient in selecting drug products. First, of course, the pharmacist is aware of price differences. Moreover, the pharmacist is intensively trained in drug pharmacology, and is considered technically qualified to dispense generic drug products safely. 9/ Indeed, pharmacists have long been allowed to select drug sources for generically written prescriptions. Yet in some states antisubstitution laws prevent the pharmacist from using his or her expertise to select a less expensive equivalent product to fill a brand-name prescription.

One way to promote price competition, then, would be enactment of less restrictive state laws. About 40 states do now permit some form of pharmacist



selection. The state laws, however, vary greatly in their potential effectiveness; indeed, as I will explain in a few moments, some "substitution" laws impose so many burdens and restrictions on the substituting pharmacist that substitution simply does not take place.

Nevertheless, the most sensible role for the federal government at this stage may not be enactment of preemptive legislation. Because the states are currently in a period of transition--some are beginning to seek actively to make their substitution laws effective--it may be more appropriate to continue to monitor closely the impact of the various state laws, and reserve judgment as to whether federal intervention is warranted. As I mentioned earlier, our staff is currently analyzing the state laws and attempting to determine which approaches work best to encourage pharmacists to substitute low-cost generics. Our report will be finished and made public this fall, but we intend to continue our scrutiny of competition in the prescription drug market as the various state laws make their mark.

Furthermore, there is a serious drawback to enacting federal legislation before we have definitive evidence that it is needed: the difficulty and cost of federal enforcement. An attempt by the FTC--or, probably, any federal agency--to police every sale of a prescription drug would undoubtedly be burdensome.



A better approach, at this stage, would be to observe and evaluate the states' efforts to enforce their laws through the pharmaceutical regulatory bodies and mechanisms already at their disposal.

We do, however, have some specific comments about H.R. 1963, the bill now before the Subcommittee. This bill contains what we believe, based on our studies to date, to be some of the most essential features of a good substitution law. At the same time, we recommend that certain revisions be made, if a determination is made that legislation should be enacted by Congress at this time.

H.R. 1963 permits, rather than requires, substitution of a lower-priced generic drug for a drug prescribed by brand name. That is a wise approach. A pharmacist who is allowed to substitute lower-cost drugs has an economic incentive to substitute and to pass on cost savings to consumers in order to compete with other pharmacists for the consumer dollar. And competition at the retail level is likely to be enhanced by the recently recognized right of pharmacists to advertise drug prices. 10/ If pharmacist substitution does occur, the manufacturers selling higher-priced drugs to the pharmacists will be motivated to lower their prices in order to compete with the substitutes. Thus, competition at these two levels of drug distribution will produce lower prices for consumers.



In short, this is an instance where, according to information available at this time, the market is likely to work well enough by itself that a regulatory mandate is not required.

For the same reason, the best approach to substitution would not attempt to force pharmacists to pass on to consumers all cost savings. H.R. 1963 does not attempt to do this. In those states that have mandatory pass-ons, the pharmacist cannot profit by so much as a penny for costs incurred in using his or her skills to search for, stock and dispense lower-cost generics. Rather than encourage competition, then, mandatory pass-ons provide an economic disincentive for substitution by the pharmacist. A good substitution program should allow the pharmacist to bill at his or her usual retail price for a lower cost generic equivalent, since the marketplace should work to ensure that pharmacists pass on to consumers a healthy portion of the cost savings. Only if the market fails should more restrictive actions be considered.

While H.R. 1963 does not have a mandatory pass-on, it permits a pharmacist to select only the lowest cost product in stock, whether the drug was prescribed by brand name (section 2(a)(1)(B)) or by established name (section (2)(b)(1)). This restriction is probably neither necessary nor workable. It is unnecessary because, as I have outlined, the market is likely to accomplish



the same end unassisted. It is not workable because, first, the pharmacist could technically comply by pricing the least expensive product in stock only 1¢ below the brand name drug prescribed. Second, a pharmacist who did not wish to be forced to sell the substitute at the price of the least expensive drug in inventory could refuse to stock the lowest-cost products at all--so that the effect would be to raise overall retail drug prices. Indeed, with respect to generically-written prescriptions, there is evidence that this type of restriction on the pharmacist does not save consumers money. One study showed that greater savings have been generated in Michigan, which has no such provision, than in Wisconsin, which does have one. 11/

Moreover, to determine whether a violation of the lowest-price-in-stock provision has occurred, the Commission would need to ascertain the various prices of drugs in a pharmacist's inventory at the time a particular substitution took place. This determination might be impossible; it would certainly be costly. Especially in light of this enforcement problem, it makes more sense to test the forces of competition in an unfettered market before authorizing or mandating substitution of only the lowest-priced drug in stock. We therefore recommend that H.R. 1963 be revised to permit pharmacist substitution of any lower-cost equivalent drug product.



A sound approach to substitution also must retain physician control over what drug product the patient buys. H.R. 1963, like current state substitution laws, gives the physician who wishes to prescribe a brand-name drug for a specific medical purpose absolute authority to do so. However, a good substitution law must ensure that the physician who directs that a prescription be filled by a brand-name drug is doing so deliberately, by requiring simply that the physician take a second or two to handwrite "medically necessary." (That is the phrase already used in HEW's Maximum Allowable Cost program.) If the physician fails to take this action, the pharmacist can substitute a generic equivalent. In those states that have repealed anti-substitution laws, the "medically necessary" legend is rarely added, although prescriptions are still frequently written in brand-name language. 12/ So we recommend that H.R. 1963 explicitly require the doctor to write "medically necessary" if he or she wishes to prevent substitution for medical reasons.

Another key element of a workable approach to generic substitution is the adoption of a "positive formulary," a list of generic drug products that are safe, effective and therapeutically equivalent to the brand-name products. (A "negative formulary," a list of nonsubstitutable drug products, might serve the same purpose, but of those pharmacists responding to our



survey who favored a formulary, most preferred the positive formulary approach.) As you know, the FDA is working to develop a positive formulary and has endorsed New York's list. Such lists help the pharmacist, who is the most logical person to search out the lower cost substitutes, to choose safely. And through vigorous FDA enforcement of quality control, the pharmacist can be confident of the continuing reliability of these lists. Thus, we recommend that H.R. 1963 define a "substitute drug" as one which is deemed equivalent by the FDA formulary.

We note that H.R. 1963 includes a provision preempting state law: section 4 of the bill provides that a state may not establish or enforce a law or practice which prohibits a pharmacist from taking an action authorized or required by section 2. It is not clear to us whether a state law would be in violation if, while posing as a "substitution" law, it imposes requirements so burdensome that pharmacists are deterred from engaging in product selection. For example, some state laws include extensive requirements as to the manner in which a pharmacist must notify the patient that substitution has occurred, inform the patient of the exact price savings, and in some cases obtain the patient's affirmative consent. Other laws require that the pharmacist notify the physician by telephone or in writing each time a substitute is dispensed. Some



of these requirements may serve legitimate state interests, but they also may frustrate substitution. If any overly burdensome provisions are to be preempted by federal legislation, the bill may have to address them specifically.

Finally, with respect to pharmacist liability: our study shows that pharmacists are very concerned about what they perceive to be the increased risk of lawsuits arising from the substitution of generic equivalents, and that this fear often deters them from substituting as often as they would do otherwise. In addition, some brand-name manufacturers appear to be magnifying this fear through dissemination of scare stories, so-called "educational" seminars, and so on.

To the best of our knowledge, and according to every brand-name manufacturer and trade association we have contacted, not one lawsuit has been filed against a pharmacist for legally substituting a lower-cost generic drug product or for selecting the source of a generically written prescription. Neither are the major pharmacy insurers we contacted aware of any insurance claims filed. Although the pharmacist may be selecting drug sources more often, the nature of his or her activity remains the same--pharmacists have for years filled generically written prescriptions without incident. Therefore, we see no basis for the exaggerated claims being presented about liability, and we think it



is imperative that pharmacists receive objective information about potential liability, and about the type of protection afforded by the insurance policies of the pharmaceutical manufacturers and by the pharmacists' own policies.

This brings me to my closing point. A substitution law, even one which embodies all of the features we have identified as essential, will only be effective if it is accompanied by adequate educational programs. Pharmacists must be provided with the facts about liability and with comparative source information. Physicians must be assured that they retain absolute authority to insist upon a particular drug source when they think it medically necessary. And consumers must be informed about the availability of generic drugs and the savings they make possible. Federal programs to support these educational efforts could help to ensure that a substitution law, at the state or federal level, will work.

At the FTC, we will continue to monitor carefully the success of substitution, and stand ready to take whatever action is necessary to ensure the health of price competition in the prescription drug market.

Thank you. I will be glad to answer any questions.



## FOOTNOTES

1/ Pharmacy Times, April 1978, p. 41. The figure increased by 13% between 1976 and 1977, according to pharmaceutical industry figures.

2/ Our Bureau of Economics staff estimates the potential savings for 60 popular multisource drugs at \$341 million.

3/ For example, HEW recently found that wholesale prices for 100 capsules of generic drug ampicillin in 250 mg doses varied from \$6.00 to \$18.74. Address by James T. Doliuso, "A Perspective of Bioavailability/Bioequivalence," 23rd National Meeting of APHA Academy of Pharmaceutical Sciences, Phoenix, Arizona (Nov. 14, 1977). Similar disparities exist for other drugs. See, e.g., Vol. 2, Wisconsin Drug Formulary (Feb. 1977).

4/ Presentation by Joseph L. Fink, III and Daniel J. Kerrigan, "Physicians' Knowledge of Drug Prices," 23rd National Meeting of APHA Academy of Pharmaceutical Sciences, Phoenix, Arizona (Nov. 14, 1977).

5/ Bond and Lean, "Sales, Promotion, and Product Differentiation in two Prescription Drug Markets," a Bureau of Economics Staff Report to the Federal Trade Commission, Feb. 1977, p. 1. Some more recent trade estimates have put total pharmaceutical advertising and promotion outlays at \$1 billion for 1977. Advertising Age, Feb. 13, 1978, p. 68.

6/ Bond and Lean, supra, p. 76; see also Pharmacy Times, April 1977, p. 38.

7/ Bond and Lean, supra.

8/ Bond and Lean, supra.

9/ Goldberg, et al., "Evaluation of Impact of Drug Substitution Legislation," Vol. NS16, No. 2, Journal of the American Pharmaceutical Ass'n. (1976).

10/ See, Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748 (1976).

11/ Theodore Goldberg, "Cost Implications of Drug Product Selection Legislation," presented at Invitational Dissemination Workshop on Drug Product Selection Legislation, Detroit, Michigan, April 13-14, 1978.

12/ In Michigan, "D.A.W." (Dispense as Written) was written on 6.4% of prescriptions in the first year of product selection, and decreased to 4.0% the second year. Similarly, it was indicated only 3.6% of the time in Wisconsin. It was applied as frequently to single-source prescriptions as to multisource. Theodore



Goldberg, *supra*. In Ontario, "No Substitution" is indicated on less than 1% of prescriptions. Allan E. Dyer, "Implementation and Implications of Applying Drug Product Selection to Selected Populations," presented at Invitational Dissemination Workshop on Drug Product Selection, Detroit, Michigan, April 13, 1978. The FTC pharmacist survey shows similar results.

Moreover, it has been demonstrated that if preprinted prescription blanks requiring the physician to sign one of two lines--"D.A.W." or "Substitution Permitted"--are used, doctors preclude product selection in most cases. In Delaware, 62.1% of prescriptions were signed on the "D.A.W." line. Fink and Myers, "Effectiveness of Drug Product Selection Legislation in Delaware," adapted from presentation to the American Pharmaceutical Assn., Montreal, Canada, May 17, 1978. A New York Board of Pharmacy survey showed 74% of the preprinted forms were signed on the "D.A.W." line. N.Y. Times, June 2, 1978 at B6. The FTC survey shows similar results.

Mr. PERTSCHUK. The only additional point I want to make is if you do pass this bill I think it should be renamed. I think that the name now, the Substitute Prescription Drug Act, is accurate enough, but even more accurate is the Drug Pricing Deregulation Act.

I think of all of the measures that this subcommittee has addressed and that we have addressed, this is one peculiarly which fits all of the current prescriptions even on a reading of proposition 13.

We are getting the Government out of the business of business. What you really have here is a case in which there is an antiquated, perhaps justified, structure of regulation, at one time tying the market not at the behest of the consumers, but of the industry. And what we are really asking for with the basic thrust of the testimony and the bill itself is to free up the market, to let the marketplace work so that consumers can benefit from competition in appropriate areas and with appropriate safeguards and satisfy all the rubrics that are currently in vogue.

Mr. ECKHARDT. Chairman Pertschuk, once you do get the model act prepared, and I understand that is forthcoming--

Mr. PERTSCHUK. Yes, sir.

Mr. ECKHARDT. What would you suggest be done with it?

Mr. PERTSCHUK. Well, advocacy at various levels. This is also a unique area, it seems to me, because I know you have been through a number of issues in which the cry from those affected was "leave it to the States, there is movement."

This is a unique situation in which there is movement. That is, 40 States, most of them within the last 2 years, have moved in this area and it is not an accident. There exists a very significant constituency for change at the State level.

This national consumer alliance on prescription drugs contains a number of groups--the AARP, from whom you have heard, the National Council of Senior Citizens, and others--that have a direct strong economic stake in the outcome of this legislation. I am impressed by their efforts.

Bill Haddad had a conference here of State legislators and other groups interested in reform at the State level, and I was damned impressed with the strength of those groups involved. They have been organized and they are active and they are there. They are



there to take the FTC's work product and the research we have done and the work that Don Kennedy is doing at the FDA and use it in advocacy before the State legislatures.

We, too, through our regional offices will make our support available to the State legislatures where we are welcome because this is a sensitive matter concerning the benefits of our research and of the model law. That is a sensitive area. We will do it by invitation and not thrust ourselves upon the State legislatures.

Mr. ECKHARDT. So you feel that there is enough impetus behind the act both by consumers who are disturbed, if not outraged, about the prices of certain named drugs and by the druggists themselves who must recognize their product may be priced out of the market and their earnings cut in half by the high price of the drug from the manufacturer. You feel that those two economic pressures are likely to result in State action and that Federal action would not be called for at this time?

Mr. PERTSCHUK. Yes. I think also you cannot ignore the fact that the pharmaceutical manufacturers also have substantial resources and also have been effective at the State level particularly in advocating provisions that may thwart the purpose of the legislation.

I think it is entirely appropriate that the committee should hold in abeyance its decision—not necessarily indefinitely, because it is possible that even with strong popular support the effort will be frustrated at the State level and it may become appropriate for Congress to entertain action. But for the time being there is momentum, there is real movement and I think the support of FDA, HEW, and our modest contribution will help.

Mr. ECKHARDT. Then the model bill will afford a means of furthering adoption of State legislation.

Mr. PERTSCHUK. We hope so, yes, sir.

Mr. ECKHARDT. You state that you feel that there should not be any mandatory provision with respect to the price savings pass-on, that that should be taken care of by competition. Do you feel that there might be some provision in a model law which required the posting, not necessarily of a single price for all drugs, but the posting of the prices charged for the brand name drug and the equivalent?

Mr. PERTSCHUK. Mr. Chairman, I have always supported the concept of drug posting. I understand this morning in a brief discussion I had that there are some concerns about those mandatory provisions.

I think what I would like to do is consult with the staff and identify the pros and cons and supply that for the subcommittee. I don't really know what they are. I gather there are some questions that relate to the enforceability of it but while on its face the application makes sense as part of the scheme, clearly freeing up drug advertising, it is a very important part of drug advertising, of the competitive scheme, but that is not a form of deregulation of eliminating restrictions on advertising.

The posting of prices designed to enable the consumer to see the significance of the differences also seems to be part of a competitive scheme. But there may be some defects of which I am not aware and I would supply that for the record.



Mr. ECKHARDT. Do you know whether there is any activity in the antitrust field with respect to brand name drugs at the present time either by the Justice Department or by the Federal Trade Commission?

Mr. PERTSCHUK. There is some activity in the FTC, but it is at a prepreliminary stage. I don't think I am free to comment beyond that.

Mr. ECKHARDT. Are there any questions of the staff?

Ms. SEDDON. I would like to get a feel for the circumstances under which it would be appropriate for the Congress to act should the Congress decide not to pass this bill right now. What should the committee look for?

Mr. PERTSCHUK. Well, I think we will continue to monitor and obviously supply for the committee the experience of the States. I would think you would look to the next legislative session to evaluate this trend toward the adoption not only of substitution laws, but laws with provisions like the ones that we have talked about and absent the kinds of provisions that thwart the substitution; that is, monitoring the activity.

There are underway a number of studies of the effectiveness of State laws with varying provisions and we will monitor those, too. I think that as the next legislative sessions come to a close and as you have a year or two experience with actual practice under the State laws, you will have a better picture of whether unnecessary restrictions of generic drugs can substantially be removed under State laws.

Ms. SEDDON. That is all.

Mr. ECKHARDT. Thank you very much, Mr. Chairman.

Mr. PERTSCHUK. Thank you very much.

Mr. ECKHARDT. Commissioner Kennedy.

**STATEMENT OF HON. DONALD KENNEDY, COMMISSIONER, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ACCOMPANIED BY GENE KNAPP, ASSOCIATE DIRECTOR FOR DRUG MONOGRAPHS, BUREAU OF DRUGS; AND RICHARD COOPER, CHIEF COUNSEL**

Dr. KENNEDY. Mr. Chairman, with me are Gene Knapp, Associate Director for Drug Monographs in the Bureau of Drugs at FDA on my left; and Richard Cooper, Chief Counsel of the Food and Drug Administration on my right.

I think I will read the first portion of my statement, Mr. Chairman, and then just try to highlight the remainder of it.

Mr. ECKHARDT. You may proceed as you prefer, sir.

Dr. KENNEDY. I am very grateful for the opportunity to testify on the subject of generic substitution before your subcommittee. Before turning to some specific comments on Department and agency activities and our views on H.R. 1963, I want to make some general remarks about cost and quality in multisource drugs.

This year, as I am sure you know, nearly a dozen prescriptions will be written for each of us Americans and these drugs will cost or account for about \$70 of the \$740 or so which constitute the per capita cost of health care in this country for the current year.



Moreover, the price of drugs does not fall on our fellow citizens equally—it impacts most heavily on the elderly, the chronically ill, short the people who have the greatest need for drugs and in general also have lower incomes than the rest of us.

The average cost of prescription drugs, though heavy enough, does not begin to define the social dimensions of the drug price squeeze.

This administration is firmly committed to doing something about the problem and our part of that task at the Food and Drug Administration is concentrated on four areas.

First, on payment limitations applied through the health care reimbursement system.

Second, standards for price advertising in drugs are part of the problem that we share with Chairman Pertschuk.

Third, new legislative proposals that we are bringing before the Congress this year as part of the Drug Regulation Reform Act of 1978.

And, finally, the support of State and local government efforts to sweep away artificial barriers that impede price competitive selection among approved therapeutically equivalent drug products.

It is on the last of these efforts that I want to speak for a few minutes this afternoon.

Whenever Government policies that favor price competition among drugs are proposed, an ongoing controversy between FDA and the drug industry about generic versus brand name drug quality escalates another step. We are responsible for the assessment of drug quality in the United States, and I shall review briefly but carefully our assessment of the quality differences between “generic” and “brand name” drugs.

Before doing so I want to set out three criteria that any analysis of that quality difference has to meet.

First, I would like to point out that the quality differences between brand name and generic drugs are important only for part of the prescription drug universe.

FDA has felt that it can evaluate therapeutic equivalents only among those multisource drug products that have passed through the most stringent and the most modern version of the drug approval process.

For that reason, only post-1962 drugs that are the subject of new drug applications—we abbreviate them NDA’s—and pre-1962 or abbreviated new drug applications, ANDA, have been or will be included in formulary lists provided by FDA to assist the States.

I might say parenthetically, Mr. Chairman, that catches the majority of the multisource prescription drug universe. To be meaningful, therefore, any assessment of quality difference must be restricted to this universe that I have just described.

Second, distinctions between brand name and generic drug manufacturers must be made according to objective criteria if quality comparisons are to mean anything. To compare the large and small firms, Pharmaceutical Manufacturers Association member firms versus nonmembers or “research intensive versus nonresearch intensive” firms is not meaningful at all unless an independent definition of these categories can be worked out and stated at the beginning of the analysis.



Finally, adequate indicators must be specified carefully; if FDA's own compliance data are used, and we think they can be, there must be appropriate corrections for the size of the universe that is being sampled in the particular analysis.

Let me now turn to the debate itself for a moment. Manufacturers have asserted directly or by implication both in their own advertising and in congressional testimony that brand name drugs are of a higher quality than their generic competitors. It is clear that this assertion is believed by many because it supports significant price differences between brand name and generic products.

Recent discussions of the quality issue have focused on the list of therapeutically equivalent drugs provided to the State of New York by FDA. All drugs on this list hold NDA's or ANDA's. The list does not contain products that have known bioavailability problems. They have been weeded out. Nor does it address issues other than the issue of therapeutic equivalence of the products listed.

So when we say that these drugs are therapeutically equivalent, that means that whether a drug is or is not a brand name product has no influence on the probability that it will probably be deficient in some quality measure.

Your chances of getting a bad pill or a good pill is the same from each manufacturer in the multisource universe defined by us in that list.

Mr. ECKHARDT. Let me interject a question here, if you will. You say that the fact that brand named drugs support a higher price indicates that the public perceives differences. May it not be that the public simply feels that it is assured that the drug by the known brand name is adequate? In other words, the public is not willing to take a chance. It may not know it to be better. But it may be similar to the public accepting a product from a well-known merchandiser as being likely to be within the brackets of acceptability. It may not necessarily be better but it is known not to be inferior.

Dr. KENNEDY. Yes; I think that is a further exploration of the matter. I do think it suggests that not necessarily the public but the people responsible for casting into motion the process of purchasing the drug who may in most cases be the physician or in some cases the pharmacist. The person who is making that selection believes that there is a quality difference. Whether the brand name provides an extra measure of insurance against inferiority or whether it simply means an elevation in quality, the fact remains, it seems to me, that people's behavior suggests that the brand name manufacturers have somehow persuaded the relevant part of the universe that there is something different there—something different.

In Senate testimony last fall the president of the Pharmaceutical Manufacturers Association claimed that FDA had failed to meet its plant inspection goals and argued that as a consequence we could not make any quality guarantees of the kind that we were making. When we pointed out that the wrong table had been used in PMA's analysis and that PMA had neglected the fiscal quarter in 1977, these deficiencies evaporated.

A more recent study by Eli Lilly & Co. purports to show differences between research intensive firms and others in FDA's own



recall statistics. This report is under review at FDA and we will have a full response to it. But it is already clear that this study failed each of the criteria that I set out earlier in my testimony. It measures all class I and class II recalls and specifically emphasizes drug products that are not included in FDA's list of therapeutically equivalent products and, therefore, it is irrelevant to the argument that we are setting out. It arbitrarily neglects one large research firm with a very bad recall record and so skews the data badly and it counts large recalls as equivalent to small recalls, thereby understating the greater adverse impact of the larger recalls.

The fact is that we have yet to see a defensible challenge to FDA's assertions about their therapeutic equivalence. There may indeed be differences among drug plants or among drug companies, but we do not believe that any analysis conducted according to criteria that I have just described will yield consistent differences between generic and brand name firms or products.

Indeed, brand name firms often display their confidence in generic manufacturers by leasing their production facilities in order to make drugs that they then market under their own labels.

Let me now turn briefly and in summary fashion, Mr. Chairman, to some of the programs of the HEW and the FDA in this area.

Clearly the formal barriers that now exist at drug proceedings are at the State and local government level. We think these barriers are artificial and inappropriate, but we do not have any regulatory role—that is, a direct one—in the way that prescriptions are written or dispensed.

What we do have is a regulatory role in assuring the safety and efficacy of approved drugs. Thus, the agency can assist Federal, State, and local authorities in assuring the quality of drug products available for selection under the State or local laws.

At the Federal level, as you know, the Government is a major purchaser of drugs and a third-party payer and our Department is concerned about factors that generate unnecessary expenditures of public funds for these drugs. The maximum allowable cost, or MAC regulations are designed to limit the reimbursement for approved multiple source drugs purchased by the Department to the lowest cost at which a multiple source drug is available. These went into effect 3 years ago and when fully implemented they should result in savings of \$20 to \$30 million under HEW-funded health programs.

Mr. ECKHARDT. Will you pardon me to inject a question at this point?

Dr. KENNEDY. Yes.

Mr. ECKHARDT. What sort of publicity, if any, does your agency give as to this program? Is it possible for the public to know what the Federal Government considers as an equivalent drug and what it recommends with respect to the use by a governmental office?

Dr. KENNEDY. Well, it is a good question, Mr. Chairman. The fact is that in specific connection with the MAC program the process of generating maximum allowable cost regulations for the particular drug groups has gone much more slowly than its most ardent proponents thought it would at the beginning. We have only a small number of groups of products—MAC as we call it—and as a result that program really does not yet have a large enough uni-



verse to make it worth saying very much about to people in general as a guide to doing things for themselves.

What we are hoping is that lists of the kind that we prepared for New York State or helped New York State prepare for itself will go further in that direction. FDA is now working on a so-called positive formulary list of equivalent multisource drugs products that it will make available to the States wherever they are desired.

It is certainly my intention, when we get this work done, to make the list available on a very wide scale basis and to publicize it just as effectively as we can. That is one of the reasons for doing it.

Mr. ECKHARDT. Suppose we take a break at this time. I shall return.

Dr. KENNEDY. Yes, sir.

[Brief recess.]

Mr. ECKHARDT. The subcommittee will come to order.

You may proceed, Dr. Kennedy.

Dr. KENNEDY. Well, Mr. Chairman, I was going to mention that the Drug Regulation Reform Act also contains provisions that will encourage generic prescriptions, such as a label requirement about the prominence of generic names, provisions to facilitate the approval of generic products once exclusive marketing rights expire, a provision for equivalency testing for all drug approvals where appropriate, and a Federal compendium organized in such a way as to facilitate generic prescribing by providers.

I mentioned in response to one of your questions, Mr. Chairman, that in addition the Department is actively assisting the States in their efforts to establish rational drug product selection programs. In addition to providing some assistance, at its request, to New York State Whits formulary, we have also entered into an arrangement with the State of New York to assist it in evaluating the ability of low bidders to produce quality products.

I would only add, I think, before turning to some problems with H.R. 1963, that we view the issuance of an approved drug list by the FDA as an important step in aiding drug selection programs.

As far as H.R. 1963 is concerned, Mr. Chairman, I am really just going to highlight my remarks because my views on it so closely comport with those of Mike Pertschuk. I think that the States are doing so well in general in altering State laws and removing State imposed barriers to rational drug product selection that this trend ought to be watched. There is a strong Federal tradition of deferring to the State and local authorities in matters affecting professional practice. It seems to us that direct Federal intervention in this matter should await the experience that is developed in the course of the trend we are seeing now.

So for our part, we think that the appropriate Federal role is for agencies like FDA to provide all the assistance to the States that they can provide, such as the provision of a model law and the quality evaluation that I have already mentioned.

I think with that, Mr. Chairman, I will ask permission to enter the rest of my remarks in the record and wonder whether you have questions for me.

[Testimony resumes on p. 185.]

[Dr. Kennedy's prepared statement follows:]



STATEMENT OF DONALD KENNEDY, COMMISSIONER, FOOD AND DRUG ADMINISTRATION,  
PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman:

I am grateful for the opportunity to testify on the subject of generic substitution before your Subcommittee. Before turning to some specific comments on Department and Agency activities and our views on H.R. 1963, I want to make some more general remarks about the cost and quality of multisource drugs.

This year nearly a dozen prescriptions will be written for each of us Americans, and these drugs will account for about \$70 of the \$737 per capita cost of health care. Moreover, the price of drugs does not impact our fellow citizens equally. It falls heavily on the elderly and on the chronically ill, who have the greatest need of drugs and--in general--the lowest incomes. Thus the average cost of prescription drugs, though heavy enough, does not begin to define the social dimensions of the drug price squeeze.

This Administration is firmly committed to doing something about the problem. Our present efforts are concentrated in four areas:

- payment limitations applied through the health-care reimbursement system;
- standards for price advertising;
- new legislative proposals that will promote generic prescribing, contained in the Drug Regulation Reform Act of 1978; and



- support of State and local governmental efforts to sweep away artificial barriers that impede price competitive selection among approved therapeutically equivalent drug products.

It is on the last of these efforts, Mr. Chairman, that I would like to focus the Subcommittee's attention for a few minutes.

Whenever Government policies that favor price competition among drugs are proposed, an ongoing controversy about generic vs. brand-name drugs escalates another step. The Food and Drug Administration (FDA) is responsible for the assessment of drug quality in the United States, and I shall review, briefly but carefully, our assessment of the quality differences between "generic" and "brand-name" drugs. Before doing so, I want to set out three criteria that any analysis of these differences must meet:

First, quality differences are important only for part of the prescription drug universe. FDA has felt that it can evaluate therapeutic equivalence only among those multisource drugs that have passed through the most stringent and modern version of the drug approval process. Thus, only post-1962 drugs that are the subject of new drug applications (NDA's) and pre-1962 drugs that are the subject of NDA's or abbreviated new drug applications (ANDA) have been or will be included in formulary lists provided by FDA to assist the States. To be meaningful, therefore, any assessment of quality difference must be restricted to this universe.



Second, distinctions between "brand-name" and "generic" manufacturers must be made according to objective criteria if quality comparisons are to mean anything. To compare large and small firms, Pharmaceutical Manufacturers Association (PMA) member firms vs. nonmembers, or "research-intensive vs. nonresearch-intensive" firms is not meaningful unless an independent definition of each category can be developed.

Third, quality indicators must be specified carefully; if FDA's compliance data are used, there must be appropriate corrections for the size of the universe sampled.

Let me now turn to the debate itself. Manufacturers have asserted directly or by implication, both in advertisements and in Congressional testimony, that "brand-name" drugs are of higher quality than their generic competitors. It is clear that this assertion is believed by many, because it supports large price differences between brand-name and generic products.

Recent discussions of the quality issue have focused on the list of therapeutically equivalent drugs provided to the State of New York by FDA. All drugs on this list hold NDA's or ANDA's. The list does not contain products that have known bioavailability problems, nor does it address issues other than the issue of the therapeutic equivalence of the products listed. Our statement that these drugs are "therapeutically equivalent" means, therefore, that whether a drug is or is not a brand-name product has no influence on the probability that it will be deficient in some quality measure.



This position has been challenged repeatedly over the past several months by spokesmen for the brand-name pharmaceutical industry. In Senate testimony last fall, the president of the PMA claimed that FDA had failed to meet its plant inspection goals, and argued that as a consequence we could make no quality guarantees. When we pointed out that the wrong table had been used in the PMA analysis and that PMA had neglected the extra quarter in FY 1977, these deficiencies evaporated. A more recent study by Eli Lilly and Company purports to show differences between "research-intensive" firms and others in FDA's own recall statistics. This report is under review. But it is already clear that it fails each of the criteria I set out earlier in my testimony: because it measures all class I and II recalls, it specifically emphasizes drug products that are not included in FDA's lists of therapeutically equivalent products; it arbitrarily neglects at least one research firm with a bad recall record; and it counts large recalls as equivalent to small recalls, thereby understating the greater adverse health impact of the larger recalls.

The fact is that we have seen no defensible challenge to FDA's assertions about therapeutic equivalence. There may indeed be differences among drug plants, or among drug companies; but we do not believe that any analysis conducted according to the criteria I have just described will yield consistent differences between generic and brand-name firms or products. Indeed, brand-name firms often display their confidence in generic manufacturers by leasing their production facilities in order to make drugs that they then market under their own labels.



HEW/FDA Activities

I will not<sup>W</sup> turn, Mr. Chairman, to an analysis of the Department of Health, Education and Welfare (HEW) and FDA activities in this area. Formal barriers to drug product selection are the creation of State and local governments. We believe these barriers are artificial and inappropriate but FDA has no direct regulatory role in the way prescriptions are written or dispensed. The Agency does, however, have a regulatory role in assuring the safety, effectiveness, and bioequivalence of approved drugs. This Agency can thus assist Federal, State and local authorities in assuring the quality of drug products available for selection under these laws.

Federal Level

As a major purchaser of drugs (and as a third-party payor through Medicare and Medicaid programs), the Department is concerned about factors that generate unnecessary expenditures of public funds for drugs. The Maximum Allowable Cost (MAC) regulations (45 CFR 250.30), designed to limit the reimbursement for approved multiple source drugs purchased by the Department to the lowest cost at which a multiple source drug is generally available to providers, went into effect in August 1975. When fully implemented, the program is expected to result in a savings of 20 to 30 million dollars yearly under HEW-funded health programs.

The FDA has established standards to promote price advertising of prescription drugs that will enable consumers to make intelligent choices among available brands (21 CFR 200.200, 200.100, and 202.1). We have



also published regulations designed to ensure the quality, safety and effectiveness of pharmaceutically equivalent drug products (bioavailability and bioequivalency of multisource drug products (42 FR 1624; January 1, 1977) and a comprehensive revision of its regulations (21 CFR 320) regarding current good manufacturing practices for drugs (41 FR 6878; February 13, 1976)). These measures should assist product selection systems that authorize the interchange of therapeutically equivalent, approved multisource drug products. Under the Government-wide Quality Assurance Program and the MAC program, this Agency assures the quality of medical products, including drugs, procured for Federal programs.

#### Drug Regulation Reform Act

As you know, the Department has also proposed a total revision of current drug laws--the Drug Regulation Reform Act of 1978 that is currently pending before Congress. The bill would encourage generic drug use in a number of ways. It would require generic names in labeling and advertising to be at least equal in size to any brand name. It would facilitate the approval of generic versions of pioneer drug products once the pioneer's exclusive marketing rights expire. It would mandate bioequivalency testing for all drug approvals where appropriate, and encourage the posting of comparative prices of therapeutically equivalent approved multisource brand and generic drug products. It would make it possible to recommend additional substitutable drug products, because all drug products would be under a single system of



licensure. As I mentioned, FDA has limited its recommendations on therapeutically equivalent drugs to those that are the subject of approved applications for safety and efficacy. A number of drugs manufactured by more than a single firm are legally on the market without approved applications.

#### Physician Education

The bill would also address a concern that has recently been raised by advocates of rational drug product selection--namely, that physicians may need some help in generic product use. The bill would establish a Federal drug compendium to assist health care professionals in selection. Drug products would be listed by diagnostic and therapeutic categories, and within each category listing would be by established (generic) name. This format would encourage practitioners to recognize therapeutic equivalents among approved drug products containing the same chemical entity.

#### State Level

This Department is actively assisting the States in their efforts to establish generic selection programs. The FDA recently entered into an agreement with the State of New York to assist in evaluating the ability of low bidders for New York disbursement programs to produce quality products. As noted earlier, the FDA currently performs a similar service for Federal programs. We are also completing a list of approved therapeutically equivalent drugs and helping with a model State drug product selection law that should further assist States in selecting



drugs for their local programs. We view the issuance of an approved drug list as an important step in aiding drug product selection programs, because of certain caveats that I will discuss more fully in commenting on H.R. 1963, to which I now turn.

#### H.R. 1963

H.R. 1963 would preempt State and local substitution laws and place regulatory enforcement with the Federal Trade Commission (FTC). The bill would permit a pharmacist to substitute the lowest priced drug in the pharmacy inventory for a drug prescribed by its proprietary name, and require a pharmacist to substitute the lowest cost product in the pharmacy inventory when a drug is prescribed by its established name--unless the prescribing physician or the patient specifically give contrary instructions. The proposal would also prohibit dispensing a substitute drug product chosen by a pharmacist if the patient requests some other substitute product.

#### Preemption

The FTC is completing an exhaustive study of drug product substitution, and State, local and professional practices governing drug product selection. FTC's final report should address the need for Federal intervention in this area, particularly in terms of requirements for direct FTC involvement under its unfair trade practices authority. We therefore defer to FTC as to the appropriateness of section 5 of the bill.



Present antisubstitution laws are State-imposed barriers to drug product selection. Each of the 50 States had, at some point, substitution bans. Recently there has been a trend among the States to repeal or substantially modify them; and now 40 States permit some form of substitution or drug product selection by pharmacists. This trend is, in our view, of direct benefit to consumers.

At the same time, it is strong enough to suggest that Federal preemption at this time may be unwise. The Federal Government has traditionally deferred to State and local authorities in matters affecting professional practice. Since the States are actively directing their efforts toward a goal fostered by the Federal Government, we believe that direct Federal intervention should await the experience developed in the course of this trend. In the interim, we will concentrate on efforts to provide the States whatever assistance that may be necessary. This includes preparing a model State law and completing our approved drug listing. Thus, we do not believe that the enactment of H.R. 1963 is called for at this time.

#### Technical Problems with H.R. 1963

##### Substitute Drug

In addition, we do have some technical problems with the bill. The reference to section 502(e)(2) at page 6 of the bill should read 502(e)(3). We also suggest that the proposed definition of "substitute drug" in section 2(d) of the bill be further refined and clarified. The definition refers only to qualitative similarities between pharmaceutically



equivalent drug products. We believe that a "substitute drug" must be a true pharmaceutical equivalent to the drug prescribed. It must be the same in active ingredient strength, dosage form, and be approved and recognized as equivalent by FDA. It must also be therapeutically equivalent.

Any definition should also be drafted so that it would exclude those instances in which apparently equivalent drug products should not be used interchangeably.

We believe that all pharmaceutically equivalent drug products can be considered therapeutically equivalent providing they are marketed under approved NDA's, are manufactured under the same standards, meet identical or comparable specifications, and (in those instances where positive evidence of bioequivalence is necessary), are shown to be bioequivalent.

FDA does not represent different dosage forms of the same active ingredient as necessarily being therapeutically equivalent. Different brands of the following dosage forms have not been generally shown to be pharmaceutically equivalent and therefore cannot be regarded as therapeutically equivalent:

- Enteric coated tablets;
- Controlled release products;
- Injectable suspensions, other than antibiotics;
- Suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity;



- Different delivery systems for aerosol and nebulizer drugs; and
- Topical ointments are considered to be a different dosage form than ointments and, therefore, may not be therapeutically equivalent.

#### Lowest Cost

H. R. 1963 would require a pharmacist to select the lowest priced drug in the pharmacy inventory where a prescription is written for a drug under its established name. The intent of this provision is to provide the consumer with the least costly effective drug product available, but we are concerned about the long-term impact of such a mandate on the quality of drugs in this country. Such a provision may stimulate needed price competition, but it may also be a serious anticompetitive feature in that larger manufacturers could by selective cost-cutting, force the smaller manufacturers out of the market, particularly at the State and local level. Also, because of the highly variable pricing practices in the drug industry, it would be almost impossible to enforce equitably. We expect FTC to address this issue in its upcoming report.

#### CONCLUSION

Rational policy dictates that artificial drug product selection barriers be lowered at the State and local level. The Federal Government is benefiting from programs such as the MAC program and the Government-wide Quality Assurance Program. So should the States and all consumers.



Any efforts to extend comparable Federal programs to the State level should include, as do the Federal programs, mandatory FDA participation to assure that only appropriate pharmaceutically equivalent products are selected for substitution.

That concludes my formal presentation. My colleagues and I are prepared to answer any questions that you might have.

Mr. ECKHARDT. Without objection, it will be so ordered.

The Federal role has frequently been in the direction of information as for instance, in the Magnuson-Moss warranty bill where we set standards for information disclosure in a warranty. Do you think that there is any Federal role with respect to the requirement that disclosures be made, for instance, the fact of generic equivalents, and the individual pharmacist's price differentials, with respect to drugs in the equivalency?

Dr. KENNEDY. We do believe so and one of the proposals in fact in the Drug Regulation Reform Act of 1978 is a provision for pharmacy price posting of comparative prices for multisource drugs. It is fair to say that there has been some objection to that for reasons having nothing whatever to do with our original intentions.

There is a feeling on the part of many retail pharmacists, I think, particularly the proprietors of small retail pharmacies, specialty pharmacies, that these provisions will put them at a relative disadvantage with respect to larger chain drug houses. But that is a difficulty that I think can be addressed and we hope resolved in other ways. I do think that informational requirements are a good way to go and I think that price posting is one of them and, as Mike Pertschuk said earlier, the elimination of artificial restraints on advertising is another one.

Mr. ECKHARDT. When you say "restraints on advertising, I gather that Mike Pertschuk was referring to restraints imposed by States and the removal of those restraints by the States. Is that the way you understand it?

Dr. KENNEDY. There may be some of those, but in the past there have been some restraints, as I understand it, with regard to certain kinds of competitive price advertising. In fact there is a minor, but I think not insignificant, defect in FTC and FDA authority. It is a jurisdictional overlap that has given us a problem with respect to price advertising, that we are now trying to address and resolve.

You see, FTC has authority over the advertising of over-the-counter drugs. As you know, we have advertising authority for prescription drug products. There are some problems in the area of prescriptions to the general public and not to doctors.

I think that some competitive price advertising by retail firms now—not by drug manufacturers, but retail firms—has been caught up in that gap and we have not really known how to handle it adequately. I think we can solve that problem.



Mr. ECKHARDT. What type of regulations are presently imposed on competitive advertising of drugs? Pharmacy A wishes to advertise that he has available a generic drug that is at a price considerably lower than that drug which is usually sold under a brand name elsewhere. How would he ever be restrained from so advertising? What would restrain him?

Dr. KENNEDY. Well, there is an FDA regulation—Gene, maybe you can do this better than I.

Mr. KNAPP. Generally there is concern in the agency that when a pharmacist advertises he really is in the advertising business by our view the same as if the company advertises a drug.

So what FDA is attempting to do through regulation is to specify the conditions by which a pharmacist may advise the consumers of the prices of his drugs. The State authority decides whether or not the pharmacist may advertise. FDA has attempted to give guidance as to how they may where the State makes the decision that they may advertise.

Mr. ECKHARDT. Give me an example of how that would work.

Dr. KENNEDY. Let me try, Mr. Chairman. To advertise generic price comparisons, a retail pharmacy chain, for example, would often feel that it would have to provide some assertions about relative quality. If it did that, it would come under the provisions of our advertising regulations designed for drug manufacturers that would require disclosure of a lot of detailed labeling of those prescription drugs as a part of an advertisement that referred to quality.

In short, what I am saying to you is that advertising regulations aimed originally at brand name manufacturers in their advertising to doctors would inadvertently catch a retail pharmacy chain that was advertising primarily about price but mentioning quality. We might require, for example, that they add to their advertisement detailed labeling about the indications and adverse reactions, and so forth, of that drug.

Mr. ECKHARDT. That would make it inadvertently impossible to advertise, would it not, in an ordinary publication?

Dr. KENNEDY. For certain kinds of advertising it would provide interference and we are attempting to repair that defect but that is what I had in mind.

Mr. ECKHARDT. Do you have any questions?

Mr. RINALDO. I am sorry I was not here for your presentation, as I had a conflict at that time. I do, however, have a few questions that I would like to ask. I did have the opportunity to read your prepared testimony, and I feel that your comments concerning the Eli Lilly study are most interesting. I must confess that I have not seen the study, and I request unanimous consent that the record remain open so that the Lilly Co. could respond to the Commissioner's testimony, and that response be made a part of the record.

Mr. ECKHARDT. Without objection, it will be so left open. Was there a reference to the Lilly Co.?

Mr. RINALDO. Yes.

Dr. KENNEDY. As I recall, I made reference to it and remarked at the same time that the comments that I was to make about the criteria for such studies and about the failure of that Lilly study to meet them was preliminary to a more detailed analysis that we



were doing in the Food and Drug Administration. We would hope that we could later supplement our testimony as well with the more detailed analysis that I alluded to in my testimony.

Mr. ECKHARDT. Without objection, the record will be held open with respect to that whole subject.

[The following letter was received for the record:]

ELI LILLY & Co.

Indianapolis, Ind., August 11, 1978.

Hon. ROBERT ECKHARDT,  
Chairman, Consumer Protection Subcommittee,  
Washington, D.C.

DEAR MR. ECKHARDT: On July 27, 1978, FDA Commissioner Donald Kennedy testified before your Committee regarding H.R. 1963, the "Generic Drug Substitution Act." Since the Commissioner made specific reference to analytical work done by Eli Lilly and Company, the company appreciates the Committee's courtesy in allowing us to respond on the record to the Commissioner's criticism.

The company feels that the central objective here, and the one upon which all parties agree, is the achievement of the best possible patient care. In the area of prescription drugs, FDA spokesmen have for years assured the Congress and the media that drug therapy can be provided at reduced cost since the total effect of the agency's inspection, testing and enforcement activities ensures a "single standard of drug quality." Although the Lilly study documents such agency statements back to 1967 (copies of the study are enclosed for the record), the recent statements of the current Commissioner clearly convey the message:

"A review of the records for Class I and Class II recalls from fiscal 1974 to the present shows that large and small firms are involved to approximately the same degree."<sup>1</sup>

"We've maintained compliance records on all of the firms who make drugs. As far as our records are concerned, large and small firms, brand name firms and generic firms, have indistinguishable records of performance. We testified to that effect before Senator Nelson's Committee in hearings several weeks ago. We know that the pharmaceutical manufacturers disagree with that, but we think they're wrong."<sup>2</sup>

"If there is any confusion in anyone's mind about FDA's position on the generic-brand name issue, let me dispel it now. FDA enforces a single standard of quality for all drugs sold in this country. We regularly inspect all drug processing plants to be sure they meet strict standards. We analyze thousands of drugs each year, and we maintain comprehensive information about recalls and compliants. We find no evidence of widespread differences in drug quality on the basis of a company's size or its status as a 'brand name' manufacturer."<sup>3</sup>

Using publicly available data, published by the FDA, the Lilly study tested these assertions. It examined FDA records of "Class I" recalls of defective products that might cause serious adverse health consequences or death; "Class II" recalls of defective products that might cause temporary adverse health consequences; FDA-initiated court actions such as seizures, injunctions, and prosecutions; and FDA/USP Drug Problem Reporting Program records. For recalls and court actions, the study covered the four-year period from January, 1974, through December, 1977.

When analyzed according to relative incidence by each of three separate measures (on the basis of relative sales volume, prescriptions, and drug uses), the data showed that firms with comparatively small research budgets have at least:

Seven times more recalls,

Forty-three times more FDA-initiated court actions against them, and

One and one-half times more FDA/USP Drug Product Problem Reports than the twenty-three corporations in the research-intensive category.

The main purpose of the Lilly study was to test the evidential basis for FDA assurances of equality of products and manufacturers. In subsequent sections of this document, each of the Commissioner's criticisms of the Lilly study will be discussed.

<sup>1</sup> Statement by FDA Commissioner Donald Kennedy before the Subcommittee on Monopoly, Select Committee on Small business, United States Senate, November 14, 1977.

<sup>2</sup> Interview by Betty Furness of Commissioner Kennedy, "Today" Program, NBC-TV, January 24, 1978.

<sup>3</sup> Press conference statement of Commissioner Kennedy quoted in FDC Reports, June 12, 1978, page "T&G-3."



THE IMPORTANCE OF NEW DRUG APPLICATION (NDA) STATUS IN MAKING DRUG QUALITY COMPARISONS

"First," the Commissioner declared, "quality differences are important for only part of the prescription drug universe." He further specified that only the drugs "that have passed through the most stringent and modern version of the drug approval process"—that is, drugs that are the subject of NDAs or ANDAs—can be assessed for quality differences.

This is too limited a standard. All prescription drugs, regardless of ADA/ANDA status, are subjected to a spectrum of statutory and regulatory requirements. In the words of the agency's own publication:

"Not only must each drug meet FDA requirements, so must each plant. All firms—large and small—must register with FDA; all are subject to periodic inspection, and all must follow FDA Good Manufacturing Regulations (GMPs) that touch on every aspect of making drugs, from building maintenance to quality control. These regulations apply to all producers and are intended to assure that all drugs meet the same standards of safety, strength, purity, and effectiveness."<sup>4</sup>

Many drugs too old to have been subject to NDA/ANDA procedures have instead been reviewed by the "Drug Efficacy Study Investigation" conducted by the National Academy of Sciences' National Research Council. These, and other drugs both with and without NDAs, are also often the subject of compendial standards set by such organizations as the United States Pharmacopoeia (USP).

In sum, the Commissioner's contention that an NDA/ANDA is a prerequisite to making drug quality comparisons is inconsistent with previous, and recent, agency statements and the agency's Congressionally-mandated responsibility to protect public health.

COMPANY CLASSIFICATION WITHIN THE PHARMACEUTICAL INDUSTRY

The second point made by the Commissioner concerned the need for rational groupings of companies for the purpose of comparing quality. He implied that "brand name" and "generic" would be such a grouping. Supportable definitions are needed, but the Commissioner's suggestion does not fulfill this need. Interestingly, the industry stratification definition used in the Lilly study seems consistent with that used in an April, 1978, study prepared by the FDA's own Office of Planning and Evaluation:

"The pharmaceutical industry has been characterized in numerous ways, one of which, as shown in the model, is by degree of research commitment. That is, some firms invest considerably more in R & D than others, an event that enables us to dichotomize the industry into firms that are either research-intensive or not. . . . Note that Research-Intensive and non-intensive firms may each derive revenues from both new drugs and generics."<sup>5</sup>

Lilly is itself an example of the reasonableness of this definition. The company is one of the nation's largest manufacturers of drugs marketed under their generic names while at the same time the company is investing very heavily in pharmaceutical research and development.

CORRECTIONS FOR THE SIZE OF THE UNIVERSE SAMPLED

The third, and last, study criterion posed by the Commissioner would require "appropriate corrections for the size of the universe sampled" when FDA compliance data are used. Since the Lilly study included one-hundred percent of the human-use prescription drug enforcement incidents in the four-year study period, and even employed a public accounting firm (Arthur Andersen and Company) to audit the correctness and completeness of the data collection, the relevance of the "sampling" question seems remote. If the essential contention is (as the Commissioner later repeated) that research-intensive company recalls are "bigger," two points are important:

Re-examination of the FDA Enforcement Report data, in detail, for the last full year in the study (1977) revealed more than fifteen million defective units recalled from "other" companies and less than one million from research-intensive companies, despite the differentially more complete reporting of the research-intensive company data. It is also noteworthy that the companies in the research-intensive sample supplied approximately three-quarters of the total prescription drug market, while producing less than one-fifteenth the defective units.

<sup>4</sup> 4. "Generic Drugs: How Good Are They?" FDA Consumer, February, 1978.

<sup>5</sup> 5. Dr. Fay Dworkin, "Impact of Disclosure of Safety and Efficacy Data on Expenditures for Pharmaceutical Research and Development," Economic Analysis Group, Evaluation Staff, Office of Planning and Evaluation, Food and Drug Administration, April, 1978.



Looking solely at recalls, and their quantities, misses what are critically important implications of FDA-initiated court actions. Not only is the "other" company court action incidence grossly higher (forty to eighty times higher, depending on the scaling factor), but the very character of an FDA-initiated prosecution, injunction, or seizure tends to involve multiple lots of multiple products. The Commissioner did not comment on court action incidence.

#### THE RELEVANCE OF FDA CLASS "I" AND "II" RECALLS

"Because it measures all Class I and II recalls, "the Commissioner remarked about the Lilly study, "it specifically emphasizes drug products that are not included in FDA's lists of therapeutically equivalent products . . ." Again the Commissioner presumes that the study was designed solely to comment on the lists of NDA and ANDA holders such as the agency recently helped the State of New York to compile. Hopefully, it is already clear that this presumption is incorrect; the Lilly study is relevant to the full range of the agency's drug quality assurance responsibilities, not just one part.

FDA Class "I" and "II" recalls were included in the Lilly study because the Commissioner had himself established this definition in his testimony before the Nelson Subcommittee, and submitted "documentation" consistent with this definition, and because of the agency's own description of the seriousness of such recalls:

"Class I: A situation in which there is reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death"

"Class II: A situation in which the use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote"

The Lilly analysts did not second-guess the regulatory determination of the agency explicit in the recall classification. Nor did it seem reasonable to dismiss the implications for public health inherent in the marketing of a new prescription drug without the safety and efficacy review of an NDA or ANDA.

A detailed re-examination of the 1977 Enforcement Report data also demonstrated that, had recalls of products for lack of NDA or ANDA been excluded, the demonstrable of the research-intensive companies would have been at least as great as it was without any prescription drug recalls excluded.

#### ALLEGATIONS THAT ONE RESEARCH-ORIENTED FIRM WAS ARBITRARILY EXCLUDED

This was a "large research firm with a bad recall record," according to the Commissioner, "and so skewed the data badly." The company knows of no such firm excluded, but if the Commissioner will specify which, the impact will be evaluated.

#### ASSERTION THAT RESEARCH-INTENSIVE COMPANY RECALLS ARE BIGGER

Please note the comments under "Corrections for the Size of the Universe Sampled," above.

#### CONCLUSION

The question being addressed in both the Commissioner's testimony and in the Lilly study is the degree of confidence the public and the Congress can have in FDA assurances of uniform supplies of safe, high quality prescription drugs.

In addition to their personal, professional judgment, agency spokespersons have stated that their enforcement records demonstrate product and manufacturer uniformity. The Lilly study, "FDA Enforcement Activities Within the Pharmaceutical Industry," questions the agency conclusions based on such evidence.

The company again thanks the Committee for the opportunity to express its views and would be pleased to respond to any questions or comments.

Very truly yours,

EDGAR G. DAVIS.

Mr. RINALDO. Thank you, Mr. Chairman.

In my home State of New Jersey, and in my district, there are several major research-oriented pharmaceutical companies. Will the legislation that is under discussion today, which requires that, in effect, only the least expensive or cheapest drug products be used, have an impact on pharmaceutical research?



Dr. KENNEDY. I think I would like to separate, if I might, my answer into two parts. It is very difficult to determine the kind of economic impact that any such regulation will have.

On the surface the general expectation I think would be that the intensification of price competition for multiple-source drugs might well result in lowered incentives for research investment in those firms that are attempting to market brand name drugs. We are experiencing lower sales as a result of enhanced lower source competition. I think most economists would probably argue that they depend upon a variety of things that are determined by the policies of the companies that are so affected.

As far as we know, a very large percentage, perhaps 90 percent or so, of the generic drugs marketed in this country are actually marketed by brand name firms in themselves. So we are not really talking I think for the most part about a repartitioning of money from one kind of firm to another, but rather, primarily about enhancement of competition among the same set of firms that are now investing 6 percent or so of sales in research.

Mr. RINALDO. Economically, based upon your answer, I can assume that you feel there would be a lessening of that research effort. It naturally follows, at least in my opinion, that if there is a lessening of that research effort, because of decreased investment by the pharmaceutical firms that specialize in this type of research, there will be a commensurate decrease in the benefits that the average consumer receives from that research.

Dr. KENNEDY. Well, I think my answer was a little more cautious than that.

Mr. RINALDO. Excuse me for interrupting, but your answer was not based, if I recollect it correctly, on any hard data. It was based on no studies that have been made, to the best of your knowledge?

Dr. KENNEDY. Predicting what any large sector of this economy is going to do in a condition where part of its business grows more competitive I think is very difficult. But certainly if the incentive is changed at all it has changed in the direction of reducing it.

Mr. RINALDO. Thank you.

The State of New Jersey is also in the process, as I understand it, of adopting a drug formulary to implement the generic drug law that is already in effect in our State. The law states that drugs on the list must be interchangeable.

Now, will the FDA, if this legislation becomes law, certify that the drugs on the list are interchangeable?

Dr. KENNEDY. Our doing that won't depend at all on whether the bill we are discussing today becomes law. We would intend to do so anyhow and we are now developing a so-called positive formulary of therapeutically interchangeable drugs which we will give to any State to meet its needs on its request. I am not familiar in detail with the nature of the New Jersey law although I would, before we supplied them with a list, become so.

The reason that I mentioned that is that depending on the details of that law they might need a different kind of list than if they had a law of exactly the same type as New York. But my understanding from Mr. Knapp here is that our people have already been meeting with New Jersey and we will do the best we can to meet their needs for an equivalence formulary.



Mr. RINALDO. Now, I detect that a difference exists between what you just called an equivalence formula, which I guess means therapeutically equivalent——

Dr. KENNEDY. Yes.

Mr. RINALDO. And interchangeability.

Dr. KENNEDY. We don't use the word "interchangeability" except by mistake, Mr. Rinaldo.

Mr. RINALDO. Obviously, a few mistakes were made here.

Dr. KENNEDY. I am sorry. I hope very much that the record will correct that if I did so. Sometimes when people say "interchangeability" to me I don't notice it. What we said we provided on the cover of the New York list, what we have said in the testimony that we will provide and will talk about are lists of drugs that are therapeutically equivalent. And the reason for that is that interchangeability is a political decision. It is the decision of the States whether to interchange drug A for drug B. When we say that two drugs are therapeutically equivalent, we mean that the active principal will do the same thing and that the same amount of it will get into the blood stream in the same length of time so that it will exert the same physiological effect.

To use an example that my colleagues are fond of, if you had two different pediatric formulations of an antibiotic and one was banana flavored and the other was orange flavored, then we would call them therapeutically equivalent. But a State may not want to decide that they were interchangeable.

Mr. RINALDO. Would you not say that to the consumer at least, this is a very confusing distinction?

Dr. KENNEDY. Well, I would hope that the States who are responsible for this kind of legislation, for supplying the list, and for regulating the profession of pharmacists, can make these clear. The matter is technically confusing, I grant you that. But it is not confusing to pharmacists and to the people who are making the State laws. And once they understand it, the consumer then understands that the multisource products belonging to a particular therapeutically equivalent class all have the same quality standard and so forth.

I think that the average consumer can see what is intended by that, what the drugs are intended to do and that they meet a quality standard that says that they will do the same job.

Mr. RINALDO. I think that you are oversimplifying the point. The New Jersey law—and I am sorry I don't have a copy of it here—is similar, to the New York law. Yet I continually read about problems between the Pharmaceutical Society, for example, of the State of New York, and the FDA. Isn't there a case right now where the Pharmaceutical Society of the State of New York is in court trying to block implementation of your approved drug list?

Dr. KENNEDY. It is not our approved drug list, Mr. Rinaldo. It is the State of New York's drug list. We had them make it.

Mr. RINALDO. Yes, I know that. But am I correct in saying that it is an FDA-approved New York drug list?

Dr. KENNEDY. It is a New York list of FDA approved drugs.

Mr. RINALDO. That is the problem. If we have difficulties right here, I keep wondering about that consumer out there.



Dr. KENNEDY. Well, yes, I think that that is the problem. You spoke of difficulty between the pharmacists and the Food and Drug Administration. As far as I know there is not any. The problem is, I think, between the pharmacists and the State of New York. There are features of that law that the pharmacists do not like. It is that the pharmacist is required to substitute the lowest cost drug in that therapeutically equivalent class and, as a matter of fact, my testimony today has been that we don't favor such features of legislation so we didn't promote that provision. It is not the lowest.

I am sorry. Let me correct that.

Gene Knapp tells me that it is not the lowest, but the point is that there are a number of provisions that States can install that pharmacists will like more or less. It has nothing whatever to do with FDA's role in defining the universe of quality equivalents. There are surely some others in the New York State list. We have never pretended that there would not be and these errors are now being corrected in our own data base in preparation for issuing a more general list that will be made available to other States at the end of the summer or early in the fall.

Mr. RINALDO. You are stating errors in a list that you previously endorsed; is that your statement?

Dr. KENNEDY. That New York made at our direction. Let me tell you the kinds of errors—

Mr. RINALDO. No; you didn't answer my question.

Didn't you say you are correcting errors in a list—and I will use your phrase—that the FDA previously endorsed; is that correct?

Dr. KENNEDY. No; the correction I made was that it was a list of drugs that FDA had approved and that FDA was prepared to say were therapeutically equivalent on the grounds that I outlined earlier in my testimony.

The kinds of errors that are involved are essentially in the identification of manufacturers, certain discontinued dosage forms, matters of that sort which do not involve health and safety issues, they simply involve the fact that our computer data base was not up to date on such things as certain manufacturers going out of business, being absorbed by other manufacturers or the discontinuation of certain product lines.

So all of the errors in large lists are subject to the usual kind of discontinuations and new starts that are a feature of any active economy. But with those errors corrected, we think that the lists of therapeutically equivalent products will be very useful to the States.

Mr. RINALDO. The bottom line as I understand it—and I know I am running out of time, Mr. Chairman, but this topic fascinates me because it is supposed to be so simple and we cannot seem to understand it completely.

The bottom line is to make the cost of the drug cheaper—less expensive—to the consumer; is that correct?

Dr. KENNEDY. Where the consumer does not have to accept a quality decision.

Mr. RINALDO. Now, we have a case in New York involving the Pharmaceutical Society and different companies. These are just a few minor points. We have a list that is an FDA-approved New York list, we have errors in the list. We need additional testing. I



see many ramifications, even to the point where there is the possibility, as you admitted earlier, that the amount of research being done could diminish.

What I would like to know is—and this is my final question—testing is being done, to determine what we call therapeutic equivalency. Who is doing the testing and who bears the eventual cost?

Dr. KENNEDY. Well, in the first place the correction of the New York State list and indeed the production of the corrected list that we will make available to all the States does not involve a requirement for increased testing.

The catching up simply involves going around to manufacturers, making sure of the discontinuation of certain product lines, and verifying that they are or aren't making a certain dosage. They are technical corrections. New biological measurements are not being made on the products. You are quite right that to maintain FDA's quality surveillance of the drug product universe we do do testing at the National Center for Drug Analysis in St. Louis at the FDA regional and district laboratories. We do all the things that are necessary to undergird those statements about the quality of equivalents. But we have to do that anyway. Our purpose in doing that is not first and foremost to tell States what drug products they can consider to be equivalent. Our purpose in doing that primarily is to insure the safety of the medications that American physicians prescribe to American citizens.

Mr. RINALDO. I have no further questions, Mr. Chairman.

Thank you, Mr. Kennedy.

Dr. KENNEDY. Thank you very much.

Mr. ECKHARDT. To be clear on the provisions of H.R. 1963, I do not understand that the bill requires the druggist to supply the cheapest therapeutically equivalent drug but rather requires the pharmacist, if he elects to use the substitution, to use the cheapest substitution within his inventory.

Dr. KENNEDY. Yes; I misspoke, Mr. Chairman.

Mr. ECKHARDT. With respect to the list of equivalent drugs that you referred to, when will that be completed?

Dr. KENNEDY. We just shifted the target and I think we will have it completed about the end of October probably.

Mr. ECKHARDT. Thank you very much, Mr. Kennedy, for your very helpful testimony.

Dr. KENNEDY. Thank you, Mr. Chairman.

Mr. ECKHARDT. Dr. Pittman.

#### STATEMENT OF JAMES A. PITTMAN, JR., M.D., EXECUTIVE DEAN, UNIVERSITY OF ALABAMA SCHOOL OF MEDICINE

Dr. PITTMAN. Thank you, Mr. Chairman.

Mr. ECKHARDT. Dr. Pittman, have you considered putting your statement in the record, and you may summarize?

Dr. PITTMAN. Yes, sir.

Mr. ECKHARDT. It will be so ordered.

Dr. PITTMAN. Mr. Chairman, members of the subcommittee and staff, this city has been a vivid demonstration of the importance of proper prescription writing and filing over the past 2 weeks, so that does not need any emphasizing right now. And since my typed statement is rather lengthy, I will put it in the record.



Mr. ECKHARDT. Without objection.

Dr. PITTMAN. I have several points in summary here. First, substitution of one brand of a chemical for another is desirable under some circumstances, particularly when this saves the patient money for the equivalent product.

Second, the physicians must retain the authority to require the dispensing of a particular brand since the physicians have the greatest and most intimate knowledge of the individual patient's idiosyncrasies.

Third, a physician in restricting his prescription to a single brand should be prepared to defend this decision to his peers; that is, he should have an explicit and defensible reason for this restriction.

Fourth, the savings realized should be passed on to the consumer, but savings will be difficult to calculate in instances other than the ones in which the patient pays directly for the dispensed drug.

I am opposed to enactment of H.R. 1963 into law for these reasons. First, the amendment or alternation of ant substitution laws which existed in some number of States, 49 or 50 plus the District, began only in this decade, and most of the new laws have been passed only in the last 2 or 3 years, although some 39 States now have amended or abandoned those prior ant substitution laws.

None of these laws is perfect and many have substantial flaws; thus we should wait for a better understanding of what the best law is.

Second and more importantly, the Federal law in this area would preempt local, State, and professional practice acts for pharmacy and medicine would go too far into Federal regulation professional practices at this time.

Should, however, such a Federal law be enacted, several conditions should pertain and I think I agree with the comments of Mr. Pertschuk today. I think basically H.R. 1963, if we are to have such a law, is a pretty good one, well written.

The conditions are first there should be no positive formulary; that is, there should be no list of interchangeable drugs on a State level. The upcoming FDA comprehensive list should be adequate for this and should function in that fashion.

I was sorry to learn that they planned not to include the drugs in that list which have bioequivalency problems. In other words, I think that in order to be of maximum use to the physician and possibly to the consumer, it ought to have all FDA approved drugs, including those with problems in a separate list, in the formulary.

Next, the FDA should be the enforcing agency, not the FTC. The reason for that is simply that I think the FDA has a lot more experience with medical matters and that I can foresee a lot of liaison committees and things of that sort if it were given to the FTC. I am not sure ultimately it would make much difference, but I think that the FDA would have greater ability in this enforcement.

Next, as far as the format for providing the mechanism for the physician to permit or deny substitution, I think the New York format is the best and easiest one.

Those are the conditions I think which should be observed if we have a national law, which I would oppose at this time.



Finally, I think most physicians are not interested in protecting the PMA or the drug companies. We are concerned about the research being done and the new drugs coming out. But I think the main reason for concern of physicians and the reason physicians may resist substitution is worry about erosion of their authority to make decisions about the practice of medicine and their ability to make decisions about patient care.

I think that the profession of pharmacy along with the other health provisions is headed for trouble of a numerical kind with a great proliferation of pharmacists and other health professionals who in the 1980's will essentially be competing for employment.

Laws regarding drug substitution should be aimed at helping the consumer, the individual patient, not helping the professional, whether he is a pharmacist or a physician.

I think the reason I am here is that I was the principal author of a resolution passed by the Drug Research Board of the National Academy of Sciences. Review of that matter is in my written statement.

That concludes my summary, Mr. Chairman.

[Dr. Pittman's prepared statement follows:]

STATEMENT OF JAMES A. PITTMAN, JR., M.D., EXECUTIVE DEAN, UNIVERSITY OF ALABAMA SCHOOL OF MEDICINE

Mr. Chairman, I am James A. Pittman, Jr., M.D., Executive Dean of the University of Alabama School of Medicine, based at the University of Alabama in Birmingham (UAB) and Professor of Medicine there. The background and experience from which I speak are those of an internist and endocrinologist with a long standing interest in pharmacology. I assume I am here because I was the principal author of a resolution regarding drug substitution passed by the Drug Research Board of the National Academy of Sciences, which resolution became the object of much controversy. Part of the history of that controversy is already recorded in hearings of the Senate Subcommittee on Monopoly of the Select Committee on Small Business, May 16, 1975, chaired by Senator Gaylord Nelson. (1)

I shall try to answer the questions in your letter to me of June 30, but it may be more understandable if I provide a narrative description of the problems involved.

In 1973 the DRB (Drug Research Board) was asked to examine the antitrust laws with the possibility of urging their endorsement in the interest of protecting the quality of the drugs dispensed to American patients and, hence, the quality of their medical care. Initially, we were ready to do this. However, we were requested by the APhA (American Pharmaceutical Association) to defer such action until we had heard their side of the story. We did this, fully expecting to hear exhortations about the role of the pharmacist in "health care delivery." It was an interesting surprise that instead we were presented with data relating brand names to chemical contents and to actual manufacturer, as opposed to marketing companies. The most blatant example of this was chloral hydrate, which was marketed by 17 different companies under their labels, but which was all actually manufactured by a single firm, the R. P. Scherer Company, because they had the technology for soft gelatin capsules. The differently labeled products were sold at markedly different prices. We (a subcommittee of the DRB, chaired by me) then wrote another resolution endorsing substitution of an equivalent drug product by the pharmacist, if the prescribing physician has no objection. Here is that draft:

"1. The patient's best welfare should be the ultimate goal of statutes and regulations concerning drug product selection. In operational terms, this means the best product for the lowest price.

"2. The physician must have the ultimate responsibility and authority in drug product selection, since the physician alone has intimate knowledge of the patient and his pathology. However, the physician must be ready to be held accountable on grounds of price and quality for his selections of drug products.

"3. The pharmacist may have greater knowledge of the quality and costs of drug products in some situations.

"4. It is appropriate that decisions with regard to choice of drug product be made by the individual having the greatest amount of information concerning the particu-



lar selection in question. Having selected the chemical to be used for therapy, the physician, therefore, may explicitly delegate to the pharmacist, or retain to himself, selection of the particular drug product to be received by the patient.

"5. In some way, it should be made clear that no economic benefit should accrue to the pharmacist by virtue of his authorization to substitute one product for another."

This resolution was written at a meeting at the National Academy of Sciences building in Washington on 26 September 1974, which included representatives of the PMA (Pharmaceutical Manufacturers Association) and APHA (American Pharmaceutical Association), including several pharmacists, under the general direction of the DRB members.

This wording was then recast in a format appropriate for a resolution, with the proper "whereas" phrases, etc., then it was presented to the full DRB at its meeting of 25 October 1974. The final resolution passed by the DRB was as follows:

"1. Whereas, The patient's welfare should be the ultimate goal of statutes and regulations concerning drug product selection, which in operational terms means the best product for the lowest cost, and

"2. Whereas, The physician must have the ultimate responsibility and authority in drug product selection, since he has the fullest knowledge of the patient's needs and responses with attendant obligation to be held accountable for his selection of particular drug products, and

"3. Whereas, The pharmacist may, in some situations, have greater knowledge of drug products than other health professionals, including knowledge of both quality and costs, and

"4. Whereas, It is appropriate that decisions with regard to the choice of drug products be made by the health professional possessing the greatest amount of information involved in the particular selection in question, with attendant accountability, therefore, be it

"5. Resolved, That the physician, having selected the chemical entity to be used for therapy, should be required either to delegate to the pharmacist, or explicitly to retain to himself, selection of the particular drug product to be dispensed and received by the patient.

Washington, D.C., 25 October 1974."

Despite the controversy which has followed publication of this resolution, I have seen nothing to change my view that it is the desirable one. However, the words of Alfred Gilman, coauthor of the classic pharmacology text and dean of American pharmacologists, stick in my mind. He said, "Remember, if you give a patient a pill which you think is equal to an expensive one dollar pill and it cost only 10 cents but does not do the job, you have not saved 90 cents; you have wasted 10 cents, and you have in addition put the patient in jeopardy."

Let me now turn to your specific questions. I shall identify them in the eight paragraphs into which they are grouped in your letter.

1. "Under what circumstances, if any, can 'generic' drugs be substituted for drugs prescribed by trade name?" I would refer you here to two publications: the booklet published by the State of New York earlier this year titled *Safe, Effective and Therapeutically Equivalent Prescription Drugs*, (2) and the one published in 1974 by the Office of Technology Assessment of the Congress titled *Drug Bioequivalence* (3). The first contains a statement in a letter to the New York Commissioner of the Department of Health from the Commissioner of Food and Drugs of the federal Food and Drug Administration (FDA) as follows: "We (i.e., FDA) believe that all pharmaceutically equivalent drug products can be considered therapeutically equivalent providing they are marketed under approved new drug applications, are manufactured under the same standards, meet identical or comparable specifications, and, in those instances where positive evidence of bioequivalence is necessary, are shown to be bioequivalent." This statement takes into consideration the flexibility in definition of "bioequivalence" discussed by the Drug Bioequivalence Study Panel in their book *Drug Bioequivalence*. That is, the comparability of two preparations of digoxin is much more critical than is the comparability of two preparations of aspirin, so the limits of comparability must be much more narrow for the critical drug—digoxin in this case.

The problem here is burden of proof. The big companies say their product is superior. The small ones say their product is equal. On whom does the burden of proof lie? Is it up to the big company to prove theirs is superior? Or is it up to the small company to prove theirs is equal? Both the Drug Bioequivalence Study Panel and the State of New York handle this problem for the majority of drugs by declaring it irrelevant. They say that for the great majority of drugs meeting the conditions in the FDA sentence just quoted, variations in bioavailability are not



sufficient to be considered anything but "minor" and "insignificant"; thus, members of such drug pairs or groups may be considered "equivalent" for clinical purposes. I think most physicians will be quite willing to accept this, unless evidence to the contrary comes to light.

For the minority of drugs which (a) are used for treatment or prevention of serious illness, (b) have steep dose-response curves or unfavorable therapeutic indices, or (c) contain active ingredients that are relatively insoluble or are converted to insoluble forms in gastrointestinal fluids, bioavailability data are important and should be precisely comparable to other preparations in order for the drug product to be considered bioequivalent to the other preparations. (3) Again, I believe most physicians not only accept this but tend to prefer the presence of data to absence of data.

Thus, to answer your first question, I think generic drugs can be substituted when the above conditions are met.

2. "Is federal legislation to allow substitution needed, or are existing state laws adequate?" I would answer that neither are current state laws adequate nor is a federal law desirable at present. As recently as the early 1970's all 50 states and the District of Columbia had laws forbidding substitution. In 1971 Massachusetts passed a drug substitution law associated with a formulary. However, I have heard that this was not a very satisfactory law from anyone's point of view. It required physicians to write all prescriptions using generic names (which many physicians probably did not know for many drugs; for example, "liothyronine" for triiodothyronine or "Cytomel"); but it did provide a formulary for their guidance; but the formulary contained only multiple source drugs, not those available from single sources only; and, finally, there were no sanctions of any substance. So the whole thing was a waste, except for the experience gained. Shortly thereafter Kentucky and Maryland passed substitution laws associated with formularies and formulary committees. However, at least for the one in Maryland, this did not work because of difficulties in obtaining data on which to base decisions; so the Maryland law was recently abolished and a new law written. Michigan passed a law in 1973, and this has come closest to being a model law for other states. It, and the Florida law passed about the same time, were before the DRB during our deliberations in 1974. The Massachusetts law was replaced with a new law in 1976 and a Massachusetts Formulary Commission was established in 1977. Thus, the development of these laws is still in an early stage in the United States and they are far from perfect. Since 1971 some 39 states have altered their laws on this subject to permit or require substitution under specified conditions if the physician has no objection. And now we have the New York State formulary of "equivalent prescription drugs," Canadian drug lists of interchangeable products, several other state lists, and a national FDA list coming out next month. It seems to me that we should see how this situation works for at least several years prior to taking other actions, particularly federal actions. Not only would we gain experience which could guide the perfection of such a federal law, should this appear desirable, but such a law might not even prove necessary in the presence of good state laws.

Another objection to federal legislation in this area is that it must necessarily deal with professional practice acts in the various states and regulate how health professionals behave. Is it really desirable, at this particular point in American history, for the federal government to do that? Perhaps it will be in the near future; but in my estimation, that time is not yet.

Of course, where there are federal programs, such as Medicare, drug use in these programs will be controlled by the federal laws and regulations for these programs. This would also hold for National Health Insurance, particularly now with MAC (Maximum Allowable Cost) regulations and all this other activity regarding drug substitution. So, I am speaking against passage of HR 1963 or similar legislation at this time.

3. "What are the potential cost savings to consumers if substitution legislation is enacted? Should legislation require that any savings be passed on to consumers?"

Estimation of financial savings is crucial and difficult. In fact, if one takes the long view of including investments in research efforts using drug profits and then the financial benefits of the new products resulting from such research, estimation of financial savings is impossible. All one can do is make a stab at such estimates and hope they reflect reality reasonably accurately. Since this is the case, the question of cost benefits is likely to remain controversial.

In the case of the little lady 53 years old without third party coverage of any kind, it is easy to see the savings she would gain by having R. P. Scherer's chloral hydrate dispensed under the Purepack label at \$1.48 per hundred as opposed to purchasing R. P. Scherer's Squibb Noctec at \$5.00 per hundred. And that is where



the measurement must be made, at cost to purchaser. However, the more completely the costs are borne by the government, the more difficult it will be to define and determine costs. For example, if the government owns the pharmacy and pays the pharmacist a salary (as in the VA or the army), how much of the overhead should be included? The costs discussed in that situation will be purchase prices charged to the hospitals or the agencies. However, overhead will remain a problem, just as it will be a problem in determining the reasonable price for a given pharmacy. In New York, the pharmacist will now have to stock several different drug products, whereas before he may have stocked fewer or only one in his inventory. This will require more space, which he may reasonably charge as overhead. I have been told by some physicians in private practice in New York that "this law will benefit the big chains and favor them over the little guy, the corner druggist. This will mean that at 11:00 o'clock at night, a patient can't find a prescription." I might add that the New York law contains such severe sanctions against offending pharmacists that I feel sure they will be extremely careful to comply, and such extreme care will add costs, such as larger inventories.

Add to this the cost of bureaucracy, publications, enforcement, and related costs, which themselves may be difficult to define and determine, and the savings estimates become even more uncertain. Furthermore, decisions as to which costs should be included must often be arbitrary, so that one can bias estimates for or against savings. Despite these considerations, it still seems probably there will be substantial savings when there are differences in cost of several hundred percent for some equivalent preparations.

I might add here that savings on a grand scale were not in the minds of some of us on the DRB when we passed our resolution. We were still thinking of the individual case in which a patient pays directly for the prescription with his or her own money, as I believe is the case for some 88% of the prescriptions filled in the United States last year. The situation seems much clearer and easier to see here in the case of the individual paying his own way directly out of his own pocket.

As for the question of passing the savings on to the consumer, clearly this is the whole intent of this exercise. More specifically, changes in charges and compensation for equivalent drug products should not simply shift dollars from the pocket of the manufacturer to that of the pharmacist, especially in view of the concerns over dwindling research productivity of American pharmaceutical firms over the past decade or so.

The reason this is not specifically mentioned in the final resolution, as it is in the last paragraph of the earlier draft reproduced above, is that that last paragraph was considered to have been incorporated in the first paragraph of the final resolution in the phrase "the best product for the lowest cost." The explicit intent was to pass the cost on to the consumers; i.e., the patients taking the drugs.

At this point one begins to worry about the treatment of pharmacists. What is the incentive for the pharmacists to participate? In New York, the law is quite specific and firm in its incentives, which are negative. I should think the pharmacist should be neither rewarded nor penalized financially for this mode of prescribing. More about this in a moment.

4. "Should legislation allow or require substitution?" Legislation should require substitution only for those programs in which federal or state money funds the purchase. In other cases substitution should simply be permitted, or denied, if the physician has a reason for such denial. And reasons which may be quite real to a given patient (e.g., an elderly lady who just refuses to believe that the pink pill is the same as her former yellow pill, or the child who refuses to take the orange flavored preparation but will accept the chocolate one), although they may seem trivial and unjustified to "objective observers" or auditors. To mandate or require substitution goes way too far in regulating practice decisions and in completely removing the discretion from decisions needed for the good practice of medicine. Note that the DRB resolution says that the physician should be required to make an explicit decision about this; it does not say what the decision must be. In my estimation, the complexities of drug manufacturing, naming and labelling, and marketing, as well as dispensing, plus the fact there are now some 20,000 prescription drug products on the market in the United States—these factors, plus the universal tendency to trust established or reputable companies, have tended to make modern physicians in the U.S. not even consider the question. It was for this reason that the DRB finally agreed to change "the physician may delegate substitution" to "the physician is required to delegate or retain to himself" the final decision.

Therefore, the answer to this question is that such laws should permit substitution, not require it, but physicians should be required to make the decision. I believe



that this requirement will ultimately work to the advantage of retaining such decisions finally in the hands of the physician as the "health professional" most intimately involved with and knowledgeable about the problems in his particular patient.

5. "Should selection of the drug substitute be left entirely to the discretion of the pharmacists, or should a list of drugs that can be substituted be established? Alternatively, should a list of drugs which cannot be substituted be established?"

I vote for the latter. I understand the initial formulary in Massachusetts was "a disaster," quickly thrown together and inadequate, and possibly inaccurate. I have already mentioned the formulary problems in Maryland. The New York State list contains some single item drugs, but it inexplicably omits some (e.g., sodium L-thyroxine tablets, such as "Synthroid" or "Letter;" propylthiouracil; desiccated thyroid); it omits the pre-1938 drugs, such as nitroglycerine and phenobarbital; and it contains no price information (which, I believe, is also the case for all other such state lists in the U.S., although provincial lists in Canada do contain price information). Furthermore, why not just use the national FDA list of approved drugs, soon to be published? If the FDA statement referred to above, from the New York State drug list, proclaiming equivalence of such products is true, then why go to the expense and trouble of preparing other lists? In my estimation, the concern should be focused on those few drugs where equivalence is a real problem, and these should be listed (e.g., a "negative formulary" as opposed to a "positive formulary").

6. "Should provision be made for prescribing practitioners to require that a prescription be filled with a trade name drug, and if so, how should this be done?" As just discussed, and as stated in the resolution passed by the DRB, the physician must surely be allowed to retain the authority to make this decision. In addition, as also emphasized in the DRB resolution, when the physician makes such a requirement, he should be ready to defend that decision with his reasons. Although I have pointed out that some of the reasons may be quite personal and may appear trivial at first glance, the intent of the DRB resolution was that the physician be accountable for his decision to restrict the dispensing to a trade name drug. His decision should be able to stand the light of intense scrutiny by peers or experts in the field. If the prescribing physicians understand this intent, and the possibility of spot checks of such restricted prescriptions, I think they will not frivolously restrict the drug product to a brand name or do so without careful consideration of the reasons.

The mechanism should be one which is not excessively burdensome or bureaucratic, and I think the New York system of two lines for the prescriber's signature, one permitting substitution and one not, is probably the simplest and easiest. Other possibilities include having two boxes on each prescription, one permitting and one denying substitution, with a requirement for initialing one of them, etc. The New York form is the best.

7. "Should a provision delineating the liabilities of pharmacists be included?" I see no reason for including this in the law. It is not ordinarily done for other health professionals, and, in any case, if larger liabilities are incurred, this is simply another cost to the program, and such costs will appear in "overhead" charges, to be included in the costs of the drugs, as mentioned above.

8. "Should the Federal Trade Commission or the Food and Drug Administration enforce the Act?" My bias is that it should be the Food and Drug Administration, the FDA, simply because that agency already has some background in these problems and understanding of them, and because these things concern matters which are already under the purview of the FDA. Should enforcement be assigned to the FTC, one can envision FDA-FTC liaison committees, joint meetings, and coordination councils which would be needed. As is the case with so many organizational issues in Washington, it might not ultimately matter much. However, my strong bias would be that it should be in the FDA.

I should like to express one other concern, and I hope it is not interpreted simply as an anti-pharmacist prejudice or view of one trying to preserve the elitist "aristocratic" position of the physician on what is currently termed "the health care team." The concern is that some of the activity in this area of drug substitution laws is the result of concerns about the future of pharmacy as a profession rather than concerns about serving the patient better or restraining costs. According to DHEW publications, (4) the numbers of all health professionals will increase drastically over the coming 12 years, with increases in physicians, osteopaths, dentists, veterinarians, optometrists, podiatrists, nurses, probably chiropractors, and—especially—pharmacists. These increases are both in terms of absolute numbers and in terms of number of health professionals per capita population. In fact, although pharmacists are projected to increase from 129,300 in 1970 to 179,900 in 1990, their proportion in the mix of health practitioners will fall from 9.7 percent in 1970 to 7.2



percent in 1990. At the same time, the per capita number of pharmacists in the U.S. population will increase more in the 20 years between 1970 and 1990 than it increased in the preceding 70 years of the entire twentieth century! The response of some pharmacists to this crunch has been to promote a place for the pharmacist as "a full member of the health care team." America was seen as suffering from an acute shortage of "health practitioners," and pharmacists were gearing up their educational systems, increasing the length of the curriculum, recommending that pharmacy schools include physical diagnosis in the curricula, and generating requirements for pharmacy schools to receive federal capitation that they have programs in "clinical pharmacy," so that they could "fill the gap."

I believe we are just beginning to see the first skirmishes of what will become an increasingly intense rivalry between the various health professions for a "place on the team." Mr. John Byington, head of the Federal Consumer Product Safety Commission, said in a recent speech, "I believe that tomorrow's prescriptions can and must be a diagnostic record upon which the pharmacist can base his or her determination of the proper drug therapy and then oversee the proper dispensing of such drugs, all recorded, and in accordance with a full drug history of that patient." (5) That is, serious claims are being made that the pharmacist be "the only member of the health care team handling drugs." Such thoughts are nonsense.

In my estimation, most physicians, as opposed to official statements of organizations, really are more concerned about retaining their ability to make decisions regarding the care of their patients rather than about how much drug companies are making or what the stands of various medical organizations may be.

Any change in these laws, or new legislation in this area, should be for the benefit of the patients served, not the physicians or the pharmacists.

The question to which the Committee must constantly recur, Mr. Chairman, is, "Whose problem are we trying to solve?"

Thank you for the opportunity to present my views.

#### REFERENCES

1. Pittman, James A., Jr.: Hearings before the Subcommittee on Monopoly of the Select Committee on Small Business, United States Senate, 94th Congress, First Session, on Present Status of Competition in the Pharmaceutical Industry. Part 26, Government Procurement (vol. 7). U.S. Government Printing Office, Washington, D.C., 1975, pp. 11781 and 12302.
2. New York State Department of Health: "Safe, Effective and Therapeutically Equivalent Prescription Drugs." New York, Health Education Service, P.O. Box 7126, Albany, New York, 1978.
3. Drug Bioequivalence Study Panel, Dr. Robert Berliner, Chairman: Drug Bioequivalence. Office of Technology Assessment. U.S. Government Printing Office, Washington, D.C. 20402, 1974.
4. DHEW: "The Supply of Health Manpower: 1970 Profiles and Projections to 1990." DHEW Publication No. (HRA) 75-38, December 1974.
5. Byington, S. John: Dedication of New Pharmacy Building, Auburn University, Auburn, Alabama, November 12, 1976. *Ala. J. Med. Sci.* 14:233, 1977.

Mr. ECKHARDT. Thank you, Doctor.

Ms. Seddon, do you have any questions?

Ms. SEDDON. What is your feeling about the recommendation Mr. Pertschuck made that the prescribing practitioner make a decision as to whether or not the pharmacist could make a substitution by writing out "medically necessary" as opposed to using a check-off method?

Dr. PITTMAN. I think that physicians would grumble a bit about that, but there would not be any big major problem. After the Michigan law was passed, I believe in 1973, I discussed that with some physicians up there. That law requires the physician, if he wants to restrict the dispensing to a brand name, like DAW, to write DAW (dispense as written) on the prescription; and some of the physicians have said, "I have already written what I wanted, why do I have to write on there I meant what I said?"

In other words, they feel they have already done it. But I think that is not a big issue. I think it might have the effect of enhancing



substitution a little bit because it would be a little more cumbersome.

Ms. SEDDON. When the Drug Research Board adopted the resolution favoring substitution and stating that the prescriber make a decision as to whether or not the pharmacist could make a substitution did you give thought to the manner in which that should be done?

Dr. PITTMAN. Yes. The history of that was that the DRB, which does not exist any more, the Drug Research Board in 1973 was asked to consider enforcing the ant substitution laws because I think the PMA felt that we would do that in the interest of protecting quality.

We were prepared to do it, and at a DRB meeting the APhA said we should hear their side of the question. So we did, anticipating that we would just hear some exhortations about the role of the pharmacist, et cetera; but instead they presented the data which is in my testimony before Senator Nelson showing that the brand name didn't necessarily correspond with the content of the active ingredients, and/or it didn't correspond with the manufacturer.

The example which was most dramatic to us was chloral hydrate. If a little old lady comes to me and says, "I cannot sleep," I am going to give her some sleeping medicine, but I want to be sure it is really good. So I will prescribe Squibb Noctec and she takes it down to the pharmacist, and the pharmacist takes that and he looks at it and there is Squibb Noctec. That is \$5 a hundred. Right next to it is Purepec chloral hydrate, which is \$1.48 a hundred. It is illegal for him to make that switch. He will lose his license if he does.

Well, you say the Squibb is better. However the crunch is that they are both manufactured by the R. P. Scherer Co. They are both manufactured in the same place. You get into an argument about, the ingredients, but basically I think the argument is good. So the DRB reversed itself and wrote a statement saying that we endorsed altering the substitution law. We endorsed the proposition that the physician should consciously make a decision. He should be required to do this each time he writes a prescription either to retain to himself the decision on the single brand that he dispensed or delegate that to the pharmacist. At that time we did consider the mechanism and the mechanism was considered then of having two boxes on the prescription pad to be checked, one of which had to be checked to make the prescription a valid prescription—one permitting substitution, or one denying.

Ms. TAYLOR. One of the difficulties is that doctors have little knowledge of the price of drugs. In the FTC testimony today it was mentioned that 64 percent of the 144 doctors asked had ranked themselves as having little or no knowledge of drug prices.

Do you favor the doctor's accountability for his decision with respect to the drug that he is dispensing? Should doctors be more aware of drug prices so as to be better able to make the decision and defend it? And, if so, how best do you think this could be done?

Dr. PITTMAN. The doctor should be aware of so many more things these days that I would hate to add one more thing. We weighed our mail—my wife happens to be a physician, too—and we get between 30 and 40 pounds of mail a week.



Now, you can't read it. It is impossible. The reason to go through it carefully is that bills and checks get mixed up with the newspapers and stuff. So I really don't know that that would help much.

Sure they should be more aware of it. There are other problems with what they should be aware of. As mentioned earlier, there are 20,000 different drug products available for prescription now.

There was a study in the *Annals of Internal Medicine* (82: 601, May 1975) of pharmacists' knowledge, versus physicians' knowledge, and the pharmacists are just in a much better position to know it. The physician decision should be based primarily on the medical matters and only secondarily on the economics.

Now, if the child, as Mr. Kennedy mentioned, likes a chocolate flavored but not an orange flavored one, I don't think that is a trivial reason. That is a perfectly legitimate reason for the doctor to say it has to be the chocolate; but that is not a price matter. The doctor's decision should be made on the basis of the medical issue.

Mr. ECKHARDT. Thank you, Doctor.

Dr. Lloyd.

#### STATEMENT OF WILLIAM B. LLOYD, M.D., ASSOCIATE DIRECTOR, NEIGHBORHOOD HEALTH SERVICES PROGRAM

Dr. LLOYD. Mr. Chairman and members of the committee, I am Dr. William B. Lloyd, a physician specialized in the practice of internal medicine and the medical director of the Mid-Westside Neighborhood Health Services Program in New York City, a federally funded community health center. For the past 12 years I have practiced medicine and been involved in medical administration on a full-time basis.

I have read H.R. 1963 and am strongly in favor of the goal which this legislation attempts to achieve. If anything I believe that the legislation does not go far enough toward the establishment of a truly national, uniform and systematic approach to the dispensing of prescription drugs. National legislation will be preferable to State legislation in this area since the responsibility for approving a drug, monitoring manufacturing processes, and assuring that there are no problems of product bioequivalence presently lies with the Food and Drug Administration. The issue of bioequivalence is a most important one since the consumer and the physician must be assured that substituted drugs are as active as brand name drugs. States by and large are not able to perform or monitor the expensive testing required to establish bioequivalence. As has been mentioned, New York State, which has developed a State formulary and has a substitution law depends upon the FDA bioequivalence testing to insure that quality is maintained.

The cost of prescription drugs to many patients is substantial and unfortunately tends to fall most heavily on those patients who are the least able to afford these costs, the elderly and the disabled. For example, if we consider a patient with hypertension who is receiving Apresoline 25 mg four times daily, Inderal 40 mg four times daily and hydrodiuril 50 mg daily, and we assume a 100-percent markup by the pharmacist from the wholesale price the patient will pay in the neighborhood of \$34.50 monthly.



Substitution of generic hydralazone for the Apresoline and generic hydrochlorothiazide for the Hydrodiuril will lower this cost to approximately \$23.50—Inderal is still protected by patent.

In the case of a depressed patient receiving Elavil 50 mg. three times a day, the cost of the brand name drug, assuming only a 50-percent markup could approximate \$65 per month while the generic equivalent, amitriptyline, could be available for about \$25 per month.

The substitutions permitted by this bill will potentially allow substantial savings to be passed on the consumer. It can do so not only by permitting the substitution of cheaper generics for brand name items, but also can reduce the pharmacists' and hopefully the consumers cost in situations where only brand name items exist. With the massive proliferation of drugs which has taken place over the past 20 to 30 years, pharmacists have been faced with an increasingly severe inventory and supply problem. In order to remain competitive pharmacists have been forced to stock several different brands of the same item. Passage of this legislation will permit the stocking of only a single brand name item when no generic exists and where a generic equivalent does exist will permit the pharmacist to stock only that single item. Given the strong competitive atmosphere between pharmacies which exists today in major cities and towns, these savings will, I believe, generally be passed on to the consumer. This is not necessarily the case, of course, in small towns or rural situations where very little competition may exist.

Nonetheless, I would not be in favor of legislation attempting to require pharmacists to pass these savings on to the consumer since I feel this would be extremely difficult to enforce. The consumer is at present wholly at the mercy of the pharmacist with regard to drug cost and this will not be worsened by the proposed legislation and might be improved.

This legislation, while it will require substitution by the pharmacist under some conditions will leave to the prescribing physician the power to authorize or not authorize such substitution. At the present time, lacking a national formulary and standardization of tablets and capsules by shape and color, I believe it is wisest to leave this authority in the hands of the prescribing physician. However, I would urge that legislation mandating the substitution of lower priced equivalents be considered if a national formulary and drug standardization could be developed to deal with the problems which I will discuss.

The proliferation of generic equivalents and their increasing substitution for brand name drugs has produced a number of problems for physicians, pharmacists and patients which can interfere with the physician's delivery of high quality medical care and may even enhance the possibility of dangerous errors being made. These problems arise from the multiplicity of tablet and capsule sizes, shapes and colors which has accompanied this proliferation. It is quite common in medical practice to discuss with a patient his or her drug regimen in terms of the color and shape of the medication being prescribed. This problem is particularly acute with generics since the established names are long and unfamiliar words for patients to recognize and remember. Generic substitution makes



this medical discussion extremely difficult since the physician, at the time of prescribing the drug, may have no idea what the size and shape will be of the tablet or capsule to be dispensed.

Patients in addition often become accustomed to a particular size and shape of medication and when this varies, will assume that an error has been made and may not take the medication. The proliferation of color and sizes has also increased the likelihood of pharmacist error in dispensing since an automatic and simple sight recognition of the product is much more difficult. I believe that the establishment of national standards regarding the size, shape, and color of tablets and capsules would avoid this problem.

All manufacturers of a specific item, whether in brand name or in generic form, would be required to manufacture the product in a specified color and size. Along with this uniformity in manufacturing the development of a national formulary containing a section that permits visual identification of tablets and capsules, similar to the section presently found in the Physicians Desk Reference, and also containing a description of drug actions, permitted indications, toxicity and side effects will largely resolve this problem. If such standardization could be achieved, and the present monitoring of drug manufacture and bioequivalence carried out by the FDA were to continue, then I see no reason why mandatory generic substitution could not be safe and effective. Drug standardization, coupled with the licensing of manufacturers—and importers of imported drugs—and strict testing for bioequivalence would allow the selection of the drug to be substituted to be made at the discretion of the pharmacist. The pharmacist would presumably make such decision based upon local availability, delivery, and cost since appearance and quality would be uniform.

Finally, Mr. Chairman, I fail to understand why drugs prescribed under title 18 of the Social Security Act are exempted from this legislation. Although title 18 at present pays for very few drugs, I anticipate that drug costs in the future will be insured under title 18 and generic substitution should certainly be encouraged, if not mandated.

Thank you.

Mr. ECKHARDT. Thank you very much, Dr. Lloyd, for your testimony.

Do you have any questions?

Ms. TAYLOR. No.

Mr. ECKHARDT. Your testimony has been very helpful to the committee.

Dr. Fink.

#### STATEMENT OF JOSEPH L. FINK III, ASSOCIATE PROFESSOR OF PHARMACY ADMINISTRATION, PHILADELPHIA COLLEGE OF PHARMACY AND SCIENCE

Dr. FINK. Mr. Chairman, if you would prefer, I will paraphrase or I could read it.

Mr. ECKHARDT. All right.

Without objection, your testimony will be submitted in the record and you might summarize.

Dr. FINK. Mr. Chairman and members of the subcommittee, as a background my name is Joseph L. Fink, and I am a pharmacist as



well as an attorney. In addition, by way of background, I served as executive director of a State pharmaceutical society at the time the Product Selection Act for that State was enacted, the State being Delaware.

I shall address three of the questions presented in your invitation to testify. First, is Federal legislation to allow substitution needed, or are existing State laws adequate?

To briefly respond, my answer would be no. I think that at this time the States are beginning to rectify some errors which they made in the rush to adopt this legislation in recent years and to have action at the Federal level now would interfere with their opportunity to rectify their situations and it would slow down innovation which I think is still needed.

I don't think anyone has come up with the perfect answer for a piece of product selection and the States are still attempting to wrestle with that problem.

The second question is the issue of cost savings. This is a difficult issue to address as has been raised earlier. I have attached to my testimony a copy of a study which we completed in the State of Delaware concerning the effectiveness of that State's legislation [see p. 214].

One thing I would call to your attention on what was submitted is the way it was, a manuscript. I received word this morning that it is now in print in a journal. I will be supplying a copy of that printed article to your staff for inclusion.

We found that savings exist in the State of Delaware for 7 out of 10 drugs for which we could get the savings data. It is 1.8 cents per unit for one drug and 13.2 cents per dosage unit for another drug.

Naturally the amount of savings which an individual patient will realize depends upon the number of dosage units prescribed, the duration of therapy, how many refills are needed and so forth.

Because of the limited nature of the study and the limited resources which the State of Delaware had available we were not able to extrapolate the savings to a statewide basis. However, I am aware of the fact that this subcommittee has received testimony from Dr. Theodore Goldberg and his group has made some estimates that run into the millions of dollars.

The last question I wish to address is whether the liability of pharmacists should be addressed in any of this type legislation. Of the approximately 40 States which have enacted product selection acts, about 13 of them have addressed the liability issue.

Generally the approaches of the States fall into two categories. First, those laws which limit the liability of the pharmacist to the same liability would be present in dispensing a generically written prescription and, second, laws which limit the evidential impact of drug product selection by stating that substitution alone shall not constitute an act of negligence if it was made in a reasonable and prudent fashion or if the substitute drug was in a generally recognized formulary or Government list.

The first approach was in California, the second approach is known as the Oregon approach because I believe it originated with that State's legislature.

To my knowledge, none of these provisions has yet been tested in court. How they will fare when they come under judicial scrutiny



it is difficult to say. There are a number of analogous situations that might enable us to anticipate how the courts will consider this. One is the situation that existed several years ago with the medical malpractice crisis when the State legislatures attempted to abrogate the ability of patients to sue for medical practices. Some of those have come under judicial scrutiny and have not been able to withstand it primarily because of conflict with States' constitutions.

However, another category of cases are those involving blood banks where State legislatures give immunity from products liability and other contractual cases for blood banks and those have withstood judicial scrutiny. So whether or not these provisions which are currently in the State laws will stand up is difficult to say.

However, I should emphasize that the primary responsibility in the case of disputed drug quality rests with the manufacturer of the product. The Federal Food, Drug, and Cosmetic Act makes this perfectly clear. The pharmacist has never had a responsibility to test each dosage unit of drug product dispensed to exactly check the potency or contamination. This is the responsibility of the manufacturer. The manufacturer has always accepted this responsibility, and most of them have discharged it relatively well.

The pharmacist does have the responsibility to be alert for gross imperfections such as an inordinate precipitate in an injectable fluid, flecks of metal in tablets, et cetera. The prudent pharmacist would certainly be alert for such potential problems.

Manufacturers have recently been recognizing their responsibility in this area by promulgating statements of liability and indemnification for the client to use in the product selection situation.

In situations where substitution is mandated as in New York where the legislation requires that the pharmacist choose a lower priced product from a list which New York compiled of FDA approved drugs—I think I got that right—I think the State should indemnify the pharmacist because if the pharmacist does not comply with the statute he is in violation of the law. If he does comply with the statute, and substitutes or engages in product selection with a product which the State of New York deems therapeutically and something goes wrong, he has just been complying with the law and his action has been essentially mandated by the State, so that he should not bear the additional potential liability exposure for that action.

In conclusion, the law provides a quality control mechanism for professional practice and the legislative decision to contain the pharmacist's liability exposure in a drug product selection situation should be balanced against the need to encourage this activity by pharmacists to reduce health care expenditures. On balance, it is probably better for a legislative body to make a good effort to insulate or indemnify the pharmacist who engages in drug product selection to encourage cost savings than not to address the issue at all.

The States have acted in this field and they are attempting to make their legislation more workable.

Since regulation of the practice of health professionals generally falls within the purview of the States', police power, it would be



appropriate probably at this time for the Congress to withhold action until the States have an opportunity to straighten out some of their problems.

That is the conclusion of my summary.

If you have any questions, I will be glad to attempt to respond to them.

[Testimony resumes on p. 239.]

[Dr. Fink's prepared statement follows:]



STATEMENT OF JOSEPH L. FINK III, ASSOCIATE PROFESSOR OF PHARMACY  
ADMINISTRATION, PHILADELPHIA COLLEGE OF PHARMACY AND SCIENCE

Mr. Chairman, members of the Subcommittee, I am Joseph L. Fink III, Associate Professor of Pharmacy Administration at the Philadelphia College of Pharmacy and Science, the nation's oldest college of pharmacy. By education and training I am a pharmacist, licensed to practice in Delaware and Pennsylvania, as well as an attorney. I am a member of the Pennsylvania Bar and practice law in that state. In addition, until recently I served as Executive Director of the Delaware Pharmaceutical Society and was in that position at the time the State of Delaware enacted its drug product selection legislation. I am pleased to accept your invitation to testify this afternoon on H.R. 1963, the "Substitute Prescription Drug Act", and am testifying as an individual because of my academic and professional interest in this topic.

I shall address three of the questions presented in your invitation to testify. First, is federal legislation to allow substitution needed, or are existing state laws adequate? Second, what are the potential cost savings to consumers if substitution legislation is enacted and should legislation require that any savings be passed on to consumers? Third, should a provision delineating the liabilities of pharmacists be included?

First, I feel that federal legislation to allow substitution is not needed. Since 1970, nearly forty states have acted to modify their anti-substitution statutes or regulations to restore to the pharmacist his



prerogative in selecting the brand of multi-source product to be dispensed on a prescription. While their approaches have varied and, in fact, no two statutes are identical, variation in innovation is needed in this area. If a model substitution statute or regulation were to be adopted by all states, there would be no opportunity for evaluating which approach is better. It is likely that the best approach would represent a hybrid of current legislation in the states. However, if the Congress were to act to preempt state legislation in this field, this would forestall the opportunity to observe what various statutory provisions are good and which need improvement. Moreover, we have already seen that in some states where product selection legislation was enacted, the legislature has seen that their original attempt could be improved and amended the act to further encourage drug product selection. To conclude this point, the overwhelming majority of the states have acted on drug product selection legislation and the bulk of the remainder have similar bills under consideration. In just eight years the state legislatures have, by and large, responded to the need for controlling costs in this sector of the health economy and they should be encouraged to review existing legislation in light of research on the impact of statutory changes with an eye toward improving the effectiveness of their legislation.

The issue of cost savings in drug product selection is one that is hard to pin down. A number of studies have been conducted on this topic yet it is difficult to determine an exact amount of savings that may be anticipated.



I mentioned earlier that the State of Delaware has enacted drug product selection legislation. As part of that law the General Assembly of the state mandated that an effectiveness study be conducted from time to time to determine whether the act is achieving its goal of reducing drug costs. The Philadelphia College of Pharmacy and Science received a contract to perform the first evaluation of that legislation and a copy of a report of the findings is attached to the copy of my testimony which you received. I should note that that report is expected to appear in print within the next two weeks in the journal Contemporary Pharmacy Practice, published by the American Pharmaceutical Association.

Especially noteworthy for your purposes is the data found in Table 3 of that report. Statistically significant savings were found to result from drug product selection for seven of the ten drugs for which data could be collected. The savings ranged from \$0.018 per dosage unit for one drug to \$0.132 per dosage unit for another. While the total amount of savings is dependent on the quantity prescribed, duration of therapy, etc., it can be seen that savings can result and that the amount of savings can be substantial. The total amount of savings could not be forecasted as part of the Delaware study due to its limited nature; however, Dr. Theodore Goldberg and the Wayne State-Wisconsin study group have made estimates of savings and you heard testimony from Dr. Goldberg at your hearing on June 22.



The last question I wish to address is whether the liability of pharmacists should be addressed in the legislation. Of the nearly forty states which have enacted drug product legislation, thirteen have addressed the liability issue in their legislation. The approaches of the states can be divided generally in two categories -- those laws which limit the liability of the pharmacist to the same liability he would have in dispensing a generically written prescription and those laws which limit the evidential impact of drug product selection by stating that substitution alone "shall not constitute evidence of negligence if the substitution was made within reasonable and prudent practice of pharmacy or if the substituted drug was accepted in a generally recognized formulary or government list."

To my knowledge, none of these provisions has yet been tested in court. In fact, there has never been a case in which a pharmacist or a physician was subjected to a lawsuit for negligence in drug product source selection. Nonetheless, we may be able to anticipate how the courts will view these limitations on the plaintiff's ability to sue.

As you are no doubt aware, a number of states enacted legislation to limit the plaintiff's ability to sue physicians for malpractice during the medical malpractice "crisis" several years ago. In some states these limits have been ruled to be unconstitutional on the basis of the state constitution. However, another related effort to limit liability has



withstood court challenges. A substantial number of states have provided immunity from suit for strict liability and breach of warranty for blood banks. The courts in a number of jurisdictions have upheld these provisions. Whether the limits imposed by state drug product selection acts will withstand judicial scrutiny is yet to be determined.

It should be emphasized that primary responsibility in the case of disputed drug quality rests with the manufacturer of the product. Should the product be subpotent, superpotent or contaminated, it is the manufacturer's responsibility. The Federal Food Drug and Cosmetic Act makes this clear. The pharmacist has never had a responsibility to test each dosage unit of drug product dispensed to determine exact potency or contamination. That is the responsibility of the manufacturer. However, the pharmacist does have the responsibility to be alert for gross imperfections such as inordinate precipitate in an injectable fluid, flecks of metal in tablets, etc. The prudent pharmacist would certainly be alert for such potential problems.

The manufacturers have recently been recognizing this responsibility by disseminating liability protection policy statements to pharmacists. The gist is the representation by the manufacturer that if the pharmacist dispenses a product which it distributed, the firm will stand behind the pharmacist to assist in certain ways with his defense of a lawsuit. These policy statements have many provisos and conditions, and, therefore, pharmacists should read them carefully.



In situations where substitution is mandated, as in New York, the pharmacist certainly should not be subjected to increased liability exposure due to his compliance with the legislature's mandate. If the legislative body decides to mandate substitution, which I feel is unwise, then it should make every effort to insulate or indemnify the pharmacist who complies with the law.

In conclusion, the law provides a quality control mechanism for professional practice and the legislative decision to contain the pharmacist's liability exposure in a drug product selection situation should be balanced against the need to encourage this activity by pharmacists to reduce health care expenditures. On balance, it is probably better for a legislative body to make a good effort to insulate or indemnify the pharmacist who engages in drug product selection to encourage cost savings than not to address the issue at all.

The states have acted in this field and many are now attempting to make their legislation more workable. Since regulation of the practice of health professionals has traditionally fallen within the purview of the states, they should be given the opportunity to improve their statutes and regulations.



EFFECTIVENESS OF DRUG PRODUCT SELECTION  
LEGISLATION IN DELAWARE\*

by

JOSEPH L. FINK III, B.S.Pharm., J.D.\*\*

and

MAVEN J. MYERS, J.D., Ph.D.\*\*\*

\* Supported by Contract No. 595918, Department of Health and Social Services, State of Delaware.

\*\* Associate Professor of Pharmacy Administration, Philadelphia College of Pharmacy and Science, Philadelphia, PA 19104.

\*\*\* Associate Dean for Pharmacy and Professor of Pharmacy Administration, Philadelphia College of Pharmacy and Science, Philadelphia, PA 19104.

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By November, 1977, 34 states had revised their antisubstitution laws to permit pharmacists to play a more active role in product source selection.<sup>1</sup> Many studies in the past have examined the possible savings to consumers by generic prescribing and dispensing.<sup>2-5</sup> It is only within recent years, with the modification of antisubstitution laws, that the actual effects of these modifications on consumer prescription prices could be studied.<sup>6</sup> Goldberg et al. have analyzed the extent of product source selection by pharmacists in Michigan prior to and following modification of that state's antisubstitution law.<sup>7</sup>

This study measured the cost savings to patients for twelve commonly prescribed multi-source drug products in the State of Delaware following modification of that state's antisubstitution law.

Interchange of brands (substitution) was allowed in Delaware beginning on December 22, 1976, when the non-equivalent drug list which was to be prepared pursuant to the Delaware Drug Product Selection Act was distributed.

Under the legislation the prescriber is required to have two signature lines on his prescription blanks, one bearing the designation "substitution permissible" and the other bearing "dispense as written." If the prescriber signs on the former line, the pharmacist may select a different brand of the same drug, unless the Delaware Drug Advisory Board does not allow substitution for that particular brand. If the prescriber signs on the latter line, the pharmacist must dispense the brand prescribed.



Objectives of the Study

The main objective of this study was to accumulate data concerning drug prices at the consumer level both prior to and subsequent to the effective date of the Delaware Drug Product Selection Act. Specifically, the study was designed to collect data which would reflect:

1. drug prices to consumers for selected multi-source drugs prior to the effective date of the Act,
2. drug prices to consumers for these drugs at some time subsequent to the effective date of the Act, e.g., eight to ten months, and
3. the savings, if any, which resulted from activity authorized by the Act.

A second objective was to determine, after the effective date of the Act, the incidence of authorization to substitute by prescribers; the incidence of prescriptions for multi-source drugs; and whether the pharmacist did substitute when authorized to do so.

A third objective was to determine Delaware pharmacists' opinions concerning two potential barriers to product source selection, the two signature line requirement for prescriptions and the requirement that pharmacists communicate to patients or their agents the price savings resulting from product source selection.



### Methodology

A list of twelve drugs which are among those most frequently prescribed in the State of Delaware and for which generic equivalents are available was completed (Table 1). The drugs to be included in the study were selected by the principal investigator in concert with the Pharmaceutical Control Officer of the Delaware Department of Health and Social Services and a practicing pharmacist with extensive experience in drug utilization review in the state.

Systematic random sampling was used to generate a group of thirty community pharmacies for the study from the list of approximately 130 pharmacies licensed by the Delaware State Board of Pharmacy. Fourth and fifth year pharmacy students were employed to collect the data upon which the study is based.

The study was designed to include a review of dispensing records at each pharmacy to collect data concerning prices on five prescriptions for each drug under study. Hence, in each phase of the study data were to be collected from 60 prescriptions in each pharmacy, for a total of 1800 prescriptions. For each of the twelve drugs under study there were to be 150 prescriptions scrutinized in each Phase.

In Phase I, baseline data were collected which would be used later to determine whether any savings resulted. Data were collected from new prescriptions for the drugs under study dispensed between September 1, 1976, and December 20, 1976. Students reviewed the new prescriptions during the time period and attempted to record the brand and quantity prescribed and the price to the consumer.



Prescriptions which were to be paid for by a third party were excluded from the study since the consumer would not be paying directly for the medications. Also, pharmacists who participate in such plans use a pricing system dictated by the contract which they sign with the plan, which may not be the same as they use for patients who pay for their own medication.

In Phase II, students visited the pharmacies to collect data on the same drugs, but for new prescriptions dispensed during the period October 1, 1977, to December 1, 1977. Students were instructed to collect data similar to those collected during Phase I, with the additional indication of whether the prescription from which the data were collected was signed on the "substitution permitted" signature line or the "dispense as written" line, or was written generically.

In Phase II, data also were collected concerning the incidence of authorization to substitute by prescribers, the incidence of prescriptions for multi-source drugs, and whether the pharmacist did substitute when authorized to do so. The students reviewed the first 100 new prescriptions dispensed on or after October 1, 1977, at each pharmacy and recorded the relevant information.

To determine pharmacists' opinions concerning the effects of the two signature line requirement and communication to patients of cost savings, a two-item instrument using a Likert-type scale was prepared and presented to the pharmacist during the student's Phase II visit.

Unfortunately, two of the original thirty pharmacies which were used for Phase I could not be used for Phase II. One pharmacist closed his practice and the other was ill at the time the Phase II data was collected. Hence, data for Phase II ~~was~~<sup>were</sup> collected from only twenty-eight pharmacies.



## Results

Phase I. The mean consumer price per dosage unit during Phase I for each of the twelve drugs included in the study is indicated in Table 2. Mean consumer price per dosage unit was derived in the following manner: The price to the consumer was divided by the number of dosage units dispensed; a mean of these values was determined for each pharmacy; and then each pharmacy mean was used to determine a mean consumer price per dosage unit. Thus, the means shown in Table 2 are not strictly weighted, e.g., a prescription for thirty dosage units contributed the same weight to the pharmacy mean as a prescription for fifty dosage units.

In some cases, it was not possible to collect complete information concerning five prescriptions for each drug under study because the pharmacy did not dispense five new prescriptions during the period for which data were being collected. In fact, in six cases no prescriptions were dispensed for papaverine and in one case each there were no prescriptions dispensed for penicillin G and sulfisoxazole during the study period. This could reflect prescribing patterns in the particular community in which the pharmacy is located or the composition of the community. For example, if a pharmacy were located in an area where the elderly population was small, papaverine hydrochloride might not be heavily dispensed.

Phase II. The mean consumer price per dosage unit during Phase II for each of the twelve drugs included in the study also is found in Table 2. In addition, Table 2 contains data concerning differences in mean prices for the studied drugs during Phase I and Phase II.

Data (excluding generically written prescriptions) comparing mean price per unit on prescriptions where substitution was authorized appear



in Table 3. In these cases, the mean price per unit was determined for each prescription and then a mean of these means was taken.

Data (excluding generically written prescriptions) comparing the number of dosage units ordered on prescriptions where substitution was authorized with the number of dosage units ordered where substitution was not authorized appear in Table 4.

During Phase II, 100 consecutive new prescriptions were analyzed in 27 of the 30 pharmacies utilized in Phase I (three pharmacies were unable to participate in this part of the study). Data collected included which signature line was signed by the prescriber, whether the prescription was for a single source or multi-source drug, and if the pharmacist did, when possible, substitute.

These data are shown in Table 5 and in Figure I. For the pharmacist to substitute, the following three conditions must have been present: the prescriber must have signed the prescription on the "substitution permissible" line, the prescription must have been a multi-source product, and the product must not have appeared on the Delaware Drug Advisory Board's Nonequivalent Drug List. Even if all these conditions were present, the pharmacist still had to decide whether substitution would occur.

Since possible savings are related to the frequency with which authorization to substitute was granted, data were collected concerning the incidence of prescriptions for multi-source drugs which were signed on the "dispense as written" line.

Data on pharmacists' opinions concerning the two potential barriers to substitution, the two signature line requirement and the communication of price savings to patients, are found in Table 6.



Discussion

Considerable variation in price occurred from pharmacy to pharmacy. This has been observed in other studies.<sup>8,9</sup> A number of factors could contribute to this. First, some pharmacists utilize a professional fee system of pricing in which the amount added to the drug cost is not related to the amount which the pharmacist paid to obtain the drug. Other pharmacists use a mark-up system of pricing in which the amount added on does vary with the cost of the drug to the pharmacy. Second, some pharmacists who dispense a larger number of prescriptions can purchase the drugs in large quantities, thereby obtaining a lower cost per unit. Third, the services which the pharmacist offers -- maintenance of patient medication records, patient consultation, drug utilization review, delivery service, credit, etc. -- may lead to increased costs of operation and, hence, higher prices. Fourth, when a prescription is written generically the pharmacist has the choice of which brand to dispense. The variation in prices of the brands selected by the pharmacists studied would also contribute to the variation in prices seen here. Finally, if there were little variation in price from one pharmacy to another, it would raise questions concerning price collusion.

The quantity dispensed was not a controlled variable in this study. Thus, to the extent the data collected for this study included some prescriptions for which the ingredient costs were relatively small, the average retail price per unit may be overstated when larger quantities were dispensed. This effect is due to the pricing systems used.

Under the mark-up system of pricing which some pharmacists use, the mark-up is not a constant percentage; rather, it varies with the cost of ingredients.<sup>10</sup> When the cost of ingredients was relatively low, the per-



centage added would be higher than it would be when the cost of drug dispensed was higher. In addition, a minimum charge is likely to be used at the lower end of the pricing scale.<sup>11,12</sup> This takes into account, to a certain extent, the fact that some fixed costs, i.e., cost of container, cost of preparing individualized labeling, etc., associated with dispensing medication do not vary with the cost of ingredients. Some past studies have controlled quantities dispensed,<sup>8</sup> while others have not.<sup>9</sup>

A test was done for the differences in means between mean dosage units ordered for prescriptions for the sampled drugs where substitution was authorized and where it was not authorized (Phase II, excluding generically written prescriptions). No statistically significant differences were found (Table 4).

An attempt was made to collect acquisition cost data from the pharmacies studied but insufficient data could be collected to be of any value since most pharmacists did not record cost of ingredients on the prescription but rather merely the retail selling price. Additionally, cost data concerning the brand usually dispensed for generically written prescriptions were sought but, again, insufficient data could be obtained to be useful.

The data in Table 2 reflect the differences in mean prices per unit in Phase I and Phase II. Although the mean price per unit for ten of the twelve drugs studied decreased between Phase I and Phase II, the differences between the mean prices of the two phases was not statistically significant at the 95 percent confidence level.

The Bureau of Labor Statistics Consumer Price Index for pre-



scriptions increased from 116.4 in September, 1976, to 124.6 in October, 1977,<sup>13</sup> a 7.04 percent increase. A similar increase would have been expected in Delaware but was not evidenced in this study.

The effects of the Delaware legislation can best be seen in Table 3, which shows the differences in mean prices per dosage unit for the studied drugs under two conditions, where substitution was authorized and where it was not (generically written prescriptions are excluded). Statistically significant savings at the 95 percent level of confidence were found for seven of the ten drugs for which data could be collected:

Chlordiazepoxide HCl  
 Propoxyphene HCl Compound-65  
 Erythromycin  
 Hydrochlorothiazide  
 Papaverine HCl  
 Sulfisoxazole  
 Tetracycline

The difference between the mean prices for the other three drugs in Table 3 were not found to be statistically significant at the 95 percent confidence level.

Of particular interest in Table 3 is the column labeled "Difference" which is the average amount of savings per dosage unit.

The incidence of authorization to substitute in the Phase II sampled prescriptions was 37.9 percent (Table 5 and Figure 1). In 56.9 percent of the cases where the prescriber signed on the "dispense as written" line, the prescription was for a single source product for which substitution



was impossible. In 52.4 percent of the cases where substitution was authorized, the prescription was for a multiple source product and substitution was possible.

The extent of actual substitution when the two prerequisites existed, i.e., authorization was given and a multiple source product was prescribed, also is seen in Table 5. In a majority of cases (56.2 percent) the pharmacist did substitute when the opportunity was presented. In three pharmacies substitution occurred 100 percent of the time when authorization was given, while in two pharmacies substitution never occurred when authorization was given.

In 43.1 percent of the cases where authorization to substitute was withheld, a multiple source product was prescribed. Thus, there is potential for increasing the extent of substitution. Additional evidence concerning the possibility of savings from substitution is that 46.8 percent of all prescriptions reviewed for this portion of the study were for multiple source drugs. Of the 1263 prescriptions for multiple source drugs which were reviewed, 541 bore authorization to substitute, for a 42.8 percent rate of substitution authorization on multiple source prescriptions. However, the decision of what drug entity to prescribe and whether to authorize substitution is a complex one and substitution should probably not be expected on all prescriptions for multiple source products. Data concerning single source products are also provided in Table 5 to show the extent to which substitution would not have been possible.

The two signature line requirement does not appear to be a great barrier to substitution (Table 6). Pharmacists indicated that they perceived



this as being a problem to prescribers slightly more frequently than "sometimes". However, caution must be exercised in interpreting these data since the pharmacists were placed in the position of evaluating the difficulty prescribers are having with the requirement. While pharmacists would have a better feel for the extent of the problem than most other health professionals, their assessment of the difficulties another is having may not be accurate. That this may not be accurate is supported to a degree by the extent to which prescribers sign on the "dispense as written" signature line.

The requirement that the patient be informed of the potential savings which may result from substitution does not appear to be a barrier to substitution (Table 6). Overall, the pharmacists reported that this was a slight problem. However, six did indicate that this was "often" a problem.

#### Conclusions

The Delaware Drug Product Selection Act appears to be accomplishing its goals to an extent. Prices per unit for ten of the drugs studied did not increase during the study period in contrast with a 7.04 percent increase in the Consumer Price Index for prescriptions during the same period. The Act appears to be effective in holding down medication costs for the drugs included in this study.

Statistically significant savings when substitution under the Act was authorized were found for seven drugs in this study. The amount of savings per unit ranged from \$.027 to \$.132. Depending on the quantity prescribed and duration of therapy, the savings could be substantial.



Extrapolation of savings to a state-wide basis is extremely complex<sup>14</sup> and was not possible as part of this study. In a much larger, complex study being conducted in Michigan and Wisconsin, the researchers have estimated the savings resulting from the product selection act in Michigan to be between 15 and 20 million dollars per year.<sup>9</sup>

The overall incidence of authorization to substitute was found to be only 37.9 percent. However, when all prescriptions for multiple source drugs were reviewed, 42.8 percent bore authorization to substitute.

When substitution was authorized, 52.4 percent of the time substitution was possible since the prescription was for a multiple source product. When the pharmacists had the opportunity for substitution, they exercised that prerogative 56.2 percent of the time.

Pharmacists, on average, did feel that the two signature line requirement in the legislation was "sometimes" a barrier to substitution. Thus, the extent of authorization to substitute when a multiple source product was prescribed, i.e., 42.8 percent, has a potential for increasing.

If prescribers authorize substitution more often and pharmacists do substitute when authorized, then significant savings may be realized. Patients should be urged to discuss this possibility with their family physician and their family pharmacist to determine if there is a potential for savings on the medication they are using. Perhaps now that the existence of savings has been documented in Delaware, prescribers and pharmacists will use this legislation more frequently to save patients money while maintaining the high quality of care provided to patients in Delaware.



# References

1. "National Association of Chain Drug Stores. Generic Substitution - An Overview." mimeo. November 7, 1977.
2. Strom, B.L., et al., "Drug Anti-substitution Studies I: Estimation of Possible Savings by Repeal of Anti-substitution Laws", Drugs in Health Care 1:99-103 (Fall) 1974.
3. Gumbhir, A.K., and Rodowskas, C.A., Jr., "Consumer Price Differentials Between Generic and Brand Name Prescriptions", Am. J. Pub. Health 64:977-982 (October) 1974.
4. Azarnoff, D.L., et al., "Prescription Writing by Generic Name and Drug Cost", J. Chron. Dis. 19:1253-1256 (1966).
5. Task Force on Prescription Drugs, Final Report, U. S. Department of Health, Education, and Welfare. Washington, DC, 36-37, 1969.
6. Sharpe, T.R., "Economic Issues in the Antisubstitution Controversy," Am. J. Pharm. 149:53-59 (March-April) 1977.
7. Goldberg, T., et al., "Impact of Drug Substitution Legislation: A Report of the First Year's Experience", J. Am. Pharm. Assoc. NS17:216-226 (April) 1977.
8. Wertheimer, A.I., "Pricing Pharmaceutical Services - Art, Science or Whim?" J. Am. Pharm. Assoc. NS13:11-12 (January) 1973.
9. Berki, S.E., Richards, J.M. and Weeks, H.A., "The Mysteries of Prescription Pricing in Retail Pharmacies", Med. Care 15:241-250 (March) 1977.
10. Gagnon, J.P. and Rodowskas, Jr., C.A., "Reimbursement Methods for Pharmaceutical Services", J. Am. Pharm. Assoc. NS14:675-678 (December) 1974.
11. Myers, M.J., "Advantages of the Professional Fee", J. Am. Pharm. Assoc. NS8:639-643 (December) 1968.
12. Jacoff, M.D., "Professional Fee Evaluation", J. Am. Pharm. Assoc. NS3:565-568, 594 (November) 1963.
13. Bureau of Labor Statistics, "Consumer Price Index for Urban Wage Earners and Clerical Workers: U. S. City Average - Prescriptions", Washington, DC (undated).
14. Goldberg, T., et al., "Evaluation of Economic Effects of Drug Product Selection Legislation", paper presented to the 105th Annual Meeting of the American Public Health Association, Washington, October 31, 1977.



Table 1. Drugs Studied

Ampicillin 250 mg. (any salt)  
Chlordiazepoxide HCl 10 mg.  
Propoxyphene HCl Compound-65  
Erythromycin 250 mg. (base or any salt)\*  
Hydrochlorothiazide 50 mg.  
Meprobamate 400 mg.  
Papaverine HCl 150 mg. (Sustained Release)  
Penicillin-G 400,000 U.  
Penicillin-VK 250 mg.  
Prednisone 5 mg.  
Sulfisoxazole 500 mg.  
Tetracycline HCl 250 mg.

\*The Delaware Drug Advisory Board has indicated that interchange is not permissible among the various salts of erythromycin. (Non-equivalent Drug List, p. 6).



Table 2. Mean Consumer Price per Dosage for Studied Drugs in Phases I and II

| Drug                | Phase I | Phase II | Difference | Phase I | Phase II | Phase I    | Phase II   | D.F. | t     |
|---------------------|---------|----------|------------|---------|----------|------------|------------|------|-------|
|                     | Mean    | Mean     |            | n       | n        | S.D.       | S.D.       |      |       |
| Ampicillin          | .159    | .159     | 0          | 146     | 137      | $\pm .049$ | $\pm .041$ | 57   | .040  |
| Chlordiazepoxide    | .098    | .096     | -.002      | 143     | 115      | $\pm .030$ | $\pm .029$ | 55   | .293  |
| Propoxyphene        | .132    | .126     | -.006      | 143     | 134      | $\pm .051$ | $\pm .041$ | 56   | .467  |
| Erythromycin        | .210    | .201     | -.009      | 148     | 140      | $\pm .061$ | $\pm .061$ | 56   | .541  |
| Hydrochlorothiazide | .077    | .069     | -.008      | 150     | 138      | $\pm .026$ | $\pm .030$ | 56   | 1.062 |
| Meprobamate         | .064    | .058     | -.006      | 146     | 109      | $\pm .034$ | $\pm .028$ | 55   | .731  |
| Papaverine          | .109    | .104     | -.005      | 86      | 67       | $\pm .045$ | $\pm .059$ | 44   | .315  |
| Penicillin-G        | .103    | .102     | -.001      | 130     | 91       | $\pm .037$ | $\pm .043$ | 50   | .103  |
| Penicillin-VK       | .152    | .136     | -.016      | 149     | 134      | $\pm .040$ | $\pm .039$ | 56   | 1.535 |
| Prednisone          | .075    | .071     | -.004      | 150     | 135      | $\pm .043$ | $\pm .035$ | 56   | .341  |
| Sulfisoxazole       | .078    | .074     | -.004      | 141     | 121      | $\pm .030$ | $\pm .034$ | 55   | .421  |
| Tetracycline        | .092    | .096     | +.004      | 150     | 140      | $\pm .033$ | $\pm .034$ | 56   | .395  |



Table 3. Mean Prices per Unit for Studied Drugs in Phase II\*  
(Substitution Not Authorized Versus Substitution Authorized)

| Drug                | Substitution                      |            | Difference | Not Auth. |       | D.F. | t**     |
|---------------------|-----------------------------------|------------|------------|-----------|-------|------|---------|
|                     | Not Authorized                    | Authorized |            | S.D.      | S.D.  |      |         |
| Ampicillin          | .234                              | .153       | -.081      | ±.006     | ±.058 | 21   | 1.920   |
| Chlordiazepoxide    | .113                              | .061       | -.052      | ±.036     | ±.017 | 110  | (7.540) |
| Propoxyphene        | .146                              | .098       | -.048      | ±.055     | ±.036 | 114  | (3.761) |
| Erythromycin        | .280                              | .148       | -.132      | ±.084     | ±.050 | 58   | (7.061) |
| Hydrochlorothiazide | .101                              | .057       | -.044      | ±.060     | ±.027 | 59   | (3.246) |
| Meprobamate         | .111                              | .071       | -.040      | ±.034     | ±.006 | 9    | 1.601   |
| Papaverine          | .131                              | .047       | -.084      | ±.036     | ±.022 | 47   | (8.938) |
| Penicillin-G        | -----All generically written----- |            |            |           |       |      |         |
| Penicillin-VK       | .144                              | .126       | -.018      | ±.047*    | ±.047 | 61   | 1.543   |
| Prednisone          | -----All generically written----- |            |            |           |       |      |         |
| Sulfisoxazole       | .075                              | .048       | -.027      | ±.026     | ±.021 | 87   | (3.342) |
| Tetracycline        | .133                              | .081       | -.052      | ±.068     | ±.038 | 40   | (3.180) |

\* Excludes generically written prescriptions.

\*\* Those drugs with t values enclosed in parentheses are those for which the difference between the mean values was found to be statistically significant at the 95% confidence level.



Table 4. Mean Dosage Units Ordered for Studied Drugs in Phase II\*  
(Substitution Not Authorized Versus Substitution Authorized)

| Drug                | Not Authorized                    | Authorized | Difference | Not Auth.<br>n | Auth.<br>n | Not Auth.<br>S.D. | Auth.<br>S.D. | D.F. | t**   |
|---------------------|-----------------------------------|------------|------------|----------------|------------|-------------------|---------------|------|-------|
| Ampicillin          | 16                                | 22         | +6         | 2              | 19         | 5.66              | 4.31          | 1.38 | 1.46  |
| Chlordiazepoxide    | 71                                | 81         | +10        | 58             | 22         | 31.4              | 26.3          | 47.1 | 1.45  |
| Propoxyphene        | 33                                | 34         | +1         | 71             | 24         | 32.5              | 24.1          | 55.5 | 0.160 |
| Erythromycin        | 25                                | 28         | +3         | 35             | 22         | 15.1              | 17.3          | 41.8 | 0.669 |
| Hydrochlorothiazide | 58                                | 66         | +8         | 38             | 22         | 28.3              | 20.6          | 57.1 | 0.920 |
| Meprobamate         | 69                                | 76         | +7         | 7              | 10         | 30.2              | 31.3          | 15.4 | 0.463 |
| Papaverine          | 90                                | 99         | +9         | 24             | 11         | 20.6              | 40.6          | 12.9 | 0.695 |
| Penicillin-G        | -----All Generically Written----- |            |            |                |            |                   |               |      |       |
| Penicillin-VK       | 27                                | 29         | +2         | 21             | 33         | 7.65              | 14.8          | 51.9 | 0.652 |
| Prednisone          | -----All Generically Written----- |            |            |                |            |                   |               |      |       |
| Sulfisoxazole       | 68                                | 80         | +12        | 59             | 9          | 32.8              | 49.3          | 9.39 | 0.707 |
| Tetracycline        | 36                                | 45         | +9         | 13             | 29         | 29.6              | 29.6          | 24.9 | 0.911 |

\* Excludes generically written prescriptions.

\*\* None of the t values show statistically significant differences between the mean values at the 95% confidence level.



Table 5. Incidence of Authorization to Substitute, Prescribing of Single Source Products, and Actual Substitution in 27 Delaware Pharmacies (Phase II)

|                             | Single Source<br>Products | Multi-source<br>Products |                       |                | Total             |
|-----------------------------|---------------------------|--------------------------|-----------------------|----------------|-------------------|
| Dispense as<br>Written      | 955<br>(35.4%)            | 722<br>(26.7%)           |                       |                | 1677<br>(62.1%)   |
| Substitution<br>Permissible | 482<br>(17.8%)            | Did<br>Substitute        | Did not<br>Substitute | Total          | 1034<br>(37.9%)   |
|                             |                           | 304<br>(11.2%)           | 237<br>(8.8%)         | 541<br>(20.0%) |                   |
| Total                       | 1437<br>(53.2%)           | 1263<br>(46.8%)          |                       |                | 2,700<br>(100.0%) |



Figure 1.

**Incidence of Authorization to Substitute, Prescribing of Single Source Products, and Actual Substitution in 27 Delaware Pharmacies (Phase II)**

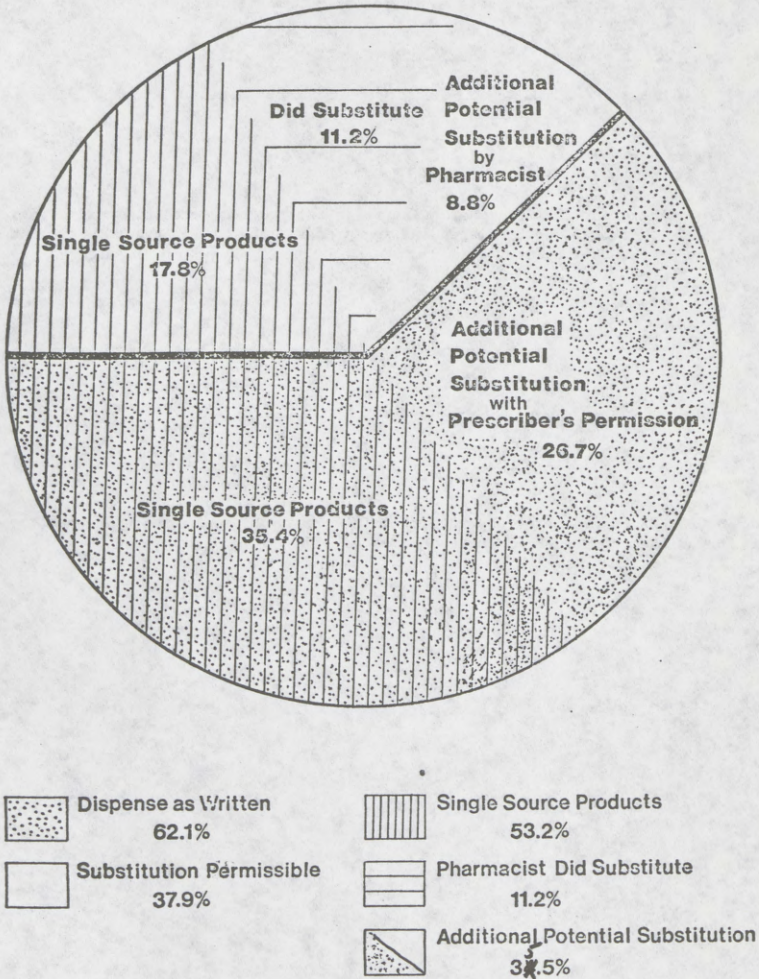




Table 6. The Two Signature Lines and Patient Communication About Savings  
as Barriers to Increased Substitution \*

Please indicate how often you think the following requirements pose problems by encircling the appropriate number, with 1 = often posing a problem and 5 = never posing a problem.

The two signature line requirement for prescriptions is a barrier to increased physician authorization of the pharmacist to substitute.

| <u>Often</u> |          | <u>Sometimes</u> |          | <u>Never</u> |              |             |  |
|--------------|----------|------------------|----------|--------------|--------------|-------------|--|
| <u>1</u>     | <u>2</u> | <u>3</u>         | <u>4</u> | <u>5</u>     | <u>Total</u> | <u>Mean</u> |  |
| 11           | 4        | 6                | 1        | 6            | 28           | 2.54        |  |

The requirement that the pharmacist relay information concerning price savings to the patient prior to dispensing the prescription is a barrier to substitution by our pharmacists.

| <u>Often</u> |          | <u>Sometimes</u> |          | <u>Never</u> |              |             |  |
|--------------|----------|------------------|----------|--------------|--------------|-------------|--|
| <u>1</u>     | <u>2</u> | <u>3</u>         | <u>4</u> | <u>5</u>     | <u>Total</u> | <u>Mean</u> |  |
| 6            | 2        | 6                | 0        | 14           | 28           | 4.21        |  |

\* Only 28 pharmacists responded to this question. One closed his practice and the other was ill during Phase II.



# Physicians' Knowledge of Drug Prices

Joseph L. Fink III\*

Associate Professor of Pharmacy Administration, Philadelphia College of Pharmacy and Science, Philadelphia, PA 19104

Daniel J. Kerrigan

Community Pharmacist, Eckerd's Pharmacy, Wilmington, DE 19801

**Abstract.** Questionnaires were sent to a stratified random sample of Philadelphia County physicians to determine their knowledge of drug prices. From each of four fields, internal medicine, obstetrics/gynecology, pediatrics, and psychiatry/neurology, 100 specialists were chosen. Responses indicated that many physicians are, or feel themselves to be, poorly informed on the subject. An overwhelming (~66%) reliance on patients for drug information was found. Physician/pharmacist communication might improve physicians' knowledge of drug prices.

Costs in the health care sector of the economy are coming under increased scrutiny, yet this phenomenon is not new to pharmacy. Drug prices have been under study by governmental and consumer groups for some time. As one article on the subject emphasized, "Prescription drugs are unusual in being one commodity where the person who chooses is not the one who pays" (1). Governmental action is seen in preparation for a drug compendium with drug prices for distribution to physicians, pharmacists, and others (2). In addition, FDA is conducting a study to determine to what extent physicians take cost into account in deciding whether to prescribe antibiotics (3).

It may be difficult for physicians to obtain accurate price information (4). A recent study found that only 23% of the formularies that were reviewed as part of a larger study provided price codes to inform the physician of the economic implications of his or her act of prescribing (5). To rectify this situation to a degree, a bill was introduced in Congress that would require manufacturers and wholesalers to include explicit selling price information in drug advertising (6).

Other countries have taken steps to educate their physicians concerning drug costs. The Ontario Ministry of Health distributes semiannually to physicians in Ontario a comparative drug price index for products of assured quality (7). In Australia, prescribing is monitored, and if drug costs become a problem, one way of addressing the problem is having a government pharmacist discuss the situation with physicians during routine visits (8).

In the United States, efforts to contain drug costs have been seen primarily at the state level; a majority of the states have modified their antisubstitution laws to permit drug product selection by the pharmacist in certain situations (9). Yet many of these states have retained the physician's ability to prohibit product selection by the pharmacist. Acceptance of three proposed programs to reduce prescription prices by physicians was found to be related to the physicians' perception of prescription drug prices as being excessive (10). Hence if physicians do not perceive drug prices to be excessive, they may reserve the right of drug product selection.

Two other studies dealing with physicians' knowledge of drug prices were reported. One study was conducted in Palo

Alto, California (11), and the other at the Mayo Clinic (12). The first study was restricted to a number of different antibiotics, while the second was limited to 86 different drugs used by pediatricians. No study could be found that assessed the situation in a large city or compared the performances of different medical specialists. This paper is a preliminary report on a study undertaken in an eastern city among physicians from four specialty groups.

## Methodology

A stratified random sample of physicians whose practices were in Philadelphia County was drawn from each of four areas of specialization: internal medicine, obstetrics/gynecology, pediatrics, and psychiatry/neurology. One hundred physicians from each field of specialization were selected from the Directory of Medical Specialists (13). A questionnaire was prepared and pretested (see Appendix A). The primary feature of the instrument was a request that respondents indicate the average amount patients of theirs would pay for each of the listed prescription items when purchased at a pharmacy.

Four different questionnaires were used, one for each specialty. A list of medications to be used for the study (see Appendix B) was prepared with two objectives in mind: first, to compare estimates for drugs used in the specialist's field and second, to compare estimates for drugs widely used by many physicians. Five medications included on each of the four lists were drugs used mainly within the scope of the specialist's practice. The remaining two drugs for which each group was requested to provide estimates were the same for all specialties, i.e., Darvon Compound-65 (a combination product containing propoxyphene hydrochloride, aspirin, phenacetin, and caffeine) and Valium (diazepam) 5 mg. These two products were selected because of their widespread use by physicians and because they would provide a basis for comparison among all four specialties using the same drugs.

In the case of each specialty a number of questionnaires were undeliverable. The final number of questionnaires received by each specialty was:

|                       |    |
|-----------------------|----|
| internal medicine     | 89 |
| obstetrics/gynecology | 95 |
| pediatrics            | 85 |
| psychiatry/neurology  | 96 |

Data for comparison of drug price estimates were collected by mailing a list of the drugs to be studied to a random sample of 53 pharmacies in Philadelphia County selected from the Yellow Pages of the Philadelphia telephone directory. This list was the result of stratified sampling designed to collect 10% of the pharmacies in the county. Responses were received from 16 for a 30.8% response rate. The mean prices to be used for comparison are found in Table 1.

\* To whom inquiries should be directed.



Table 1. Mean Drug Prices From Philadelphia Pharmacies

|                         | Mean Price | Number of Pharmacies | "Acceptable" Range $\pm 20\%$ |
|-------------------------|------------|----------------------|-------------------------------|
| Darvon Compound 65 mg   | \$6.03     | 16                   | \$4.83-\$7.23                 |
| Valium 5 mg             | \$6.68     | 16                   | \$5.34-\$8.02                 |
| V-Cillin-K 250 mg/5 ml  | \$4.07     | 14                   | \$3.26-\$4.88                 |
| Erythrocine 200 mg/5 ml | \$6.05     | 14                   | \$4.84-\$7.26                 |
| Actifed syrup           | \$2.96     | 16                   | \$2.37-\$3.55                 |
| Phenergan expectorant   | \$3.29     | 16                   | \$2.63-\$3.95                 |
| Tri-Vi-Flor drops       | \$4.44     | 13                   | \$3.55-\$5.33                 |
| StuartNatal 1 Plus 1    | \$4.69     | 15                   | \$3.75-\$5.63                 |
| Premarin 1.25 mg        | \$5.98     | 15                   | \$4.78-\$7.18                 |
| Ovral                   | \$4.06     | 16                   | \$3.25-\$4.87                 |
| Bendectin               | \$9.10     | 15                   | \$7.28-\$10.92                |
| Monistat cream          | \$8.51     | 16                   | \$6.81-\$10.21                |
| Lanoxin 0.25 mg         | \$2.17     | 16                   | \$1.74-\$2.60                 |
| Orinase 500 mg          | \$6.64     | 16                   | \$5.31-\$7.97                 |
| Indocin 25 mg           | \$7.70     | 16                   | \$6.16-\$9.24                 |
| Aldomet 250 mg          | \$6.06     | 16                   | \$4.85-\$7.27                 |
| Inderal 10 mg           | \$4.11     | 16                   | \$3.29-\$4.93                 |
| Haldol 2 mg             | \$11.97    | 14                   | \$9.58-\$14.36                |
| Thorazine 25 mg         | \$3.73     | 15                   | \$2.98-\$4.48                 |
| Elavil 25 mg            | \$7.20     | 15                   | \$5.76-\$8.64                 |
| Dilantin 100 mg         | \$3.36     | 14                   | \$2.69-\$4.03                 |
| Sinemet-25/250          | \$13.05    | 13                   | \$10.44-\$15.66               |

## Results

The number of responses received from physicians in each specialty is indicated in Table 2. Because no follow-up techniques were utilized, the overall response rate of over 31% is highly acceptable. A substantial number of the respondents declined to offer estimates, stating that they had no idea. Data concerning these responses are found in Table 3. It is noteworthy that while one would expect more responses from those who had made estimates, over 32% of the respondents indicated that they had no idea of the drug prices. This large response from those who did not make estimates may be attributed to the fact that the questionnaire also requested a self-assessment of drug price knowledge as well as an indication of the frequency of use of several different drug price information sources.

A wide diversity of practice environments, e.g., teaching hospital, nonteaching hospital, and private office, as well as a spread of years in practice, was seen among the respondents. For brevity, these data are omitted here.

Respondents were asked to provide a self-assessment of their drug price knowledge using a Likert-type scale. Data from this portion of the study appear in Table 4. Nearly two thirds (63.9%) of the respondents making an indication ranked themselves in the two least informed categories, while only 12% ranked themselves in the two most informed categories.

The source of the physicians' drug price information may influence its accuracy. Data concerning sources most frequently utilized by the respondents are found in Table 5. Information provided by patients is most frequently used by an overwhelming majority.

A number of cross tabulations are possible with the generated data. A few are presented here.

For comparison, the standards utilized in the two previous studies were adopted (11, 12). An estimate of drug price was considered to be "acceptable" if it fell within  $\pm 20\%$  of the average price obtained from the pharmacies. The number of acceptable estimates by specialty is shown in Table 6. As can be seen, pediatricians had the best performance, ~45% acceptable responses, and the internists as a group also performed slightly better than the average for all respondents.

The question occurs whether "unacceptable" estimates were too high or too low. Data in response to this question appear in Table 7. For nearly all respondents, unacceptable estimates were nearly 2.5 times more likely to fall on the low side than on the high side. Performance of the internists was an exception. This group overestimated prices more frequently than it underestimated.

As was stated earlier, two drugs, Darvon Compound-65 and Valium 5 mg, were included for all specialties to permit comparison of the specialties. Data for "acceptable" estimates for these two drugs are found in Table 8. While one would expect pediatricians to be the least frequent prescribers of Darvon Compound-65, they had the highest incidence of "acceptable" estimates. Moreover, with regard to Valium 5 mg, they did not have the lowest incidence of "acceptable" estimates.

## Discussion

One of the most striking findings of the study was the number of physicians who returned the questionnaire indicating that they had "no idea" what the prices would be. Of the total questionnaires returned, nearly one third bore this statement. This result alone would tend to indicate that physicians are poorly informed about the prices their patients pay for drugs.

The physicians reported a low self-assessment of their drug price knowledge. Over one third evaluated their status as being "uninformed," while less than 2% rated themselves as being "very informed." This self-assessment was found to be relatively accurate by the estimates provided. The same assessment was recently found in a national study by the American Medical Association in which 62.5% of the physicians responding reported that they did not know the cost of drugs they commonly prescribe (14).

An overwhelming reliance on patients for drug price information was observed. Nearly two thirds of the respondents listed patients as their primary source, while pharmacists, possibly the most accurate source of such information, were listed by only 21%. If physicians communicated more with pharmacists about price information, perhaps their knowledge would be better. Indeed, this course of action has been recommended to physicians (1).

Pediatricians were found to have the highest level of "acceptable" price estimates among the four specialties studied. Their performance was substantially better than the

Table 2. Responses by Specialty

| Specialty             | Number Responding | Percent Responding |
|-----------------------|-------------------|--------------------|
| Internal medicine     | 26/89             | 29.2               |
| Obstetrics/gynecology | 29/95             | 30.5               |
| Pediatrics            | 27/85             | 31.8               |
| Psychiatry/neurology  | 32/96             | 33.3               |
| Total                 | 114/365           | 31.2               |

Table 3. Responses Indicating "No Idea" by Specialty

| Specialty             | Number Responding | Percent Responding |
|-----------------------|-------------------|--------------------|
| Internal medicine     | 6/26              | 23.1               |
| Obstetrics/gynecology | 9/29              | 31.0               |
| Pediatrics            | 7/27              | 25.9               |
| Psychiatry/neurology  | 15/32             | 46.9               |
| Total                 | 37/114            | 32.5               |



Table 4. Self-Assessed Knowledge of Drug Prices

| Specialty             | 1   | 2    | 3    | 4    | 5    | Other | Total | Mean* |
|-----------------------|-----|------|------|------|------|-------|-------|-------|
| Internal medicine     | 1   | 2    | 5    | 10   | 6    | 2     | 26    | 3.75  |
| Obstetrics/gynecology | 0   | 4    | 6    | 9    | 9    | 1     | 29    | 3.82  |
| Pediatrics            | 1   | 3    | 8    | 7    | 7    | 1     | 27    | 3.61  |
| Psychiatry/neurology  | 0   | 2    | 7    | 6    | 15   | 2     | 32    | 4.19  |
| Total                 | 2   | 11   | 26   | 32   | 37   | 6     | 114   | 3.90  |
| Percent*              | 1.8 | 10.2 | 24.1 | 29.6 | 34.3 |       | 100.0 |       |

Responses range from 1, "very informed," to 5, "uninformed."  
 \* Excludes "other" responses.

Table 5. Physicians' Most Frequently Utilized Sources of Price Information

| Source                | Number | Percent |
|-----------------------|--------|---------|
| Patients              | 63/95  | 66.3    |
| Pharmacists           | 20/95  | 21.1    |
| Sales representatives | 9/95   | 9.4     |
| Other                 | 3/95   | 3.2     |

Percentages are based on 95 rather than 114, since 19 respondents did not answer this question.

Table 6. Incidence of "Acceptable" Price Estimates

| Specialty             | Number  | Percent |
|-----------------------|---------|---------|
| Internal medicine     | 45/135  | 33.3    |
| Obstetrics/gynecology | 34/133  | 25.6    |
| Pediatrics            | 59/133  | 44.4    |
| Psychiatry/neurology  | 31/114  | 27.2    |
| Total                 | 169/515 | 32.8    |

Table 7. Incidence of "Unacceptable" Estimates

| Specialty             | Overestimates |         | Underestimates |         |
|-----------------------|---------------|---------|----------------|---------|
|                       | Number        | Percent | Number         | Percent |
| Internal medicine     | 52/135        | 38.5    | 38/135         | 28.2    |
| Obstetrics/gynecology | 16/133        | 12.0    | 83/133         | 62.4    |
| Pediatrics            | 12/133        | 9.0     | 62/133         | 46.6    |
| Psychiatry/neurology  | 18/114        | 15.8    | 65/114         | 57.0    |
| Total                 | 98/515        | 19.0    | 248/515        | 48.2    |

Table 8. Incidence of "Acceptable" Price Estimates for Darvon Compound-65 and Valium 5 mg

| Specialty             | Darvon Compound-65 |         | Valium 5 mg |         |
|-----------------------|--------------------|---------|-------------|---------|
|                       | Number             | Percent | Number      | Percent |
| Internal medicine     | 6/19               | 31.6    | 9/20        | 45.0    |
| Obstetrics/gynecology | 6/19               | 31.6    | 4/18        | 22.2    |
| Pediatrics            | 9/17               | 53.0    | 6/17        | 35.3    |
| Psychiatry/neurology  | 5/14               | 35.7    | 6/17        | 35.3    |
| Total                 | 26/69              | 37.7    | 25/72       | 34.7    |

second best group, the internists. Surprisingly, the pediatricians' performance was also strong in their price estimates for Darvon Compound-65, a drug one would expect them to use infrequently.

In "unacceptable" estimates, three of the four specialty groups were more likely to err on the low side than on the high side. In fact, the obstetrician/gynecologist group underestimated nearly two thirds of the time. However, the internists were more likely to overestimate than to underestimate.

### Conclusions

Physicians in this study reported that they are uninformed about drug prices. This self-assessment is borne out by their performance in estimating prices for specific prescription drugs and by conclusions of other researchers (11, 12). Perhaps one reason for physicians' lackluster performance is their reported reliance on patients for drug price information. They should be urged to communicate more with pharmacists in their area to obtain a more accurate picture of prevailing prices.

However, even physician/pharmacist communication may not make physicians take cost into greater account in prescribing. A study among physicians in Sweden found that cost has a low weight in the prescribing decision (15). If the same is true in the United States, perhaps providing physicians with drug price information will not be as effective in reducing drug expenditures as is anticipated.

### Appendix A: Sample Questionnaire

#### Pediatricians

#### Instructions:

Below are seven medications with quantities indicated. In the space provided to the right, please estimate the average amount a patient of yours would pay for each of these prescriptions when purchased at a pharmacy.

Following that section are four brief questions to obtain information about your practice. Following completion of those questions, please return this sheet in the postage-paid envelope provided.

#### Estimated Price

1. Darvon Compound-65 # 50 \_\_\_\_\_  
 Valium 5 mg # 50 \_\_\_\_\_  
 V-Cillin K 250 mg/5 ml 100 ml \_\_\_\_\_  
 Erythrocine 200 mg/5 ml 100 ml \_\_\_\_\_  
 Actifed syrup 120 ml \_\_\_\_\_  
 Phenergan expectorant 120 ml \_\_\_\_\_  
 Tri-Vi-Flor drops 50 ml \_\_\_\_\_



2. Which one of the following best describes your practice?
- ( ) teaching hospital based  
 ( ) nonteaching hospital based  
 ( ) private office based  
 ( ) other: \_\_\_\_\_
3. How long have you been in practice?
- ( ) 5 years or less  
 ( ) 6-10 years  
 ( ) 11-15 years  
 ( ) 16-20 years  
 ( ) 21 years or more
4. Would you rate your knowledge of drug prices as:
- |               |   |   |   |   |            |
|---------------|---|---|---|---|------------|
| Very informed |   |   |   |   | Uninformed |
| 1             | 2 | 3 | 4 | 5 |            |
5. Please rank the following sources of drug price information in order of their use by you: (1 = most frequently used, 2, 3, etc.)
- ( ) colleagues  
 ( ) manufacturers' representatives  
 ( ) patients  
 ( ) pharmacists  
 ( ) other: \_\_\_\_\_

#### Appendix B: Drugs Used in the Study

##### For All Respondents

- Darvon Compound-65 50
- Valium 5 mg 50

##### Internal Medicine

- Lanoxin (digoxin) 0.25 mg 50
- Orinase (tolbutamide) 500 mg 50
- Indocin (indomethacin) 25 mg 50
- Aldomet (methyldopa) 250 mg 50
- Inderal (propranolol hydrochloride) 10 mg 50

##### Pediatrics

- V-Cillin K (penicillin V potassium) 250 mg/5 ml 100 ml
- Erythrocine (erythromycin) 200 mg/5 ml 100 ml
- Actifed syrup (a combination product containing triprolidine hydrochloride and pseudoephedrine) 120 ml
- Phenergan expectorant (a combination product containing promethazine hydrochloride) 120 ml
- Tri-Vi-Flor drops (a combination product containing sodium fluoride and vitamins A, C, and D) 50 ml

##### Obstetrics/Gynecology

- StuartNatal 1 Plus I (a combination multiple-vitamin product) 50
- Premarin (conjugated estrogens) 1.25 mg 50
- Ovral (a combination product containing norgestrel and ethinyl estradiol) 21

- Bendectin (a combination product containing doxylamine succinate and pyridoxine hydrochloride) 50
- Monistat cream (miconazole nitrate) 85 g

##### Psychiatry/Neurology

- Haldol (haloperidol) 2 mg 50
- Thorazine (chlorpromazine) 25 mg 50
- Elavil (amitriptyline hydrochloride) 25 mg 50
- Dilantin (phenytoin) 100 mg 50
- Sinemet-25/250 (a combination product containing carbidopa and levodopa) 50

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#### References

- (1) M. C. Smith, When friends or patients ask about... the cost of drugs, *J. Am. Med. Assoc.*, 235, 294 (1976).
- (2) *American Druggist*, 175, 3 (July 1977).
- (3) *American Druggist*, FDA probes doctors on how they use antibiotics, 176, 24 (Sept. 1977).
- (4) B. A. Kemp and P. R. Moyer, Equivalent therapy at lower cost, *J. Am. Med. Assoc.*, 228, 1009 (1974).
- (5) T. D. Rucker and J. A. Visconti, Hospital formularies: Organizational aspects and supplementary components, *Am. J. Hosp. Pharm.*, 33, 912 (1976).
- (6) U.S. Congress, S. 1831, Section 404, 95th Congress, 1st Session (July 11, 1977).
- (7) A. E. Dyer, PARCOST: The Ontario experience in selecting quality drugs, *Drugs Health Care*, 1, 16 (1974).
- (8) D. A. Knapp, D. E. Knapp, and G. E. Brooks, Drug use in Australia and the United States as reflections of legislation and social attitudes, *Drug Intell. Clin. Pharm.*, 11, 298 (1977).
- (9) *Drug Topics*, Product selection now in 34 states, 121, 14 (Sept. 15, 1977).
- (10) A. A. Nelson, Jr., and J. P. Gagnon, Physician acceptance of three proposed programs designed to reduce prescription prices, *Drugs Health Care*, 1, 27 (1974).
- (11) D. R. Lowy, L. Lowy, and R. S. Warner, A survey of physicians' awareness of drug costs, *J. Med. Educ.*, 47, 349 (1972).
- (12) R. F. Kaine and E. J. O'Connell, Physicians' appreciation of drug charges to the patient, *Clin. Pediatr.*, 11, 665 (1972).
- (13) "Directory of Medical Specialists," vols. 1 and 2, 17th ed., American Board of Medical Specialists, Chicago, Ill., 1975-1976.
- (14) *American Medical Association News*, How MD's, pharmacists view mutual problems, 20, 5 (Oct. 24, 1977).
- (15) J. Lilja, How physicians choose their drugs, *Soc. Sci. Med.*, 10, 363 (1976).



Mr. ECKHARDT. Thank you very much, Dr. Fink.

Do you have any questions, Ms. Seddon?

Ms. SEDDON. I have one or two.

If you were an attorney general in a State that adopted a law to allow substitution, which of the two provisions you have described regarding pharmacists' liability, would you prefer to defend?

Dr. FINK. If the choice were the California approach and Oregon approach, I would prefer the California, one for a policy reason and the other as a legal reason. The policy reason is that the language of the California approach is fairly straightforward in saying that the pharmacist's liability shall be limited to being similar to that where he is dispensing a drug on a generically written prescription. Pharmacists can understand that more easily.

When you use the Oregon approach concerning rules of evidence and what is admissible and not admissible, that is more confusing. Pharmacists are pharmacists. They are not attorneys and the more straightforward you can be with them and the more straightforward the language of the legislation is I think the more it will encourage them to engage in product selection.

The legal issue I think is that the California approach represents less of an interference with the court system and the system for redress of grievance within the State than does the Oregon approach and, therefore, I think the California approach would be preferable.

Ms. SEDDON. Could you give us a sense of the types of cases that have been brought when a pharmacist dispenses a drug for a prescription that is written generically? What does that tell us about the liability of pharmacists?

Dr. FINK. There has never been a case like that. There has never been a case to my knowledge or in any of the literature that I have read, and I have lectured and written fairly extensively on the subject, where a pharmacist or a physician has been sued for a drug source product selection decision about which brand of drug will be dispensed on an order.

I think there are several reasons for this. One is the problem of proof. As you know, in order to establish liability on the part of the physician or the pharmacist, the plaintiff is going to have the burden of proving direct causation in that the breach of duty led directly to the damages suffered. That is going to be a difficult burden to meet. The plaintiff is going to have to show by a preponderance of the evidence that the fact that he did not recover from some disorder or the reason that he did not get a desired therapeutic response was because brand A was dispensed rather than brand B.

Let's say we have a patient who has an infection and rather than recovering in the normal 2 weeks that the one who has this infection and who is treated with brand B, the so-called brand name product, usually recovers—he lags for 4 weeks, losing 2 more weeks of work. He claims that it was because he was treated with brand A drug and not the brand name drug, brand B.

He is going to have to show at trial that the reason he did not recover, that he lingered for 2 weeks more, was because that particular product was used and that is going to be an extremely difficult thing to prove. Who knows? Even if he had received the



brand name product, he might not have recovered for 4 weeks. He has to establish by the preponderance of the evidence that the reason he didn't recover was because he received brand A rather than the brand name drug brand B, which is extremely difficult to prove.

No. 1: It is difficult to get the witnesses to testify on this point. The witnesses that testify to that under oath and that degree of certainty is not available yet. Second, it is difficult to find an attorney with the expertise to handle the case.

Mr. ECKHARDT. Thank you very much.

Dr. FINK. You are welcome.

Dr. LOWER. I want to ask one question in regard to your study of the drug substitution in Delaware. I might preface it by saying it relates to two striking differences that I found between your resolves and those that Dr. Goldberg found in his Michigan study.

First, if I correctly interpret your table 3 in your study, the differences for substituted and nonsubstituted drugs would average about 40 percent. That was calculated on a cent-per-unit difference and it averages out around 40 percent.

Now, that is about twice as high as the 21-percent savings on drug product selection that Dr. Goldberg found in Michigan.

Second, the rate for substitution also appears to be much higher in Delaware. It can be inferred from your data, for example, that about 47 percent of the prescriptions were for multiple source products and of those about 24 percent were actually substituted. That 24 percent contrasts with the 1.5 percent that Dr. Goldberg found in Michigan.

Are those real and valid differences between the two States, and, if so, what provisions in the law might account for them? And if they are not real and valid differences, what methodological differences might account for those two results?

Dr. FINK. First, I would like to address the methodological differences. About 2 months ago Dr. Goldberg and I were on a program together in Montreal, both presenting papers about our studies on this topic and that question was raised. Why are the Michigan figures so low as to incidence of substitution and why are the Delaware figures so high relative to one another?

He gave the best answer that I can think of and that is that in Delaware we received the contract from the State of Delaware to conduct the study which was a limited amount, about \$4,700, and we could not do everything we wanted to do. So we only studied 12 drugs rather than all multiple source drugs as he is doing.

The incidence we found was for very popular drugs, drugs which are used frequently, both by brand name and some of them by generic name.

Second, his study found that in Michigan the rate of substitution was less. I think one reason that could account for this is that Delaware is quite different from Michigan. In Delaware there are only 130 pharmacies. There are 200 pharmacists. There are probably 300 or 400 physicians. The State is essentially like a county in most areas. Everybody knows everybody. Things are on a much more personal basis.

I can tell you from firsthand experience that physicians and pharmacists in Delaware have very close relationships, much closer



than in many other areas of the country, because it is a small State, and, therefore, I think physicians probably tend to have more confidence in the pharmacists often knowing them personally.

In fact, some physicians were permitting substitution by pharmacists even before the legislation came into effect by a blanket contractual agreement with the pharmacist which would permit him to do so.

Hence, I think it is a methodological difference and I also think it is a difference in the makeup of the two States.

Dr. LOWER. But that suggests another thing. The rate of prohibited substitution by physicians—or writing “dispense as written”—isn’t that considerably higher in Delaware than it is in Michigan?

Dr. FINK. Yes; but the reason for that is the way you do it. In Delaware we have a two-signature line requirement. The prescriber’s prescription blanks must have two-signature lines. One says “may substitute” and the other says “do not substitute” and the physician has to decide on which line he is going to sign.

Now, one oversight in the Delaware legislation was that they didn’t specify where these signature lines were to be placed so rather than putting one on the right and one on the left, some physicians put one signature line immediately above the other, then sign over both and the pharmacist does not know what he is supposed to do. That has happened.

Now, in Pennsylvania, which has a two-signature line requirement, they required a vertical line separating the two so it is clear where it has been signed. There is no layout spelled out in the Delaware legislation with regard to which line goes on which side. The prescriber can put it on the right where he customarily signs so that you would get more banning of substitution.

In Michigan it is relatively harder for the physician to prevent substitution. He has to do it in his own handwriting. I think that is the difference. Personally, I favor the approach of Michigan which requires them to affirmatively stop to think about it and consider whether this patient really requires this brand name product or wouldn’t the patient be just as well off with a therapeutically equivalent, less expensive product?

One other point that relates to economics which I didn’t include in my statement was the point that was raised by Mr. Rinaldo and that is, will enactment of this type of legislation provide a disincentive for research intensive pharmaceutical manufacturers? I think the answer to that is no. I think it will work in just the opposite direction. It will provide for an incentive for research-intensive pharmaceutical manufacturers—the reason being the U.S. patent system. If you have a patent on a product, you have a lawful monopoly for 17 years, nobody else can make it, and that is the greatest incentive in the world to develop a new drug product.

So I think enactment of this type of legislation will foster that.

Dr. LOWER. That is an interesting point. I thought of that, too, during that testimony.

Thank you.

Mr. ECKHARDT. If there is a therapeutic equivalent, how is the brand name product patentable except with respect to the copy-right on the brand name?



Dr. FINK. It would be patentable for the first 17 years. What I am talking about here is a situation——

Mr. ECKHARDT. If it was covered first?

Dr. FINK. Right. For the first 17 years it would be protected, then it would be available through the effect of this legislation. But for the first 17 years this legislation has no effect on it. So if a manufacturer is conducting research and his scientist develops something that he is able to get a patent on, then your legislation will have no effect on it at all because it is a single-source product. The pharmacist, when the physician writes a prescription for that product, only has that manufacturer's brand to choose from so the manufacturer has a legal monopoly for 17 years and that is his incentive.

Mr. ECKHARDT. He has an incentive then to try to perfect something different from that which he has not done before?

Dr. FINK. That is right.

Mr. ECKHARDT. Thank you very much for your testimony. It was most helpful.

Dr. FINK. You are welcome.

Mr. ECKHARDT. That completes our witnesses for today.

The subcommittee will be in recess until the call of the Chair.  
[The following statements were received for the record:]

STATEMENT OF HON. BENJAMIN S. ROSENTHAL, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF NEW YORK

Mr. Chairman, members of the subcommittee, I appreciate this opportunity to present my views to you and to urge adoption of a comprehensive generic drug substitution law. I have long been a strong advocate of such legislation. The retail pharmaceutical industry has been shielded from the competitive pressures of a free enterprise system for too long now, and this costs the American consumer several hundred million dollars annually.

In order to lower the cost of prescription drugs, legislation must be approved to encourage the use of lower-priced generic drugs, to facilitate comparison shopping on the part of consumers, and to foster price competition on the part of retail pharmacists. We must at the same time insure the safety and effectiveness of the medicine we use.

To accomplish this, several steps must be taken:

First, retail pharmacists must be required to dispense the lowest cost equivalent drug in their inventory whenever a doctor's prescription is presented. The only exception should be if the doctor states in his own handwriting, "no substitutions".

Second, the Food and Drug Administration must develop a positive formulary of prescription drugs for which there are no demonstrated bioequivalence problems and for which substitutions will be required.

Third, a drug's established or generic name must be used whenever and wherever its brand-name appears—from advertising to labeling.

Fourth, all pharmacies must be required to post in a prominent place the prices of the 100 or so top selling drugs.

Finally, the Federal Trade Commission, the Food and Drug Administration, and the Secretary of Health, Education and Welfare must work together to encourage the retail advertising of prescription drug prices.

The dispensing of generic drugs in place of their brand name equivalents would save Americans millions of dollars each year. Repeated surveys by government agencies at all levels, by public interest organizations, by academicians and others, and by my own office both in New York and Washington, have consistently demonstrated that a wide disparity exists between prices of generic and branded drugs. This disparity exists not because brand-name drugs are any safer or more effective but because doctors have been continually subjected to the promotional efforts of the large pharmaceutical firms.

It has been estimated that the pharmaceutical industry annually spends \$5,000 per physician in this country, or 25 percent of revenues from sales using detail men, free samples, direct mailings, advertising in medical journals, and free gifts for



medical students in order to persuade doctors to prescribe brand-name drugs. This billion-dollar expenditure has nothing to do with the patient's health, but is used to beguile him and his doctor and to combat his attempts to get a better drug buy. It tends to monopolize doctors' sources of information and keep many from adopting critical and scientific attitudes toward drugs.

This influence on doctors begins early—in fact, even before they become doctors. It starts in medical school with a free black bag, a stethoscope and some textbooks. It continues with visits from salesmen, invitations to industry-financed conferences, gifts, and a massive effort at post-graduate indoctrination by those who profit from brand-name prescribing, over-prescribing and mis-prescribing.

The doctor's primary source of information about available drugs is the Physicians Desk Reference (PDR), a catalogue which illustrates prescription drugs and explains their usage. It is filled with advertising by major drug manufacturers, distributed free of charge to most doctors, and is found in every hospital. Contrary to its implied universality, the PDR is incomplete—it mentions only a few generic names for widely prescribed, basic drugs. The widespread use of this volume actually serves to conceal from doctors the existence of other manufacturers who can often supply the same drugs at lower cost. The high price of these medicines is passed on to the patient, who is caught unaware in this web of economic gain. It is scandalous, in my opinion, Mr. Chairman, that in the United States this type of compendium is produced by private industry; in nearly all other nations the importance of such a listing and its need for universality is recognized, and the responsible governmental authority publishes this document.

The efforts of the major pharmaceutical firms to influence doctors have been successful. Physicians, unaware or unconcerned that a majority of the prescriptions they write are for multiple-source drugs, continue to prescribe medication by brand-name. If pharmacists were required to substitute generic equivalents for such multiple-source drugs, as is the case in only a handful of states, the distorting effects of the industry's pro-trademark promotional campaign could be sidestepped to a certain extent and consumers saved a considerable amount of money.

Opponents of generic dispensing—primarily the brand name manufacturers whose philosophy is "big makes best"—argue that distinct manufacturing processes may produce therapeutic differences in equivalent drugs made by different companies.

The assertion that repeal of anti-substitution laws will result in a deluge of inferior, foreign-made drugs into the U.S. market is typical of the hysterical, misleading and inaccurate scare tactics employed by opponents. Obviously, the high U.S. standards will remain in effect. According to the FDA:

All drugs, whether they are sold under their brand names or their generic names, must meet the same FDA standards for safety, strength, purity, and effectiveness. And all drug manufacturers, big or small, are subject to FDA inspection and must follow the Agency's Current Good Manufacturing Practice Regulations. That is why FDA believes there is no significant difference in quality between generic and brand name drugs.

In fact, some of the big brand-name products may actually have been produced by one of the small drug firms. It is not unusual for big and small drug companies alike to buy bulk from the same manufacturer and package the product under their own separate names, some generic and some trademarked.

Even the American Pharmaceutical Association admits it is unlikely that a drug "meeting established standards under federal drug laws will not perform clinically as expected," according to the testimony of its executive director, William Apple, before the Senate Finance Committee.

Furthermore, it is unfair of manufacturers to imply that pharmacists are not professional or responsible enough to stock and dispense only those drugs in which they have faith.

The National Academy of Sciences' Drug Research Board, in 1975, unanimously called for repeal of anti-substitution laws. It concluded that "in the absence of data to the contrary, there is no inherent reason for choosing the more expensive drug product simply because of the familiarity of the physician or pharmacist with the brand-name."

It is ridiculous to prohibit the general public from taking advantage of low-cost generic drugs when they have been used successfully for many years by the Veterans Administration, teaching institutions, hospitals in general, and even the Defense Department at a substantial cost savings. In addition, the Department of Health, Education and Welfare encourages pharmacists to dispense generically in the Medicare and Medicaid programs by using a maximum allowable cost (MAC) schedule, stipulating maximum reimbursements for multiple-source drugs. If gener-



ic drugs are good enough for these groups, why should everyone else be forced to pay for over-priced and over-promoted brand-name products?

Resistance to drug substitution comes not only from brand-name manufacturers who stand to lose money as a result of increased competition, but also from many doctors. Their concern is more a matter of professional pride than of economics, although their professional organizations have pocket-book motivation.

I want to stress that my proposals would in no way permit a pharmacist or anyone else to overrule a physician's decision. The basic diagnosis and the judgement for treatment remain with the physician, as they must. If he wishes a particular drug to be dispensed, his decision must and will be followed. All he need do is mark the prescription in his own handwriting, "no substitution" or "dispense this brand only."

The bill before us today, H.R. 1963 is a step in the right direction. It does not, however, go far enough. Pharmacists must be required, not just allowed, to substitute the lowest cost generic equivalent. If substitution is merely allowed, there would be too much temptation for the pharmacist to stock only the more profitable brand-name drug. The cozy relationship that has developed over the years between the pharmacists of this country and the brand-name drug companies is too strong to be broken by a law that only allows substitution to take place. A loophole like this could deprive consumers of most of the benefits a generic drug substitution bill could offer.

Furthermore, any legislation should state clearly that if the pharmacist does not stock or has run out of a generic equivalent drug, he should be required to dispense the brand-name drug at the lower generic price or refer the customer to another pharmacy.

The drug industry will not change overnight if we require substitution. Many drugs on the market today still are single-source and patent-protected. But, as patents expire, the number of multiple-source drugs increases, and even the name-brand manufacturers are marketing some so-called "generic lines" to capitalize on growing public awareness.

I also propose that the pharmacist be required to pass along to the consumer any savings that result from the substitution of a generic drug. I realize that a free market is the most effective means of accomplishing this, but given the lack of competition and consumer awareness in the market for prescription drugs, such a provision is needed, at least temporarily.

In order to insure the safety and health of Americans and to allay any fears about the quality of generic drugs, I propose that the FDA assemble a list of drugs for which there have been no demonstrated problems with bioequivalence and for which substitutions will be required. One potential use for such a formulary of drugs would be as an information resource by consumers to help them persuade their local pharmacist to stock a particular generic drug. In any case, it is about time that we have an official government-assembled compendium of prescription drugs clearly identifying therapeutic equivalents. The formulary should be continually revised and expanded by the FDA.

Besides the overuse of brand-names, one of the main reasons for high drug prices and high corporate profits is the lack of competition. I propose that H.R. 1963 be amended to require the posting of the prices of the 100 or so top selling drugs, as determined by the FDA. The list should be arranged alphabetically by generic name and should contain the lowest price charged for each generic and brand-name drug in its most commonly dispensed dosage, form and quantity. This measure would facilitate comparison shopping on the part of consumers and encourage them to be more price-conscious. Pharmacists have always seemed to treat the prices they charge as if they were top Defense Department secrets. The mandatory posting of drug prices would help change this as well as encourage some sorely needed competition at the neighborhood pharmacy counter.

I strongly suggest that H.R. 1963 be further amended to require the use of a drug's generic name whenever its brand-name appears. This would mean the use of generic names on prescription labels, in all retail advertising and on price posters. The use of different brand-names for the same drug is often very confusing to the consumer as well as to his doctor. The mandatory use of generic names will make it much easier for the consumer to shop intelligently for the lowest price. By introducing an element of consistency, generic labeling also will make drug-price posting and advertising, now permitted under a recent Supreme Court decision, more meaningful. Competition, a crucial element in our economy but one too long absent from retail pharmacy, will be enhanced as consumers become able to shop for the best buy.



Although the Supreme Court has allowed retail pharmacists to advertise, many have been reluctant to do so. I urge the subcommittee to consider a provision to authorize the FTC, FDA, and the Secretary of HEW to cooperate in encouraging pharmacists to advertise drug prices. All restrictions or impediments to price advertising on the part of states or their boards of pharmacy should be strictly prohibited. In addition, guidelines on the use of advertising should be issued so as to prevent any abuse in this area.

Over the years, pharmacists, doctors and drug companies together have effectively insured that the consumer purchases the most expensive drug on the market. We must change this. We must introduce an element of the free enterprise system into the retail drug industry. The amendments I have proposed today, if adopted, would mark a major advance in combating inflationary health costs, while contributing to the health and safety of consumers. Mandating the substitution of generic drugs will encourage the use of the lowest cost drugs available. A formulary developed by the FDA will assure the American consumer that he is getting a safe and effective drug. The mandatory use of generic names, the posting of drug prices and the promotion of retail advertising will help consumers shop wisely, while trimming the fat off the prices we now pay for prescription drugs.

The proposals I have set forth today would mean significant savings for millions of Americans at absolutely no risk to personal health. They pose a threat only to the bloated profits of a number of large corporations who would rather keep the American consumer paying in the dark.

#### STATEMENT OF THE AMERICAN MEDICAL ASSOCIATION

The American Medical Association takes this opportunity to submit its comments regarding H.R. 1963, the "Substitute Prescription Drug Act".

H.R. 1963 would authorize pharmacists, when a physician issues a prescription order for a drug designated by a "brand" or "proprietary" name, to dispense a substitute drug ("generic drug") to the patient if the physician does not specify on the prescription order that only the product named in the order should be dispensed and if the cost of the substitute drug to the patient is less than the named product and any other equivalent drug in the pharmacist's inventory. If the patient requests that the order be filled with a drug product different from that selected by the pharmacist, the substitution authority would not apply. Once the pharmacist exercises the option of substituting a "generic drug" for the "brand name" product or when the physician prescribes generically, the pharmacist would be required to dispense the lowest cost generic product that was available in his inventory.

Provisions of H.R. 1963 would apply to all prescription drug transactions, including those for which no federal reimbursement is involved, except for drug benefits payable pursuant to Part B of Medicare. The bill would preempt all state laws and regulations regarding drug substitution that would be different in effect from the provisions of the bill.

For the reasons stated below, the American Medical Association recommends that H.R. 1963 not be enacted.

#### PREEMPTION OF STATE LAW

The bill would preempt all state laws regarding the prescribing and dispensing of drugs that would differ from the requirements contained in the bill.

The regulation of drug prescribing and dispensing has traditionally and properly been placed with the states. State regulation in this area is pervasive in all fifty states.

We believe that the preemption contemplated by this bill is inappropriate and unnecessary, especially in the case of substitution of drug products. Nearly forty states have enacted legislation that would modify the so-called anti-substitution laws. Each state has developed a program that it believes best suited to its local conditions, needs and practices. Not all states have adopted the same program and the fact that there are various programs for substitution indicates that there is no one right program that would be optimal nationwide.

We also question the basis for federal intervention into the practice of medicine and pharmacy, especially with private transactions when no federal expenditures or interests are directly involved.

We do not believe that direct federal intervention into the practice of pharmacy and medicine is appropriate or that state pharmacy laws should be preempted by federal legislation.



## PRESCRIPTION DRUGS PRESCRIBING

The use of therapeutic drugs in the treatment of illness and disease is an integral part of the practice of medicine. The decision to select drug therapy and then to select the particular drug that the patient is to receive has been properly vested with the physician. Treatment decisions are made by the physician based upon professional training, clinical experience and knowledge, familiarity with the patient and the patient's condition, and knowledge and experience with individual drugs.

The American Medical Association supports physician prescribing of drugs generically when, in the physician's professional opinion, such action would be in the best interest of the patient. However, cost considerations must remain secondary to the medical needs of the patient. When the physician, in exercising his professional judgment, believes that it is appropriate to delegate the source selection of a drug to the pharmacist, such intent can be made known by the physician's prescribing the generic name of the drug or if the brand name is used, by a notation "generic substitution allowed" ("GSA").

In this manner, the physician makes the affirmative medical determination regarding drug substitution and the presumption is established that when the physician prescribes by brand name and does not specifically authorize substitution that the brand name drug should be dispensed.

It is the physician who is professionally, ethically and legally responsible for the total course of the patient's treatment. Therefore, it is incumbent that the orders of the physician be carried out as written unless the order affirmatively indicates that a delegation is authorized. In this way, the physician can remain assured that the patient is receiving the best care possible with all therapeutic decisions known and coordinated by the physician.

## INTERCHANGEABILITY OF DRUGS BY GENERIC EQUIVALENCE

The Commissioner of Food and Drugs has repeatedly stated that generic substitution of drugs is appropriate in all classes of drugs. This statement is based upon the fact that FDA controls the approval, marketing, manufacturing and distribution of all drug products in the country. Therefore, it is contended by the FDA that there is only one standard of drugs available nationwide. While the Commissioner's statement may be corrected for certain drugs where bioavailability or bioequivalence is not a problem or where effective therapeutic ranges are not narrow, we do not believe that absolute equivalence for all drug products bearing the same generic or established name can presently be presumed or assured. FDA does monitor drugs to insure that they meet standards of strength, quality and purity. FDA is also now developing a program to monitor bioavailability of drugs. However, no control is currently exercised to assure that all inert ingredients of generic drugs are exactly the same and that patient compliance can be assured when drugs are substituted.

In monitoring good manufacturing practices, FDA sets minimum standards that must be met. If a formulator chooses to meet only these minimum standards of compliance, the obligation to FDA and therefore the "public health" is met. However, other formulators may choose to establish higher than mandated levels of quality control. By establishing higher standards, a formulator may establish a better record of quality control than those formulators who have chosen only to meet the minimum standards required by law. This reputation for quality control may be known to physicians who choose to prescribe by brand in order to rest assured that the product will produce the expected therapeutic response in the patient.

As recently as May of this year, the Journal of the American Medical Association (JAMA 239:1478, 1978) reported that significant bioequivalence problems exist for tetracycline hydrochloride. This finding is especially significant inasmuch as tetracycline, as an antibiotic, is subject to stringent FDA batch testing. It was noted that absorption rates and blood levels over a range of patients were inconsistent and that for some subjects certain products would not produce the desired therapeutic response at the dosages administered while for other patients blood levels would be adequate. If generic substitution of drugs is to be based upon the presumption that all generic drugs will produce the same therapeutic effect, then no patient should display substantially different blood plasma levels as a result of the interchange. The reported study indicates that such assurances cannot be made even for an FDA batch certified product.

Even the Department of Health, Education, and Welfare, in its maximum allowable cost reimbursement program, requires an affirmative showing that there are no bioavailability and bioequivalence problems for a drug product before a maximum allowance cost level will be set.



Therefore, we are not convinced that all drug products can be interchanged based upon generic or established names. Under the provisions of this legislation, the physician would have no assurance that the product actually dispensed to the patient would have the same therapeutic effect as the drug named in the prescription order.

#### BRAND NAME SUBSTITUTION UNDER H.R. 1963

H.R. 1963 would authorize a pharmacist to substitute a generic drug product for a brand name product unless: the physician would indicate on the order that no substitution should take place; or the price of the lowest cost generic equivalent in the pharmacist's stock would be higher than the drug as prescribed; or if the patient requests that no substitution take place.

The provision shifts the responsibility of drug source selection from the physician, where it properly belongs, to the pharmacist by giving the pharmacist total discretion as to whether substitution of a brand name product should or should not take place. We do not believe that this shift in responsibility is proper or in the best interest of the patient. Upon what factors is the pharmacist to base the decision on whether or not to substitute for a brand name? In most cases the pharmacist is not aware of the nature of the patient's medical condition. In many cases, the pharmacist may never even see the patient.

We do not believe that a physician's direct order to dispense a particular drug product should be interfered with. It should be the physician who determines whether substitution is appropriate. The physician can then either prescribe generically or, if a brand name is used, the prescription order can indicate whether substitution would be authorized.

#### DISPENSING THE LOWEST COST DRUG IN STOCK

Unless specifically directed by the physician or patient to the contrary, H.R. 1963 would require that whenever dispensing a prescription order for a drug prescribed generically or when a substitution is being made for a "brand name" drug, a pharmacist would be required to dispense the lowest cost substitute drug in inventory.

It appears that the intent of this provision is to insure that there be a cost savings to patients on drug purchases. However, in our opinion, the selection of prescription drugs based upon price as the sole determinative would most assuredly lower the quality of patient care. Furthermore, when a pharmacist would fill or refill with a product based on the price only, neither the patient nor the physician would be assured that the patient would receive the same or comparable drug product every time a new supply of the drug was needed. This is especially critical when the range of the drug's efficacy is very limited.

The problem of patients receiving a different drug product every time a prescription is filled is also critical for older patients who use numerous drugs for extended periods of time. Oftentimes, identification of a drug by color is the only method for the patient to remember the proper drug to be taken at a particular time. However, under the terms of the bill, a patient receiving the lowest price drug when initially filling the prescription could receive a pink tablet, and when refilling the same prescription receive a blue tablet. This situation may lead to patient confusion and lower patient compliance. Likewise it is not unusual for a patient to notice an error in filling the drug prescription because the drug dispensed is the "wrong" color.

Finally, there is no assurance that the cost savings from the use of the least expensive drug would be passed on to the patient or that low cost generics would necessarily be stocked by a pharmacist.

We believe that the provisions for substituting only the lowest cost available generic drug are inappropriate and should be deleted. We believe that this provision raises a basic inconsistency in the bill, whereby pharmacists are presumed competent to make the medical decision of whether a physician's direct order should be followed or not but are not competent to select the source of the product except according to price.

#### CONCLUSION

The American Medical Association recommends that H.R. 1963 not be enacted. We believe that the bill would improperly interfere with both the practice of medicine and of pharmacy as well as being an inappropriate intrusion into an area properly subject to state regulation. We believe that enactment of this legislation would interfere with the physician/patient relationship whereby the patient can rely upon the physician for the total medical management of his condition. We also believe that the bill would unduly restrict the professional judgment of pharmacists



by requiring that a pharmacist dispense only the lowest cost substitute drug contained in the pharmacist's inventory.

The possible cost savings to be derived from this type of mandatory federal control does not adequately offset the risk to patients when certain drugs, for whatever reasons, provide inconsistent therapeutic responses. We wholeheartedly concur in the following statement of a former Secretary of HEW:

"Every physician must be free to prescribe whatever medication he believes is most appropriate for his patient. It is not the business of government to tell doctors what marketed drugs they may or may not prescribe. This is, and must remain, solely a matter of the professional judgment of the prescribing physician."

In this regard, it should not have to be necessary for a physician to take affirmative action to negate directives of the government to the contrary.

The American Medical Association recommends that H.R. 1963 not be adopted.

STATEMENT OF HENRY DEREWICZ, DIRECTOR OF PHARMACY SERVICES, THE JOHNS HOPKINS HOSPITAL, BALTIMORE, MD.

Mr. Chairman, members of the Subcommittee, I am Henry Derewicz, Director of Pharmacy Services at Johns Hopkins Hospital in Baltimore, Maryland and am associate clinical professor at the University of Maryland School of Pharmacy. I have been a pharmacist for 20 years and have been associated with three other major institutions in the United States during my career. I am a member of the American Society of Hospital Pharmacists, having just completed my term of appointment to its Board of Directors. I am pleased and honored that the Subcommittee has afforded me this opportunity to express some personal and professional views on H.R. 1963, the Substitute Prescription Drug Act.

I support the principles of this legislation, authorizing the pharmacist to engage in product selection when filling prescription drugs and pre-empting state antitrust and product selection laws. My experience has convinced me that there is no good reason not to do it and some very good reasons why it should be done.

BACKGROUND

For over 150 years hospital pharmacists, through the hospital formulary system, have engaged in drug product selection as part of high quality medical care. The formulary system has traditionally been perceived as a tool for promoting quality drug therapy within the hospital. It has also facilitated simplified, safer and more efficient prescribing by including only one drug product under its generic nomenclature when multiple sources of supply are available. Lastly, it is a tool for containing drug costs. As the Task Force on Prescription Drugs stated in its final report:

"The use of a formulary is not a mark of second class medicine, but is, in fact, associated with the provision of the highest quality of medicine in the outstanding hospitals in the Nation.

Although use of a formulary is not a guarantee of high quality medical care, rational prescribing, effective utilization review, and control of costs, the achievement of these objectives in a drug program is difficult if not impossible without it."

While a hospital formulary is not wholly cost-related in purpose, it is beyond question that it has substantial economic benefits. I have attached an article, Swift & Ryan, Potential Economic Effects of a Brand Standardization Policy in a 1000-Bed Hospital, which appeared in the December 1975 issue of the American Journal of Hospital Pharmacy and which documents these benefits. Elimination of product duplication, reduction of inventory, use of non-brand name drugs when possible and competitive bidding have resulted in significant cost savings without any diminishment in quality of patient care. The Final Report of the Task Force on Prescription Drugs indicated that a savings of 55.3 percent on 63 multiple source drugs was possible using generic prescribing and product selection; overall savings of 25-36 percent is probably a more accurate estimate if the pharmacist is given authority to choose the least expensive drug product for his patient. By 1981 the patent protection of 84 percent of the top 409 drugs on the Master Drug List will have expired, providing potentially greater savings to consumers of drugs under the formulary system.

The hospital formulary system provides a mechanism for pharmacists and representatives of the medical staff to exercise informed judgement to evaluate, assess and select those therapeutic and diagnostic moieties (drug entities) most useful in patient care. (I have attached the Statement of Guiding Principles of the Hospital Formulary System, published by the American Society of Hospital Pharmacists, for your information.) Initially, the Pharmacy and Therapeutics Committee, consisting of representatives of the medical staff, pharmacy service and other professional



departments, make an evaluation of the clinical appropriateness of including a particular drug entity in a hospital formulary; hospital pharmacists play a significant role in providing the Committee with evaluative information necessary to make its decisions.

Once a drug entity is selected for inclusion in a formulary, the pharmacist assumes authority and responsibility for selecting specific drug products for use in a hospital from sources of supply of the drug entity. Generally this product selection authority is controlled by the pharmacist in the exercise of professional judgement without other restrictions. Over fifteen years ago, a study at the University of Chicago concluded that even without a formulary system, as many as 50 percent of all drug orders within an institution were written by nonproprietary name and thus granted authority to the pharmacist to engage in drug product selection; examples of clinically critical drugs ordered by nonproprietary name are preoperative medications (e.g., atropine, scopolamine), postoperative medications (e.g., morphine), intravenous admixture fluids, electrolytes and antibiotics. A recent study by the American Society of Hospital Pharmacists indicated that over 70 percent of all hospitals authorize the pharmacist to select the source of drug products for use in a formulary.

Product selection by the pharmacist involves a determination of quality and then cost considerations. Factors such as manufacturing process, non-therapeutic adjuvants, formulation, palatability and the like must all be considered in drug product selection. In some cases we may not purchase the lowest unit cost drug product, but rather, after consideration of such factors as those listed above, purchase one that is, in the exercise of professional discretion, believed to be the most effective product available.

Pharmacists are the only health professionals uniquely and specifically trained in all aspects of drug selection, quality control, biopharmaceutics, formulation, storage, packaging, use and control. A minimum of five years of professional education is required for entry into the profession and many practitioners now go on to complete additional specialized training and obtain advanced professional degrees.

Before moving to specific provisions of H.R. 1963, let me summarize my earlier comments. Pharmacist controlled selection in hospitals has been the standard of practice for more than thirty years without any adverse effects upon patients. I therefore, conclude that society should be given the benefit of the expertise of the pharmacist in a manner that will aid the patient and the physician.

#### THE BILL

I propose that Section 2(a)(1)(A) be more restrictive with respect to discretion granted to the physician to over-ride product selection authority of the pharmacist. Accordingly, while a physician over-ride is appropriate, I believe it should be a clearly conscious decision based upon specific therapeutic considerations. In order to avoid the unfortunate circumstances in which many prescription forms are pre-printed with the words "No Substitution," I recommend that Section 2(a)(1)(A) be amended to allow a physician to prohibit product selection only by handwritten direction in the case of a written prescription or by specific direction in the case of an oral prescription.

I also believe that Section 2(a)(1)(B), requiring dispensing of the lowest cost drug in inventory should be modified. Experience with the New York product selection law appears to demonstrate that "lowest cost" mandates often give rise to considerable antagonisms which might undermine the effectiveness of H.R. 1963. I also believe that in the long run it is preferable to use the natural forces of the marketplace to effect lower product costs than to attempt it by legislative order; in the case of H.R. 1963 the profession's confidence in a simple and straightforward law, the economic incentive to reduce inventory costs and a growing consumer awareness of savings through use of generic drugs will all combine to effect the goals of H.R. 1963 without risking the traumatic disruptions that a mandatory lowest cost policy might have.

In attempting to diminish the cost of drugs as commodities, we must recognize that they are potent substances which play a valuable role in health care. While the Food and Drug Administration attempts to assure that generic equivalents are of identical quality, even FDA recognizes that it cannot guarantee that such drugs will be "therapeutically equivalent." The therapeutic effect of any product is a function of compliance with a therapeutic regimen, and compliance may depend upon such noneconomic factors as palatability, color and size. For example, we serve our patient poorly if we are required to dispense a blue elixir as the lowest cost product if it is not palatable to a child although the red elixir, though more expensive, may be generally more palatable to children. An elderly patient accustomed to getting



white capsules for one condition and blue pills for another is ill served if economics suddenly creates a confusing situation when yellow—or worse, white capsules replace her blue pills. The pharmacist, as a health professional, must be able to exercise a professional judgement as well as an economic one in the interest of his patient and better health care. Accordingly, I recommend that Subsection 2(a)(1)(B)(ii) be deleted from the bill.

It is ironic that while we hear so much about the high price of prescription drugs and the need to systematically control health care costs, H.R. 1963 ultimately leaves this control to the quixotic choices of the consumer. It troubles me that at one extreme consumers and others complain about—and often blame the pharmacist for—the high cost of prescription drugs and at the other extreme the efforts of the entire legislative branch and of individual practitioners to develop a systematic methodology to reduce costs through product selection can be thwarted by the actions of individual consumers. It is especially illogical to do this when increasingly, the cost of prescription drugs are not borne by individuals but are public costs, borne by us all, through tax deductions and health insurance.

There already exist numerous quality controls to assure that drug product selection authority is exercised prudently: FDA identifies equivalent drugs and those with bioavailability/bioequivalency problems; physicians prescribe drugs and can make informed decisions whether product selection is permissible; pharmacists review a prescription to determine if economic and health factors justify product selection. All these decisions, based upon scientific and professional knowledge, should not be thwarted by a person exercising “the privilege” granted under Section 2(a)(2). I recommend Section 2(a)(2) be deleted.

I also support the concept of federal pre-emption of state antisubstitution laws; it is time for pharmacists and consumers throughout the country to have the benefit of uniform product selection laws instead of the outmoded patchwork of differing state laws.

Finally, I am concerned that H.R. 1963 might be construed to prohibit a hospital from operating a hospital formulary system. In light of the salutary effects of the formulary system, I recommend that Sections 3 and 4 be amended to explicitly authorize operation of a hospital formulary system.

#### CONCLUSION

I am confident, Mr. Chairman, that this bill, with these recommended changes, will aid the consumer without adversely affecting health care. Product selection in my hospital, and in the 7,500 other hospitals in this country has not presented any problem that a pharmacist, practicing in accord with professional standards cannot solve. My colleagues in the community, I am sure, can also protect the public health and save the consumer money, if you will give them that opportunity.

Thank you.



# statement of GUIDING PRINCIPLES ON THE OPERATION OF THE HOSPITAL FORMULARY SYSTEM

Approved by American Hospital Association, American Medical Association,  
American Pharmaceutical Association and AMERICAN SOCIETY OF HOSPITAL PHARMACISTS

## Preamble

► THE TREATMENT OF PATIENTS IN HOSPITALS in many cases is dependent upon the effective use of drugs. The multiplicity of drugs available makes it mandatory that a sound program of drug usage be developed within the hospital to ensure that patients receive the best care and protection possible.

In the interest of better patient care, there should be a program of objective evaluation, selection and use of medicinal agents in the hospital. This program is the basis of rational drug therapy. The hospital formulary concept is a method for providing such a program in hospitals and has been utilized as such over the years.

The hospital formulary system is based upon its approval by the organized medical staff, the concurrence of individual staff members and the functioning of a properly organized Pharmacy and Therapeutics Committee<sup>1</sup> of the medical staff. The basic policies and procedures governing the hospital formulary system should be incorporated in the medical staff bylaws, or in the medical staff rules and regulations.

<sup>1</sup>For recommendations of AHA and ASHP, see Statement of Pharmacy and Therapeutics Committee, adopted by the Board of Trustees of the American Hospital Association and the Executive Committee of the AMERICAN SOCIETY OF HOSPITAL PHARMACISTS in February 1959.

Action approving the above Statement was taken by the ASHP Board of Directors, meeting in Washington, January 10, 1964.

The Pharmacy and Therapeutics Committee, composed of physicians and pharmacists, selected under the guidance of the medical staff, represents the official organizational line of communication and liaison between the medical staff and the pharmacy. The Committee is responsible to the medical staff as a whole and its recommendations are subject to approval by the organized medical staff, as well as to the normal process of administrative approval.

This Committee assists in the formulation of broad professional policies relating to drugs in hospitals, including their evaluation or appraisal, selection, procurement, storage, distribution, use and safety procedures.

## Definition of Hospital Formulary and Hospital Formulary System

The hospital formulary is a continually revised compilation of pharmaceuticals which reflects the current clinical judgment of the medical staff.

The hospital formulary system is a method whereby the medical staff of a hospital, working through a Pharmacy and Therapeutics Committee, evaluates, appraises and selects from among numerous available medicinal agents and dosage forms those that are considered most useful in patient care.

The hospital formulary system provides for the procuring, prescribing, dispensing and administering of drugs under either their nonproprietary or proprietary names in instances where drugs have both names.

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### Guiding Principles

The following principles may serve as a guide to physicians, pharmacists and administrators in hospitals utilizing the hospital formulary system:

1. The medical staff shall appoint a Pharmacy and Therapeutics Committee composed of physicians, and pharmacists and outline its purposes, organization, function and scope.

2. The hospital formulary system shall be sponsored by the medical staff based upon the recommendations of the Pharmacy and Therapeutics Committee. The medical staff should adapt the principles of the hospital formulary system to the needs of the particular hospital.

3. The medical staff shall adopt written policies and procedures governing the hospital formulary system as developed by the Pharmacy and Therapeutics Committee. Action of the medical staff is subject to the normal process of administrative approval.

These policies and procedures shall afford guidance in the evaluation or appraisal, selection, procurement, storage, distribution, use, safety procedures, and other matters relating to drugs in the hospital and shall be published in the hospital's formulary or other media available to all members of the medical staff.

4. To insure the maintenance of the responsibility and prerogatives of the physician in the exercise of his professional judgment, the hospital formulary system shall not contain any policies or procedures which, prior to the time of prescribing, provide for consent by the physician to the dispensing of a nonproprietary drug or to the dispensing of a proprietary brand different from the brand which he prescribed. However, it shall be within his discretion at the time of prescribing to approve or disapprove the dispensing of a nonproprietary drug or the dispensing of a different proprietary brand.

5. The medical staff shall adopt the policy of, and formulate the procedure for, including drugs in the formulary by their nonproprietary names, even though proprietary names are and will continue to be in common use in the hospital. Physicians may be encouraged to prescribe drugs under their nonproprietary names, although the nomenclature used is entirely a matter of the individual medical practitioner's discretion.

6. In the absence of written policies approved by the medical staff relative to the operation of the hospital formulary system, and authorization from the prescribing physician, the pharmacist must dispense the brand prescribed, bearing in mind his professional prerogative to confer with the physician should the prescribed brand be unavailable.

7. A hospital shall make certain that its nursing personnel are informed in writing (through its established means of communication) about the existence of the formulary system in the hospital and the procedures governing its operation.

8. In the formulation of policies and procedures, the terms "substitute" and "substitution" should be avoided, since these terms have been used to imply the unauthorized dispensing of a brand different from that prescribed or the dispensing of an entirely different drug, neither of which takes place under a properly operated hospital formulary system.

9. Provision shall be made to apprise the medical staff of changes in the working of the hospital formulary system or in the content of the hospital formulary.

10. Provision shall be made for the appraisal and use by members of the medical staff:

- a. of drugs not included in the formulary.
- b. of investigational drugs.<sup>2</sup>

11. The pharmacist, with the advice and guidance of the Pharmacy and Therapeutics Committee, shall be responsible for specifications as to quality, quantity, and source of supply of all drugs, chemicals, biologicals and pharmaceutical preparations used in the diagnosis and treatment of patients, and for assuring that quality is not compromised for economic considerations. When applicable, such products shall meet the standards of quality of the *United States Pharmacopeia* or *National Formulary*.

12. The labeling of a medication container with the nonproprietary name of the contents is always proper. The use of a proprietary name other than that describing the actual contents is improper if it is used in a manner that can be taken as descriptive of the contents, even though personnel familiar with the hospital formulary system may understand that it is not descriptive. The following format is recommended for labeling individual patient's containers used within hospitals:

(Nonproprietary Name)  
(Name of Manufacturer or Distributor)  
Note for information of staff:  
Prescription or order for  
(Proprietary Name)  
dispensed as per formulary policy; contents are  
same basic drug as prescribed but may be of  
another brand.

### Recommendation

A hospital formulary system, based upon these guiding principles, is considered to be important in drug therapy in hospitals. In the interest of better patient care, its adoption by hospital medical staffs is recommended.

<sup>2</sup> For recommendations of AHA and ASHP, see Statement of Principles Involved in the Use of Investigational Drugs in Hospitals, adopted by the Board of Trustees of the American Hospital Association in September 1957, and approved by the Executive Committee of the American Society of Hospital Pharmacists in June 1958.



where it is more constructive.

One should point out that ordinarily the mode of medication is abruptly terminated when the patient leaves the hospital and enters outpatient status. At this point he is assumed to be capable of appropriately medicating himself. Data on this point would indicate that this assumption is highly questionable.<sup>6,12</sup> It is our position that once the default probabilities have been assessed, the professional relationship that increases compliance must be initiated in advance of hospital discharge. Our data suggest that if effectively carried out, the beneficial effects of this relationship on treatment will persist after the patient has been discharged to outpatient status.

It is not uncommon for psychotropic drugs to be the only treatment provided to schizophrenic patients. Often this is prescribed and dispensed in routine fashion. Because pharmacists are the last professional contact in outpatient and other settings, they have an unusual opportunity not only to enlarge their therapeutic contribution through monitoring and counseling, but through their contact with patients, to humanize patient care and, in the process, improve it.

#### References

1. Latiolias C and Berry C: Misuse of prescription medications by outpatients, *Drug Intell Clin Pharm* 3:270-277 (Oct) 1969.
2. Stewart RB and Cluff LE: Commentary: a review of medication errors and compliance in ambulant patient, *Clin Pharmacol* 13:463 (Jul-Aug) 1972.
3. Lasagna L: Fault and default, *N Engl J Med* 289:267 (Aug 2) 1973.
4. Blackwell B: Patient compliance, *N Engl J Med* 289:249 (Aug 2) 1973.
5. Hoffmann RP, Moore WE and O'Dea LF: Medication problem confronted by the schizophrenic outpatient, *J Am Pharm Assoc NSI* 4:252 (May) 1974.
6. Gillien R and Barsky A: Diagnosis and management of patient noncompliance, *J Am Med Assoc* 228:1563-1567 (Jun 17) 1974.
7. Parkes CM, Brown GW and Monck EM: The general practitioner and the schizophrenic patient, *Brit Med J* 1:972-976 (Apr 7) 1962.
8. Lipman RS et al: Neurotics who fail to take their drugs, *Brit J Psych* 111:1043-1049 (Nov) 1965.
9. Bernstein R and Mason P: Effects of phenothiazine discontinuance in patients compensated from acute psychosis, *J Mt Sinai Hosp NY* 33:131-139 (Mar-Apr) 1966.
10. Wiener I: Psychodiagnosis in schizophrenia, 1st edition, John Wiley and Sons, New York, 1969, p 366-370.
11. Forrest FM and Forrest IS: A simple test for the detection of chlorpromazine in urine, *Am J Psych* 113:931-932 (Apr) 1957.
12. Forrest IS and Forrest FM: A rapid urine color test for thioridazine, *Am J Psych* 116:928-929 (Apr) 1960.
13. Rorschach H: Rorschach Ink Blot Test, Huber, Berne, Switzerland, 1921.
14. Irwin DS, Wertz W and Morgan D: Phenothiazine intake and staff attitudes, *Am J Psych* 127:1631 (Jun) 1971.
15. Richards A: Attitude and drug acceptance, *Brit J Psych* 110:46-52, 1964.

*Am J Hosp Pharm* 32:1242-1250 (Dec) 1975

## Potential economic effects of a brand standardization policy in a 1000-bed hospital

Robert G. Swift, Jr. and Michael R. Ryan

The potential economic effects of a brand standardization policy on 50 multiple source, nonproprietary drugs in a 1000-bed hospital which uses a unit dose drug distribution system were studied.

Inpatient drug usage cost and inpatient drug inventory cost for the year 1974 were compared under the existing nonformulary system and a simulated formulary system of brand standardization. Drug usage cost was defined as expenditures made by the study hospital for drugs which were administered. Drug inventory cost was defined as the dollar value of drug inventory being stored for use in the hospital.

Potential savings in excess of \$55,000 for drug usage cost and \$9,000 for drug inventory cost could have been realized with a brand standardization policy on 50 nonproprietary drugs. The differences in costs were significant at the 0.005 level. It is concluded that a brand standardization policy can be an effective means of reducing drug usage cost and drug inventory cost in a large hospital.

**Key words:** Costs; Drug distribution systems; Economics; Equivalency, generic; Inventory; Pharmacy, institutional, hospital

This study determined potential economic effects of a brand standardization policy on a large, private, nonprof-

it hospital which uses a unit dose drug distribution system. Drug usage cost and drug inventory cost for 50 nonproprietary drugs were studied under both a nonformulary system and a formulary system of brand standardization for the year 1974. Because the hospital under study does not control, in any manner, the drugs prescribed or purchased for that hospital, the data collected under this system were used as the nonformulary data. Data for the formulary system of brand standardization were projected from nonformulary data and computer simulation. A

Robert G. Swift, Jr., M.S., is a pharmacist for Appalachian Regional Hospitals in Hazard, Kentucky. Michael R. Ryan, Ph.D., is Associate Director, American College of Apothecaries, and Associate Professor and Director of the Division of Pharmacy Administration, College of Pharmacy, University of Tennessee, Memphis 38163.

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comparison of drug usage cost and drug inventory cost between the nonformulary and formulary systems indicated potential economic effects of a brand standardization policy in a large hospital.

#### Review of the Literature

Data concerning the financial effects of any policies which restrict drug purchasing are relatively scarce in the literature. In 1966, the Task Force on Prescription Drugs<sup>1</sup> estimated a potential material savings of 41.5 million dollars obtainable by using lower cost nonproprietary drugs for 63 multiple source products. The Secretary of the Department of Health, Education, and Welfare (HEW) has estimated a savings in HEW-funded drug programs of 22-36% on multiple source products by implementing the maximum allowable cost regulations<sup>2</sup> which place a ceiling price on multiple source, nonproprietary drug items. In 1971, Strom, Stolley and Brown<sup>3</sup> calculated that a national savings of at least 224 million dollars annually could be realized if the acquisition cost of the least expensive product was used for 100 of the most frequently used nonproprietary drug products. Rucker<sup>4</sup> has stated that cost savings generated by using the lowest cost generically equivalent items are not likely to exceed 6%. However, Rucker further stated that these savings are not insignificant in multibillion dollar drug programs. Each of these studies projected possible national savings by standardizing drug products of multiple source, nonproprietary drugs. However, these studies did not examine possible national savings which could result from the implementation of volume and bid purchasing procedures. Savings due to reduced inventories also were not discussed.

By examining average per recipient drug expenditures for state medical care programs, Hammel<sup>5</sup> concluded that the data found no support for the existence of a relationship between the use of a formulary and expenditure reductions for all services. He found southern states with formularies had higher average per recipient expenditures than southern states not using restrictive formularies. Western states which had implemented formulary systems showed only slightly lower average per recipient expenditures than western states not using formularies. However, variations in drug benefits provided by each state as well as administrative costs incurred in each of these state programs could affect the average per recipient expenditures. Therefore, in this type of study, variables other than the use of restrictive formulary systems could potentially bias the data.

Several states have implemented formulary systems to reduce drug expenditures. The Massachusetts Drug Formulary Commission estimated that it "might save ten million dollars" in the first year through effective use of the formulary in Massachusetts.<sup>6</sup> The Pennsylvania Department of Public Welfare introduced a formulary system in an effort to reduce state drug costs.<sup>7</sup> Meyer, Bates and Swift<sup>8</sup> have estimated a savings of \$400,000 annually in the state of Tennessee by establishing price ceilings for

13 drugs. Again, the state savings are only in terms of standardizing drug products. The effects of implementing bid purchasing and controlling inventory levels were not discussed.

In studying approximately 20 of 95 western Pennsylvania hospitals, Wolfe<sup>9</sup> found that drugs with generically equivalent alternatives constituted 29.53% of all drug orders and accounted for 16.81% of total drug cost. A savings of 21.19% of this drug cost was predicted if the lowest cost generically equivalent drugs were always purchased and other considerations were ignored. Wolfe concluded that an overall savings of 3.57% of total drug costs amounting to \$600,000 for all western Pennsylvania hospitals could be realized. He further extrapolated these figures to predict a national hospital drug cost savings of approximately 42 million dollars annually. In this study, it was not mentioned if any of the 20 hospitals studied were using a unit dose drug distribution system. The use of unit dose packaging would have reduced the sources of nonproprietary drugs and possibly lowered the total savings estimate. Also, the use of bid purchasing or volume purchasing to lower acquisition costs was not done.

Foulkes<sup>10</sup> reported a 61% reduction in antibiotic costs by having physicians fill out a cost comparison requisition form. This form presented a cost comparison of different product entities with similar therapeutic activity. In three months, acquisition costs of seven antibiotics were reduced from \$3,400 to \$1,256—a difference of \$2,144. This study revealed a large reduction in cost of seven antibiotics even without brand standardization or bid purchasing. Of course, decreased use of the expensive antibiotics would probably be associated with an increased use of less expensive antibiotics.

Francke and others<sup>11</sup> compared annual expenditures and annual inventories for formulary and nonformulary hospitals in the United States. With the exception of hospitals with 300 to 399 beds, the annual expenditures for drugs and the annual inventories in hospitals with formulary systems were lower than in hospitals without formulary systems. In this study, the group of formulary hospitals was not divided by type of formulary system. This could affect the annual expenditures and annual inventory data. Also, at that time, the implementation of unit dose drug distribution systems in hospitals had not begun.

Possibly the most comprehensive study in the area of economic effects of formularies in hospitals was conducted by Rosner.<sup>12</sup> Using 24 nonteaching, voluntary hospitals ranging in size from 216 to 417 beds, Rosner measured the correlation of hospital size and three types of formulary systems to the cost per inpatient day and inventory turnover rate of pharmaceuticals.

The three types of formulary systems studied were: (1) unrestricted, (2) brand standardization, and (3) restrictive. Under the unrestricted system, all trade name products were available to the physician. With brand standardization, all nonproprietary drugs were available to the physician but trade name products of identical non-



proprietary drugs were restricted. The restrictive formulary system allowed for the use of only those nonproprietary drugs approved by the hospital and present on the formulary list. Thus, as formularies become more restrictive, it can be assumed that fewer products will be stocked in the pharmacy.

Rosner found that:

1. As the restrictiveness of the formulary increased, drug cost per inpatient day increased and inventory turnover rate decreased.
2. Brand standardization allowing the pharmacist greater authority to dispense a brand of drug other than the one prescribed was associated with a decrease in drug cost per inpatient day and an increase in inventory turnover rate.
3. As the number of items in inventory increased, drug cost per inpatient day increased and inventory turnover rate decreased.
4. Increases in hospital size were associated with decreases in drug cost per inpatient day and increases in inventory turnover rate.

From these data, Rosner concluded that "the mere existence of a formulary system is an empty weapon." This was demonstrated by increased drug cost per inpatient day and decreased inventory turnover rate under more restrictive formulary systems. Rosner further stated that formulary systems "can be used to further financial performance only if the pharmacist has the power to actually use it to restrict inventories." This conclusion was based on the data showing brand standardization policies which reduced the number of items in inventory, decreased the drug cost per inpatient day and increased inventory turnover rates for pharmaceuticals. Rosner did not determine dollar values of savings with formulary systems in this study. The study tried only to correlate three types of formulary systems with trends in drug cost per inpatient day and inventory turnover rate. Also, no mention was made of whether unit dose drug distribution systems were used in any of the 24 hospitals under study.

#### Objectives of the Study

The primary objective of this study was to analyze one type of restrictive formulary system, brand standardization, in a large hospital and determine its potential economic effects. Aspects of this brand standardization system included:

1. Stocking only one product of multiple source, nonproprietary drugs;
2. Obtaining competitive price quotations from drug manufacturers on these drugs; and
3. Establishing computerized inventory control methods for these drugs.

Analysis of the data produced by this study indicated dollar values of savings that might be possible by the use of this system in the areas of (1) drug usage cost of the drugs being studied and (2) inventory cost of these drugs.

Another objective of the study was to determine effects

of a brand standardization policy on the number of items of inventory kept in stock by the pharmacy. The data obtained by meeting these two objectives would provide information to hospital administrators regarding the economic benefits of a brand standardization policy.

A third objective was to determine the effect of a brand standardization policy on sources of drug supplies. A comparison of drug suppliers under both nonformulary and formulary systems was made for the drugs under study.

This study dealt only with the monetary aspects of a brand standardization policy in a large hospital. Judgments involving the quality of drug products used were excluded from the scope of this study. Bioavailability, more specifically, problems in bioavailability which have a potential for therapeutic inequivalence, is a complex area. General agreement is that some, but not all drugs contain the potential for therapeutic inequivalence.<sup>13</sup> However, there is much controversy over the extent and degree of lack of therapeutic equivalence of different formulations of the same drugs. One belief is that it is a serious and widespread problem.<sup>14</sup> Others believe that therapeutic deficiencies among products which comply with the official compendia standards are grossly exaggerated.<sup>15,16</sup> In this context, it is felt that bioavailability problems were not a serious deterrent to product selection by lowest cost in hospital formulary systems. In event the medical staff is of the opinion that a specific brand name product should be used, the mechanism for implementation would be the pharmacy and therapeutics committee.

#### Methodology of the Study

To analyze potential economic effects of a brand standardization policy in the hospital under study, 50 high use, multiple source, nonproprietary drug products commercially available in unit dose packaging were chosen and evaluated under both the nonformulary system currently in use and the proposed formulary system of brand standardization. Some drug entities appear more than once in the study since several dosage forms of the same drug appeared on the list. The 50 nonproprietary drug products selected for use in this study are shown in Table 1. The drugs are divided into therapeutic categories as established by the *American Hospital Formulary Service*.<sup>17</sup> The reason for this categorization was to determine which, if any, therapeutic categories of drugs responded more favorably, in terms of cost savings, to a formulary system of brand standardization.

The parameters used for evaluation were usage cost of the drugs and inventory cost of the drugs for the year 1974. Drug usage cost was defined as the dollar value expended by the hospital to purchase the drugs which were administered during 1974. Inventory cost was defined as the dollar value of drug products being stored for use in the pharmacy at a given point in time.

Because the hospital in which this study was conducted placed no restrictions on physician prescribing practices



Table 1. The 50 Nonproprietary Drugs Selected for Use in the Study According to Therapeutic Categories<sup>a</sup>

1. Antihistamine drugs
  - a. Diphenhydramine 50 mg capsule
  - b. Diphenhydramine 50 mg syringe
2. Anti-infective agents
  - a. Ampicillin 250 mg capsule
  - b. Ampicillin 500 mg capsule
  - c. Ampicillin 250 mg/5 ml oral suspension
  - d. Ampicillin 250 mg injection
  - e. Ampicillin 500 mg injection
  - f. Ampicillin 1.0 g injection
  - g. Carbenicillin 1.0 g injection
  - h. Doxycycline 100 mg capsule
  - i. Erythromycin 250 mg tablet
  - j. Penicillin G 5,000,000 unit injection
  - k. Procaine penicillin 600,000 unit syringe
  - l. Tetracycline 250 mg capsule
3. Autonomic drugs
  - a. Belladonna alkaloids with phenobarbital tablet
4. Blood formation and coagulation
  - a. Heparin 5,000 unit syringe
  - b. Heparin 7,500 unit syringe
  - c. Thrombin 1,000 unit topical liquid
  - d. Warfarin 5 mg tablet
  - e. Warfarin 10 mg tablet
5. Cardiovascular drugs
  - a. Digoxin 0.25 mg tablet
  - b. Isosorbide dinitrate 10 mg tablet
6. Central nervous system drugs
  - a. Acetaminophen 325 mg tablet
  - b. Aspirin 650 mg suppository
  - c. Chlorpromazine 25 mg tablet
  - d. Chlorpromazine 50 mg tablet
  - e. Diphenylhydantoin 100 mg capsule
  - f. Diphenylhydantoin 100 mg injection
  - g. Promethazine 25 mg injection<sup>b</sup>
  - h. Promethazine 50 mg injection<sup>b</sup>
  - i. Propoxyphene 65 mg capsule
  - j. Propoxyphene 65 mg with APC capsule
7. Electrolytic, caloric and water balance drugs
  - a. Potassium chloride 20 mEq injection
  - b. Potassium chloride 40 mEq injection
  - c. Potassium chloride 20 mEq/15 ml oral liquid
  - d. Potassium gluconate 20 mEq/15 ml oral liquid
8. Enzymes
  - a. Hyaluronidase 150 unit injection
9. Expectorants and cough preparations
  - a. Glyceryl guaiacolate 5 ml oral liquid
  - b. Glyceryl guaiacolate 10 ml oral liquid
10. Gastrointestinal drugs
  - a. Aluminum hydroxide - magnesium hydroxide 30 ml oral suspension
  - b. Bisacodyl 5 mg tablet
  - c. Bisacodyl 10 mg suppository
  - d. Castor oil 60 ml oral liquid
  - e. Dioctyl sodium sulfosuccinate 100 mg capsule
11. Hormones and synthetic substitutes
  - a. Prednisone 5 mg tablet
12. Oxytocics
  - a. Oxytocin 10 unit injection
13. Serums, toxoids and vaccines
  - a. Tetanus toxoid fluid 0.5 ml injection
14. Spasmolytics
  - a. Dyphylline 500 mg injection
  - b. Papaverine 150 mg capsule
15. Vitamins
  - a. Cyanocobalamin 10000 µg injection

<sup>a</sup>Therapeutic categories are given as listed in the *American Hospital Formulary Service*.

<sup>b</sup>Listed in the *American Hospital Formulary Service* as both an antihistamine and a central nervous system drug; placed in central nervous system category because of its phenothiazine structure and its principal use in the hospital under study as an antiemetic.

or pharmacy storage of any drug product, this system served as the nonformulary system. Data on drug usage cost and inventory cost for the 50 drugs under study were collected from actual 1974 drug purchasing and charging records. In calculating drug usage cost and drug inventory cost, the following formulas were used:

$$\begin{aligned} \text{Drug Usage} \times \text{Drug Cost} &= \text{Drug Usage Cost} & (1) \\ \text{Drug Inventory Level} \times \text{Drug Cost} &= & (2) \\ \text{Drug Inventory Cost} &= & (2) \end{aligned}$$

By adding costs for all brand name products of a nonproprietary drug, the total cost for that nonproprietary drug in the nonformulary system was determined.

Because implementation of a brand standardization policy in this hospital has not been possible, steps were taken to predict drug usage cost and inventory cost for the 50 drugs under the formulary system.

All known drug manufacturers<sup>18-20</sup> providing products in unit dose packaging were asked to submit competitive price quotations on the drugs under study. The lowest quotation was taken as the acquisition cost for that product under brand standardization. Drug usage for a drug in the formulary system was assumed to be identical to that in the nonformulary system. Knowing the acquisition cost and drug usage, the drug usage cost for drugs under the formulary system could be predicted accurately.

The use of a model was chosen as the method for determining inventory levels for drugs under the formulary system. A model is one way to evaluate several combinations of variables and determine the best results under the circumstances tested. To solve problems with a model, an artificial situation is created and designed to act as much like the real situation as possible. In this study, computer simulation was used to evaluate the variables of (1) daily drug demand, (2) shipping lag time for drug orders and (3) drug reorder points. Simulation of daily drug demand for one year was used to estimate inventory levels required for each of the 50 drugs. The inventory model produced estimations of average daily inventory and drug usage information. Multiplying acquisition cost by average daily inventory produced an estimate of inventory cost for drugs under the brand standardization system. For the inventory model to be acceptable, the drug usage information had to be within 5% of the actual drug usage formed for that nonproprietary drug under the nonformulary system.

#### Analysis of the Cost Comparison Data

A comparison of the drug usage cost and drug inventory cost for nonformulary and formulary systems generated the data needed to determine potential economic effects of a brand standardization policy on a 1000-bed hospital that uses a unit dose drug distribution system. These comparisons were made by therapeutic categories. Examination of therapeutic categories revealed which categories were more responsive to potential monetary benefits available with a brand standardization policy.



Significant differences in drug usage cost and drug inventory cost between the formulary and nonformulary systems were obtained when the data were evaluated by statistical analysis with the Wilcoxon matched-pairs signed-ranks test. This test was selected over other non-parametric tests, most notably the chi-square test, because (1) the two samples were related, not independent, and (2) both magnitude and direction of sample differences were considered. The Wilcoxon matched-pairs test has a power-efficiency of about 95% of the parametric  $t$  test without requiring the stringent population assumptions needed for the  $t$  test.

With this test, the null hypothesis was:

$H_0$ : There is no difference in drug usage cost or drug inventory cost between the nonformulary and formulary systems.

The alternative hypothesis was:

$H_1$ : Drug usage or drug inventory cost will be less for the formulary system.

Because the alternative hypothesis states the direction of the change, a one-tailed test was required. The level of significance used was  $\alpha = 0.005$ .  $H_0$  is rejected and  $H_1$  accepted when the probability associated with the occurrence of  $H_0$  yielded by the statistical test is equal to or less than 0.005.

#### Results and Discussion

Tables 2 and 3 present the drug usage cost data and drug inventory cost data by therapeutic categories. From Table 2, it can be seen that the therapeutic categories of anti-infective agents and central nervous system drugs accounted for the largest portion of potential drug usage

cost savings. Savings in these two categories amounted to \$27,254.09 or 77.6% of the total savings under the brand standardization policy. These categories comprised 58.5% of total drug usage costs for the nonformulary system. At least 50% savings in usage cost were found in the following therapeutic categories:

1. Anti-infective drugs,
2. Cardiovascular drugs,
3. Central nervous system drugs, and
4. Spasmodic agents.

Three categories showed a usage cost savings of less than 10%. These categories were:

1. Blood formation and coagulation drugs,
2. Enzymes, and
3. Hormones and synthetic substitutes.

In the area of drug inventory cost shown in Table 3, three categories consisting of anti-infective agents, central nervous system drugs and electrolytic, caloric water balance drugs accounted for the majority of the savings incurred under brand standardization. These categories were responsible for inventory cost savings of \$7,758.63 amounting to 82.6% of the total savings. These three categories comprised 74.6% of the total inventory cost for the system of no brand standardization. Enzymes and blood formation and coagulation were the only two therapeutic categories which showed less than a 40% savings in inventory cost under the brand standardization policy. These categories showed an increase in inventory cost under the formulary system.

Examination of the totals presented in Table 2 revealed that under the current system of no brand standardization in the hospital under study, the usage cost to the hospital during 1974 for 50 nonproprietary drugs in 15 thera-

Table 2. Effect of Brand Standardization on Drug Usage Cost for Various Therapeutic Categories

| THERAPEUTIC CATEGORIES                  | COST OF DRUGS<br>(\$)            |                               | SAVINGS WITH<br>BRAND STANDARDIZATION |      |
|-----------------------------------------|----------------------------------|-------------------------------|---------------------------------------|------|
|                                         | NO BRAND<br>STANDARD-<br>IZATION | BRAND<br>STANDARD-<br>IZATION |                                       |      |
|                                         |                                  |                               | \$                                    | %    |
| Antihistamine drugs                     | 2,203.20                         | 1,408.75                      | 794.45                                | 36.1 |
| Anti-infective drugs                    | 26,466.27                        | 12,757.88                     | 13,708.39                             | 51.8 |
| Autonomic drugs                         | 165.92                           | 88.66                         | 77.26                                 | 46.6 |
| Blood formation and coagulation         | 11,710.02                        | 10,992.82                     | 717.20                                | 6.1  |
| Cardiovascular drugs                    | 254.77                           | 117.13                        | 137.64                                | 54.0 |
| Central nervous system drugs            | 26,192.84                        | 12,647.14                     | 13,545.70                             | 51.7 |
| Electrolytic, caloric and water balance | 5,552.95                         | 3,322.08                      | 2,230.87                              | 40.2 |
| Enzymes                                 | 1,065.24                         | 1,065.24                      | 0.00                                  | 0.0  |
| Expectorants and cough preparations     | 2,672.06                         | 2,022.43                      | 649.63                                | 24.3 |
| Gastrointestinal drugs                  | 4,201.08                         | 2,892.03                      | 1,309.05                              | 31.2 |
| Hormones and synthetic substitutes      | 140.79                           | 130.67                        | 10.12                                 | 7.2  |
| Oxytocics                               | 1,507.91                         | 1,166.63                      | 341.28                                | 22.6 |
| Serums, toxoids and vaccines            | 1,831.65                         | 1,509.60                      | 322.05                                | 17.6 |
| Spasmodics                              | 2,018.91                         | 1,008.57                      | 1,010.34                              | 50.0 |
| Vitamins                                | 1,005.90                         | 718.50                        | 287.40                                | 28.6 |
| Totals                                  | 86,989.51                        | 51,848.13                     | 35,141.38                             | 40.4 |



Table 3. Effect of Brand Standardization on Drug Inventory Cost for Various Therapeutic Categories

| THERAPEUTIC CATEGORIES                  | COST OF DRUGS<br>(\$)            |                               | SAVINGS WITH<br>BRAND STANDARDIZATION |       |
|-----------------------------------------|----------------------------------|-------------------------------|---------------------------------------|-------|
|                                         | NO BRAND<br>STANDARD-<br>IZATION | BRAND<br>STANDARD-<br>IZATION |                                       |       |
|                                         |                                  |                               | \$                                    | %     |
| Antihistamine drugs                     | 387.63                           | 92.22                         | 295.41                                | 76.2  |
| Anti-infective drugs                    | 5,327.08                         | 981.84                        | 4,345.24                              | 81.6  |
| Autonomic drugs                         | 11.12                            | 6.55                          | 4.57                                  | 41.1  |
| Blood formation and coagulation         | 810.26                           | 850.88                        | -50.62                                | -6.2  |
| Cardiovascular drugs                    | 65.40                            | 5.32                          | 60.08                                 | 91.9  |
| Central nervous system drugs            | 2,980.07                         | 728.43                        | 2,251.64                              | 75.6  |
| Electrolytic, caloric and water balance | 1,503.66                         | 314.91                        | 1,188.75                              | 77.3  |
| Enzymes                                 | 49.50                            | 73.26                         | -23.76                                | -48.0 |
| Expectorants and cough preparations     | 406.32                           | 152.35                        | 253.97                                | 62.5  |
| Gastrointestinal drugs                  | 633.23                           | 346.12                        | 287.11                                | 45.3  |
| Hormones and synthetic substitutes      | 40.08                            | 8.28                          | 31.80                                 | 79.3  |
| Oxytocics                               | 127.28                           | 53.07                         | 74.21                                 | 58.3  |
| Serums, toxoids and vaccines            | 262.44                           | 100.20                        | 162.24                                | 61.8  |
| Spasmolytics                            | 445.54                           | 72.76                         | 372.78                                | 83.7  |
| Vitamins                                | 108.36                           | 43.80                         | 64.56                                 | 59.6  |
| Total                                   | 13,157.97                        | 3,839.99                      | 9,317.98                              | 70.8  |

peutic categories was \$86,989.51. If a brand standardization policy had been in effect and the drug product with the lowest price quotation obtained through bid purchasing had been used for each nonproprietary drug, the usage cost to the hospital for these 50 drugs would have been \$51,848.13. The use of brand standardization with bid purchasing would have resulted in a drug usage cost savings of \$35,141.38 or 40.4% for 50 nonproprietary drugs in 1974. This potential \$35,141.38 savings for the 50 nonproprietary drugs under study amounted to more than 2.5% of total inpatient drug cost for 1974.

Statistical analysis of the drug usage cost data by the Wilcoxon matched-pairs signed-ranks test revealed a significant difference in the cost between the two systems.

Examination of the totals found in Table 3 revealed that under the current system of no brand standardization, the drug inventory cost to the hospital for 50 nonproprietary drugs in 15 therapeutic categories during 1974 was \$13,157.97. If a brand standardization policy had been implemented using inventory control procedures for each drug, the drug inventory cost to the hospital in 1974 would be estimated at \$3,839.99. This would have resulted in a potential drug inventory cost savings on 50 nonproprietary drugs of \$9,317.98 or 70.8% for the year 1974. This potential savings of \$9,317.98 for the 50 drugs under study accounted for approximately 4.0% of total inpatient inventory cost for 1974.

Statistical analysis of these inventory cost data by the Wilcoxon matched-pairs signed-ranks test revealed a significant difference in inventory cost between the two systems.

From the projected savings in the areas of drug usage cost, \$35,141.38 and drug inventory cost, \$9,317.98, under a brand standardization policy, a total savings of \$44,459.36 would have occurred. This amount represented the capital spent by the hospital under study in 1974,

which could have been used for other purposes. It should be noted, however, for purposes of future planning, the reduction in inventory represents a one-time savings while the reduction in usage costs can be expected to continue for a much longer period of time.

The number of items in a drug inventory has been shown to correlate with drug costs.<sup>12</sup> This correlation revealed the fewer items in inventory, the lower the cost. Table 4 lists the nonproprietary drug products in the study and the number of items stored in inventory for both the no-brand standardization system currently in use and the proposed brand standardization system. This table shows 93 items in the nonformulary system while showing only 50 items in the formulary system. This difference represents a reduction of 49%. Much of this product duplication occurred with the anti-infective agents—ampicillin, erythromycin and tetracycline. For 31 of the 50 multiple source drugs under study in the nonformulary system, the hospital stocked only one brand.

As stated earlier, the evaluation of the quality of drug products used in this study was beyond the scope of the study. However, Table 5 lists the companies from which the nonproprietary drugs under study were purchased in 1974, as well as the drug companies submitting the lowest price quotations for these drugs. In this study, 19 nonproprietary products selected for use under the brand standardization system because of lowest price were also the products dispensed most often under the nonformulary system in use during 1974. Another six drug products used in the formulary system because of their low price were being stocked in the hospital under study in 1974. Thus, one half of the nonproprietary drugs under study in the brand standardization system currently were being purchased by the hospital. Of the 25 nonproprietary products used in the study which were not being purchased by the hospital, 20 were sold by drug manufactur-



Table 4. Effect of Brand Standardization on Number of Items in Inventory

| NONPROPRIETARY<br>DRUG PRODUCTS                         | ITEMS OF INVENTORY<br>STOCKED                 |                                         | NONPROPRIETARY<br>DRUG PRODUCTS              | ITEMS OF INVENTORY<br>STOCKED                 |                                         |
|---------------------------------------------------------|-----------------------------------------------|-----------------------------------------|----------------------------------------------|-----------------------------------------------|-----------------------------------------|
|                                                         | NO<br>BRAND<br>STAN-<br>DARD-<br>IZA-<br>TION | BRAND<br>STAN-<br>DARD-<br>IZA-<br>TION |                                              | NO<br>BRAND<br>STAN-<br>DARD-<br>IZA-<br>TION | BRAND<br>STAN-<br>DARD-<br>IZA-<br>TION |
| Acetaminophen 325 mg tablet                             | 1                                             | 1                                       | Erythromycin 250 mg tablet                   | 5                                             | 1                                       |
| Aluminum hydroxide-magnesium hydroxide suspension 30 ml | 3                                             | 1                                       | Glyceryl guaiacolate 5 ml oral liquid        | 1                                             | 1                                       |
| Ampicillin 250 mg capsule                               | 6                                             | 1                                       | Glyceryl guaiacolate 10 ml oral liquid       | 1                                             | 1                                       |
| Ampicillin 500 mg capsule                               | 6                                             | 1                                       | Heparin 5000 unit injection                  | 1                                             | 1                                       |
| Ampicillin 250 mg/5 ml oral suspension                  | 5                                             | 1                                       | Heparin 7500 unit injection                  | 1                                             | 1                                       |
| Ampicillin 250 mg injection                             | 5                                             | 1                                       | Hyaluronidase 150 unit injection             | 1                                             | 1                                       |
| Ampicillin 500 mg injection                             | 5                                             | 1                                       | Isoorbide dinitrate 10 mg tablet             | 2                                             | 1                                       |
| Ampicillin 1.0 g injection                              | 3                                             | 1                                       | Oxylocin 10 unit injection                   | 2                                             | 1                                       |
| Aspirin 650 mg suppository                              | 1                                             | 1                                       | Papaverine 150 mg capsule                    | 3                                             | 1                                       |
| Belladonna alkaloid with phenobarbital tablet           | 2                                             | 1                                       | Penicillin G 5,000,000 unit injection        | 2                                             | 1                                       |
| Bisacodyl 5 mg tablet                                   | 1                                             | 1                                       | Potassium chloride 20 mEq injection          | 1                                             | 1                                       |
| Bisacodyl 10 mg suppository                             | 1                                             | 1                                       | Potassium chloride 40 mEq injection          | 1                                             | 1                                       |
| Carbenicillin 1.0 g injection                           | 2                                             | 1                                       | Potassium chloride 20 mEq/15 ml oral liquid  | 2                                             | 1                                       |
| Castor oil 60 ml oral liquid                            | 1                                             | 1                                       | Potassium gluconate 20 mEq/15 ml oral liquid | 1                                             | 1                                       |
| Chlorpromazine 25 mg tablet                             | 1                                             | 1                                       | Prednisone 5 mg tablet                       | 2                                             | 1                                       |
| Chlorpromazine 50 mg tablet                             | 1                                             | 1                                       | Procaine penicillin 600,000 unit syringe     | 3                                             | 1                                       |
| Cyanocobalamin 1000 µg injection                        | 1                                             | 1                                       | Promethazine 25 mg injection                 | 1                                             | 1                                       |
| Digoxin 0.25 mg tablet                                  | 1                                             | 1                                       | Promethazine 50 mg injection                 | 1                                             | 1                                       |
| Dioctyl sodium sulfosuccinate 100 mg capsule            | 1                                             | 1                                       | Propoxyphene 65 mg capsule                   | 1                                             | 1                                       |
| Diphenhydramine 50 mg capsule                           | 1                                             | 1                                       | Propoxyphene 65 mg with APC capsule          | 1                                             | 1                                       |
| Diphenhydramine 50 mg injection                         | 1                                             | 1                                       | Tetanus toxoid fluid injection               | 1                                             | 1                                       |
| Diphenylhydantoin 100 mg capsule                        | 1                                             | 1                                       | Tetracycline 250 mg capsule                  | 7                                             | 1                                       |
| Diphenylhydantoin 100 mg injection                      | 1                                             | 1                                       | Thrombin 1000 unit topical liquid            | 1                                             | 1                                       |
| Doxycycline 100 mg capsule                              | 1                                             | 1                                       | Warfarin 5 mg tablet                         | 1                                             | 1                                       |
| Dyphylline 500 mg injection                             | 2                                             | 1                                       | Warfarin 10 mg tablet                        | 1                                             | 1                                       |
|                                                         |                                               |                                         | Total Items of Inventory                     | 98                                            | 50                                      |

ers from whom the hospital had previously purchased products. Therefore, of the 50 nonproprietary products used in the formulary system, 45 were purchased from manufacturers currently dealing with the hospital.

#### Conclusions

Three conclusions were drawn from the data found in this study:

1. Brand standardization policies will lower drug usage cost and drug inventory cost in large hospitals,
2. Brand standardization policies will reduce the number of items in inventory for a large hospital, and
3. Brand standardization policies which reduce costs and

inventories can be implemented with minimal changes in drug suppliers.

From the data found in this study, potential savings were shown to be available under a brand standardization policy which allows for additional savings through bid purchasing. These savings amounted to \$35,141.38 in drug usage cost and \$9,317.93 in drug inventory cost for a total savings of \$44,459.36 for the year of 1974. When implementing a policy of brand standardization, the therapeutic categories of anti-infective agents and central nervous system drugs would be logical places to begin because these categories appear to account for a large amount of the potential savings.



Table 5. Drug Suppliers, Ranked According to Highest Volume, for 50 Nonproprietary Drug Products under Systems of No Brand Standardization and Brand Standardization

| NONPROPRIETARY<br>DRUG PRODUCTS                         | DRUG SUPPLIERS                                                                                                                                                                                                                                                                                                                                                                               |                               | NONPROPRIETARY<br>DRUG PRODUCTS              | DRUG SUPPLIERS                                                                           |                                                         |
|---------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------|----------------------------------------------|------------------------------------------------------------------------------------------|---------------------------------------------------------|
|                                                         | NO BRAND<br>STANDARD-<br>IZATION                                                                                                                                                                                                                                                                                                                                                             | BRAND<br>STANDARD-<br>IZATION |                                              | NO BRAND<br>STANDARD-<br>IZATION                                                         | BRAND<br>STANDARD-<br>IZATION                           |
| Acetaminophen 325 mg tablet                             | McNeil                                                                                                                                                                                                                                                                                                                                                                                       | McNeil                        | Diphenylhydantoin 100 mg capsule             | Parke-Davis                                                                              | McKesson                                                |
| Aluminum hydroxide-magnesium hydroxide suspension 30 ml | Rorer                                                                                                                                                                                                                                                                                                                                                                                        | Rorer                         | Diphenylhydantoin 100 mg injection           | Parke-Davis                                                                              | Rachelle                                                |
| Ampicillin 250 mg capsule                               | Wyeth<br>Squibb<br>Bristol<br>Wyeth<br>Reid-<br>Provident<br>Parke-Davis<br>Ayerst<br>Squibb<br>Bristol<br>Wyeth<br>Ayerst<br>Reid-<br>Provident<br>Parke-Davis<br>Bristol<br>Wyeth<br>Ayerst<br>Squibb<br>Bristol<br>Beecham-<br>Massengill<br>Ayerst<br>Wyeth<br>Parke-Davis<br>Bristol<br>Parke-Davis<br>Wyeth<br>Beecham-<br>Massengill<br>Ayerst<br>Bristol<br>Wyeth<br>Ayerst<br>Wyeth | Squibb                        | Doxycycline 100 mg capsule                   | Pfizer                                                                                   | Rachelle                                                |
| Ampicillin 50 mg capsule                                |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Dyphylline 500 mg capsule                    | Mallinckrodt                                                                             | Savage                                                  |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Erythromycin 250 mg tablet                   | Savage<br>Abbott<br>Lilly<br>Upjohn<br>Bristol<br>Robins                                 | Lilly                                                   |
| Ampicillin 250 mg/5 ml suspension                       |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Glycerol guaiacolate 5 ml liquid             |                                                                                          | Phillips<br>Roxane<br>Phillips<br>Roxane<br>Parke-Davis |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Glycerol guaiacolate 10 ml liquid            | Robins                                                                                   |                                                         |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Heparin 5000 unit injection                  | Parke-Davis                                                                              | Parke-Davis                                             |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Heparin 7500 unit injection                  | Parke-Davis                                                                              | Parke-Davis                                             |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Hyaluronidase 150 unit injection             | Wyeth                                                                                    | Wyeth                                                   |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Isosorbide dinitrate 10 mg tablet            | Ives                                                                                     | Ives                                                    |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Oxytocin 10 unit injection                   | Stuart<br>Parke-Davis                                                                    | Parke-Davis                                             |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Papaverine 150 mg capsule                    | Sandoz<br>Marion<br>USV<br>Hyrex-Key<br>Pfizer<br>Squibb<br>Abbott                       | Invenex                                                 |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Penicillin G 5,000,000 unit injection        |                                                                                          | Squibb                                                  |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Potassium chloride 20 mEq injection          | Abbott                                                                                   | American-<br>Quinine<br>Elkins-Sinn                     |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Potassium chloride 40 mEq injection          |                                                                                          |                                                         |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Potassium chloride 20 mEq/15 ml oral liquid  | Warren-Teed<br>Cooper                                                                    | Phillips<br>Roxane                                      |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Potassium gluconate 20 mEq/15 ml oral liquid | Warren-Teed                                                                              | Phillips<br>Roxane                                      |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Prednisone 5 mg tablet                       | Philips<br>Roxane<br>Upjohn<br>Wyeth<br>Squibb<br>Pfizer<br>Wyeth                        | Philips<br>Roxane<br>Wyeth                              |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Procaine penicillin 600,000 unit injection   |                                                                                          |                                                         |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Promethazine 25 mg capsule                   | Wyeth                                                                                    | Reid-<br>Provident<br>Reid-<br>Provident<br>Abbott      |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Promethazine 50 mg capsule                   | Lilly                                                                                    |                                                         |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Propoxyphene 65 mg capsule                   |                                                                                          | Phillips<br>Roxane<br>Wyeth                             |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Propoxyphene 65 mg with APC capsule          | Lilly                                                                                    |                                                         |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Tetanus toxoid fluid 0.5 ml injection        | Wyeth                                                                                    |                                                         |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Tetracycline 250 mg capsule                  | Squibb<br>Robins<br>Parke-Davis<br>Bristol<br>Upjohn<br>Lederle<br>Roerig<br>Parke-Davis | Squibb                                                  |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Thrombin 1000 unit topical liquid            |                                                                                          | Parke-Davis                                             |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Warfarin 5 mg tablet                         | Endo                                                                                     | Abbott                                                  |
|                                                         |                                                                                                                                                                                                                                                                                                                                                                                              |                               | Warfarin 10 mg tablet                        | Endo                                                                                     | Abbott                                                  |



To further illustrate these savings, with a current average hourly wage for pharmacists of \$7.00, the total savings found in this study could have provided an extra 6351 hours of pharmacists' time or more than three full-time positions during 1974. This total savings could have provided funding for 6.5 additional pharmacy residents in 1974, or seven additional pharmacy technicians. Extra manpower provided by these savings also could have been used to improve and develop services in other areas of the hospital.

These savings, of course, were realized from only 50 nonproprietary drugs accounting for only 98 items of inventory. If this type of policy was applied to all multiple source drugs in the hospital under study, the savings would certainly increase.

Two other factors should affect future monetary benefits available with brand standardization. The first factor is the probable increase in multiple source products as a result of patent expirations of current, popular, single source drugs. The most notable of the drugs facing patent expiration in the near future is diazepam. This one drug, currently manufactured by Roche Laboratories, accounted for a higher dollar volume of patient charges than any other single drug in the hospital under study during 1974. When this product becomes available from multiple sources, the cost of this drug can be expected to drop sharply. The other factor which should affect future monetary benefits from brand standardization is the apparent trend by manufacturers to jointly investigate a new drug and then market identical products under different trade names. This could result in the use of price competition as one element of the marketing strategy. With nonformulary systems, product duplication of these nonproprietary drugs is inevitable. An anti-infective agent manufactured as Bactrim by Roche Laboratories and Septra by Burroughs Wellcome Laboratories is an example of this technique. Cefazolin, a cephalosporin antibiotic is another example. It is manufactured as Ancef by Smith, Kline and French Laboratories and Kefzol by Eli Lilly and Company. A policy of brand standardization would allow hospitals to maximize savings under these two circumstances.

Of the 50 multiple source drugs studied, the hospital stocked drugs from only one source in 31 cases. Even with this, a 49% reduction in the number of items in inventory and a 70.8% savings in inventory cost were found under brand standardization. These figures indicated a favorable response of inventories to a brand standardization policy. These responses appeared to be due to (1) fewer items of inventory and (2) lower drug costs due to bid

purchasing.

The quality of drugs dispensed must be of primary concern to all hospital pharmacists. As stated earlier, evaluation of the quality of drugs used in the brand standardization system was beyond the scope of this study. However, it is interesting to note that 45 of the 50 drug products used in the brand standardization policy theoretically were purchased from drug manufacturers with whom the hospital under study was currently dealing. This fact gives evidence that brand standardization policies can significantly reduce drug usage cost and drug inventory cost while requiring only minimal changes in drug suppliers.

#### References

1. U.S. Department of Health, Education, and Welfare, Task Force on Prescription Drugs: Final report, Government Printing Office, Washington, D.C., 1969.
2. U.S. Department of Health, Education, and Welfare: Maximum allowable cost for drugs, *Fed Regist* 39:40302-40305 (Nov 15) 1974.
3. Strom BL, Stolley PD and Brown TC: Drug substitution studies: estimate of possible saving by repeal of antissubstitution laws, *Drugs Health Care* 1:99-103 (Spring) 1974.
4. Rucker TD: Drug insurance, formularies and pharmacy, *Med Marketing Media* 6:11-18 (Oct) 1971.
5. Hammel RW: Insights into public assistance medical care expenditures, *J Am Med Assoc* 219:1740-1744 (Mar 27) 1972.
6. Burack R: Massachusetts generic drug law, *N Engl J Med* 285:1327-1328 (Dec 2) 1971.
7. Anon: Pennsylvania welfare patients get prescriptions from formulary, *Hospitals* 41:108 (Sep 16) 1967.
8. Meyer MC, Bates H and Swift RG: The role of state formularies, *J Am Pharm Assoc NS14*:663-666 (Dec) 1974.
9. Wolfe H: How cost effective are generics?, *Hospitals* 47:100, 104, 106, 108 (May 1) 1973.
10. Foulkes RG: Can hospitals control drug costs?, *Hosp Admin (Canada)* 13:19, 22, 24, 25 (Jul) 1971.
11. Francke DE, Latiolais CJ, Francke GN, et al: Mirror to hospital pharmacy, Mack Printing Company, Easton, Pennsylvania, 1963.
12. Rosner MM: The financial effects of formularies in hospitals, *Am J Hosp Pharm* 23:673-675 (Dec) 1966.
13. Berlinger RW et al: Drug bioequivalence, a report of the Office of Technology Assessment, Drug Bioequivalence Study Panel, U.S. Government Printing Office, Washington, D.C., 1974.
14. Schiffman DO: On therapeutic equivalency and the anti-substitution laws, *J Am Med Assoc* 223:552-553 (Jan 29) 1973.
15. Feldmann EG: Drug product selection—freedom with responsibility, *J Am Pharm Assoc NS12*:368-374, 387 (Jul) 1972.
16. Schenberg IL: The quality and cost of prescription drugs, *J Am Pharm Assoc NS14*:241-243, 251 (May) 1974.
17. American Hospital Formulary Service, American Society of Hospital Pharmacists, Washington, D.C., 1974.
18. McLeod DC: Single unit packages of drugs available today—part 1, *Am J Hosp Pharm* 24:502-509 (Sep) 1967.
19. McLeod DC: Single unit packages of drugs available today—part 2, *Am J Hosp Pharm* 24:696-703 (Dec) 1967.
20. Stuart DM: Unit dose medications, *PharmIndex* 4-12 (Apr) 1973.

[Whereupon, at 4:30 p.m., the subcommittee adjourned.]





