P U B L I C H E A R I N G

before

ASSEMBLY COMMERCE, INDUSTRY AND PROFESSIONS COMMITTEE

on

ASSEMBLY BILL NO. 1257
(Generic Drug Substitution)

Held:
June 3, 1974
Assembly Chamber
State House
Trenton, New Jersey

MEMBERS OF COMMITTEE PRESENT:

Assemblyman Bryon M. Baer (Chairman)
Assemblyman Martin A. Herman
Assemblywoman Mary Keating Croce
Assemblyman Robert M. Ruane
Assemblyman C. Gus Rys
Assemblyman Arnold J. D'Ambrosa

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A-1257 (LATEST AMENDED VERSION) XXIV-R3

AN ACT concerning prescription drugs, authorizing substitution of drugs under certain circumstances, establishing a Drug Utilization Review Council, providing penalties for violations and making an appropriation for the purposes thereof.

BE IT ENACTED by the Senate and General Assembly of the State of New Jersey:

1. As used in this act unless the context clearly indicates otherwise:

a. "Brand name" means the proprietary name assigned to a drug by the manufacturer thereof.

b. "Established name" with respect to a drug or ingredient thereof, means (a) the applicable official name designated pursuant to the Federal Food, Drug and Cosmetic Act (Title 21, USC 301 et seq.), or (b) if there is no such official name and such drug or ingredient is recognized in an official compendium, then the official title thereof in such compendium, except that where a drug or ingredient is recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply, or (c) if neither (a) or (b) is applicable, then the common or usual name, if any, of such drug or ingredient.

c. "Prescription" means an order for drugs or combinations or mixtures thereof, written or signed by a duly licensed physician, dentist veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in man or animals, and includes orders for drugs or medicines or combinations or mixtures thereof transmitted to pharmacists through word of mouth, telephone, telegraph or other means of communication by a duly licensed physician, dentist, veterinarian or other medical practitioner licensed to write prescriptions intended for the treatment or prevention of disease in men or animals.

d. "Council" means the Drug Utilization Review Council.

e. "Chemically equivalent" applies to those drugs whose chemical constituency of active drug substance is identical.

f. "Reference drug product" means the product which is adopted by the council as the standard for other chemically equivalent drugs in terms of testing for the therapeutic equivalence. In all cases, the reference drug product shall be a currently marketed drug which is the subject of a full (not abbreviated) new drug application approved by the Federal Food and Drug Administration.

g. "Therapeutically equivalent" applies to those chemically equivalent drugs of the same strength and dosage form which in equal quantities produce the same clinical effect as the reference drug product as determined under the following criteria:

(1) Equivalence shall be demonstrated by bioavailability data meeting the bioavailability standards established for the reference drug product. Such standards shall where possible include

(a) in vitro dissolution data based on tests performed, where applicable, according to the latest edition of the United States Pharmacoepia or National Formulary; and

(b) blood serum concentration levels, based on clinical tests performed at 15 minute intervals upon a mixed patient population representing different parameters of age, sex, and state of health, demonstrating

(i) absorption rate and phase

(ii) peak level

(iii) duration of peak level

(iv) elimination phase;

and, where deemed necessary,

(c) clinical tests to demonstrate at the site of action levels of the substance having therapeutic activity,

such as tissue levels, fluid levels, or urine levels.

2. There is hereby established in the Department of Health a Drug Utilization Review Council to consist of eight members appointed by the Governor, and the Commissioner of Health or his designee. Of the members to be appointed by the Governor, two shall be licensed pharmacists, two shall be licensed physicians, two shall be persons with professional scientific or research experience in pharmacology, and two shall be members of the general public. The members appointed by the Governor shall serve for a term of five years and until their successors have been appointed and qualified, but of those first appointed, two shall be appointed for a term of two years, two for a term of three years, two for a term of four years, and two for a term of five years.

Vacancies shall be filled in the same manner as the original appointments but only for the unexpired term. Council members shall serve without compensation but the members appointed by the Governor shall be entitled to reimbursement for any necessary and reasonable expenses incurred in the performance of their duties hereunder, provided that the amount of such reimbursement shall not exceed $1,000.00 annually.

The council shall meet annually and elect a chairman and secretary from among its members. The chairman and secretary shall serve for a term of one year. The council shall meet at such other times to carry out its functions and duties at the call of the chairman or a majority of its members. The council shall be entitled to employ such technical and clerical personnel as it deems necessary within the limits of any appropriations made available therefor.

3. The council shall prepare a list of approved drug products by established names that are determined by the council to be therapeutically equivalent to brand name

drug products. No drug product shall be included in such list until after a public hearing has been held thereon after at least 20 days' notice. Such notice shall be mailed to all persons who have made a timely request of the council for advance notice of its public hearings and shall be published in the New Jersey Register.

The council shall distribute copies of the list of approved drug products and revisions thereof and additions thereto among physicians and other authorized prescribers and licensed pharmacists, and shall supply a copy to any person upon request, upon payment of the price established by the council.

The council shall be authorized to adopt reasonable rules and regulations, in accordance with the provisions of the Administrative Procedure Act, P.L. 1968, c. 410 (C.54:14B-1 et seq.), to carry out its functions and duties under this act and to effectuate its purposes.

The council shall also have the authority by rule or regulation, to specify the number of times a prescription may be refilled when not specified by the physician, to standardize dispensing quantities and to permit dosage form exchange where the council determines that no substantial therapeutic difference will result.

4. Notwithstanding any other law, unless the physician or other authorized prescriber explicity states otherwise when transmitting an oral prescription or in the case of a written prescription, indicates in his own writing or by initialing an appropriate, imprinted statement, a different brand name or nonbrand name drug product of the same established name shall be dispensed by a pharmacist if such different brand name or nonbrand name drug product shall reflect a lower cost to the consumer and is contained in the latest list of approved drug products published by the council, provided, however, that such action by the pharmacist shall be authorized only if in each case the pharmacist indicates on the prescription and immediately transmits notice, either orally or by written notice to be mailed no later than the end of the business day, to the prescriber specifying the drug product actually dispensed and the name of the manufacturer thereof.

5. Notwithstanding any other law, where a different brand name or nonbrand name drug product of the same established name shall reflect a lower cost to the consumer but is not included in the latest list of approved drug products published by the council, or where in the professional judgment of the pharmacist there is no valid proof of efficacy for the drug product prescribed, or the pharmacist's patient profile record discloses drug sensitivity, allergies or adverse reactions to the drug product prescribed, or there exist a more appropriate drug product than the drug product prescribed, a different brand name or nonbrand name drug product shall be dispensed by the pharmacist, provided, however, that such action by a pharmacist shall be authorized only if in each case the pharmacist notifies the prescriber of the drug product to be dispensed and the name of the manufacturer thereof, and receives the approval of the prescriber to substitute such drug product for the drug product prescribed. The pharmacist shall be required to indicate on the prescription the date and time of the prescriber's approval and whether the approval was communicated orally or in writing.

Whenever the latest list of approved drug products contains drug products of the same establish name, section 4 hereof shall be applicable notwithstanding that a brand name or nonbrand name drug product of the same established name as such drug products included on the list would reflect a lower cost to the consumer.

6. The pharmacist shall include on the label of any drug product dispensed pursuant to a prescription the brand name of such drug product, or the established name and the name of the manufacturer if a nonbrand name drug product is dispensed, except where the prescriber indicates to the contrary on the prescription. The full savings in cost resulting from any substitution hereunder shall be passed on to the consumer.

7. Any person violating any provision of this act shall be liable to a penalty of not less than $100.00 the first offense, and not less than $200.00 for each subsequent offense. Such penalty shall be collected and enforced by summary proceedings pursuant to the Penalty Enforcement Law (N.J.S. 2A:58-1 et seq.). Process shall issue at the suit of the Board of Pharmacy or the Attorney General, and shall be either in the nature of a summons or warrant.

8. There is hereby appropriated $7500.00 for the council for the purposes of this act.

9. This act shall take effect immediately.

BILLS LISTED FOR CONSIDERATION BY THE
ASSEMBLY STANDING REFERENCE COMMITTEES
OCTOBER 15, 1974

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ASSEMBLYMAN BYRON M. BAER (Chairman): This hearing on Assembly Bill 1257 will come to order.

I am Assemblyman Byron Baer, Chairman of the Committee. On my right is Assemblyman Martin Herman, who is Vice Chairman and who is also the sponsor of Assembly 1257. On my left is Assemblyman Gus Rys.

We already have a rather full list of witnesses. If there are persons present who are not now on the agenda - and if you haven't seen that agenda, Tom Bryan, who is the Staff Director to the Committee has a copy at the front desk - those persons not on the agenda may have their names placed on it by registering with Mr. Bryan. Because of the number of witnesses, we will need to hold to the schedule fairly closely. The schedule permits a total of about 20 minutes for each witness, which according to the way things normally work out, w i l l probably be taken up with ten minutes of initial testimony and ten minutes with questions that the Committee members may ask.

I hope that we can proceed without having a strict time limit on presentations and that you will limit yourselves with this over-all schedule in mind. If we do run behind, we will then have to begin limiting witnesses to strict periods of time.

There will be a 15-day period following this hearing, in which any person can submit written testimony or evidence to the Committee on this bill. That will be included in the hearing report which will be ultimately printed. So if anybody has had any difficulty in getting testimony ready in time for this hearing, that will be available.

Any statements from any Committee members before we proceed with the first witness? (No response.)

Dr. Duncan Hutcheon.

D R. D U N C A N H U T C H E O N: Assemblyman Baer, members of the Committee, and ladies and gentlemen, my name is Dr. Hutcheon. I am Professor of Pharmacology and Associate Professor of Medicine at the New Jersey College of Medicine. I have been trained in medicine and pharmacology and am presently doing clinical pharmacology at the Martland Hospital in the New Jersey Medical School.

The purpose of the laws that have been passed over the last 70 years have been to insure safety and efficacy to the consumer. The main point of the laws is to avoid the use of hazardous drugs and avoid some of the disasters that have occurred in the past. Economic factors, of course, are important, but are secondary to these main considerations.

On this basis, I would like to review two or three points in relation to the bill which I think deserve a little bit more consideration. If we look at page 2, the term "chemically equivalent" comes up, and then it goes on to talk about "therapeutically equivalent" and "biologically equivalent."

First of all, in relation to chemical equivalents, this is a much more complicated factor than would be indicated here. Just because a compound has the same chemical structure as another doesn't mean that it necessarily has the same properties and the same therapeutic activities. Standards have to be established and adhered to. All of these drugs are the results of complex chemical syntheses or extraction procedures and the purity has to be defined. Usually the USP lays down standards of purity and these have to be considered. So chemical equivalency there, I think needs some qualification.

The second thing that concerns me is the amount per tablet or dosage form. Exact standards have to be applied there to make sure that each dosage form contains the amount

stated. These sound simple, but the assays for these things are quite difficult and it is important in order to insure reliability that these are accurate. These are important factors. They may sound relatively mundane. But in 1970, 47 per cent of the Digoxin preparations were recalled from the market because of inaccurate dosage - nothing to do with bioavailability at that point - they just didn't meet the standards.

The third point is in relation to bioequivalency and here the bill spells out exactly how bioequivalency might be tested on preparations. These details I think should be omitted from the Act because they just don't apply to all drugs, perhaps to very few drugs, the exact details the way they are specified here. I think while bioequivalency information should be important, it should be spelled out in the Act in less detail than is given here.

The final point has to do with page 4, Section 4, line 9, where the point is made that the name of the drug product shall reflect a lower cost to the consumer. This appears earlier on in the Act too. The emphasis in the Act seems to be on economic factors and I would like to see built into the Act more cautionary words on consumer protection, safety, etc.

This brings up the point, how the Act could be monitored? How could drug preparations be assayed to make sure that they do fall within the limits of the law? This means reliance has to be on the Federal agency, the Federal Food and Drug Officers and their laboratories. At the present time, as we are all aware, the Federal Government is looking into this whole complex problem of generic substitution. Senator Kennedy's Committee has this under way. And because we will have to rely on the Food and Drug Administration for the surveillance of this and the

enforcement, I feel it would be unwise at this point to push through this Act until the Federal Government has the results of these committee studies that are currently under way.

I think that is about all I have to say to begin with. I would be happy to answer any questions, if you have any.

ASSEMBLYMAN BAER: I would like to ask in relation to your third point, that there is too much detail on the bioequivalency, have you specific language changes or proposals to make regarding that?

DR. HUTCHEON: Yes. I would suggest instead of the details there that perhaps we might say "standards shall include comparative bioavailability data provided in accordance with current FDA approved criteria and requirements," something of that order.

ASSEMBLYMAN HERMAN: Doctor, I assume that if the appropriate standards and safeguards which you speak of were available, you would be in favor of this type of legislation?

DR. HUTCHEON: I don't think at the present time we can say that. When we are treating patients - I am speaking more as a clinical pharmacologist in what I have said so far - but when we are treating patients, there are many sources of error and variation in our patients. And we want to make sure that the preparations that we are giving have the standards of efficacy and are free from toxicity. If we are in doubt about them, it makes therapy that much more difficult.

ASSEMBLYMAN HERMAN: Assuming for the purposes of health care, we could overcome the questions of doubt, you would have no objection then to this bill - assuming your objections could be overcome or met?

DR. HUTCHEON: Right. Again as to the timing, I think following the Federal Food and Drug legislation, which is pending, New Jersey should have legislation which would

conform with that.

ASSEMBLYMAN HERMAN: Just a few other questions if I may.

I believe you mentioned the safety factor in prescription at the present time. If I understand the law correctly, aren't doctors now permitted to prescribe by generics?

DR. HUTCHEON: Yes.

ASSEMBLYMAN HERMAN: And when doctors prescribe generically, the choice of brand is then left to the pharmacist; is that correct?

DR. HUTCHEON: That is correct.

ASSEMBLYMAN HERMAN: So basically today we do have built into our law permission where granted by the doctor to allow the pharmacist to exercise his best professional judgment in picking that brand of generic or generic which would fit the prescription as it is prescribed.

DR. HUTCHEON: That is correct. The only problem is - this doesn't apply across the board to all drugs. There are some drugs that a physician would just want to get one single manufacturer's preparation.

ASSEMBLYMAN HERMAN: That is not my question. The question was very simply, Doctor, this: Physicians are allowed under today's law to prescribe generically, are they not?

DR. HUTCHEON: Yes, certainly.

ASSEMBLYMAN HERMAN: And they are doing so throughout the United States with increasing frequency; isn't that correct, sir?

DR. HUTCHEON: Yes, I would say that.

ASSEMBLYMAN HERMAN: All right, Doctor. Thank you.

ASSEMBLYMAN RYS: Doctor, would you clarify one point? You spoke about 47 per cent being inaccurate in your statement. Was that 47 per cent of the manufacturer's

prescriptions?

DR. HUTCHEON: Forty-seven per cent of the preparations that were on the market were examined by the Food and Drug Administration and found to not meet the standards of purity described. That was just with Digoxin and now batch certification has to be obtained before these preparations are on the market.

ASSEMBLYMAN HERMAN: But only with this drug though, isn't it?

DR. HUTCHEON: Yes, I think that is true. But the principle applies to many other drugs - antibiotics, reserpines - many drugs that have a high degree of potency and toxicity. Then the standards of accuracy are very important.

ASSEMBLYMAN RYS: He answered my question.

ASSEMBLYMAN BAER: I want to thank you very much, Dr. Hutcheon, for your testimony. Is any of that in writing?

DR. HUTCHEON: I did write to Assemblyman Herman, giving the essentials of that.

ASSEMBLYMAN BAER: If you had something in writing, I would have asked you to leave it with us.

ASSEMBLYMAN HERMAN: For the record, Mr. Chairman, I believe that a report signed by Stanley S. Bergen, Jr., on behalf of the New Jersey Health Sciences Group, has been previously filed with our Committee.

DR. HUTCHEON: This is supplementary.

ASSEMBLYMAN BAER: Thank you very much for your helpful testimony.

Next will be Dr. Diller B. Groff. (Assemblyman Baer is advised Dr. Groff is not in the room, but is expected.) Mr. Bryan, will you inform me when Dr. Groff arrives?

Mr. Joseph D'Amico, President, New Jersey Pharmaceutical Association.

J O S E P H G. D ' A M I C O:

My name is Joseph G. D'Amico. I am President of the New Jersey Pharmaceutical Association which represents 3,400 registered pharmacists practicing in over 1,600 New Jersey community and hospital pharmacies.

Until recently the Pharmaceutical Industry's patent position precluded any mass movement to generic prescribing or dispensing. Within the last few years the expiration of patents and the velocity of the consumer movement have created a pressure which makes the time ripe for an issue such as Generics.

The traditional positions of Pharmacy, Medicine, and Industry are well known. Medical practitioners have long felt that it was their prerogative to choose a brand. Most pharmacists, too, maintained brand loyality. These idealogies were carefully nurtured by the industry through their methods of promotion.

In New Jersey, Pharmacy has taken no official position since it appeared to be an issue which would be resolved at national level. The Association, through its Therapeutics Committee, did introduce a resolution to the United States Pharmacopeial Convention calling for standardization of excipients and binders in U.S.P. products which would reduce product variation and, therefore, reduce the scope of the bioavailability question. This resolution was accepted for study. We intend to continue seeking long term solutions along this line. The New Jersey Legislature has chosen to look at this issue during the current session. We are now examining the

question at state level and attempting to develop viable state solutions. The results of several brain storming sessions proved innovative and far reaching. Potential savings to consumers would number in the millions of dollars. Health care would reach the highest quality ever. Our proposal provides the consumer with both monetary savings in conjunction with optimum service and quality.

An in-depth analysis of the New Jersey prescription market has provided data supporting the conclusion that "generics save money". The prescription market in New Jersey averages about $300,000,000.00 per year of which 12% is now written generically. At present 30% of all prescriptions which can be written generically are now so written. Since the potential generic market exceeds 40% of all prescriptions written, converting this to dollars would give us a generic market in New Jersey of approximately $120,000,000.00. If prescriptions were filled generically, pharmacies by utilizing buying procedures currently available only to high volume chains could pass a savings of approximately $.50 to $1.00 per generic prescription to their consumers for a total of $7,500,000.00 to $15,000,000.00 in the State of New Jersey. An additional projected savings of $5,000,000.00 could be realized if transaction time between physicians and pharmacists were considerably reduced. The monetary savings to the public make generic bills very attractive to current Legislators. Before any Legislation is enacted, the inherit dangers of brand selection without controls must be considered. These hazards must be reduced to an absolute minimum before the generic issue can be considered a consumer benefit.

The historic brand allegiance that was widespread in the past is not merely based on unfound criteria. Established companies have quality control and bioavailability data which smaller concerns

are not likely to have. It is important to consider the patient's health when dispensing any product whether it is generic or brand.

In order to minimize the potential hazards of ineffective medication, a Council should be established to act on various products which can be interchanged safely. The New Jersey Pharmaceutical Association has proposed that any bill providing for the selection of one brand for another should also provide for a Drug Council. This Council would act on a drug by drug basis utilizing bioavailability data to determine "therapeutically equivalent" products. "Therapeutically equivalent" applies to those chemically equivalent drugs of the same strength and dosage form which in equal quantities produce the same clinical effect as a reference drug product. The standards for equivalence would be based on in vitro dissolution data performed according to the standards set up by the United States Pharmacopeia or National Formulary and blood serum concentration levels demonstrating absorption rate, peak level, duration of peak level and elimination phase. Clinical tests to demonstrate the site of action levels would also be required when deemed necessary by the Council to establish equivalence of drugs whose chemical constituency of the active drug substance is identical to the reference drug product. The product would have to satisfy all quality controlled tests performed by the reference drug.

The powers of this Council would also be expanded to cover areas which involve the reduction of pharmacist to physician transaction time. For the purpose of this article, transaction time can be defined as the time expended by physicians, pharmacists and other health personnel in phone calls and other person to person correspondence for the purpose of discussing prescription and patient problems. As the number of possible drug interactions increase, and as the

record keeping of the pharmacist becomes more sophisticated, the time allotted for pharmacist - physician contact becomes greater. These interactions between medicine and pharmacy are necessary to insure the patient of optimum health care. Other areas related to the dispensing of prescriptions also involve physician - pharmacist consultation. All of these areas are costly and time consuming. Many of them are unnecessary and outdated, yet are required by the present law (both Federal and State) governing the Professions of Pharmacy and Medicine, for example: the Durham - Humphrey Law.

The areas involving transaction time and falling under the jurisdiction of the Council would include the standardizing of number of refills when physicians do not provide refill instructions, the standardizing of quantities, and dosage form exchange. When considering various drugs for standard refills, the Council would consider the optimum dosage required for effective levels. Many drugs would not lend themselves to inclusion in this area since their uses vary, drugs chosen for inclusion in this area would be carefully screened by the Council as would be those drugs included in the area of standard quantities. This area, too, would only apply to those drugs whose dosage regimen lend themselves to specific dispensing quantity or quantities. Once a drug is included in this area a pharmacist may then choose the closest quantity to that prescribed by the physician as long as it is within a reasonable range. The area of dosage form exchange would permit a pharmacist to dispense a liquid for a tablet in those cases where the patient is unable to take the form prescribed by the physician. All of these areas would considerably reduce the number of phone calls required in order to fill those prescriptions by reducing the time involved. This would benefit the consumer in 2 ways: He would receive his prescription faster and he would realize a monetary savings as a result of the

decrease in transaction costs. It must be stressed that each drug considered would have to be acted on an individual basis, and may be included in one or more of these areas.

To be operative the Council members would have to be drawn from those professions most closely related to patient care and product dispensing, namely, Medicine and Pharmacy. It has been suggested that the Council consist of 2 members from the New Jersey Medical Society, 2 members from the New Jersey Pharmaceutical Association, the Commissioner of Health, the Director of Consumer Affairs, and the Secretary of the Board of Pharmacy. The Commissioner of Health, or his designee, would act as Chairman of the Council. The presence of the Council would insure patients of the highest possible health care while considerably decreasing the expenditures for drugs. If this issue is resolved as described here, Medicine, Pharmacy and the patient will be beneficiaries (Physicians would not be overburdened with phone calls from pharmacists). The pharmacist will be able to optimize his professional training, and the patient consumer will benefit by reduction of drug expenditure.

While generic bills have become plentiful in the Legislature, none provides for the controls necessary to insure the use of quality products. Since not all chemically equivalent products maintain blood levels necessary to be effective, a Council qualified to review bioavailability data and product equivalency is necessary. The Council would be similar to the P&T approved now and used by the hospitals. Its effect would be to introduce a coherency in Community Health Practice where at present it does not exist.

It has been charged that pharmacists given a choice of drugs to be dispensed would choose the cheapest item available disregarding quality. A recent survey conducted by American Druggists

has shown that products marketed by major pharmacy houses are still the first choice of most pharmacists when dispensing generically written prescriptions.

The survey covers 10 drugs that are among those most frequently prescribed generically. Because the same 10 products were included in an American Druggist survey conducted in 1972, comparison can be made.

In addition to the 10 drugs surveyed in 1972, the latest study included two others - propoxyphene and nitrofurantoin.

One conclusion suggested by the 10-drug study is that, even in a period as short as two years, significant changes can take place in a company's standing among pharmacists as the source for a particular drug entity. There were only two cases, it is true, where the company that ranked first in 1972 dropped to a lower standing in 1974. But even among the others, there were some notable shifts, both upward and downward.

The question presented to a nationwide sample of pharmacists, in 1972 and in 1974, was: "When I receive a generically written prescription calling for (name of drug), I usually fill it with this brand (or list manufacturer whose product you usually use)".

The survey drew usable responses from 1,711 owners of independent pharmacies and 393 managers of chain pharmacies.

One fact worth noting at the outset, in analyzing the data, is that on only five of the 10 products does a single manufacturer "dominate"-if domination is defined as winning the preference of 50% or more of pharmacists. These five are:

Digoxin, where Burroughs Wellcome has increased its share from under 80% in 1972 to over 90% in 1974. This no doubt reflects the widespread publicity given to news reports raising questions

about the bioavailability of products reports which generally referred to B-W's Lanoxin as a standard for the rest of the field to match.

Nitroglycerin, where Lilly experienced a slight decline, but still holds an 87.7% preference rating. Among chains, Lilly's rating rose to well above 90%, while Parke-Davis' dropped. Among independents, on the other hand, Parke-Davis gained somewhat at Lilly's expense, but Lilly remains clearly the dominant supplier.

Penicillin G potassium, where Pfizer continues to hold just about 50% of the votes. It should be noted here that Wyeth and Squibb are making gains, particularly among chains, where both companies doubled their preference ratings.

Phenobarbital, where, between 1972 and 1974, Lilly climbed from just under 50% to comfortably over that point. Lilly still does not have a commanding lead among chains, but it is well ahead of second-place Parke-Davis among independents.

Thyroid, where Armour, the long time leader, scored gains among both independents and chains.

The only drug which saw first place in pharmacists' preference change hands from 1972 to 1974 was ampicillin. In this big - and therefore hotly-contested - market, Squibb rose from second to first place among chain and independent pharmacists combined. Wyeth rose from 5th to 2nd place, and Parke-Davis dropped from 1st to 3rd.

Pfizer, which entered the ampicillin fray with a "branded generic" went from nowhere in 1972 to an 11.3% preference rating this year. Among chains, in fact, Pfizer now rates first, with 19.4%.

Also a newcomer to the ampicillin field, Smith Kline & French has achieved a 6.1% rating with its branded generic.

Among generic houses, the one that seems to have made the most progress over the past two years in building pharmacist patron-

age is Purepac.

On meprobamate, for example, Purepac jumped from a 10% rating among chain pharmacists in 1972 to 21.2% in 1974, putting it in first place in the chain group. Purepac's rating fell off slightly, however, among independents, and Wyeth's Equanil still leads the field. In fact, Wyeth's overall lead is bigger now than it was two years ago.

Of the remaining items surveyed, all markets were dominated by major pharmaceutical manufacturers. For example; Ampicillin - Squibb, Wyeth, Parke-Davis; Meprobamate - Wyeth, Purepac, McKesson; Prednisone - Upjohn, McKesson; Reserpine - Ciba, Purepac, Upjohn; Tetracycline - Squibb, Lederle, Upjohn, Pfizer; Propoxyphene - Lilly, SK&F, Lederle; Nitrofurantoin - Eaton, McKesson, Lederle.

As illustrated by this study, the pharmacist does rely on the major houses for the generics dispensed.

The question of liability has also been posed. It has been charged that liability would increase from the dispensing of different brands of the same products. Historically, cases involving drug injuries have resulted from the wrong drug rather than the wrong drug brand. For example, two cases cited in the May 15th issue of the Citation, a publication of the American Medical Association, illustrated this point.

The first case involved the use of methotrexate for the treatment of psoriasis. The patient sued the physician for malpractice, contending that methotrexate was not approved or recommended for use in treating psoriasis. As a result of taking the drug, the patient suffered portal cirrhosis of the liver and esophageal varices. He also sued the drug manufacturer, contending that it knowingly sold the drug for treatment of psoriasis in spite of the lack of approval

by the Food and Drug Administration.

The verdict for the physician and the drug company was unanimous. This case was Kowalski v. Rees (California Superior Court, San Francisco Co., Docket No. 606709, Jan. 9, 1974).

The second case appeared on page 40 of the same issue, and involved a pharmacist who had incorrectly dispensed Phenaphen capsules instead of Fiorinal. The patient claimed that he blacked out, fell and was injured after he took one capsule. Admitting his mistake, the pharmacist said that the two drugs were very similar and should not have caused the blackout. A jury verdict held the pharmacist free from any liability. The case cited was Gonsales v. Rosati (California Superior Court, Santa Clara Co., Docket No. 269708, Jan. 17, 1973).

While many people feel the solution should lie at Federal level, these proposals would only cover public programs such as Medicaid, Medicare and National Health Insurance if, and when, it is enacted. In addition, this Federal program is many years away while Mr. Herman's proposal would be an immediate benefit to all the consumers of New Jersey.

That concludes my testimony.

ASSEMBLYMAN BAER: Thank you for your testimony, Mr. D'Amico.

I would like at this point to call attention to the presence of additional Committee members, Assemblywoman Croce and Assemblyman D'Ambrosia.

Any questions?

ASSEMBLYWOMAN CROCE: Would you be in favor of this bill if they took out of it "two shall be members of the general public"? On page 5 of your statement, you do not include members of the general public as members of the Council.

MR. D'AMICO: I believe your question was, would I be in favor of this particular bill.

ASSEMBLYWOMAN CROCE: Yes, if the bill included two members from the general public, would you still be in favor of it or would you prefer it the way you have it on page 5?

MR. D'AMICO: We have no objection to the two lay members being on this Council.

ASSEMBLYMAN HERMAN: Presently, Mr. D'Amico, as I asked the previous witness, isn't it true that pharmacists are allowed to select generics if the doctor prescribes that way?

MR. D'AMICO: At the present time, if a physician prescribes generically, it is at the discretion of the pharmacist as to which brand is chosen.

ASSEMBLYMAN HERMAN: Well, as of today, the way the law is presently written, when a doctor prescribes generically, do you know of any special controls that exist which would mandate product selection by the pharmacist, once a generic is prescribed?

MR. D'AMICO: To the best of my knowledge, if a physician prescribes generically, there is no control - nothing to my knowledge that would inhibit his selection.

ASSEMBLYMAN HERMAN: So basically, what it comes down to, the way the present law is set up, is that the doctor, the prescriber, who is increasing prescribing generically, puts his trust in the pharmacist when it comes to product selection as far as generics are concerned.

MR. D'AMICO: I would agree.

ASSEMBLYMAN HERMAN: So that does exist today?

MR. D'AMICO: Yes, it does.

ASSEMBLYMAN HERMAN: And does exist on an increasing basis, not only in New Jersey but throughout the United States?

MR. D'AMICO: I can speak from personal experience in my own pharmacy that this is the case, that there is a greater trend to generic prescribing by physicians.

ASSEMBLYMAN HERMAN: I believe your testimony has been there is a most active participation by most all major drug companies for a larger share of the generic market.

MR. D'AMICO: That is correct. My testimony does point that out.

ASSEMBLYMAN HERMAN: In fact, I believe, if my research is correct, that Tetracycline and Ampicillin rank four and seven in the top 50 drugs. Am I correct?

MR. D'AMICO: I am not sure of their exact position, but I believe that is fairly accurate as far as I can recollect. I don't have the information that you have before me at the present time.

ASSEMBLYMAN HERMAN: Both of these are generic prescriptions?

MR. D'AMICO: Yes, they are.

ASSEMBLYMAN HERMAN: One thing I would like to establish for the record, if I may: Could you just tell us briefly when it comes to the training for drug recognition, drug therapy, and various things that go into this basic subject matter of prescription and right prescription, what sets the pharmacist apart from the doctor by way of schooling or additional schooling in this area which would give him the qualifications which your report seems to indicate that he has?

MR. D'AMICO: I think the basic, over-all training of pharmacists generally is in the area of drugs, their therapeutic effect, the pharmacology of drugs, and all of

the other ramifications of drugs and drug products. I would say this is the primary responsibility in training in this area. I agree that physicians have quite a bit of training, but not to the same extent as pharmacists. I think based on this educational background, in my opinion, at least, the pharmacist is probably the most qualified or at least very qualified to make drug product selections and is in a position, I think, to assist physicians in this whole area.

The pharmacist must graduate from a five-year College of Pharmacy at the present time. As I said, most of the training and education is directly involved with drugs and their effects and their manufacture and every aspect of drugs.

So I would unquestionably place the pharmacist in the best position to make drug product selection.

Are there any other questions specifically?

ASSEMBLYMAN HERMAN: No. I was trying to establish the differential in training, if there was one. I assume what you are recommending is not one acting on his own, but sort of a medical interrelationship, medical partnership.

MR. D'AMICO: Right. In my testimony, I recommend the formation of a Council and the purpose of the Council would be to work among pharmacists, physicians and people in government to establish criteria for the selection of those drugs which they feel have qualifications for interchange and not for an open-end drug product interchange. We feel there should be some controls to protect the consumer-patient. And we feel this is probably the best approach to solve that particular problem.

ASSEMBLYMAN HERMAN: Thank you very much.

ASSEMBLYMAN RYS: Mr. D'Amico, don't the major companies supply all the analyses, data and experience pertaining to a drug? The major companies, when they

have a drug coming on the market, test it. They must test it before it is released. Don't they supply all the data and analyses of that drug free to a druggist?

MR. D'AMICO: They supply a lot of information about the testing data which relates to the patient and the use of the drug. But as far as the infinite details, I have never seen any in-depth studies because it wouldn't really be pertinent as far as our use of the drug and our involvement with the patient would be concerned. I would say that every major manufacturer has complete and thorough data to substantiate the research of the drug.

ASSEMBLYMAN RYS: Another question then: Would you possibly know the percentage of difference in price of a drug that was manufactured in the United States and an equivalent drug in other countries?

MR. D'AMICO: The question you are asking is: Would I be aware of the difference in the testing procedures?

ASSEMBLYMAN RYS: No, the cost of the drug to you.

MR. D'AMICO: I am aware that the cost of drugs manufactured overseas is less than those produced in the United States. I am not really sure of the quality of the drugs that are imported from overseas however. I know there is a difference in price, but I am not sure if the quality is the same.

ASSEMBLYMAN RYS: All right. You think the price is lower, but you are not sure that the quality is the same. Are those drugs being used in this country?

MR. D'AMICO: Are they being used by pharmacists?

ASSEMBLYMAN RYS: Yes.

MR. D'AMICO: From my own personal knowledge, I couldn't give you an accurate answer. We do not use imported drugs in our pharmacy, only branded drugs which we feel are of highest quality, consistent with price.

ASSEMBLYMAN RYS: I realize that. I just wanted to try to get the percentage if they were being used in

certain categories.

On page 2 of your report, you mention an analysis of the prescription market in the State of New Jersey. Did you have an auditor compile those figures; and, if so, what company?

MR. D'AMICO: I will let Mr. Geser who helped prepare this testimony answer that.

ASSEMBLYMAN RYS: I have some figures and I was wondering whether these might be the same auditors. There seems to be a discrepancy.

Since you don't know, I will ask the question of someone else.

ASSEMBLYMAN BAER: Mr. Geser, are you going to be testifying later?

MR. GESER: I just came to assist him.

ASSEMBLYMAN BAER: All right. Then will you briefly identify yourself and answer the question.

MR. GESER: My name is Alvin Geser. I am the Executive Officer of the New Jersey Pharmaceutical Association. I am accompanying our President, Mr. D'Amico, today, to assist him in answering any questions, and I helped to prepare this testimony.

This was not done by auditors. This was done by extrapolations and statistical analysis of the United States prescription market and the New Jersey market. The data was not collected by survey, but we believe it represents fairly and accurately the statistical model of the State of New Jersey as far as the prescription market is concerned.

ASSEMBLYMAN RYS: I have a report here that was handed to me of the market statistics of New York in 1973 by Lee Associates that shows RX sales were only $39 million.

MR. GESER: In the New Jersey market?

ASSEMBLYMAN RYS: Right.

MR. GESER: That could not be right.

ASSEMBLYMAN HERMAN: Could you identify the report so we all know what report you are talking about, Mr. Rys?

ASSEMBLYMAN RYS: I will give it in later on.

MR. GESER: If you are saying that the prescription market in New Jersey is only $50 million in size, that, I believe, could not be right. For example, the Medicaid market in New Jersey is close to $20 million in prescriptions alone and it doesn't represent more than 15 or 20 per cent of the market.

ASSEMBLYMAN RYS: The thing I was trying to have explained was the difference between what is in this report and the $300 million.

MR. GESER: We developed some of this data on the basis of national data, some of which was developed by Lee Associates. The national data indicates a prescription market of approximately $6 billion. If you adjust that downward on New Jersey's population base and then take Medicaid and work the other way, the $300 million is a fairly reasonable estimate of the market in our opinion.

ASSEMBLYMAN RYS: All right.

ASSEMBLYMAN BAER: Are there any other questions? (No questions.)

I want to thank you very much for your very helpful testimony, Mr. D'Amico.

MR. D'AMICO: It has been my pleasure.

ASSEMBLYMAN BAER: I would like to point out, since I did not point out earlier, that this hearing on A 1257 is on both the bill as originally introduced and the proposed amended version. I think most of you have received copies of the amended version. If there is anybody here who hasn't, that can be gotten from Mr. Bryan at the front desk on your left of the aisle.

I would like to also request before we call the next witness that in the future if anyone has a long prepared

statement such as the one we just had, I would appreciate it if you orally summarize it. Any written statements submitted will be printed in full and will be studied and read very carefully by members of the Committee. So if a long statement could be summarized, I think it would still make it possible for the Committee to ask questions and generally review the testimony within the time limitation we have.

I would like to next call Dr. George H. Schneller, Director of Pharmacy Research and Development of Wyeth Laboratories.

G E O R G E H. S C H N E L L E R: Mr. Chairman and members of the Committee, my name is George Schneller. I am a registered pharmacist and also have training in Chemistry with a Ph.D. degree. I have been employed since 1936 as a Pharmaceutical Chemist in the prescription pharmaceutical manufacturing industry. Currently, I am Director of Pharmacy Research and Development at Wyeth Laboratories of Philadelphia, Pennsylvania. The responsibility of the scientists and technicians whom I direct is to develop the formulas and manufacturing processes for pharmaceutical preparations and also the tests and standards by which their quality, including potency, dose-to-dose uniformity, stability and bioavailability, will be assured.

I have also been for six years a member of the Executive Committee of the Academy of Pharmaceutical Sciences, which is a scientific arm of the American Pharmaceutical Association, and am currently the President of that Academy. I am speaking not in that capacity, but as an individual. However, I can say that my remarks here are compatible with the consensus of the Academy, which is made up of both industrial and university scientists and which includes in its membership the foremost national investigators and practitioners of the science of

biopharmaceutics, of which bioavailability is a sub-topic, and the Academy has done important collaborative work to clarify this difficult subject for the benefit of pharmacists and the public.

I wish to speak with regard to the scientific universe in which the proposed Council is expected to operate. That universe is still characterized by uncertainty regarding which drugs represent bioavailability hazards - the number is large, but exactly how large is still unknown; how the list of such drugs is to be established; how the bioavailability of the drugs on that list, once established, is to be standardized by regulation or by compendial tests. In view of that uncertainty, it would appear that it is unrealistic to impose on any group of scientists and professional men at the present time, with such an extremely limited budget to boot, the responsibility of drawing up a list of approved drug products, such as that contemplated in the bill.

I see on the list of witnesses other individuals who will develop more fully the details of the major scientific problems which still need to be solved before such a Council could discharge that responsibility.

I will limit my remarks to an explanation of how public declarations of certain regulatory officials, even though optimistic, actually reveal clearly on close reading that the achievement of a clear understanding of the bio-equivalence problem is still in the future. Such public statements often contain such words as "not insurmountable," the problem being controllable. But meanwhile the scientific staffs of the same agencies, speaking to scientific groups, such as ours, frankly disclose a clear recognition of the magnitude of the problem remaining. An FDA official has stated that the agency will spend half a million dollars during the next year on bioavailability

studies, and this surely does not reflect a state of comfortable assurance with regard to the state of affairs.

I would like to go back momentarily to the final report of the HEW Task Force on Prescription Drugs, published in 1969. A statement in that report which has been widely quoted is that the possibilitites of bioavailability in equivalents has been grossly exaggerated. However, that same Task Force in the same report listed five criteria for drugs which would need careful study, and gave a list of 25 drugs which in their opinion needed such study and recommended that the studies which had been begun be continued. Actually three or four such studies were done and some or all of them were done by an individual, Dr. Martin, who I see on the list of witnesses for the future. Incidentally, of those three or four studies, most showed very great differences in bioavailability between marketed products.

However, that project was not continued and no further word was heard from the HEW or the FDA on bioavailability studies until the Digoxin problem surfaced three years later, following which a lot of study was made in determining bioavailability equivalence or nonequivalence of the many products on the market, and that study continues to this day.

Commissioner Alexander M . Schmidt of the Food and Drug Administration gave three very recent speeches on problems of quality and related problems. The first speech was given on May 8th before the National Association of Boards of Pharmacy in Atlanta, Georgia. The second speech, which was virtually identical - and I have official copies of both of them - was given to a meeting of the National Association of Chain Drug Stores. The third one was given only on May 16th before the Ogden, Utah, Surgeons Society, and that is reported in the press as having features which resemble the other two.

I would like to read from the official copy of that speech comments which he made about the bioavailability

problem.

ASSEMBLYMAN HERMAN: Would you establish for the record who Dr. Schmidt is?

DR. SCHNELLER: Yes, Dr. Schmidt is the Commissioner of Food and Drugs.

ASSEMBLYMAN HERMAN: Thank you, sir.

DR. SCHNELLER: I am quoting now.

ASSEMBLYMAN BAER: Are these long statements because I am a little bit concerned we are going to more than consume the time available just in the reading of your statement, let alone reading within that statement the statements of others.

DR. SCHNELLER: There is one triple-spaced page and I have a few concluding remarks.

ASSEMBLYMAN BAER: All right.

DR. SCHNELLER: I am quoting now, and I will give emphasis to expressions and terms in the quotation which are future in meaning and in intent and which in my opinion indicate clearly that the intentions and the capability of the FDA of ultimately solving the problem are without questions, b u t that as of today and for the immediate future, the Commission is not guaranteeing that the situation is actually under control. I am quoting.

"Our regulatory efforts are directed at identifying specific bioavailability problems and taking appropriate steps to resolve them. The FDA has developed major initiatives to do this. These initiatives begin with a new FDA rule to set scientific standards for the appropriate conduct of bioavailability studies. This regulation will finalize a proposal first published more than a year ago. Also we will shortly propose a process for identifying which drugs may require bioavailability studies and which may not, and in what priority. In so doing, we intend to state our conviction that bioavailability testing for every drug is at once unnecessary and impractical.

"We propose to ask help from a newly-formed expert advisory committee. If the committee is approved, we will expect its expert members to advise us not only on the size and seriousness of a priority problem, but on the means for dealing with it. Depending on the data and advice we get, I would expect that most bioequivalency problems can be handled with new compendial standards, thorough relabelling, or, as an interim solution, through bioavailability certification, such as we now have ordered for Digoxin.

"We are confident that the program will demonstrate that bioavailability problems -- to whatever extent they exist -- can be identified and managed."

Finally, I would like to point out that the Digoxin incident, while it has already been mentioned today and no doubt will be mentioned again, is a good example of the difficulty which the FDA faces in identifying problems, obtaining definitive scientific answers, and then putting them into regulatory effect. The Digoxin problem of bioavailability, not the uneven content of tablets which had occurred two years prior to that, but the bioavailability problem of Digoxin tablets on the market surfaced in December, 1971, and it took two years for the FDA to get the blood-level studies, the radio-isotopic determinations, with an expenditure of very substantial sums, to evaluate the products on the market. And only early in 1974 did they take the definitive action which had several phases.

First of all, in cooperation with the USP a dissolution procedure was added to the monograph. Secondly, a very substantial number, about 12, of manufacturers of tablets were declared inadequate in bioavailability, and they have been recalled at the rate of one or two a month now, and I think the number has reached about twelve.

It is still continuing. In other words, some manufacturers' tablets are still on the market and are only now being recalled. The FDA has indicated, however, that other digitalis products, namely Digitoxin, which although used generally in the same area of therapy, nevertheless has a different personality with regard to its release rates, solubility, etc. But that too represents a potential hazard. However, there is no action in sight for that. Before they can take action on that second digitalis drug, they will have to perform additional studies, consider them, and come to a resolution of the matter.

They also have announced that digitalis leaf tablets, which was the original form in which digitalis was taken and which might be considered as a standard drug that can be relied upon, regardless of source, because of its age, actually represents serious differences and will have to be controlled in the same way.

Other than those products, there are many products in various important therapeutic classes, such as anti-arthritics, where we have the corticosteroids, phalbutazones; and antidiabetic drugs, namely, tolbutamide. This product has been under patent until very recently. But in Canada there are many sources on the market which have been shown to be nonequivalent. There are reports of diabetic patients travelling in Canada who have taken the product available on the market and have encountered serious difficulties in the control of their sugar levels. The anticoagulants, which are used for long-term prophylactic therapy after heart attacks; the cardiac drugs which I have mentioned; and anti-asthmatics - these all are important drugs which are suspect; that is, there is evidence that they are not equivalent. But that evidence has not been sorted out. There have not been systematic blood-level comparisons of the products on the market and that has to be done

before there will be a clear vision of exactly where we stand and exactly what the prospects are for standardizing the products on the market.

ASSEMBLYMAN BAER: Thank you for your testimony, Dr. Schneller. Let's see if we have some questions from the Committee.

ASSEMBLYMAN HERMAN: Doctor, I assume that you read the Pharmaceutical Manufacturers Association Newsletter.

DR. SCHNELLER: I see them.

ASSEMBLYMAN HERMAN: I have a copy of the Newsletter of February 1, 1974. And this is published by the Pharmaceutical Manufacturers Association, I believe. Is that correct?

DR. SCHNELLER: You read it.

ASSEMBLYMAN HERMAN: It quotes Dr. Charles Edwards, who is HEW's Assistant Secretary for Health, and I would like to read for the record a quote from the Newsletter of the Association: "On the bioequivalence issue again, Edwards said, bioavailability columns are 'relatively rare' and at present are manageable. Unless there are specific indications of major problems, he says. . ." and then he went on to describe the problem with digoxin.

I believe you commented on the reports of ---

DR. SCHNELLER: May I comment on that.

ASSEMBLYMAN HERMAN: Sure.

DR. SCHNELLER: Could you tell me what group he was addressing?

ASSEMBLYMAN HERMAN: I believe that was before a Senate Subcommittee.

DR. SCHNELLER: That is something that I implied, but I guess I didn't want to stress it too strongly in my statement; and, that is, sometimes the remarks of a man in public life like that depend in part on what group he is addressing. Commissioner Edwards - and I

can give you the chapter and verse and the quotations - addressed a luncheon meeting of our Academy a few years ago, and in that talk he told us the bioavailability is extremely important and represents a tremendous amount of knowledge that has to be collected.

ASSEMBLYMAN HERMAN: When was that?

DR. SCHNELLER: About three years ago. And, as I indicated before, very little has happened in the last three years with respect to this.

ASSEMBLYMAN HERMAN: I am just quoting from your Association's Newsletter.

DR. SCHNELLER: I would like to give another quotation from Charles Edwards, which I will document if this Committee desires. He said in addressing a non-PMA group of manufacturers that any manufacturer, regardless of size, should be able to make products of equal quality. But he went on to say - however, some manufacturers are unwilling or unable to make the necessary capital investment; some manufacturers do not yet realize that it is necessary to check every batch; some manufacturers do not have adequate personnel. I will be glad to document that quotation.

ASSEMBLYMAN HERMAN: Fine, Doctor. Perhaps we can proceed to a man whom you have quoted today, Dr. Schmidt. In your Pharmaceutical Association Newsletter dated May 10, 1974 - I assume it is in reference to the speech that you mentioned of May 8th or thereabout - appeared the following, and I quote from the Newsletter: "While acknowledging that some drugs vary in bioavailability and, therefore, in bioequivalency, the Food and Drug Commissioner, Alexander M. Schmidt, M.D., is convinced that bioequivalency is not the rampant problem that some of our critics are insisting it is." I believe that that is in your Newsletter. I would like to ask you ---

DR. SCHNELLER: May I comment on that? I will

leave with the Committee the official copy received from Alexander Schmidt with regard to the two speeches, one before the Board of Pharmacy on May 8th and one before the Wholesale Drug Association on May 9th, or at least those pages which deal with bioavailability. Exactly what does that statement mean? "It is not the rampant problem..." - but no one has said it is a rampant problem; we have said it is a serious problem and needs more study. I will be glad to leave this. The parts that I read here are underlined. I will be glad to leave also the second speech, which contains virtually the same comments.

ASSEMBLYMAN HERMAN: Let me ask you a couple other questions if I may, Doctor.

I believe that Wyeth is a large marketer of branded generics, is that correct?

DR. SCHNELLER: Wyeth markets ---

ASSEMBLYMAN HERMAN: Did I understand you are with Wyeth?

DR. SCHNELLER: Yes, I am with Wyeth Laboratories.

ASSEMBLYMAN HERMAN: I understand Wyeth markets a large variety of branded generics.

DR. SCHNELLER: What do you mean by branded generics?

ASSEMBLYMAN HERMAN: Or generic drugs.

DR. SCHNELLER: Every drug is a generic drug. So exactly what is your question? I don't understand it.

ASSEMBLYMAN HERMAN: Perhaps I don't understand, Doctor, and that is what I am here to do, to understand some of these things that have been brought out. Ampicillin, for instance, ---

DR. SCHNELLER: Wyeth markets ampicillin.

ASSEMBLYMAN HERMAN: O.K. According to statistics that I have in front of me - for instance - and I am just quoting from an issue of the American Druggist, dated May 15, 1974, from page 28, entitled, "Generic Preferences,

1974 versus 1972," it says that in '72 Squibb produced 18.9 of the over-all ampicillin market; in '74, it was up to 21 percent. It then goes on to say, Wyeth was second, Parke-Davis, etc., all the way down to SK&F and Upjohn. Then it lists a number of other drugs, one of them being tetracycline, but I won't get into that since it doesn't appear that Wyeth, according to these statistics, is in the first eight. I don't know whether you manufacture that or not.

Let's use the ampicillin, if I may, as an example. When your representatives, Doctor, go into a pharmacy -- why should a pharmacist when he gets a prescription for ampicillin prescribe Wyeth versus Squibb's brand of ampicillin?

DR. SCHNELLER: I will answer that not as a representative going to a physician, but as a scientist in charge of product development who knows that Wyeth has expended tremendous sums of money on the development of a superior product which has been published scientifically as providing higher blood levels than other products and which has the highest assurance and scientific data supporting its superiority. Wyeth goes much beyond the official monographs and specifications to make that assurance, such as dissolution tests on every batch, which are not required by the FDA or the USP or anybody else. So if our representative went in and told that to a doctor, believe me, I would back him up.

ASSEMBLYMAN HERMAN: Let me just ask you this: I would be upset if I were sitting in Squibb's and Parke-Davis's shoes. In other words, their drugs are not interchangeable with yours? If a physician prescribes ampicillin and the pharmacist filled the prescription with Squibb's or Parke-Davis's brand of ampicillin, do you feel that the pharmacist in this instance would be

doing the patient a disservice?

DR. SCHNELLER: I cannot comment. I would expect that a Squibb or a Parke-Davis product would be of high quality. What I know is what I told you about the Wyeth product.

ASSEMBLYMAN HERMAN: Let me ask you this question, Doctor: Assuming that the pharmacist has that choice at the present time in regard to ampicillin and he has to make a product selection, would the pharmacist, based on your knowledge, Doctor, be doing the wrong thing if he filled a prescription with Squibb or Parke-Davis versus Wyeth?

DR. SCHNELLER: I would answer that by saying that Squibb and Parke-Davis unfortunately are not the only ones selling branded generic antibiotics. There are antibiotic products on the market which I would not want to take and which I feel cannot be relied upon to provide the proper therapeutic effect. There have been many examples of this in the literature. While I cannot comment on Squibb or Parke-Davis -- I believe they would be good and I have a lot of faith in them.

ASSEMBLYMAN HERMAN: So you would have no concern about the interchangeability of those brand names?

DR. SCHNELLER: I don't think that that is a fair question. I think the question is interchangeability of any brand on the market. That is what is before you.

ASSEMBLYMAN HERMAN: But what we are concerned about is interchangeability based on reasonable scientific data which would assure the optimum safety levels; isn't that what we are talking about, Doctor?

DR. SCHNELLER: We are talking largely about a track record. And if a guy comes in with a leather bag and pulls out a box of vials or antibiotics and he is unknown and no one has ever seen his plant, I think such a person does not deserve the faith of a pharmacist, and he doesn't get it. The pharmacists deal with reputable

companies, with a few exceptions.

ASSEMBLYMAN HERMAN: Just one or two more questions, if I may. Presently when prescriptions are made generically - and you admit that doctors can do this, I assume -- In New Jersey, doctors are allowed to prescribe generically, aren't they?

DR. SCHNELLER: Surely.

ASSEMBLYMAN HERMAN: O.K. The pharmacist is left with the end decision now anyway when there is a prescription that way.

DR. SCHNELLER: That is correct.

ASSEMBLYMAN HERMAN: It is left to the best judgment of the pharmacist to make that selection, isn't it?

DR. SCHNELLER: Yes.

ASSEMBLYMAN HERMAN: In that regard, isn't it also a fact that the over-all prescriptions by doctors, by prescribers, not only in New Jersey but throughout the United States, generically is increasing? In other words, generic prescription is rising at a much faster rate than prescription by brand name?

DR. SCHNELLER: I do not know that.

ASSEMBLYMAN HERMAN: For your edification, Doctor, on that subject, I would direct you to the April 1974 issue of Pharmacy Times, which seems to indicate that in the past eight years, although prescriptions increased by approximately 43.9 per cent; generically written prescriptions have skyrocketed to 101 per cent; and that last year there was almost a ten million increase in generic prescriptions over the prior year.

DR. SCHNELLER: That does not mean that it is right. For example, the generic prescription rate for digoxin, I am sure, which was cited by the gentleman who preceded me -- he said that during 1974 the Burroughs Welcome, the original brand, had its rate of prescription usage increase, but prior to that, I think it would be true to say that the proportion of generic prescriptions for digoxin was increasing until that scandal came out. I do not think

that was good for patients, that the proportion of generic prescriptions for digoxin was increasing. It did harm to the patients. For example, in Boston City Hospital, a recently-published report indicated that 23 per cent of patients being admitted for cardiac difficulty were found to have been improperly treated with digoxin. Whether that was due to inferior products or inferior dosage by the physician is not made clear by the report.

ASSEMBLYMAN HERMAN: With reference to digoxin, was that also manufactured by so-called "reputable" pharmaceutical manufacturers and they are being tested to?

DR. SCHNELLER: I don't know of any major manufacturer serving as a supplier of that product. I am more familiar with digatoxin,which Wyeth makes and which Lilly makes and which 25 or 30 other manufacturers make. But in the instance of digoxin, I do not know.

ASSEMBLYMAN HERMAN: As the law presently stands with the pharmacist being able to generically substitute, to pick the brand name or brand that he or she sees fit when a doctor prescribes a generic prescription, how does any pharmacist know that he won't have a digoxin problem on his hands? Is there any guarantee? There is none, is there?

DR. SCHNELLER: No. And there is reason to suspect that there are concealed problems which will still come to light.

ASSEMBLYMAN HERMAN: O.K. That is the point I want to make. Thank you.

ASSEMBLYMAN BAER: I want to thank you very much for your testimony. It has been very helpful, Dr. Schneller.

We will take a five-minute break at this point.

(Short Recess)

ASSEMBLYMAN BAER: Dr. Ryan will be our next witness. Doctor, do you have a prepared statement?

DR. RYAN: I do,sir.

ASSEMBLYMAN BAER: We will have copies of that made for the members of the Committee. Could you defer while we hear another witness who will be quite brief, I have been informed.

I would like to request of other witnesses that if you have a prepared statement and do not have copies of it, will you please see Mr. Bryan who will arrange to have copies made. We would like to have them so they can be distributed at the time you testify.

Mr. Irving Steinberg.

I R V I N G S T E I N B E R G: My name is Irving Steinberg. I am Vice President of the Senior Citizens of Bergen County. We have 138,000 - I say it again - 138,000 senior citizens.

We came here for help. I am not a doctor. I am not going to talk about medical matters. We only know one thing, that our people are living below the poverty level. At the present time, some of them are eating dog food. The cost of their drugs and prescriptions is something out of this world. You can't imagine it. This medicine (indicating bottle of medicine), which is a generic drug costs me 59 cents. For the brand name it costs $2.99. Some of the diabetic pills that senior citizens are taking at the present time cost six sixty-six a thousand in Canada if you go across the bridge, but cost eighty-eight dollars here in the United States.

I didn't expect to have so many doctors in opposition to this because if they weren't, they wouldn't be here today. When our people go to a doctor, we instruct them to ask for generically prescribed drugs. The doctor tells them he knows what is good for them.

In Washington in Walter Reed Hospital - I think it is Walter Reed Hospital - HEW tells us that all they get over there are generic drugs. How do the generic drugs differ from the brand-named drugs? Essentially there is no difference, according to the Food and Drug Administration.

We are here to ask you people to see what you can do for us to relieve what is going on at the present time among the elderly people. We don't come here to plead and to tell you funny stories, but we are telling you that we need help at the present time. Thank you very much.

ASSEMBLYMAN BAER: That you, Mr. Steinberg. Will you remain seated until we see if there are any questions.

MR. STEINBERG: O.K. Go ahead - shoot.

ASSEMBLYMAN BAER: Are there any questions?

ASSEMBLYMAN HERMAN: I just want to thank you for coming down here. We are trying to see that the needs of the senior citizens and the other members of the public get the best possible ---

MR. STEINBERG: I would like to correct the Vice Chairman and say that if - if, I say now - this Generic Bill goes through, it is not only going to help the senior citizens ---

ASSEMBLYMAN HERMAN: It is for everybody.

MR. STEINBERG: (Continuing) -- it is going to help the community at large. We are fighting for the same thing as the community at large. I don't know whether you people realize what is going on at the present time with Medicaid. They are not getting generic prescriptions. Why not? We are paying taxes for that. The doctors wouldn't do it. That's all there is to it. We have been fighting them and don't forget there are 138,000 senior citizens. That's an army.

Personally, I might tell you, that for the past year

and a half, I have exhausted my resources. I can't do it anymore. Thank you.

ASSEMBLYMAN BAER: Mr. Steinberg, the cost of drugs can represent a substantial percentage of the income of some senior citizens on fixed incomes, such as social security. What percentage can that be sometimes?

MR. STEINBERG: If a person is getting a $155 check and he has to pay $190 rent and $40 for prescriptions, he can't even go on county assistance because you have to be at a certain limit. If you are getting up to $155 or $165, you can't get county assistance. But I'd say the average person has a $40 or $50 bill at the end of the month.

ASSEMBLYMAN RYS: I have only one question, Mr. Steinberg. First of all,I want to thank you very much for coming all the way from Bergen County here. I presume you heard the testimony of Dr. Schneller in regard to diabetic drugs that are obtained in Canada. He didn't specify the price, but he did indicate there were inferior drugs being sold or that there were problems with a certain drug.

MR. STEINBERG: I don't know. I am not a doctor. I can't explain to you. We could get cheaper drugs if we could go to the National Council of Senior Citizens in Washington, D. C. We could also get some from Canada. But the drugs that the senior citizens - the elderly people -- I don't like that word "senior citizens" ---

ASSEMBLYMAN RYS: We will soon be up there too.

MR. STEINBERG: (Continuing) --- contain a little dope in them and cannot go by mail. So it would cost us $90 to go up there to bring it back to Bergen County. We need help from our legislators. If you can give it to us, we would appreciate it. We thank you very much.

ASSEMBLYMAN BAER: Thank you very much, Mr. Steinberg, for your very valuable testimony.

I would now like to call Mr. Foley of the New Jersey State Department of Health. We would appreciate it if instead of reading the whole prepared statement, you could summarize it and deal with those portions that are most pertinent and you feel might relate most to areas on which we might want to ask questions.

D O N A L D J. F O L E Y: I will do that.

I am Donald J. Foley, Chief of the Drug Control Program, Division of Narcotic and Drug Abuse Control, New Jersey State Department of Health. I am appearing here today in behalf of William J. Dougherty, M.D., the Acting Commissioner of Health. Dr. Dougherty wishes to thank the Chairman and the Committee for the invitation to appear and give testimony regarding the proposed amended version of Assembly Bill 1257.

The Department wishes to state, for the record, that the Department is very much in agreement with the general purpose and concept as presented in the amended Assembly Bill 1257.

The Department would like to call attention to the fact that the proposed amended version would be intra-departmental in nature. It provides within the Department of Health there will be a Council whose purpose would be to establish a list of approved drugs that may be substituted and that would be therapeutically equivalent to brand names. There are other provisions regulating the practices of pharmacy as it relates to the conditions wherein a pharmacist may substitute a Council-approved drug product for a trade-named product in a prescription. Such practice is regulated by the Board of Pharmacy, Division of Consumer Affairs, Department of Law and Public Safety.

Inasmuch as the amended version provides that the Council shall be in the Department of Health, the Department should like to limit its specific remarks to the Council concept, its functions, duties and budget.

The Department has concern that the Council will have need of technical and clerical personnel, as noted in Article 3. However, the appropriation of $7500 is felt insufficient because we will need more technical and clerical help, postage, subscriptions and journals for references, and other expenses. The Department would request a Fiscal Note be prepared to adequately provide for the needs and functions of the Council.

Also in the practice of pharmacy, the Department has had experience in enforcing some laws that do pertain to this, notably the Controlled Dangerous Substance Act; and in our experience in that area where we have to monitor the inventory, the purchase order invoices, and the completion of Federal Purchase Order Forms, we have found that the pharmacist is very knowledgeable in this area, but he is limited in his clerical time. We are also aware of the fact that the new Patient Profile Records consumes time.
We, collectively as those regulated and those in enforcement, realize that compliance to a statute is best achieved with a minimum of bureaucratic paper work, senseless report writing and unnecessary correspondence and communications. Such communications required in Article 4 and Article 5 will seriously hamper, if not scuttle the whole concept of providing Council-approved drug products to the consumer at a projected great saving.

With the pharmacist faced with the prospect of numerous, possibly 50 to 150 daily, telephone calls to the prescriber, not to mention demands made of the prescriber at the other end of the wire, we can see that both the prescriber and dispenserare going to say - "What the hell - it's not worth it - I'll not substitute" or "I'll get that pharmacist off my back; every script goes out 'no

substitution.'" Such actions would defeat the whole concept of the bill; or if written communications are the elective, you know the status of the postal service today, such communications would be received by the prescriber two to four days after the fact. What value is such communication?

It is therefore the recommendation of the Department that if (1) the prescriber is granted the option to having a particular drug dispensed without substitution, and (2) we really believe that our pharmacists are qualified, Board-licensed, experienced, participating in a continuing education program, maintaining patient profiles, qualified in the dynamics of drug interaction, drug incompatabilities and drug reactions and allergies as the New Jersey State Board of Pharmacy certified they are, then why not permit under this proposed bill that substitution of a prescribed drug be permissible by the pharmacist in all cases with drugs approved by the Council or under the circumstances set forth in Article 5?

The Department believes that the concepts set forth in this bill are long overdue and they will aid materially in the furtherance of the Federal Act, and feels that A 1257, with further review and deliberation, will result in a workable, accepted, beneficial proposal to the benefit of all our citizens.

That is synopsizing it.

ASSEMBLYMAN BAER: Thank you. Any questions?

ASSEMBLYMAN D'AMBROSIA: Is it my understanding that you are trying to eliminate so many phone calls and that you want to give the pharmacists the authority to change the prescription and use a different drug, without asking the doctor?

MR. FOLEY: Without further approval, yes, sir. There is an elective. He may choose to notify the

doctor by mail. Now you know what our postal system is. That prescriber is going to get that notification two to four days later. That is after the fact. What benefit will it be to the prescriber?

ASSEMBLYMAN D'AMBROSIA: But in the event the doctor does prescribe a specific, brand-name drug, do you think that the pharmacist should be able to substitute that with a cheaper drug without the knowledge or permission of the doctor?

MR. FOLEY: Only under the two conditions set forth in the bill, when it is a Council-approved drug or if the drug prescribed by the doctor is a drug that the pharmacist finds on examination of his Patient Profile Record will create an incompatibility or a drug inaction.

ASSEMBLYWOMAN CROCE: I have a question. Currently the doctor assumes the legal responsibility for any prescription he may write. Since we are going to allow the pharmacist to substitute, will he assume legal responsibility or is it going to be passed on to the State?

MR. FOLEY: I am not a lawyer, but I have been given to understand that that liability still resides in the prescriber.

ASSEMBLYMAN D'AMBROSIA: Well, how could the doctor be held liable if the pharmacist is substituting at his discretion without the knowledge of the doctor? This would create legal problems.

ASSEMBLYMAN BAER: Were you finished, Assemblywoman Croce?

ASSEMBLWOMAN CROCE: Yes.

ASSEMBLYMAN BAER: Then go ahead. Excuse me.

ASSEMBLYMAN D'ABROSIA: I can't understand how one can be held liable when a substitution is being made without his knowledge. I am not an attorney.

MR. FOLEY: I am not an attorney either.

ASSEMBLYMAN HERMAN: That leaves me then.

I have just a brief comment to make. I would think

that the more correct statement of law would be that the prescriber as long as he consents would be responsible. There have been two questions raised regarding liability: one, if in essence it is the "wrong" drug prescribed to begin with, then the physician is still going to be liable, notwithstanding the consent or nonconsent of the substitution, depending on which way the bill is eventually worded. The other question which has been raised is: Is this a viable substitute to begin with? The mere fact of lack of viability or impropriety of the prescription, itself, because of the substitution and not because of the nature of the "generic" drug, constitutes another problem in regard to liability, which I think can be handled.

MR. FOLEY: That is my understanding.

ASSEMBLYMAN HERMAN: Thank you very much for the position of the Department.

ASSEMBLYMAN BAER: Thank you, Mr. Foley, for your very helpful testimony.

Are copies of Dr. Ryan's statement ready?

MR. BRYAN: Yes.

ASSEMBLYMAN BAER: Dr. Ryan. Again, Doctor, if you can follow the same procedure of not reading the whole statement verbatim, but hitting the key areas and summarizing the rest, we would very much appreciate it, because of our time situation.

W I L L I A M E. R Y A N: Thank you very much.

Mr. Chairman and members of the Assembly Committee, by way of introduction, my name is Dr. William Ryan. I am a practicing physician who specializes in internal medicine and arthritis. I am certified in both areas. I am a member of the staff of St. Francis Hospital in Trenton. I practice with another internist here in Mercer County.

Although I am treasurer of the Mercer County Medical Society, a member of the board of the New Jersey Arthritis Foundation, a delegate to the Medical Society of New Jersey, and on the faculty of two medical schools, Jefferson and the New Jersey College of Medicine, I am speaking to you today as a practicing physician, one who actually writes prescriptions, who is interested in the welfare of his patients.

I wish to speak against Assembly Bill 1257 as amended, which I do not feel is in the best interest of the consumer patient or the practicing physician.

The purpose of this bill, as I understand it, is to authorize substitution of drugs under certain circumstances and to establish a Drug Utilization Review Council, all of which is aimed at reducing drug costs to the consumer patient.

While laudable in its intent, this bill will not accomplish this. A 1257 is an unnecessary piece of legislation. I think its nuisance value, especially to the patient, will outweigh its desirability. It raises a serious question about the legal responsibility of such a substitution, which was just referred to, and the comment was made, "I think we can handle that," but I didn't hear any final definition or any final answer. It takes away a fundamental right of medical practice which is that of the physician to prescribe what is in the best interest of his patient. It creates a Drug Council which would be granted difficult-to-define responsibilities in a very confusing area and whose membership composition as constituted in this bill is somewhat less than ideal.

First of all, the bill is unnecessary. As has already been mentioned this morning, there is no current

national or state law prohibiting generic prescription writing. Substitution of one quality drug product for another can and is frequently made by telephone communication between the pharmacist and the physician. If the physician feels that the low-cost generic medication is all that is indicated for his patient, he can so prescribe without this bill. The plain fact of the matter is, and the point I want to emphasize, that most physicians, including myself, have more confidence in the known quality product of a major ethical pharmaceutical company than we have in the unknown product of a minor supplier. Our patients are human beings whose very lives frequently depend on these drugs and we feel they are entitled to receive the best drug product for their condition possible. The physician wishes a specific drug for a specific purpose, and I feel this prerogative should remain.

Secondly, let me illustrate why I think this bill would be a costly nuisance. If we follow literally the working of the law, as outlinedin item four of the bill, it is obvious that this must be the case. I am referring to the fact that the pharmacist must notify the physician of prescription alterations.

Let's just say that I have a patient, Mrs. Smith, with a sore throat. She needs penicillin. She gets a prescription for the drug that I think is best for her. She goes off to the pharmacy.

You, Mr. Assemblyman, are the next patient. You want a good physical. You tell me about your high blood pressure you have had during the campaign. The phone rings. I interrupt your story and speak to the pharmacy who wants to substitute brand Y for brand X penicillin, which I would have asked for in the first place if it were my first choice.

We begin your examination. I'm listening to your heart - another interruption -- You heard the previous

witness talk about the large number of phone calls that would be necessary in a day. It is another pharmacist about another drug substitution. As your examination continues, the receptionist excuses herself to ask if it's OK for a refill on Mrs. Brown whose mandatory number of refills has expired.

In the middle of your proctoscopic, the door opens and again the nurse asks if you can please get on the phone to explain to an excited Mrs. Smith why the white penicillin tablets given her were not at all like the yellow penicillin capsules given her six months ago and she asks, couldn't there be some mistake?

Having spent an extra 10 minutes, you resent the interruptions, and I think rightly so. Most people who are being examined do. They don't mind emergencies, but they dislike sitting around while their doctor is on the phone settling, to them, some minor issue.

You hurriedly put the prescription for the blood pressure medicine in your pocket and rush to make a committee meeting.

The next evening you bring your prescription to the drug store to be filled. The pharmacist reports he can save you some on the prescription by substituting a different drug. But, alas, Dr. Ryan is at the hospital or is off and cannot be reached. So the pharmacist substitutes and sends me a written notice. Say it is a Saturday night. Monday morning, two days later, you call me to report you are not tolerating the drug well. You describe little green tablets; I remember prescribing pink ones. The written notice is in the mail. I really don't know what medication you are on. You sense confusion in my voice. I sense lack of confidence in yours. Was it worth the small cost? The doctor is disconcerted, but you, the patient, may be in serious trouble. So I ask you, who is the biggest loser? The answer, of course, is you,the consumer patient.

If the pharmacist must notify me constantly either by phone or by mail, then the number of phone calls and the number of pieces of mail to my office will substantially increase. At the present time, we get over 100 phone calls and a pound or two of mail a day. You can imagine the problem if this load is unnecessarily increased. Is our office supposed to pull the chart on each and every patient and record a drug substitution? If this happens, I will have to hire extra secretarial help and so will every physician and every druggist. The extra cost must be passed on to the consumer in some form or other. The only alternative would be a stamp on the prescription - "positively no drug substitutions."

Thirdly, although the law states that the"full savings in cost resulting from a substitution shall be passed on to the consumer," there is no real way this can be rigidly enforced. This would take a large body of enforcement officials. The cost of policing the system would be passed on to the consumer and the bill does not guarantee, therefore, that the patient will, in fact, receive the savings of the cheaper drug price.

I most vigorously object to the need for and the format of a Drug Utilization Review Council. The bill states the Council will prepare and periodically revise a list of "approved drug products which shall be therapeutically equivalent."

There are literally thousands and thousands of drugs and drug products which boggle the mind. Even experts in narrow fields find such drug evaluations difficult. I cannot see how eight men, meeting without pay - so I take it there will be only a few such get-togethers - will ever formulate such a list.

The Governor is to appoint eight men to this Council. Aside from the very general nature of their titles, we have no specifics as to what qualifications they must have. Six of the eight do not write prescriptions, and this bill

is all about prescription drugs. We don't know what professional, scientific and research experience in pharmacology means. Does it mean someone with a Ph.D. or an R.P.? Will the physicians and pharmacists be practicing members of their profession? Who will be the members of the general public who can read and understand the U.S. Pharmacopea? Will they be able to vote intelligently on a list of drugs which included Beta adrenergic blockers, aminoglucosides, steroids and ionotropic drugs?

I think it is nice to have the consumer represented, but I think it is asking too much for anyone without a background in medicine and pharmacology to make intelligent drug decisions. We would like to think of the Review Council members as the most competent, politically-uncommitted and impeccable officials that could be found. The realism of the world today makes this an uncertainty at best. I think you only have to look at page 30 of this morning's Trentonian to see exactly what I am referring to.

Finally it raises the question as to who is responsible should a patient have a reaction to a substitution drug. Who is responsible for the effects of a drug that I didn't prescribe? The last witness referred to this. I certainly don't feel if a pharmacist has substituted a drug I prescribed on a Saturday and I receive notice of that substitution by mail on Tuesday that it represents my prescription. It simply doesn't. That is what I am talking about when I am raising the question of legal liability. If the prescription responsibility is taken out of my hands, then the side effects of the drug cannot be laid at my doorstep. But who is responsible? Is the pharmacist? Is the Drug Council? Is the State of New Jersey? It is merely not enough to say that this can be handled or worked out. If I am going to be responsible for the drug's outcome, then I insist on the right to

choose the drug in my patient's best interest.

Every physician is quite concerned about the cost of patient care and drug costs. He is also concerned about the quality of patient care and the quality of the drugs he receives.

I am reminded of an old New England saying that I found in a country store up in Vermont one or two years ago. It went like this: "Quality is like buying oats. If you want nice fresh oats, you must pay a fair price. However, if you can be satisfied with oats that have already been through the horse - they come a lot cheaper."

Gentlemen, let's not be manipulated into the position of buying something for the consumer that has been through the horse once. In future deliberations, I urge you to keep the quality of the drug uppermost in your minds.

In conclusion, I feel this bill is unnecessary and impractical. It creates a Drug Utilization Council of dubious distinction and merit. It raises the legal question of liability and I urge you to reject Assembly Bill 1257. Thank you.

ASSEMBLYMAN BAER: Thank you, Dr. Ryan.

Are there any questions?

ASSEMBLYMAN RYS: Dr. Ryan, what is on page 30 of the Trentonian? I want to save myself a nickel or a dime, whatever it is.

DR. RYAN: Sure. I will tell you what happened. There was a political appointment made at the national level which the Democrats are screaming about. Apparently with the help of Senator Dole, a gentleman was --

ASSEMBLYMAN BAER: Can we keep this on 1257?

DR. RYAN: -- on a non-partisan basis? "Critics rap Nixon for naming paraplegic." He named a guy to head the Rehabilitation Services Administration who has no qualifications, other than the fact that he is a quadraplegic. So this is being objected to by a large number

of organizations, including the American Congress of Rehabilitation Medicine, the American Academy of Physical Medicine and a number of other prominent people.

ASSEMBLYMAN BAER: Dr. Ryan, ---

DR. RYAN: All I am saying is that this sort of thing can happen and does.

ASSEMBLYMAN RYS: You answered my question.

ASSEMBLYMAN BAER: Do you have any further questions?

ASSEMBLYMAN RYS: No.

ASSEMBLYMAN HERMAN: It appears that rapping the President is a nonpartisan issue.

DR. RYAN: Also rapping people at lower ranks than this. New Jersey hasn't done awfully well on the national scene.

ASSEMBLYMAN HERMAN: Thank God I wasn't around the last couple of years to see.

Doctor, just a couple of questions, if I may, especially with regard to the oats coming through the horse - I believe that speaking generically, with some of the major houses vying for a larger part of the market, that would also fit your definition of oats coming through the horse?

DR. RYAN: I am talking about smaller companies who have invested no money in drug research, who do not produce quality products.

ASSEMBLYMAN HERMAN: You are not against generics, per se, but you are concerned about the issue of the marginal producer or marginal manufacturer?

DR. RYAN: The gentleman from Wyeth Laboratories referred to it when he said there really isn't any such thing as generics, per se. We are talking about a drug product of a given company, you see.

ASSEMBLYMAN HERMAN: Let me ask you, Doctor, do you prescribe in your practice generically?

DR. RYAN: The last time I prescribed generics was in the Army in 1961 when I was under a system such as you recommend here, and I had an aversion to the system

and I haven't prescribed since. And I will give you some specifics.

In 1961, I was assigned to the Army at Fort Polk, Louisiana. We had generic aspirin down there. In the hot sun and the humidity of the Louisiana climate, this generic aspirin rapidly turned to acetic acid. You can go out and buy a bottle of St. Joseph's aspirin or Bayer asperin and not have this happen. But this stuff was pure acetic acid. The same thing happened with our Italian tetracycline. We tried to break it with a tack hammer one day and couldn't.

ASSEMBLYMAN HERMAN: Just one last comment: It would appear - I'm just kidding, Doctor - that we politicians don't even get a good light in this report because I think you made reference to our visit to your office as a story rather than the taking of a case history.

DR. RYAN: I have had an Assemblyman as a patient. First of all, I wanted to dramatize in a personal way how this would affect you if you were a patient in my office.

ASSEMBLYMAN HERMAN: Hopefully, I would be giving you a case history rather than a story.

DR. RYAN: No. It is meant to dramatize the situation, but in fact it could happen to you as happened to another Assemblyman a little while back.

ASSEMBLYMAN HERMAN: Thank you.

ASSEMBLYMAN BAER: Any further questions?

ASSEMBLYMAN D'AMBROSIA: Doctor, you mentioned the case history of your patient. I am not a doctor, of course. I am not familiar with this. But could it be possible if a drug were substituted, it could affect some other ailment that a person may have and you, having the record, would know this and,when you prescribe, you prescribe a certain brand name? Would it be possible for another brand to have a different or a side effect which could affect another

ailment that the patient may have that the pharmacist wouldn't be aware of?

DR. RYAN: That the pharmacist wouldn't be aware of?

ASSEMBLYMAN D'AMBROSIA: Well, the pharmacist doesn't have the case history of a patient; he wouldn't know if he had any other ailments.

DR. RYAN: There are so many possible side effects with any drugs that it is very, very difficult to make a definite answer to that statement. I would not want to be in the position of having a substitution for a drug made on me and be notified by mail that another drug was substituted. Then a couple of days later have the patient call me on the phone and say, "Hey, what about this drug? It doesn't look like the drug that I got six months ago. I am having headaches. What is this drug?" Or you might hear even worse. You might have him call and say, "My lawyer is going to call you in two weeks. I fell down a flight of stairs" or "I drove into a tree with that stuff you gave me."

I didn't prescribe that drug. I want a specific drug. I have been at my education long enough to feel that I know what I am prescribing, and I want the patient to have that drug. I think that is in the best interest of the patient and the patient is the consumer. The patient is the consumer who is going to take this medicine.

ASSEMBLYMAN BAER: I just wanted to ask you one last question, and that is: Relating to your testimony earlier, are you suggesting that the Drug Utilization Council proposed here would not have the qualifications or ability to determine the bioequivalence of oats as opposed to oats ---

DR. RYAN: No, they do a good job with oats

ASSEMBLYMAN BAER: (Continuing) --- as opposed to oats that has been passed through the horse once, or

the possible side effects that might be different between the two versions?

DR. RYAN: No. All I am saying is that the Drug Council would have before it an impossible task. You have eight members on a Drug Council and two of them are going to be physicians, two will be pharmacists, two will be laymen, and two will be people who are familiar with drugs. But that is going to be an impossibility. You refer to the U.S. Pharmacopoeia. Have you ever looked at the U. S. Pharmacopoeia? It is a huge thing. How can anybody make anything out of that and really intelligently understand it. It is over 1100 pages and there are new drugs coming out all the time. People in given small fields have trouble evaluating drugs. And I am just saying it is not going to be possible for them to do it.

ASSEMBLYMAN BAER: Are you suggesting that unless the Council were to be able to evaluate the bioequivalence of every drug listed in the Pharmacopoeia, there would be no purpose to their functioning? Wouldn't, in fact, they be able to serve a quite valuable function if they were to function at all, even if they were just to review initially the hundred or few hundred most commonly-used drugs and to initially determine what equivalency may exist among those?

DR. RYAN: Well, the Federal Drug Administration does that, and is constantly doing that now. I don't see why they need to duplicate that effort.

ASSEMBLYMAN BAER: Wouldn't it be unnecessary for them to in one fell swope make this determination for every drug? Isn't this something that could be done in stages?

DR. RYAN: You mean they are only going to do a couple of drugs? I mean, if they are only going to do a couple of drugs, there are a lot of different, for example, penicillin products. Just to go through the penicillin products and determine what the therapeutic equivalency is

would be a major job in itself. What are you going to do about the rest of the drugs while they are working on those? It would be a grossly impossible task.

If there is anybody that has done it at the Federal level, I am not aware of it. It is extremely difficult.

ASSEMBLYMAN BAER: You seem to be saying that if they can determine one substitution that can be made, it is not practical to permit that unless they can determine all substitutions that can be made.

DR. RYAN: What I am saying is that they have an impossible job and they couldn't do it. By the time they got around to determining the first list, there would be so many new drugs on the market, they would have to go back and redo that. You know it is an endless thing. I just think it would be impossible for them. I don't think it would be impossible for them. I know it would be impossible for them.

Your bill says that they are going to meet once a year and then at other such times --- yes, they are going to have one meeting. "The Council shall meet annually" and then "The council shall meet at such other times to carry out its functions and duties. . ." Also they are not going to be paid. They are going to have a reimbursement which shall not exceed $1,000 annually. They are going to have to spend an enormous amount of time. And then I am sure they are not going to be able to come up with too much.

ASSEMBLYMAN HERMAN: I have one or two questions. Doctor, how many major pharmaceutical companies do you deal with on an average?

DR. RYAN: Deal with? I never added them up. Probably there are 10, 12 or 15 that I frequently prescribe from.

ASSEMBLYMAN HERMAN: -- that visit you on a regular basis?

DR. RYAN: Visit me?

ASSEMBLYMAN HERMAN: When I say "visit," I mean supply you with statistical information, current drug products on the market and things of that nature which would enable you to stay current.

DR. RYAN: I am in the field of arthritis. So people that are selling digitalis or antibiotics wouldn't come to visit me that often. So I would say the number of people would be maybe a dozen.

Interestingly enough, I had a guy in this morning. He is from a small drug company out in St. Louis. He thought I might be interested in his prednisone. Incidentally, his drug company also makes and is most famous for huckleberry jelly. He gave it to me two hours ago. Would you have any confidence in a drug company --- (Laughter)

ASSEMBLYMAN HERMAN: Doctor, I am glad you raised that question because one of our leading pharmaceutical manufacturers makes dynamite, and I am not too thrilled about that either.

DR. RYAN: He said, "you can get this prednisone now cheaper, Doc."

ASSEMBLYMAN HERMAN: I think one of our leading pharmaceutical manufacturers makes Certs. And I think one of them also is a leading supplier of cosmetics.

DR. RYAN: I heard you questioning the fellow from Wyeth. You were comparing Wyeth with Squibb and Squibb with Parke-Davis. You are comparing really top-quality companies, one with another. But you know there are a lot of small companies, like Purepac and Moore and Walons. These companies you haven't even mentioned yet. You ought to compare the kinds of companies that you are going to be dealing with in this drug with a quality company in this bill.

ASSEMBLYMAN BAER: From what you are saying now, it would sound as though your concern would be not over substitutions, per se, but over where the substitutions are. In other words, it seems from what you are saying that certain products manufacturered by more than one top-quality firm you might be considering as equivalent and capable of being substituted. If this is the case, the question resolves around not the issue of substitution, per se, but what are the standards to be used in judging what can be substituted and what can't be substituted.

DR. RYAN: I would only say this, that generally speaking when I prescribe a drug, I want that drug. There are, of course, quality companies, ethical pharmaceutical companies, that do supply quality drugs. But there are other companies in which most of the physician population doesn't have that much confidence.

A couple of years back, there was a very nice article in one of the Trenton papers about a pharmaceutical company up in North Jersey that was closed up because the facilities - actually garage facilities - were somewhat less than desirable. These stories, I think at the very minimum, don't lend themselves to prescribing in confidence.

You want to prescribe a drug for the patient --- I have never had a patient come to me and thank me for saving him a couple of dollars on a prescription when it hasn't been the right drug or the best drug. You are dealing with their health. You are dealing with people who have cancer, who have heart disease, who have diabetes, and I think they deserve to have the best. You know, as the national slogan went, "It's a right, not a privilege."

ASSEMBLYMAN BAER: I want to thank you very much for your very helpful testimony, Dr. Ryan - your very illustrative testimony.

Is Mr. Anthony Gottberg present?

A N T H O N Y J. G O T T B E R G: My name is Anthony J. Gottberg from Bergen County. I am Chairman of the Labor Committee of the Senior Council of Bergen County.

I cannot, of course, make any statement regarding the efficiency of generic versus trade-name drugs. But it is a fact that in Walter Reed and the Naval Hospitals in Washington, generic drugs are prescribed.

It is also a fact that HEW, Health, Education and Welfare Council, is in favor of generic drugs and has said so. Testifying before the Senate Health Subcommittee, HEW Secretary Casper Weinberg declared recently that the government intends to encourage the use of generic drugs. It will do so by limiting payments for prescription medications under Medicare and Medicaid to the lowest cost at which the drug is generally available, unless there is a demonstrated difference in therapeutic effect.

I feel that if the President and the Congress can avail themselves of generic drugs, the general public should feel safe in using these generic drugs and prescriptions.

But the group I am speaking for are our senior citizens. As a group, of course, we visit the doctors and the pharmacists more than any other age group. We spend a great deal of our income, which is a fixed income, in this way. And the health costs have increased in the last five or six years so astronomically that many of our seniors find it absolutely impossible to take care of their health. We all know the costs of not only health, but food and housing, have gone up. They have gone up at our expense. We have deteriorated in our standards of living.

I feel that we absolutely must have this help. When you find that there are people that you represent in Bergen County - as has been said before, there are something around 138,000 in this county - whose cost of living has gone up to the point where their ability to live as they should is impossible and whereas they were just about able to manage, they are now at the poverty level - this is what is important. The cost of drugs and the cost of medical care in general have gone up so much, that I find people are cutting out drugs that they really need.

My wife, for instance, has arthritis also. It is a pretty serious case. One of the new drugs that we are now using in the local drug store costs $9.50 for a small bottle. We went in some of the stores like Macy's, the larger houses, and we are now using the same drug for $3.25 and that isn't even generic. There is no doubt if these drugs were prescribed generically, it isn't a small amount of money that would be saved. There are men and women that I know of who are spending $6 and $8 per day for drugs. They cannot afford it. With their social security, even if it is a couple with social security, getting a bit over $200, it certainly isn't enough even with a small pension which they may or may not be getting. They cannot live under those circumstances.

I feel if generic drugs are safe - and apparently it has been tried in many places, such as in hospitals in Washington - if it is suited for them, I am certainly willing to take that chance. Thank you.

ASSEMBLYMAN BAER: Thank you. Any questions? (No questions.) Thank you for your testimony and for coming all the way from Bergen County.

Dr. Stanley Kaplan.

S T A N L E Y A. K A P L A N: Ladies and gentlemen, I am Dr. Stanley A. Kaplan. I am a scientist involved in basic and applied research in the areas of biopharmaceutics, pharmacokinetics and bioavailability. I have published numerous research articles, have written chapters, review articles, and sat on many panels associated with this brand of science. In fact, what I have done is gone through A 1257 as I would through any other scientific document. Although it is a bill to you, it is, in fact, a scientific document. Decisions and judgments have to be based on the scientific merit of the bill.

Just to begin, the science is well documented. I have a folder here of pamphlets, review articles, etc., which relate to bioavailability, which is one aspect of biopharmaceutics, in terms of World Health Organization reports, various publications from various scientific researchers, Federal guidelines, which were published in the Federal Register, relating to the FDA standards for bioequivalency, the Academy of Pharmaceutical Sciences, etc. I submit this to you for your review. (Dr. Kaplan submits folder.)

What I would like to do is essentially go through this document, 1257, with you and suggest what I would suggest to any other panel, in which I was reviewing their document for scientific purposes.

Why don't we begin with page 2. Number one, we talk about ---

ASSEMBLYMAN BAER: Excuse me. Are you looking at the bill or the proposed amended version?

DR. KAPLAN: I am looking at the proposed amended version of 1257.

To begin with the word "generic" refers to the chemical name of the drug and nothing but the chemical name of the drug. If one looks at the U.S. Pharmacopoeia or any other pharmacopoeia,and one talks about generic

equivalents, one only assumes that the name is the same. In item (e), it says "'Chemically equivalent' applies to those drugs whose chemical constituency of active drug substance is identical." This should not be "chemical constituency" but "physical chemical constituency." Although the USP allows for assays to determine the substances are chemically identical, the physical properties are more important than the chemical properties, per se, in terms of altering the absorption of a drug. So, in other words, one must define the physical and the chemical properties of a drug and not just the chemical properties of a drug.

The other problem relates to synthesis from various sources - different impurities because different reactants may be involved. These impurities may be responsible for side effects. Although one doesn't know they exist, they may be present. So again the physical and the chemical properties of a drug must be evaluated and defined in any bioavailability study.

ASSEMBLYMAN BAER: Could you speak a bit slower.

DR. KAPLAN: All right.

I will discuss the Council in a few minutes. Let me pick up just a few more of these scientific points. Let us look at item ¢ (1), "Equivalence shall be demonstrated by bioavailability data meeting the bioavailability standards established for the reference drug product." The word "bioavailability" is the word that appears, not just availability, not just release rate. "Bioavailability" means a study in a living animal or in man, not in a test tube or in a flask. So item (a) "in vitro dissolution data based on tests performed, where applicable, . . .,"etc., is not a bioavailability standard. This just shows that the drug is going to be released from the dosage form. That does not necessarily relate to the bioavailability of

the drug. One can design any sort of a dissolutionary test to give you any sort of results you want. It is an arbitrary test. It may be useful for quality control purposes in terms of batch to batch disability, but in no way assures that the drug is going to be bioavailable. This is more of a quality-control guideline; it is in no way a bioavailability standard.

Item (b), as written, no one would provide the appropriate data because each drug has to be considered individually in terms of a design of a bioavailability study because of its use clinically, therapeutically, and because of the different physical chemical properties, because of the size of the dose, because of the problems of the assay procedure. Therefore, one cannot write a paragraph such as item (b). Perhaps something more appropriate would be: "blood level and/or urinary excretion levels of intact drug and/or metabolites (when appropriate) to define or compare the rate and extent of absorption of the administered dose. The assay procedure used must be defined and validated, and the physical state of the substance indicated. The data should be subjected to both pharmacokineticsand statistical evaluation." If you are looking for a generic type statement to write in such a paragraph, that would be more appropriate than giving these kinds of indications which in no way lend themselves to design of any reasonable or rational protocol.

ASSEMBLYMAN BAER: May I ask from what you are reading?

DR. KAPLAN: I just jotted this down on my copy of the bill.

ASSEMBLYMAN BAER: May I ask that you leave that with us at the end of your testimony.

DR. KAPLAN: All right.

Item (c) below is meaningless completely: "clinical tests to demonstrate at the site of action levels of the

substance having therapeutic activity, such as tissue levels" (one would have to obtain tissue levels from normal patients subjected to a bioavailability study) "fluid levels," (that is meaningless) "or urine levels." That is part of item (b).

So, in fact, if one is going to have anything related to clinical tests, it should be: "clinical tests to demonstrate the efficacy and safety of the drug product." So, in fact, when an innovator discovers or invents new drugs, he does safety and efficacy data, obtains blood levels at the same time, and all these things are correlated. So the drug in this dosage form is going to be safe and effective in my patient. Now if somebody wants to come with an abbreviated NDA many years later in terms of a supposed generic equivalent, what in fact he is doing is saying, "I am going to use all your safety and efficacy data. I am going to show that my blood levels or bioavailability or bioequivalents are the same. Therefore, I am going to come in on your NDA with an abbreviated NDA. If the person is going to do this, let him prove it. So anybody can produce a meaningful, a worthwhile, a good generic equivalent drug, but you have to prove it. The only way to know it is to prove it. The only way to prove it is through a bioavailability study.

Now how does one evaluate a bioavailability study? That relates to the Drug Utilization Review Council. Here in this folder I have a stack of documents related to bioavailability: principles of bioavailability, design of study, implementation of the study, evaluation of bioavailability data. Anybody who cannot read and understand and interpret what is in this folder should not be on any Council to determine whether or not a drug is or is not equivalent. Above and beyond this, there are clincial considerations which must be taken into account.

In other words, if we are talking about licensed

pharmacists, physicians, scientific researchers, general public, etc., true, members of the panel might come from any one of these groups. However, they should be able to understand and interpret this data.

As far as an annual review, I expect it will take two years of full-time work in order to come up with the first primary list, just considering the top 25 drugs prescribed generically in the State of New Jersey. If you are looking for a full-time panel, a board of experts, this perhaps can be a group of individuals who report to the Assembly. However, these people in no way would be qualified. Certainly if anyone is going to review such data, he should be able to determine the content uniformity of the drug, know what the impurities mean, know that the assay procedure used is correct and valid for what has been done and is assured that the assay has been run properly, to determine that sufficient data is obtained to perform bioavailability studies. Quite often you can read a manuscript, you can read a paper, and the conclusion is, yes, this drug is available - these drugs are equivalent.

That is not enough. One has to go through the paper as any scientist would do with any scientific document and assure himself that it was run properly, designed properly and evaluated properly. Conclusions are not enough. A blood level curve is not enough. The entire study should be well defined and documented. So, in fact, any Council that is going to review this should be able to understand and interpret this sort of data.

A few items in the bill don't seem to pertain to the bill at all. On page 4, it says: "The council shall also have the authority by rule or regulation, to specify the number of times a prescription may be refilled. . .", etc. where "no substantial therapeutic difference will result." Words like this cannot be thrown into a bill. They are meaningless words.

In other words, a paragraph like that just doesn't belong in, the paragraph starting with "the council."

Another aspect of it - if the drug is not on the described list, then it is indicated that one shall call the doctor and the doctor shall indicate whether or not he shall be able to give this other brand. Well, they can do that right now. So again, there are many things suggested or indicated which a pharmacist now can do himself if he wants to do these things.

On page 5, paragraph 5, it says, "Notwithstanding any other law, where a different brand name or nonbrand name drug product of the same established name shall reflect a lower cost to the consumer but is not included in the latest list of approved drug products published by the council, or where in the professional judgment of the pharmacist there is no valid proof of efficacy . . ." The words "professional judgment" are inadequate here. It should be "in the scientific judgment." The pharmacist always makes professional judgments in any decisions. But above and beyond his professional capacity, he requires certain scientific expertise in order to make such judgments. Either he has that in terms of the documents in his pharmacy, documents from drug companies when they offer certain drug products for his purchase, or else he cannot make that judgment. One cannot just use professional judgment; it has to be based on facts.

Over all, I guess what I am trying to say is that this is a scientific document and it should be rewritten in such a form that it will be acceptable to any group of scientists dealing with the subject matter of bioavailability, that it should be designed appropriately and evaluated appropriately, and any council should be made up of experts working pretty much on a full-time basis and not by a group of people meeting once a year. Thank you.

ASSEMBLYMAN BAER: Assemblyman D'Ambrosia?

ASSEMBLYMAN D'AMBROSIA: You feel you would need a full-time staff of, say, eight people for at least two years to study the top 25 drugs before a conclusion could be reached?

DR. KAPLAN: The American Pharmaceutical Association has embarked on a program. They have people working constantly to try to work up with monographs various drugs, including drug products. I know,in Canada, the Food and Drug Administration, itself, does the bioavailability studies on products. So they are the ones who are going to certify the drugs are equivalent or not equivalent. However, every drug is different. What you learn from one drug cannot be applied to the next drug. You start in all over again in terms of how the drug is used, the size of the dose, the kinds of assays, the kinds of people you can use a drug for. In certain instances, you can't even do a bioavailability. You might have to do a clinical study to prove the drug's equivalent, above and beyond that.

ASSEMBLYMAN D'AMBROSIA: So you feel that this council that we have proposed wouldn't be ---

DR. KAPLAN: It would be totally inadequate.

ASSEMBLYMAN D'AMBROSIA: It would be totally inadequate?

DR. KAPLAN: Yes. Based on the council as set up, you would never have your list of drugs.

The other problem is that bioavailability is a relatively new science. This data is now emerging. In other words, if a pharmacist comes to me and says, "What brand of drugs should I buy when many are available," I say, "Well, what has the supplier showed you in terms of bioavailability data to prove that his drug is equivalent to that drug for which he wants you to substitute. If he can provide you with that information, then purchase that brand of drug. If he can't provide you with that, then I would just let the man go."

ASSEMBLYMAN D'AMBROSIA: What is your opinion of

this bill? Do you think it is a good bill or a bad bill?

DR. KAPLAN: I think it is premature. I think it has to be rewritten in terms of the scientific input. I believe the council, as indicated, is inadequate. And I believe that the data will be eventually forthcoming from perhaps other sources. But, as written, it is bad.

ASSEMBLYMAN HERMAN: For the record, can we get your address and employer?

DR. KAPLAN: I work for Hoffmann-La Roche in New Jersey and I live in Clifton, New Jersey.

ASSEMBLYMAN HERMAN: I have one or two questions. When we talk about FDA standards for bioequivalency, we are talking about the Federal?

DR. KAPLAN: The guidelines as indicated in the Federal Register and as revised recently at a meeting.

ASSEMBLYMAN HERMAN: And they are what we would call minimum standards which must be met before the drug product is put on the market?

DR. KAPLAN: Yes. These are perhaps minimum standards. But again, they are more general. Each drug again will have to be adapted to those standards.

ASSEMBLYMAN HERMAN: In other words, in order to be marketed they have to be above the minimum standards; they can't be below them and get on the market.

DR. KAPLAN: No. They can't be above or below it. They have to be equivalent to it. It is just as bad to be above it as it is to be below it.

ASSEMBLYMAN HERMAN: And I assume in that respect there are what might be termed ranges of deviation.

DR. KAPLAN: That depends on the drug and how it is used, and that would be a clinical judgment.

ASSEMBLYMAN HERMAN: But, in essence, the marketing of generic drugs is increasing, is it not?

DR. KAPLAN: Yes, it is.

ASSEMBLYMAN HERMAN: Substantially increasing?

DR. KAPLAN: Yes, it is.

ASSEMBLYMAN HERMAN: In fact, more and more doctors are prescribing generically right now?

DR. KAPLAN: Yes.

ASSEMBLYMAN HERMAN: I believe your company is one of the major competitors in that market of generic drugs.

DR. KAPLAN: One of the minor competitors.

ASSEMBLYMAN HERMAN: One of the minor competitors.

DR. KAPLAN: Right.

ASSEMBLYMAN HERMAN: But, nevertheless, substantial. Thank you.

ASSEMBLYMAN BAER: You spoke about it taking a couple of years for a group of eight to conduct the studies which would be necessary for decisions on, I think, 25 drugs. I drew from that the conclusion that the council would have to be drastically modified to encompass that type of full-time activity. Is it your conviction that the council, itself, must perform these experiments or would it be equally adequate if the council performed an administrative function in directing what studies were to be made and reviewing the evidence that was produced from them as long as there were other employees of the council or other cooperating agencies, be it the State Department of Health or whatever, that provided this sort of backup?

DR. KAPLAN: The problem is, the drug is either equivalent or it is not. Therefore, you can't have a council with a consensus opinion. One has to review the data and/or do the studies themselves to determine whether two drug products are equivalent. So the whole concept of the council perhaps has to be rethought out in terms of what your goals are. But, as indicated here in this bill, I just don't see how it is going to work.

ASSEMBLYMAN BAER: What I am trying to find out at this point is whether you feel it is necessary for the council to personally conduct these studies or is it

adequate in many instances for whatever studies are necessary to be conducted at their direction or where the information is available to the council?

DR. KAPLAN: No. They shouldn't have to do the studies. They should be able to find the data and the information needed to make the correct decision.

ASSEMBLYMAN BAER: And they presumably might set over-all guidelines as to what parameters the studies would work within and things of that sort.

DR. KAPLAN: Correct.

ASSEMBLYMAN BAER: And if this were the case, then the council wouldn't necessarily, in terms of their own man-hour input, have to be as great as that of the research.

Let me ask you this: Would the council be able to reach conclusions as to bioequivalents on many drugs on the basis of research studies that have already been conducted by other research agencies, FDA or whatever, and be able in many instances to make those determinations without requiring additionalstudies to be undertaken for some drugs?

DR. KAPLAN: The chances are, no; in more instance than not, the studies will have to be performed on many drugs that are on the market today in order to determine whether or not they have the appropriate equivalence. In other words, the FDA is many years behind in terms of catching up. If you look at the recall list from the FDA, these drugs have been marketed many years and,month after month, they eventually catch up with the various manufacturers. They are just not staffed well enough to keep abreast of the problem. The problem is that a drug can get on the market and not dissolve until it reaches the Delaware River. And yet we may not know about it for two or three years. Quite often if a generic is prescribed, if the doctor writes generically, and the patient takes the generic drug, but is not responding, the doctor may think he made the wrong diagnosis or wonder why his patient isn't responding because his patients usually respond to this type of a drug. It just could be a poor drug product. There are many on the

market. The documentation is beginning. Maybe 30, 40 or 50 drugs have been documented. More drugs are now going to be documented in the future.

In terms of new drug development, bioavailability won't be a problem anymore. Drugs are now studied and developed in such a way that bioavailability is an intrinsic part of the development. So perhaps in 10 or 15 years from now, bioavailability will no longer be an issue. A drug will have defined bioavailability when it reaches the market, as many of the innovative companies now do when they put a drug on the market.

ASSEMBLYMAN BAER: So far as those new drugs for which this is defined, am I correct in understanding though that even where the information is available, as in those instances, the authority does not exist for the substitution to be made unless there is legislation that would permit that --

DR. KAPLAN: Correct.

ASSEMBLYMAN BAER: --and unless the legislation also defines within it some body, such as this council or whatever, that makes the judgment as to what drugs there is adequate information presently available to determine bioequivalence and that for which there isn't? So, if that is the case, then it would seem to me you are suggesting that there is a purpose and a function presently for a body such as this, even though you may wish to see the structure of the body altered or you may wish to see some of the other elements in the legislation that you referred to modified.

DR. KAPLAN: Well, I think if the data and the information were available, the decision wouldn't be that difficult if you get the appropriate experts evaluating it. So, in other words, we shouldn't be talking about a review council, but a council of experts. You want people

like clinical pharmacologists, pharmacokinetists, perhaps pharmacists as well, on such a council. These are the people who are involved with this kind of research, who correlate the drug levels with drug activity, who know whether or not certain impurities present will matter, who will know whether or not a dissolution rate which is somewhat slower will be critical or not critical, not just to be able to read a manuscript and say, "aha, you see they have done a study and these drugs are equivalent." In many instances, just because it is written doesn't mean it is true. One has to evaluate the final manuscript as well.

ASSEMBLYMAN BAER: I did want to call to your attention that the record of this hearing will be open for at least 15 days and, if you would care to submit to us any specific proposals detailing further the concept you are talking about, I am sure that the Committee would be very interested in studying it. And I invite you to submit anything further like that that you could prepare.

DR. KAPLAN: My main feeling is that a bill like this is really premature. Even the FDA has just now established a bioavailability unit to get more involved in this and perhaps by the time it is ripe for a bill such as this, the Federal standards will be such that substitution would be the thing. But the point is, right now, it is somewhat premature.

ASSEMBLYMAN HERMAN: Just one or two questions. In regard to ripeness, the question of readiness or ripeness or whatever word we wish to use, in response to that, I think you acknowledged earlier that there has been a rapid acceleration of generic prescribing. In fact, I think six out of the first fifty, if my records are correct -- six out of the first fifty drugs on the market are unspecified or generic drugs. In regard to a few of those, again getting back to the basic problem and really coming down to, what does the pharmacist prescribe, in reference to, say, tetracycline or the example I used earlier, ampicillin,

taking the first top three, Squibb, Wyeth, Parke-Davis, the pharmacist gets a prescription and it says ampicillin; Doctor, which one does he prescribe? Or, maybe, notwithstanding the amount of sales - that may just be on the basis of better marketing techniques - perhaps Bristol or Upjohn has a better product. Which of those ampicillin products does the pharmacist prescribe?

DR. KAPLAN: The pharmacist should not even stock a product from a drug company unless he is assured of the safety, efficacy and bioavailability data of the drug.

ASSEMBLYMAN HERMAN: How does he become assured of that?

DR. KAPLAN: Number one, this information is available from the drug companies. This information is published. There is scientific literature and documentation. So, in other words, if he is interested in knowing this information, he can find it in scientific literature and also from the pharmaceutical manufacturer, large or small.

ASSEMBLYMAN HERMAN: That is the point I wish to make. If a pharmacist can find that information - and he should find that information, I agree, before he prescribes - can't another body of people likewise find that information and say, "We have researched the available data, for instance, on ampicillin, as it is distributed within the State of New Jersey," - I don't mean to limit the field here, but by way of example - "and we find Squibb, Wyeth, Parke-Davis, Pfizer, Bristol and Upjohn to be products which have a viable, safe level"?

DR. KAPLAN: He should be capable of doing this.

ASSEMBLYMAN HERMAN: Can't a council do that? And, if a council were to be able to do the same thing the pharmacist should do at the present time, would you see anything wrong with then having a list of those five or six drugs being distributed in the State of New Jersey, and

saying, "We reviewed the literature and we find, if there is a prescription for ampicillin, any one of these five or six drugs could be utilized"?

DR. KAPLAN: As long as it is a council of experts, yes.

ASSEMBLYMAN HERMAN: O.K. That's the point I wanted made. Thank you.

DR. KAPLAN: Just one other point - people have been talking about Walter Reed and other government bodies,- Walter Reed and other defense installations purchase drugs through some sort of a defense procurement service and their standards are even higher than the FDA's standards in terms of drugs. They do their own drug testing. So when generic drugs are dispensed by these defense or government-type hospitals, these drugs have undergone tests by the defense procurement service.

ASSEMBLYMAN HERMAN: So why can't we use the results of their tests, Doctor?

DR. KAPLAN: Perhaps you can. I know it is confidential. But the point is that these people do their own testing. They do their own evaluation. The thing is, it is based on scientific data.

ASSEMBLYMAN HERMAN: Fine. But if this scientific data became available for use, you would not object to its being used?

DR. KAPLAN: A pharmacist should be able to utilize this information.

ASSEMBLYMAN HERMAN: O.K. And if a pharmacist should be able to utilize it, certainly a council --

DR. KAPLAN: -- a council of experts --

ASSEMBLYMAN HERMAN: (Continuing) -- should.

DR. KAPLAN: Correct.

ASSEMBLYMAN HERMAN: Thank you.

ASSEMBLYMAN BAER: Thank you very much, Doctor, for your very helpful and extensive testimony.

We will break now for lunch, unless there is any witness who is convinced that his testimony could be concluded within, say, three minutes, so that we would be able to finish the questioning before the hour. We would be willing to take a witness out of order if there was someone who felt their presentation was going to be that short.

All right, sir; would you come forward and identify yourself.

J. B. T H O M A S: My name is J. B. Thomas and I am with Hoechst Pharmaceuticals.

I am merely trying to be helpful here. If you will look on page 5, the second paragraph down, reads, "Whenever the latest list of approved drug products contains drug products of the same established name, section 4 hereof shall be applicable notwithstanding that a brand name or nonbrand name drug product of the same established name as such drug products included on the list would reflect a lower cost to the consumer."

I asked about ten or twelve people, knowledgeable, what this means, and they didn't know. I asked Mr. Bryan and he very graciously advised me as to the meaning. And, roughly - and he can correct me if he wishes on this - I think what he told me was that the pharmacist shall not substitute a nonformulary product, even though it is lowest priced,if there are generic equivalents on the formulary.

Then when I reread this paragraph, it is apparent that the word "not" has been omitted. The word "not" should precede "included"- "... not included on the list would reflect a lower cost to the consumer."

I may be incorrect, but if it is going to be written, it should be written in a manner where it can be understood.

ASSEMBLYMAN HERMAN: That is helpful. Thank you. Seriously, you are obviously correct.

ASSEMBLYMAN BAER: Thank you very much.

ASSEMBLYMAN HERMAN: That is the best, briefest, positive testimony I have heard in a long time.

ASSEMBLYMAN BAER: Before we adjourn, I would like to indicate the presence of Assemblyman Ruane.

We will be back at two o'clock.

(Recess for Lunch)

AFTERNOON SESSION

ASSEMBLYMAN BAER: The afternoon session will please come to order. The first witness will be Dr. Christopher Martin, Senior Director of Medical Affairs, Merck, Sharp and Dohme.

I understand there are other witnesses here from Merck also. Since we have a full agenda, until we have heard every firm or organization once - or one of their representatives once - I will not be calling on other representatives of the same firm or group. I think we will have to wait until toward the end of the day to hear the other Merck witnesses. Dr. Martin?

D R. C H R I S T O P H E R M A R T I N: Thank you, sir. I have prepared copies of my remarks which have been given to Mr. Bryan. What I should like to do in the brief time I will testify is draw the attention of this Committee to some specifics about the complexities of the issue under discussion.

First, my name is Dr. Christopher Martin. I am a physician and, as you indicated, I am Senior Director for Medical Affairs at the Merck, Sharp and Dohme Laboratories.

As a physician I am troubled by the presumption which underlies this proposed Bill, that we possess the know-how to make rapid, accurate, predictive judgments about the therapeutic equivalence of chemically equivalent products of the same drug.

Now I shall not review the many technical complexities which I think were covered very fully - very rapidly - here this morning by Dr. Kaplan from Hoffmann-LaRoche. I should, nevertheless, like to bring to you some specific examples of how difficult and problematical this can get.

Before joining Merck in 1970 I served on the full-time faculty of the New Jersey College of Medicine as an Associate Professor of Medicine and Director of the Division of

Infectious Diseases and between 1965 and 1970 I served as Professor of Medicine and Pharmacology at Georgetown University School of Medicine in Washington, D. C. At that same time I served as the Director of the Laboratoary of Chemical Pharmacology at Georgetown and directed a contract-supported program which linked Georgetown University with the United States Food and Drug Administration, whereby Georgetown served as the major scientific consultant to the F. D. A. and stood ready to conduct research studies related to the regulation of drugs.

In 1967, under the terms of that contract the then Commissioner of the U. S. Food and Drug Administration, Dr. James Goddard, assigned to us the problem of attempting to come up with data bearing on the comperability, or perhaps equivalence - therapeutic equivalence of chemical equivalents - of the same drug. This posed ethical as well as scientific problems because it clearly was inappropriate to attempt therapeutic comparisons unless we already had some prior evidence that the drugs were comperable. In other words, one cannot treat patients who are ill with a product about whom there is any question as to its activity.

We, therefore, settled on a design, testing various products of the same drug in normal volunteers, whereby volunteers would receive on three or four separate occasions single doses of the drug products under study. Blood and urine specimines would be collected and analyzed and from this analysis of blood levels, urine levels, etc., it would be possible to make some beginning assessments of whether or not therapeutic equivalence was probable, improbable, or indeterminate.

Among the drugs which were studied - nine drugs altogether - we found, in brief, that the drugs, all of which were on the market at that time , 1967 to 1969,

although in certain instances there were no significant differences between so-called brand and generic drugs or reference and generic drugs , there were many more instances in which there were significant differences, so much so as to raise questions about the therapeutic equivalence of these products.

I should like to speak, if I may, with the use of the flip chart here to give you examples of just such findings which have, of course, been published.

If we plot here, on this graft, blood levels and, across the bottom, hours after injection - zero to six hours-- The blood levels will be two, four, six, eight, ten, in terms of micrograms of drug - or c.c. of drug. I should like to graft for you the findings from three different products of Chlorampnenicol, a powerful antibiotic we studied. This study posed not only scientific but ethical questions as well. You may or may not know that Chloramphenicol, athough a potent and useful antibiotic is also occasionally a very toxic antibiotic that can wipe out the bone marrow of a small proportion of individuals who take it. Therefore, there was a large question as to whether or not we were on sound grounds giving this to normal, young adult male volunteers.

The well known brand product of Chloramphenicol is manufactured by the Parke-Davis Company in Michigan and has the brand name of Chloromycetin. The average blood levels achieved made a curve very much like that in the blood. (demonstrates on flip chart)

In comparison the same volunteers, when given two different so-called generic forms of Chloramphenicol, the blood levels achieved looked like this. (demonstrates on flip chart)

The differences were so large and so dramatic, it was quite clear that anyone who had typhoid fever and who was being treated with one of these generic drugs

stood a good chance of dying rather than recovering.

It was generally agreed among scientists that levels of about 2 micrograms per c.c. in the blood are necessary for activity of the drug against the invading germs or bacteria present.

This was, indeed, the case for 5½ out of the 6 hours of the test after the dose of the brand drug but was the case only for about 2 hours of the 6 with each of the two generic drugs.

Could this have been predicted beforehand in some simple way, rather than by administering it to normal volunteers with all the risks that that might involve? It turned out that the two generic formulations fulfilled all the requirements of the National Formulary of the U. S. Pharmacopoeia and of the United States Government.

Attempts were made by the U. S. Food and Drug Administration scientists who worked with us on these studies to do so-called dissolution tests - I believe one of the speakers this morning alluded to those tests - as a result of which it was possible to show that brand--

ASSEMBLYMAN BAER: Dr. Martin?

DR. MARTIN: Yes?

ASSEMBLYMAN BAER: I wonder if it would be possible for you to submit, following your testimony, in the next few days, charts, such as these, that are reduced in size, to be duplicated.

DR. MARTIN: Yes.

ASSEMBLYMAN BAER: If so, I wonder if you could indicate a numbering system on each of these charts so that it would be possible for persons to refer to these and their counterparts which you will submit, and the text indicating the numbers in the testimony.

DR. MARTIN: I should be very happy to so so.

ASSEMBLYMAN BAER: Thank you.

This, then, would be what? Chart one?

DR. MARTIN: This would be chart one, correct.

Chart two represents percent dissolved. This is minutes along here, running from 0 to 75 minutes. (demonstrates on flip chart)

Dissolution tests consist of putting a tablet, or capsule, into a tank containing a fluid which is made up to have the properties of stomach fluid, or intestinal fluid, in some way to mimic, esentially, the process of absorption in the body. When one does that, one finds that brand Chloramphenicol dissolved pretty rapidly and generic Chloramphenicol dissolves not too differently. In other words, there is no correlation between the rather rapid, quick laboratory test which, theoretically, ought to predict what would happen in man and what actually does happen in man.

In other words, the dissolution test, as studied here, does not take into account all of many factors which influence not only dissolving of the substance - of the capsule or tablet - but also the way in which it passes across the stomach wall, or the intestinal wall, to get into the system.

Now I shall not bore you with any number of additional examples of this kind of lack of correlation but I would like to point out that the kinds of differences which can occur between products of the same chemical equivalent drug need not necessarily represent inadequate degrees of absorption, as was the case here with Chloramphenicol, and may, indeed, represent quite the opposite.

One of the other drugs which Commissioner Goddard asked us to study was Diphenylhydantoin, which is the corner stone of therapy of epilepsy, discovered and developed in the 1930's. It is in wide use and most physicians - almost all physicians have used it and have gotten used to the behavior of the well-known reference product which is known as Dilantin.

When we did a similar comparison in normal volunteers of a Diphenylhydantoin reference product, the brand Dilantin--

ASSEMBLYMAN BAER: Pardon me, does the hearing reporter want any of these words spelled?

HEARING REPORTER: No, I will get them later.

ASSEMBLYMAN BAER: You will get them later? All right.

DR. MARTIN: I'm sorry the language is terrible.

Here again, the blood level is in hours and this part represents days. (demonstrates on flip chart) This is from 0 to 8 hours and from 1 to 4 days.

The brand achieved average blood levels in the volunteers that looked like this and then over the course of the following four days the level slowly fell off like that. (demonstrates on flip chart)

Of the two generics with which it was compared, one had been chosen by the F.D.A. because of complaints by some physicians that the drug appeared to be very weak. It achieved levels like this (demonstrates on flip chart) and certainly lower than the average of those achieved with Dilantin, but not statistically significantly lower, so that we would not say with assurance that it was not therapeutically equivalent. It might be for a few individuals but not for all. But the really surprising finding was with the second generic, which produced average blood levels fully twice as high as the well-known brand, the study brand, so much so that during the course of the experiment one of the volunteers almost fell down a flight of stairs. He developed signs of neurotoxicity, diplopia - or double vision - ataxia - unsteadiness on his feet - simply because this particular drug product was superbioavailable. So, identifed, therefore, was the whole spectrum of kinds of differences - or lack of differences - in these two

experiments, none of which had been predicted by previous study.

Dissolution rate tests performed by scientists at the Food and Drug Administration demonstrated that the brand dissolved like that over a course of 75 minutes. (demonstrates on flip chart) This particular superavailable generic did dissolve more rapidly but in 75 minutes there was really no great difference between it and the brand.

In other words, the dissolution test carefully performed by the federal agency did not predict what happened eventually to man.

There are many such examples. One study involved a product manufactured by a company in New Jersey, the Schering Corporation in Bloomfield - I believe. The product is known as Prednisone, which is a synthetic compound very much like hormones from the adrenal gland.

ASSEMBLYMAN BAER: This is now chart #5? - for the record.

DR. MARTIN: Yes. When one does a dissolution rate test, as we did, comparing two well-known brands of Prednisone with two generics, it turned out that the poorest dissolution rate occurred with the brand from the company in New Jersey and the best was one of the generics, which was not significantly different from the other brand used in the study. However, when this was administered to human beings - in normal volunteers - it was found that the highest blood and urine levels achieved and the best bioavailability was associated with the brand with which physicians are most familiar and which had given the poorest dissolution rate. The curve resembled something like this. (demonstrates on flip chart) We will call it brand one as compared to generic number one.

Rather than belabor this point any further, I

should like only to state that this is not a simple business and it is very complex, indeed, as members of the Committee, I am sure, are aware.

The Office of Technology Assessment, at the direction of Senator Kennedy's committee in the Senate, has been assigned the difficult task of trying to determine not what drugs may be considered equivalent but whether or not procedures and modalities can be established that will permit a determination of therapeutic equivalents. In other words, can we even scratch the surface with the kind of know-how that we need to begin to implement the proposal in this legislation?

I am a scientist, not an economist so I am not really prepared to speak to the economic aspects of this but I dare say that we should be very careful in this, with regard to this point of making certain that we are not penny wise and pound foolish. In other words, that we do not attempt to save citizens a few dollars for a drug prescription and, yet, run the risk of having him be required to return two or three more times to the doctor, or develop a complication, or lose more days work and, therefore, wages.

I'd like to sum up, therefore, by saying that at Merck, Sharp and Dohme the vast majority of the products that we produce and market were discovered in our laboratories, developed by our scientists, and manufactured by processes worked out with great care for reproducability, high quality and quality control. I think it is quite evident that it is always possible to cut corners, to reduce ones production, research, development, quality control effort and thereby reduce the price of the drug.

It is also possible to manufacture chemically equivalent drugs very well. This is being demonstrated

by the increasing role that large well-known drug companies are now getting into in terms of manufacturing generic drugs and doing it well.

These drug products are by no means inexpensive, simply because one must meet bioavailability standards, such as the kinds of studies I have shown to you and that have been discussed this morning by Dr. Kaplan and by endless concern about the quality of products which come from the company day in, day out, year in, year out.

The thrust, as we see it, of A-1257, with its assumption of equivalence and its relatively simple determination and its emphasis on price would encourage pharmaceutical manufacturers to produce down to the lowest competitive cost rather than up to the best obtainable quality.

So, Mr. Chairman, I submit that such a thrust is not in the best interest of medicine, the industry or the public that we all serve.

I would conclude by saying that A-1257 relies on unsound concepts and that it should not become law. Thank you.

ASSEMBLYMAN BAER: Thank you, Dr. Martin.

Are there any questions? Assemblyman Herman?

ASSEMBLYMAN HERMAN: Doctor, does Merck, Sharp and Dohme produce a drug called - I believe it is HydroDIURIL?

DR. MARTIN: HydroDIURIL, that's correct. That is the trade name for the chemical by the name of hydrochlorothiazide.

ASSEMBLYMAN HERMAN: And is that particular drug by Merck, Sharp and Dohme produced under license or by concent by any other major distributor - for instance, Parke-Davis?

DR. MARTIN: There are many other manufacturers of hydroclorothiazide.

ASSEMBLYMAN HERMAN: I am asking a very direct

question and the question, very simply, is this, does Parke-Davis produce this drug by way of consent from Merck, Sharp and Dohme?

DR. MARTIN: I really don't know the answer to that question.

ASSEMBLYMAN HERMAN: Well, let me ask you this, does Merck, Sharp and Dohme produce this drug for distribution through Parke-Davis?

DR. MARTIN: I can't answer that either. I am in the research division.

ASSEMBLYMAN HERMAN: All right. Let me make the record clear. Could you obtain that information and advise us?

DR. MARTIN: I dare say, yes, I could obtain that information.

ASSEMBLYMAN HERMAN: Perhaps that information is available through counsel, who I understand is here today.

DR. MARTIN: Yes, there is counsel.

COUNSEL: I believe I can answer both of those questions but I would like to double check and make sure of my answer.

ASSEMBLYMAN HERMAN: Perhaps if we could have that in writing I would appreciate it.

I wish to know if that drug is produced by Parke-Davis and if it is produced by Parke-Davis, is it distributed either through license or through consent, or manufactured by Merck, Sharp and Dohme for distribution through Parke-Davis?

ASSEMBLYMAN BAER: For the purpose of answering this question, could you come down front here as a representative of Merck? As I indicated, insofar as general testimony, I would appreciate it if you would wait till later. But to supplement this testimony in answering questions, we appreciate your presence.

MR. BYLES: Yes. For the record, the name is Daniel Byles, Corporate Staff Counsel for Merck in Rahway.

As I understand the question, you are asking if HydroDIURIl, or hydroclorothiazide is marketed by us through license from Parke-Davis or vice versa?

ASSEMBLYMAN HERMAN: No. Do you license Parke-Davis to produce it?

MR. BYLES: I will double check that but I believe the answer is no.

Your second question is do we make that for Parke-Davis?

ASSEMBLYMAN HERMAN: Yes.

MR. BYLES: Again, I'd like to double check on that and I will get that to you in writing. I believe the answer is no.

ASSEMBLYMAN HERMAN: Thank you very much.

Doctor, just a few other things, if I may. Does Merck, Sharp and Dohme engage in an active line of branded generics?

DR. MARTIN: No, they do not.

ASSEMBLYMAN HERMAN: Do they produce generics at all for distribution, vis-a-vis the brand name sale of drugs?

DR. MARTIN: No, I don't think so. There are-- Merck has its own brand of prednisone, for example. This goes back to patents.

ASSEMBLYMAN HERMAN: It goes back to the old patent rights, right?

DR. MARTIN: Yes.

ASSEMBLYMAN HERMAN: Merck was the original patent holder of this?

DR. MARTIN: I think Merck was, yes.

ASSEMBLYMAN HERMAN: Or it might produce so many drugs under licenses from other companies in the field?

DR. MARTIN: No, Merck has not made that kind of an entry into the field, such as other large companies have.

ASSEMBLYMAN HERMAN: All right. By the way, does Merck license others to produce drugs which it has under patent?

DR. MARTIN: There are such arrangements with companies overseas, for example.

ASSEMBLYMAN HERMAN: How about domestic?

DR. MARTIN: I couldn't answer that but perhaps counsel can speak to that question.

ASSEMBLYMAN HERMAN: Well, rather than have counsel get up again, perhaps he can supply us with that information either at the time that he testifys or through his written response, without taking too much of the Committee's time right now.

In reference to generic drugs, as we know them, isn't it true, Doctor, that the percentage of the prescription market is increasing with relation to generic drugs versus brand names?

DR. MARTIN: I understand this is true.

ASSEMBLYMAN HERMAN: Isn't it also true that in New Jersey if a generic drug is prescribed by the doctor it is up to the pharmacist to fill it with whatever brand name or company he sees fit to use?

DR. MARTIN: At the present time, yes.

ASSEMBLYMAN HERMAN: So, we are in agreement that that is the present law. Doctors can prescribe generically and the pharmacists can fill it in the manner they best see fit. For the record, your answer would be in the affirmative to that question?

DR. MARTIN: I gather that is the case in New Jersey, yes.

ASSEMBLYMAN HERMAN: Do you agree or disagree

with that part of the law, Doctor, which permits doctors to prescribe generically and pharmacists to pick what they believe to be, in their best professional judgment, the proper company to fill the prescription with?

DR. MARTIN: Well, it is a dangerous state of affairs, sir, because, in fact, there are no good guidelines at the present time for assuring that most such generic products are, indeed, therapeutically equivalent to the well-known brand.

ASSEMBLYMAN HERMAN: Again, going back to the example I used earlier - for the sake of consistency - Ampicillin--

DR. MARTIN: Yes.

ASSEMBLYMAN HERMAN: --does Merck produce it?

DR. MARTIN: No, it does not.

ASSEMBLYMAN HERMAN: Squibb, Parke-Davis, Wyeth, Upjohn, these are reputable firms?

DR. MARTIN: Yes.

ASSEMBLYMAN HERMAN: Have you heard in the trade that there has been any problem with Ampicillin?

DR. MARTIN: Yes, there has been with certain brands of Ampicillin.

ASSEMBLYMAN HERMAN: Has there been any problem with those particular brands?

DR. MARTIN: To my knowledge there is published information concerning the bioavailability of Ampicillins produced by those companies.

ASSEMBLYMAN HERMAN: As a scientist, you would have no qualms or reservations so long as there is the proper scientific information available to the pharmacist to allow that pharmacist to take a choice between Squibb, Wyeth, Parke-Davis, etc.?

DR. MARTIN: To the extent that the decision has been made at the Federal certification level that the product is, indeed, therapeutically equivalent to the reference product, certainly.

ASSEMBLYMAN HERMAN: So the answer to that, Dr. Martin, is that you wouldn't find that scientifically offensive?

DR. MARTIN: Not at all.

ASSEMBLYMAN HERMAN: Okay. Just following this question of the present law, Doctor, one step further - the right of the physician to presecribe generically and the right of the pharmacist to fill that prescription as he best sees fit - do you believe there ought to be any change of direction in that law or do you think we ought to leave it as it is? In other words, should we leave it to the marketplace or leave it to the companies to supply the infomation and allow the pharmacist to make whatever best professional judgment he can?

DR. MARTIN: Well, I really can't paint you a large picture of just what is the case. I think that we must evolve new systems with new knowledge. This is an important area for new knowledge. For example, that which you cited, hydroclorothiazide, that is a very difficult product, or drug, with which to determine therapeutic equivalence. The dose is so small that it is virtually impossible to measure it in the system.

ASSEMBLYMAN HERMAN: Without getting into better and best, that one drug that you mentioned, do you know that Parke-Davis produces it?

DR. MARTIN: I really don't know whether they do or not.

ASSEMBLYMAN HERMAN: I will hold that question. Thank you.

ASSEMBLYMAN BAER: Assemblyman Ruane?

ASSEMBLYMAN RUANE: Doctor, I'd like to ask you do you have any idea of how much of Merck's budget goes toward research?

DR. MARTIN: Yes, I guess that is not privileged information, the research budget for Merck, Sharp and

Dohme Company, this year, is between $90 and $100 million.

ASSEMBLYMAN RUANE: Of its total yearly budget, though, what is the percentage for research?

DR. MARTIN: Gee, I don't know what that would be. Merck as a worldwide company has sales of about $800 or $900 million, or something of that sort. So, this would be, perhaps, one-tenth of that.

ASSEMBLYMAN RUANE: And what is the policy of the government with regards to research - the United States Government?

DR. MARTIN: With regard to private research?

ASSEMBLYMAN RUANE: Do they subsidize you in any way, shape or form?

DR. MARTIN: No. Merck scientists work with the government, of course, in many instances, particularly on problems which are judged to be of major national concern. For example the U. S. Government has given Merck a large grant to set up a major cancer research center in West Point, Pennsylvania to develop information and possible evidence for the usefulness of a vaccine for the prevention of cancer. That would be considered a joint Federal Government - Merck venture.

But those instances are very unusual.

ASSEMBLYMAN RUANE: Thank you.

ASSEMBLYMAN BAER: Assemblyman Rys?

ASSEMBLYMAN RYS: I just wanted to ask you, in situations such as those you have illustrated with the charts, are the differences in the blood level as opposed to the differences shown in the tests from dissolution and things like that, is that, in most cases, identified as to what the cause is and does it relate to the purity of the product or does it relate to the form of incapsulation, or the additional substances present, or the size of the crystals? What kinds of factors are the factors that

actually cause those differences?

DR. MARTIN: Well, sir, I think you have just enumerated many such factors which do influence those blood levels and urine levels and the rate and degree of absorbtion.

For example, with those three chloroamphenicol products, where the brand Chloromycetin was absorbed very well, it was evident that, just by opening the capsule and looking at the crystals under the microscope , the crystals in the brand drug were very fine - like powder - whereas the crystals in the poorly absorbed generic were quite course and large and resembled the crystals of table salt.

Indeed, scientists at Parke-Davis have looked into this very carefully and have concluded that particle size appears to be the dominant factor in that instance. In other products - for example certain sulfa drugs - the hardness of the tablet determines how well the material is absorbed. This is the key factor in a drug which I think the previous witness alluded to this morning, tolbutamide, an antidiabetic drug, where it was possible, experimentally, to make up tablets which are produced with such hardness that they are not absorbed at all.

Conversely, one can make tablets which crumble so well - they act so fast - that they act too fast and the beneficial effects of the drug are all over in 20 minutes instead of lasting for a period of 6 hours.

So, it is possible to play with each of these factors to achieve, hopefully, the optimum conditions for handling of the drug by the body and achieving the purpose for which the drug has been discovered and designed.

ASSEMBLYMAN BAER: I see. I take it that, although these variations exist, they are more variation by design and that there is no problem whatsoever in establishing or maintaining standards that are adequate in regulating these variables. It is just a question of what the particular

design of the particular drug might be.

DR. MARTIN: Well, it is a question of identifying which variables are important for which drug. Unfortunately, different drugs are plagued by different problems. In order to get certain drugs to dissolve one must add so-called excipients - binders, fillers, etc. One must add flavoring also because the drug may have a terrible taste and the flavoring itself may influence the way in which the body absorbs the drug, or how much of it is absorbed. So, all this must be worked out beforehand and, typically, it takes a great deal of time and effort, etc., to work out an ideal set of circumstances. It is possible, of course, to skip a lot of that effort to come up with a drug product which is a chemical equivalent, to be sure, but with which there is little reliability with respect to absorbtion, either to degree or rate.

ASSEMBLYMAN MARTIN: Thank you very much for your very helpful testimony.

I'd like to call Claude V. Timberlake, Jr., Vice President of the National Pharmaceutical Council, as our next witness and I would like to request Mr. Timberlake and all remaining witnesses, in view of the problem that is beginning to develop with the time and the schedule - so that we can hear all the witnesses - to confine your initial testimony to 10 minutes. It would be appreciated. Otherwise, we will not be able to hear everybody.

Mr. Timberlake, do you have a prepared statement?

C L A U D E V. T I M B E R L A K E, J R: No, I don't. I will just talk from notes and from experience. Mr. Chairman, members of the Committee, I am Vice President of the National Pharmaceutical Council. I am a registered pharmacist. I have practiced retail; I have practiced in hospitals; prior to being elected Vice President of the National Pharmaceutical Council I spent some 28 years in the Navy. I was a pharmacist. I headed up the pharmacy

service in the Navy. I was head of the quality control system for the procurement of medical supplies and equipment for the military, some 10 years. I was a member of the Intergovernmental Procurement Advisory Council on Drugs on the U. S. P. Revision Committee and an NASNRC Council representative for the Defense Department and a member of the Defense Medical Material Board.

I am a registered pharmacist in a number of states and I have been registered in New Jersey and a resident of New Jersey while I was in the Navy - although I probably don't sound like a New Jerseyite, I really lived here for a number of years.

ASSEMBLYMAN HERMAN: It doesn't show up in the transcript.

(laughter)

MR. TIMBERLAKE: First of all, I just want to see if I can be of some assistance to you in solving a real problem. I am aware of what you are trying to do because the Navy handed me this problem 20 years ago, when Public Law 181 stated we would buy drugs and drug products at the lowest cost on a competitive bid basis.

I feel like I have sort of been taken to task by a couple of people this morning - one on each side. Dr. Ryan complained of the drugs that didn't work when he was down in Louisiana when he was in the Army. That was in 1960 and 1961. I was on the Defense Medical Material Board then and I know what he is talking about because we were really fighting to upgrade the quality of the drugs at that time.

I also can agree with Mr. Gottberg when he says that Walter Reed and the Navy Medical Center dispense all drugs generically. That's true. Every drug has a generic name. But if you walk in and see who made those drugs today you would see that the name doesn't make much difference. It is who made them that counts.

You have given me sort of a short time here so I am going to try to be as brief as I can. First of all, I am going to be frank with you when I tell you that I don't believe it is possible for you to do what you want to do in this bill - even the first step - for less than about $3½ million a year. Now I say this, based on my experience in the military where we standardized 1100 products. This is about 70% of all the drugs used by the Department of Defense for its military personnel and its beneficiaries. This amounts to around 9 million people, some 2 million people more than you have in the State of New Jersey. I think, in New Jersey, you have about 7 million people.

We, in our quality assurance program in the Department of Defense - The Defense Personnel Support Center down in Philadelphia - will run about $3½ million per year in the procurement of $125 to $150 million worth of drug products, attempting to assure chemical and physical equivalence, not therapeutic equivalence. That project was attempted in 1966. The Department of Defense just decided that it was a luxury they couldn't afford because to assure therapeutic equivalency you have to first assure chemical equivalency and physical equivalency. That is all the military is trying to do now.

People who have preceeded me here have mentioned a number of items they have had problems with. I could name perhaps 50 items, including aspirin. Digoxin - we knew the problems associated with that way back in 1966 -- Warfarin; Dilantin Thyroid Prednisone; Nitrofurantoin; Oxytetracycline; pHisoHex, which is noting but a surgical detergent. We were buying pHisoHex for the military and we were buying it under a generic nomenclature. We wrote out detailed specifications for it, around Winthrop's pHisoHex. We got it and put it into the system. The

physicians didn't know what it was. They thought they were still getting pHisoHex. Pretty soon the reports began to feed back from some 1,500 physicians in 350 hospitals that the nurses and the surgeons hands were beginning to break out from something. We traced it to the new surgical detergent that we were buying in place of pHisoHex. We worked with the company diligently to determine what the difference was. We then had to make that a sole source item with pHisoHex for about 5 years until we could come up with a formula - a chemical formula - that would do the job that pHisoHex was doing.

Nitroglycerin - I noticed that the gentleman from the senior citizens group was sitting here with a bottle of Nitrostat on the table here. That is nitroglycerin. Nitrostat is one of the products made by Parke-Davis. Nitroglycerin is the generic name. Nitrostat is the brand name. I happen to have the same bottle. This came from the Naval Medical Center in Bethesda and it is Nitrostat, made by Parke-Davis. It is nitroglycerin. This is what we get.

I am also on Lanoxin. I say Lanoxin because I know what I get. I have had a heart attack; I am in atrial fibrillation and Lanoxin keeps me alive and keeps me well and I am going to stick to it. I don't care if Lilly makes it, Parke-Davis makes it, or anybody else. I am on Lanoxin and I know it works. I am going to stick with it. That is one drug that we in the military would never buy from anybody until it is absolutely proven that therapeutic equivalency can exist. When you can get a superimposable graft, such as Dr. Martin had here, where,with two drugs,the blood levels are superimposible then you have true therapeutic equivalence.

I have a list of several things here. We have been working,in the Council, with the staff of the Bioequivalency Drug Study Group with O.T.A. They have spent quite a bit of

time with us. They have the same charge given them that you are going to give to this group, almost - the Council members; the same charge. We are working with them and I don't believe they are going to come up with an answer by the 30th of June. We tried to, in the military, for years, and we gave it up.

I think you are all familiar with the Formulary. A similar Formulary was put into law up in Massachusetts. They had five members on a Formulary Council and they came up with a list of drugs and the generic name which was supposed to be therapeutically equivalent; that was in 1973. They published that list. Now, I have, for my own edification, gone through all the F.D.A. recalls in 1973 - just for one year - and there were 72 of the drugs listed in the Massachusetts Formulary which were subject to recall because they were either subpotent, superpotent, or otherwise inferior.

ASSEMBLYMAN BAER: Do you have extra copies of that with you?

MR. TIMBERLAKE: No, but you may make zerox copies of this. I only have one copy.

I have some key statements here. One of the gentlemen referred to H.E.W. I'd like to quote a couple of statements here which will not take too much time.

"This limited experience suggests that Formularies, especially if used to replicate lists of drugs routinely available for dispensing may be an effective device for raising program costs." That was a statement contained in a talk given by Dr. Donald T. Ruckles, Chief of the Drug Study branch of the H.E.W., in New Brunswick, New Jersey at the Rutgers University Pharmaceutical Conference.

Under the Medicaid Program of H.E.W. there is a statement - "A drug Formulary may interfere with the physician's prerogative to prescribe the drug which, in his clinical opinion, is needed by his patient."

That is in the Medicaid Payment of Reasonable Charges Guidelines, Medical Assistance Manual, part #6.

In the Task Force on Prescription Drugs of H.E.W. there is another statement. "In the Interest of achieving the highest quality of medical care, recognizing the necessity of placing the fewest possible restrictions on the traditional right of physicians to prescribe according to their best clinical judgment.. ." I won't read the rest of the statements.

I have two other statements here. In the operation of a hospital Formulary system, these are the guiding principles which all hospitals are supposed to operate by if they are accredited by the Joint Commission and they were agreed to by the American Hospital Association and the American Medical Association and the American Pharmaceutical Association and the American Society of Hospital Pharmacists. There are two paragraphs which state in here - "to insure the maintenance of the responsibility and prerogative of the physician in the exercise of his professional judgment, the hospital Formulary system shall not contain any policy or procedure which, prior to the time of prescribing, provides for consent by the physician to the dispensing of an non-proprietary drug or to the dispensing of a proprietary brand different from the brand which he prescribed."

Another paragraph states, "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." These are still in effect and there are copies enough of those.

I have charts here, although I don't have enough color charts, from the H.E.W. These are Medicaid programs. It shows where - and I am not going into the detail, I'll let you study them - states who have the most restrictions on the physicians' choice of drugs have the highest cost - overall cost - in their Medicaid Programs. The states with less, or no restrictions on drugs,have the lowest cost for their physician or hospital services. This is the administrative service and training expense -- These are all Department of Health, Education and Welfare charts, they are not made by us or anybody else, except H.E.W. They show where states with the most restrictions on the physicians' choice of drugs are spending more money - cash benefits - on their public assistance programs for Medicaid and Medicare.

I have said about as much as I can in my ten minutes. I probably went over the ten minutes.

ASSEMBLYMAN BAER: That's all right. It has been very valuable testimony.

MR. TIMBERLAKE: I would be happy to answer any questions, as I have spent, as I say, some 20 years trying to make sure that my fellow personnel in the military got the best drugs at the lowest price - but they had to be good.

ASSEMBLYMAN BAER: Thank you. Your testimony has been very informative and we appreciate all the additional material that you have provided us with.

Did you have other material you were going to give us but ran out of time before you did?

MR. TIMBERLAKE: I have three recall charts here.

ASSEMBLYMAN BAER: Because I didn't mean to cut you off before you provided us with all the material that you brought down here for that purpose.

MR. TIMBERLAKE: Well, these recall charts - F.D.A. drug recalls for 1971, 1972 and 1973 - show the total recall for all drugs plus the recall for the nationally advertised brand-name drugs.

There is one other statement that I would like to make in defense of myself against Dr. Ryan. I know he got some poor drugs back in 1960 and 1961 because we bought some junk in Europe. I was one who had to go over to Europe and survey a lot of manufacturers who where manufacturing pesticides and who wanted to also manufacture tetracycline. In 1968 there were 711 drug products recalled by the Food and Drug Administration. That year there were only four of those products in the military supply system. In 1969 there were 707 recalls of defective drug products by the F.D.A.; three of those products were in the military supply system. In 1970 there were 951 recalls by the Food and Drug Administration; one product - and that was digoxin, they bought an off-brand of digoxin - was in the military supply system. In 1971 there were 862 recalls by the F.D.A.; two products were in the military supply system. In 1972 there were 861 recalls; one was in the military supply system. In 1973 there were 512 recalls - they are beginning to tighten up now, the F.D.A. is really starting to crack down on some of these people who aren't producing what they ought to - there were 2 in the military supply system.

So, the military supply system does a good job of assuring drugs which are chemically and physically equivalent but they can't approach the therapeutic equivalency bit yet.

ASSEMBLYMAN BAER: Well, thank you for that testimony. Do we have any questions from the Committee?

ASSEMBLYMAN RUANE: May I ask you what do you think is the difference between a brand name and a generic drug? You can pick any example you want.

MR. TIMBERLAKE: The difference is in who makes them. There are bad brands and there are good generics and vice versa. Lilly is one of the largest manufacturers of generics in the country.

For example, at last count there were 83 brands of Meprobamate on the market - I mean brand names. But every drug has a generic name. It's like whiskey, that's a generic name. You have all sorts of whiskey - good, bad, bootleg, etc.

ASSEMBLYMAN RUANE: With regards to the F.D.A., what is the percentage of drugs that are rejected?

MR. TIMBERLAKE: Recalled?

ASSEMBLYMAN RUANE: Yes, recalled.

MR. TIMBERLAKE: Percentage?

ASSEMBLYMAN RUANE: How many, for instance? Do you have any figures for 1972 or 1973? You have a lot of charts.

MR. TIMBERLAKE: These are taken from official drug recalls that they publish every week. I keep a list of those. Just for the past 6 or 7 years -- I just named them. In 1968 there were 711 recalls; drugs that the Food and Drug Administration recalled. These were products that were already on the market and being distributed - being dispensed.

ASSEMBLYMAN RUANE: That's not exactly my question. How many drugs are submitted for the F.D.A.'s consideration? Are there any figures on that? That all revolves around research by the individual companies, does it not?

MR. TIMERLAKE: The F.D.A. doesn't test drugs before they are put on the market. They only test new drugs. But every manufacturer that manufactures drugs -- his drugs do not have to be tested by the F.D.A. That's where everybody gets confused; they think the F.D.A. tests all drugs that are on the market and they don't.

These recalls list only those drugs that they have

picked up or that somebody has complained about - that are not working. I am sure it is just the tip of the iceberg. I think if they really tested every product that is on the market they would find at least 40% of the drugs involved don't meet compendial standards. Now that sounds like a high figure but I would almost stake my life on it because I have done it enough and that is what we found in the military. We found that 40% of the drugs that we tested after we had inspected the facilities and determined that they had the know-how and the capability to produce -- We would then have them produce a preaward sample and submit it to our laboratories and we would assay it and find out, then, that 40% of those could not meet the compendial standards. Yet, these people were still producing for the open market.

We reported it to the F.D.A. We work very closely with the F.D.A. It is not their fault. The F.D.A. just doesn't have the people, they don't have the money and they don't have the methodology to determine therapeutic equivalency.

We have supported that. I used to say a long time ago that if I were one of the large ethical manufacturers - any of them - I would support the strongest Food and Drug Administration we could possibly have because I used to see so many slop operators trying to do business with us - with the Government - and that is when we got into hot water; when the doctors' stopped using the drugs. They said, we won't use that garbage, and that is what Dr. Ryan was talking about. That's about the time when we got so many complaints from doctors. We just had to crack down. Bases have now some 300 people and they spend about $3½ million a year just on the quality assurance. They spend around 7½ million a year just on the procurement of drugs. They have a 7% surcharge on the drugs that they centrally procure and sell to the hospitals

in the military supply system. So, it is not simple, really.

ASSEMBLYMAN RUANE: I didn't say it was.

MR.TIMBERLAKE: I wish I could -- I'd be glad to help you. If you could solve this problem - if this committee could solve the problem, as you have set out for them to do, I am sure that Senator Kennedy would like to know about it and so would the O.T.A. and the Food and Drug Administration.

ASSEMBLYMAN BAER: Assemblyman Herman?

ASSEMBLYMAN HERMAN: Yes. I assume that what you attempted to do was get the best quality drug for the lowest price, is that correct?

MR. TIMBERLAKE: That's correct.

ASSEMBLYMAN HERMAN: And I assume in various areas you could obtain a high quality drug for a lower price.

MR. TIMBERLAKE: Well, we always accepted the lowest responsible bidder, that's right.

ASSEMBLYMAN HERMAN: So that was available to the military supply system through cautious and prudent purchase?

MR. TIMBERLAKE: We wrote our own specifications. We did our own inspection of every plant that we bought from.

ASSEMBLYMAN HERMAN: All right. Now, extending that thought, if I may, what would you say - based on the prudent specifications, the careful purchase of quality medicines and drugs - was saved, dollar-wise, vis-a-vis if you had to go into a drug store, or any manufacturer, and say, "I want so much of this product, notwithstanding the price; take the highest and best brand name off the shelf"?

MR. TIMBERLAKE: How much--

ASSEMBLYMAN HERMAN: In other words, I assume there was a substantial saving, doing it the way you did it.

MR. TIMBERLAKE: Well, at one time, back in 1951, we were of the opinion that we would save money if we let each hospital buy open purchase because when we bought centrally we bought under certain conditions. We couldn't return the drug. If we bought $200 thousand worth of - and we did - of hydroclorothiazide, for example, and then two months later a better drug for that diuretic use came out and the doctors went to that, we had this $175 thousand or $200 thousand left on the shelf and we couldn't return it to the company.

ASSEMBLYMAN HERMAN: Notwithstanding that, I assume - what I am trying to get at - that doing it this way, there was a saving; that you got responsible medicines at a saving.

MR. TIMBERLAKE: That's correct, we got some.

ASSEMBLYMAN HERMAN: What I am trying to say is, based on the 7 million people that you were servicing, how much of a saving were you effecting for those 7 million people?

MR. TIMBERLAKE: I don't know because these drugs were furnished to the military personnel and their dependents and retired people at no cost.

ASSEMBLYMAN HERMAN: Well, there was a cost to the Government?

MR. TIMBERLAKE: Yes.

ASSEMBLYMAN HERMAN: Now the point I am trying to make is, the Government had to go out and buy these drugs.

MR. TIMBERLAKE: That's right.

ASSEMBLYMAN HERMAN: Now, you tried to buy the best responsible drug at the lowest price.

MR. TIMBERLAKE: That's correct.

ASSEMBLYMAN HERMAN: Which means that, in many instances, there was a drug of equal quality at a higher price.

MR. TIMBERLAKE: That's right.

ASSEMBLYMAN HERMAN: What I am trying to ascertain is, for these 7 million people whom the Government supplied and for whom you were responsible to purchase, what type of saving was anticipated, based on the yearly drug purchase?

MR. TIMBERLAKE: I don't know that those figures even exist anywhere. I really don't.

ASSEMBLYMAN HERMAN: By the way, you said that you were the Vice President of the National Pharmaceutical Council?

MR. TIMBERLAKE: That's correct.

ASSEMBLYMAN HERMAN: That's an arm of what group, if I may ask?

MR. TIMBERLAKE: The National Pharmaceutical Council's membership is made up of the 26 research-oriented pharmaceutical manufacturers in the United States.

ASSEMBLYMAN HERMAN: Okay.

MR. TIMBERLAKE: Nine of whom are in New Jersey.

ASSEMBLYMAN HERMAN: Now--

MR. TIMBERLAKE: We do not represent the Pharmaceutical Manufacturers Association.

ASSEMBLYMAN HERMAN: I beg your pardon?

MR. TIMBERLAKE: We do not speak for the Pharmaceutical Manufacturers Association.

ASSEMBLYMAN HERMAN: Okay. But you do speak for those who may be members of the Pharmaceutical Manufacturers Association?

MR. TIMBERLAKE: All of our members are members of P.M.A.

ASSEMBLYMAN HERMAN: Okay. I believe you mentioned the Massachusetts Formulary. Are you familiar with the program that is presently in effect in Ontario?

MR. TIMBERLAKE: Ontario?

ASSEMBLYMAN HERMAN: Yes.

MR. TIMBERLAKE: I am not familiar with that. The only program that I am familiar with in Canada is in Alberta where, after they repealed the antisubstitution law the cost - prescription cost - went up. I am not familiar with the par cost. I have heard of it but I am not familiar with it.

ASSEMBLYMAN HERMAN: As a pharmacist of long practice and standing, based on your testimony, as far as establishing— On a day-to-day working basis, who would you say would be more capable of making that judgment, the physician or the practicing pharmacist?

MR. TIMBERLAKE: I am glad you asked that question. Among other things, I was a naval aviator and a test pilot before I got over into the medical service corps and into the pharmacy branch in 1948. The pharmacist, no doubt, knows more about the formulation of drugs - the compounding and the formulation of drugs - than the physician, just as the aeronautical engineer knows more about the construction of an airplane than a pilot does. But it is the pilot and the physician who determine whether or not the drug works properly or the plane flies as it should.

Now, I couldn't build an airplane but I used to do a lot of testing and I sat down and I told that aeronautical engineer that there was something wrong with it; it flies one wing low; it won't go into a flat spin at so many knots; you pull out at 6 g's and the windshield flies off; there is something wrong with it.

It is the same way, the doctor doesn't know as much about the formulation of drugs as a pharmacist does but he does know what happens to the patient when he monitors that patient; he knows whether the drug is working as it is supposed to work.

ASSEMBLYMAN HERMAN: What do you see as the role of the pharmacist in todays medical team?

MR. TIMBERLAKE: I think the pharmacist has a very important role and I think one of the most important roles the pharmacist can serve in today, in the health care field, is to serve the physician in the drug-drug interaction bit. Now, most physicians, like Dr. Ryan-- He treats people for arthritis. He uses, probably, lots of indomethacin, salicylates, steroids, etc., but he doesn't use some of the other drugs that may be used on a patient who has a psychotic disorder, for example. The pharmacist is able to spot drug-drug interactions there and advise the physician.

Actually the physician and the pharmacist working together are ideal in making a decision and I don't think that it should be a decision where the pharmacist selects a drug without the physician knowing about it because if something happens the physician never knows whether or not it was the fault of the drug.

ASSEMBLYMAN HERMAN: What about if the physician knows about it? You don't see any problem there do you?

MR. TIMBERLAKE: If the physician knows about it?

ASSEMBLYMAN HERMAN: Yes. The pharmacist recommends a substitution.

MR. TIMBERLAKE: Well, if the pharmacist recommends a substitution and the physician authorizes it, then the physician, if there is a problem with it, is at fault, I think.

ASSEMBLYMAN HERMAN: Okay. Just one or two more questions. You mentioned pHisoHex.

MR. TIMBERLAKE: Yes.

ASSEMBLYMAN HERMAN: Hasn't that been-- With all due respect to pHisoHex, aren't there many hospitals that are discontinuing their use of that altogether - generically

or by brand name?

MR. TIMBERLAKE: They are using it in certain areas but they are not using it like they used to use it in pediatric wards. They have found, I think, that it may cause some problems but they still do use it.

ASSEMBLYMAN HERMAN: But not to the same extent?

MR. TIMBERLAKE: Not to the same extent, no.

ASSEMBLYMAN HERMAN: Thank you very much.

ASSEMBLYMAN RYS: Mr. Timberlake, when you were doing the purchasing for the armed services you did that by bidding, is that correct?

MR. TIMBERLAKE: If we wanted to buy aspirin - everybody takes aspirin so that's simple - we wrote a detailed specification - and I can tell you that specification was about 7 pages long. We said, it shall be in accordance with the U.S.P. and, in addition, it shall comply with the following requirements. When we opened that up for bidding anybody could bid on it. You could go in and bid on it and not even have a plant. Before we could award that contract we would have to do, first of all - the contract people would do a Dunn and Bradstreet Rating on you to find out whether you had the money to make it or not. Then the technical - the Quality Assurance Division - would go out and survey your facilities and we would spend perhaps-- I have spent as much as three and four days in a plant if it were a big plant to determine whether or not they had the capability to produce an item which met with specifications, on time and delivered to us.

Now, if we found that the firm had the capability but that they had never produced it before, we would then call for preaward samples. This was to protect the firm and to protect us. We wouldn't say, go ahead and make a whole two-car load and then we will inspect it. We would tell them to make a preaward sample - one batch -

then we would send an inspector out and we would select representative samples from that lot and bring it into our laboratory - sometimes we would even submit it to the F.D.A., or to an independent testing laboratory. Right down in Philadelphia there is a million dollar laboratory with an electron microscope; they can test almost anything they want to as far as physical and chemical is concerned.

ASSEMBLYMAN RYS: But mostly you would take the lowest bidder if he qualified for your specifications?

MR. TIMBERLAKE: If he qualified and met all the contracts and requirements, yes.

ASSEMBLYMAN RYS: This is what I am trying to lead to. What was the percentage between the highest and lowest bidder, do you recall any of that?

MR. TIMBERLAKE: Do you mean the dollar value?

ASSEMBLYMAN RYS: Could you give it to us in dollar value or in percentage?

MR. TIMBERLAKE: I really don't know because I was not the contracting officer, I was in charge of the Quality Assurance Division. I don't know, it would range. People would come in and bid a dollar on a first aid kit that they couldn't have possibly made for a dollar. The highest bid would be $25, let's say.

ASSEMBLYMAN RYS: All right. Can you recall any of the savings on the bids?

MR. TIMBERLAKE: No, I really can't. I guess I am getting a little bit senile.

ASSEMBLYMAN RYS: I wouldn't say that.

MR. TIMBERLAKE: But you have a problem and I think you are on the right track. I just hope, or wish, that you could do it because if you do you could solve a lot of problems on the national level.

ASSEMBLYMAN BAER: I want to thank you very much, Mr. Timberlake. Your testimony here has been very impressive and we appreciate your cooperation.

Our next witness will be Floyd Krengel, New Jersey Osteopathic Society.

F L O Y D K R E N G E L: My name is Floyd Krengel. I am an Osteopathic Physician and I am a member of the New Jersey Association of Osteopathic Physicians and the Chairman if its Legislative Committee.

In this capacity I would like to voice opposition of the New Jersey Osteopathic Association to Assembly Bill 1257 because of the potential health hazards to the residents of New Jersey that is created when substitution is permitted in any manner.

I need only to recall the very recent discovery of subpotent batches of Digoxin - a cardiac medicine - to remind me of this possibility.

I am a practicing physician in Asbury Park and, as such, would like to voice my personal opposition not only to the content of Assembly Bill 1257, but also to the question of the very need for any such legislation. As I understand this bill, it would create a drug utilization review council under the Department of Health. This council would then determine the therapeutic equivalence of various drugs. I am unable to see how the council, as described in this bill, possesses the knowledge to make such judgments. There are no requirements that all members possess the working knowledge of pharmacology, an information necessary to make the proper decisions, to say nothing of the physical or the financial resources which are needed.

This council would also work without pay. How can one attract the caliber of people to perform such an inportant task and expect them to work for nothing? I suspect that under these conditions any fruits of their work would be less than 100% effective.

I do not desire to practice medicine with such tools, nor would you, as possible patients, want

me to practice in this manner.

I have practiced medicine for 13 years and have always had the option to prescribe the drug by brand or trade name because I have had a successful experience with that particular brand. I do not need a pharmacist, who has never treated a patient, to question these years of experience.

Ladies and gentlemen, my office is busy enough without having to handle additional phone calls requesting authorization to substitute, or letters notifying me that substitution has taken place.

I assume that the purpose of this legislation is to save the consumer money and I laud the Committee for its efforts, but I fail to see where legislation of this nature can do anything but hurt the patient.

In summary, these are my reasons for opposing this bill. First, the potential hazard of drug substitution without adequate proof of therapeutic equivalence far outweighs any possible saving to the consumer.

Second, who is going to police this legislation if it is enacted? It is my understanding that the State Board of Pharmacy has its hands full now. Do we create another agency, at taxpayer's expense, to make sure that the saving is passed on to the consumer?

Third, what about legal responsibility? If one of my prescriptions is substituted, I certainly should not bear the legal liability if an adverse reaction takes place. Will the pharmacist shoulder this responsibility or will it fall upon the State and, ultimately, the taxpayer?

Fourth, a drug utilization review council, unless it operates with a budget similar to the Federal Food and Drug Administration cannot be an effective body.

There is certainly a possibility that a state income tax will become a reality. I do not want to see the tax rate raised to fund a State Food and Drug Administration before it is even passed.

Ladies and gentlemen, I urge you, strongly, to oppose any further consideration of this bill.

ASSEMBLYMAN BAER: Thank you. Are there any questions? Assemblyman Herman.

ASSEMBLYMAN HERMAN: Doctor, during your 13 years of experience have you prescribed drugs generically?

DR. KRENGEL: Yes, I have.

ASSEMBLYMAN HERMAN: Using the year 1973 as a guide, how many prescriptions would you say you wrote during that year?

DR. KRENGEL: During the year?

ASSEMBLYMAN HERMAN: Yes.

DR. KRENGEL: I would think at a rate of about 100 prescriptions a week - perhaps in the neighborhood of 5,000 prescriptions.

ASSEMBLYMAN HERMAN: Percentagewise, what percent of those prescriptions were generically written?

DR. KRENGEL: I would think somewhere less than 10%.

ASSEMBLYMAN HERMAN: Which means about 500 prescriptions a year?

DR. KRENGEL: I would think that would be a reasonable statement.

ASSEMBLYMAN HERMAN: What general type drug do you usually prescribe generically?

DR. KRENGEL: I prescribe ampicillin generically. I prescribe prednisone generically. I would think that offhand those would represent, by far, the bulk of the generic prescriptions.

ASSEMBLYMAN HERMAN: When you prescribe ampicillin and prednisone, who picks the brand that the patient gets?

DR. KRENGEL: The pharmacist does.

ASSEMBLYMAN HERMAN: Well then, you have relinquished your control to make a product selection under those circumstances?

DR. KRENGEL: Yes.

ASSEMBLYMAN HERMAN: And you have no qualms or reservations about doing that, Doctor?

DR. KRENGEL: No. Ampicillin is manufactured, or marketed, by many reputable pharmaceutical manufacturers. I know of none of the off-brand manufacturers that do produce the drug.

ASSEMBLYMAN HERMAN: How about prednisone?

DR. KRENGEL: Prednisone is, again, a drug that is manufactured primarily by major manufacturers.

ASSEMBLYMAN HERMAN: Such as Rexall?

DR. KRENGEL: Rexall is a distributor. I don't know if they manufacture it.

ASSEMBLYMAN HERMAN: Reliance? Wallace? Pure Pack? Notwithstanding, you would have no way of knowing, based on your prescriptions, generically, what the pharmacist would sell, would you Doctor?

DR. KRENGEL: That's correct.

ASSEMBLYMAN HERMAN: Now how many drug companies do you basically deal with in your practice? In other words, how many people regularly call upon you?

DR. KRENGEL: I wouldn't care to estimate.

ASSEMBLYMAN HERMAN: Maybe I could rephrase that question.

DR. KRENGEL: I am sure at least 2 dozen drug companies send detail men.

ASSEMBLYMAN HERMAN: And of those two dozen I assume, without naming them, you have a certain limited preference?

DR. KRENGEL: Well, there are certain standards that are used and various indications, certainly.

ASSEMBLYMAN HERMAN: Would you say I would be

overstating or understating the case to say that, perhaps, during the course of the year you rely heavily on, perhaps, maybe one-half dozen?

DR. KRENGEL: Drug companies?

ASSEMBLYMAN HERMAN: Yes.

DR. KRENGEL: Well, perhaps that would be an understatement. I have never analyzed my prescribing practices that way. I don't own any drug stock, for instance, so I don't have to write--

ASSEMBLYMAN HERMAN: I am not trying to be facetious.

DR. KRENGEL: No, I am not either.

ASSEMBLYMAN HERMAN: I am just trying to say in your busy schedule--

DR. KRENGEL: I am just trying to point out that there is no need for me to keep any kind of mental record of what company I am prescribing for at any particular time.

ASSEMBLYMAN HERMAN: Well, do you have enough time to see a couple of dozen detail men during the course of the year with regularity?

DR. KRENGEL: Oh, yes.

ASSEMBLYMAN HERMAN: Then basically the physician's reliance on drug efficacy is based on the people that he deals with -the drug houses that he deals with - for his information?

DR. KRENGEL: That is where the information is presented. Often the decision is whether or not the results that these detail men say are going to happen actually do happen.

ASSEMBLYMAN HERMAN: Basically speaking though, to a large extent, you do rely on their professional expertise? You don't do any independent studies, for instance?

DR. KRENGEL: No, I don't.

ASSEMBLYMAN HERMAN: I assume you, like all other

doctors, utilize the Physicians' Desk Reference?

DR. KRENGEL: Yes, I do.

ASSEMBLYMAN HERMAN: Which, of course, lists, I understand, year to year, all the current drugs being utilized?

DR. KRENGEL: Currently licensed, correct.

ASSEMBLYMAN HERMAN: I assume you would, from time to time, have occasion to use that document for a source of professional guidance?

DR. KRENGEL: Right.

ASSEMBLYMAN HERMAN: I was impressed by a statement in a recent Digest, Doctor. It is a statement by Dr. James D. Price, who is an M.D. and President of the American Academy of Family Physicians. I am quoting from his speech. He said, "Most of us haven't the time nor the facilities nor inclination to evaluate properly every single drug which we prescribe." He is talking to the drug industry. "This is your job, an awesome responsibility, but we expect you to fulfill it". Do you basically agree with that statement?

DR. KRENGEL: Yes, I would concur with that.

ASSEMBLYMAN HERMAN: Let me just ask you one or two questions, if I may. As a practicing physician, do the companies with whom you deal send you samples?

DR. KRENGEL: Yes.

ASSEMBLYMAN HERMAN: Perhaps, just for our edification, you could give us an idea of how many samples, in quantity, pass through your office in a given year.

DR. KRENGEL: Well, I would say that I get, in the mail, samples from two or three companies every day. This involves, generally, a small bottle, maybe, of 8 or 10 or 12 tablets or capsules; a couple of tubes of ointment or other topical preparations. I would think that in a week's time I receive 15 sample items.

ASSEMBLYMAN HERMAN: If you could, within reason, go out and buy all this - if you were to put all this together--

DR. KRENGEL: I have no idea what the cost would be.

ASSEMBLYMAN HERMAN: You do not know what it would be valued at?

DR. KRENGEL: I have no idea whatsoever.

ASSEMBLYMAN HERMAN: Do any of the drug companies with whom you deal offer you gifts or other inducements for the purchase of drugs?

DR. KRENGEL: Not recently. Sometimes at conventions, where the drug companies have display booths, they hand out letter openers and nail files and tie tacks and things like that. I would think that this habit has gotten to be of much smaller volume in the last couple of years.

ASSEMBLYMAN HERMAN: You mean of substantial gift solicitation?

DR. KRENGEL: Yes.

ASSEMBLYMAN HERMAN: In your role as a doctor, what do you see as the relationship, or what do you see should be the relationship of the doctor vis-a-vis the pharmacist, or the pharmacist vis-a-vis the doctor?

DR. KRENGEL: I think that the recent laws that require pharmacists to keep records and cross check alphabetically the various prescriptions that a patient receives is a very good one. I think that the pharmacist should function to dispense medication and to supervise the dispensing where the patient is taking more than one prescription, which may or may not be of knowledge to the presecribing physician.

ASSEMBLYMAN HERMAN: Okay, Doctor. I want to get back to that point. Don't you think, under those circumstances, that where there is an incompatibility of medicines which would show up on the drug profile card

of the pharmacist, that he has an obligation, notwithstanding the doctor's busy schedule or reticence to accept telephone calls, to inform the doctor of a possible conflict in medicines?

DR. KRENGEL: He certainly does.

ASSEMBLYMAN HERMAN: Thank you.

ASSEMBLYMAN BAER: Assemblyman Ruane?

ASSEMBLYMAN RUANE: Doctor, what is your procedure when you get samples of drugs - say you get 20 tablets of a certain drug?

DR. KRENGEL: I have a small closet in which I keep samples under lock and key. My own particular procedure with samples is, generally, to dispense them not in the small quantities, or the little bottle in which they are provided me, but if I get one-half dozen little bottles I give them all to the same patient to save them the cost of the prescription. I generally do this dispensing to welfare or medicaid patients.

ASSEMBLYMAN RUANE: You give them these sample drugs in order to test them, don't you - in effect?

DR. KRENGEL: No.

ASSEMBLYMAN RUANE: Don't you?

DR. KRENGEL: There are so few new drugs that are currently being marketed and released that I am reasonably familiar with everything that is sampled and I am familiar enough with them to anticipate what sort of effect they will have on the patient.

They are not experimental any more, this is strictly given out as a course of therapy.

ASSEMBLYMAN RUANE: Have you ever done it on that basis?

DR. KRENGEL: Have I ever participated in drug research?

ASSEMBLYMAN RUANE: Yes, for an experiment.

DR. KRENGEL: I, personally, no.

ASSEMBLYMAN RUANE: On your own patients?

DR. KRENGEL: No.

ASSEMBLYMAN RUANE: Well, then how can you prescribe one drug as opposed to another if you don't do a little research on your own?

DR. KRENGEL: I rely on the information provided me, on the therapeutic effectiveness. Again, there are so few new drugs that everything that is available now has been available for years. So, it is no longer necessary for me to "experiment" - or hardly ever necessary.

ASSEMBLYMAN RUANE: Thank you.

ASSEMBLYMAN RYS: Dr. Krengel, those people who are called detail men are well qualified, professional and experienced people in the drug industry aren't they?

DR. KRENGEL: Yes, they are qualified and they are very well informed on products which they detail.

ASSEMBLYMAN RYS: So, therefore, if they give you a sample, whether it is a dozen or maybe 10, this drug has been listed in the medical journals and all the books and, therefore, you have read about them prior to their coming to you, right - at times?

DR. KRENGEL: I don't remember the last time that a detail man presented a new drug.

ASSEMBLYMAN RYS: In other words, you knew about these samples?

DR. KRENGEL: Yes.

ASSEMBLYMAN RYS: So, therefore, they are well qualified drugs and they have been on the market.

DR. KRENGEL: Yes.

ASSEMBLYMAN RYS: So, therefore, there has been no problem with these drugs that you have been giving out?

DR. KRENGEL: That's right.

ASSEMBLYMAN RYS: That's all. Thank you, Doctor.

ASSEMBLYMAN HERMAN: Mr. Chairman, if I may?

More questions came to mind which I trust the Doctor will answer for me.

I assume that in your practice you try to be conscientious and supply the highest quality product at the lowest possible cost to your patients, is that correct? In other words, isn't there a number of particular types of medicine and drugs which come across your desk which intend to do the same thing, or maybe generically the same thing?

DR. KRENGEL: I don't think that in my prescribing practice I ever think very much about the cost, no.

ASSEMBLYMAN HERMAN: Even when, during the course of your practice, you have, perhaps, a detail man from a company come in and say, look, the patent ran out on such-and-such a drug; you no longer have to worry about one house producing it all. I have here a quality product. I'd like you to try it. It is the same thing. You have done that in your practice, haven't you?

DR. KRENGEL: I might have. I don't remember specific instances though - recently.

ASSEMBLYMAN HERMAN: Just as a matter of intellectual curiosity, during the last couple of years would you say the percentage of prescriptions which you are prescribing generically are on an increase?

DR. KRENGEL: Since ampicillin became available, I would think that in times of acute infection - mid-winter epidemics - which, because an organ is susceptible to a penicillin-type of antibiotic, I would write for vast quantities of ampicillin, generically. So, that would make the answer to your question, in that instance, yes.

I can't think of any other item that I rountinely presecribe generically.

ASSEMBLYMAN HERMAN: Isn't it true, Doctor, that in the last period of 5, 6 or 7 years, the number of

prescriptions being written by doctors, not only in New Jersey but throughout the United States, generically, are on the increase - substantially on the increase?

DR. KRENGEL: I have heard that is the case. I don't know the numbers.

ASSEMBLYMAN HERMAN: Assuming it is the case, it means more doctors must be writing more prescriptions generically than they have in the years past.

DR. KRENGEL: Well, if you say so. I don't know the numbers.

ASSEMBLYMAN HERMAN: Assuming that is the case, wouldn't the position of the Osteopathic Society of New Jersey be presently inconsistent with the actual practice - to wit, the increased writing of prescriptions generically, leaving the decision as to which brand to select up to the pharmacist?

DR. KRENGEL: Well, I would think that most Osteopathic physicians have the same prescribing habits that I have and that when the situation warrants,they prescribe generically in the same manner that I do.

ASSEMBLYMAN HERMAN: I'm just trying to put together, Doctor, the philosophical or the statement position of the New Jersey Society of Osteophthy, with the actual practice of medicine as it exists, based on the number of prescriptions that are written generically.

I was just wondering whether you might be of some help to us in, perhaps, bringing together those differences.

DR. KRENGEL: The only conclusion I can make is, in a very narrow spectrum where there is a true generic equivalent, like an ampicillin, the prescribing practices of Osteopathic physicians would be that they would prescribe that drug. But since this exists in such a small number of available areas, the number of compounds written for generically is relatively small.

ASSEMBLYMAN HERMAN: Okay, Doctor.

ASSEMBLYMAN BAER: Doctor, I want to thank you very much for your testimony. It has been very helpful.

DR. KRENGEL: Thank you.

ASSEMBLYMAN BAER: I would like to break now for about 5 minutes.

(short recess)

AFTER RECESS

ASSEMBLYMAN BAER: We will begin with Mr. Fred Weeks, Manager of Government Affairs Northeast Sandoz Pharmaceuticals. Now, you are with Mr. Vickery, is that correct?

MR. WEEKS: He is with me, actually.

ASSEMBLYMAN BAER: He is with you. Following our procedure here, I would like to hold his testimony until the tail end, unless there are any questions from the Committee which he can answer better than you can. This is to give everyone an opportunity of having at least one representative testify. Please proceed.

F R E D W E E K S: Thank you, Mr. Chairman and members of the committee. My name is Fred Weeks. I work for Sandoz Pharmaceuticals, a medium sized pharmaceutical company located in Morris County in East Hanover, New Jersey.

I have worked with Sandoz for some 16 years, starting out with them as a detail man and later was in sales management with the company and now my function is government affairs, which is a rather broad title, but I do spend most of my time in the state capitols of 9 states.

I have had the privilege of sitting in on hearings like these in most of the other states in the Northeast, that I cover.

I am happy to say, as a side note, that none of the

other states that I cover, though they have considered this kind of bill, have passed one.

ASSEMBLYMAN HERMAN: Do you think there is a direct relationship, Mr. Weeks, between your presence and their not passing one?

MR. WEEKS: I would hope so. I will not go into the scientific end of this issue since I am not qualified to do so but would rather like to spend just a moment on the economics of the issue.

One of the basic motivations behind this legislation, I assume, is to assure the consumers of New Jersey high quality medical care at a savings. In order to compute savings I think we must start with accurate statistics on where we are now before we can project ahead to where we are going in the future.

For that reason I would like to correct the record, or at least amend testimony given earlier today, on just what the financial impact of this kind of legislation would be to the citizens of New Jersey.

We heard this morning that the prescription drug market in New Jersey was $300 million. That is a grossly overstated figure. I was in the Secretary of State's office this morning attempting to learn the most recent accurate census of the State of New Jersey and I don't have it in writing but I was told that it is about 7½ million people. I submit to you that to arrive at this $300 million figure, every man, woman and child in this State would have had to have spent $40 for prescription drugs last year.

Now, if New Jersey is average - and I assume that it is - in other states, according to the Bureau of Labor Statistics, the average consumer spends somewhere between $15 or $16 per year for prescription drugs. So, we have here, immediately, a figure that we must look at with some

suspicion.

Another statistic that was brought forth this morning was that 40% of the prescriptions written have generic equivalents, or they are multiple-source drugs. This statement flies in the face of facts that have been presented by reputable market research firms who state, and have recorded in print, that the correct total is closer to 10% of the total number of prescription drugs written having multiple source.

So, you see here that we are talking right away about $100 million discrepancy in the market and we are talking about a 30% discrepancy in the percentage of possible multiple-source prescription drugs.

ASSEMBLYMAN BAER: That sounds like the discrepancies we hear on budget estimates sometimes here.

MR. WEEKS: Assemblyman Rys, I believe, earlier today mentioned a statistic that seems to jibe with something I have in my notes here and that is that according to market research individuals who specialize in the field of prescription drugs - there is a market data firm in New York City which specializes in prescription drug audits - their best estimate for the year 1973 shows that approximately 49 million prescriptions were filled in the State of New Jersey. This is certainly very close. It approximates the ratio of the population of New Jersey to the total population of the United States and also it correlates with the total number of prescriptions written throughout the country. If you take that percentage of the population of New Jersey, you come up with a figure that is very close to 49 million prescriptions.

Talking about savings, Casper Weinberger has been widely quoted by both proponents and opponents of issues like the one we are faced with here. One of his statements which is often quoted is the one he made back in December of last year where he stated - and I am paraphrasing - that

the Federal Government would begin to reimburse, under Medicare and Medicaid, for example, for the lowest cost, generally available,prescription drugs.

From his statement he estimated, or projected, for fiscal 1974, expenditures of Medicaid - under the Medicaid Program - of $534 million. Now this represents, according to Mr. Weinberger, through the policy of reimbursing for the lowest cost, generally available generic drug, a savings of $28 million on the Medicaid Program for 1974. $28 million from a total of $534 million, with my quick arithmetic, shows me that this is a saving of 5.5%.

Now the Medicaid picture in New Jersey, I think, if it were examined as it is in other states, would show that the profile of prescription use by physicians and patients who are covered by the Title 19 Program is very similar to the same kind of prescription usage as the general population. The only difference would be that you would see a far greater utilization of prescription drugs among people covered under Title 19 than you would the general population.

But let's, for the sake of argument, project this 5.5% savings to the general public, or the general consumers, of the State of New Jersey. Again, from the prestigious Lilly Digest, which is published by the Eli Lilly Company and utilized by most retail pharmacists in the running of their retail pharmacy business, the average cost of a prescription in the United States is about $4.50. The average fee of a pharmacist for filling a prescription will run anywhere from $1.80 to $2.00. Now, if you deduct the pharmacist's fee for filling a prescription, the ingredient cost of the average prescription is down to about $2.50. Now, if you apply Mr. Weinberger's 5.5% savings, by paying for the lowest cost, generally available generic drug, you are talking

saving about 13¢ per prescription for the consumers of the State of New Jersey with no guarantee of quality and no guarantee of therapeutic efficacy of the substituted drug.

Incidentally, let me go back to something here. Mr. Herman stated, repeatedly, that the use of generic drugs has increased at a dramatic rate in recent years. There are really two ways of looking at this. Actually, according to a survey, which is done annually by the Albany, New York, College of Pharmacy, in 1964 generic drugs represented 9.5% of the total prescriptions written. In 1973 generics represent 11.8% of the total prescriptions written. This is an increase of 2.3% in 10 years. There is a significant increase in the use of generic prescriptions, most notably because of the introduction of various ampicillins and other antibiotics whose patents have expired or that are multiple source drugs.

The fact still remains that 90% - or nearly 90% - of all prescriptions written are sole source prescriptions.

Other states have experimented, if you will, with a Formulary concept, with less than dramatic results. The Massachusetts experience is totally inoperative; it doesn't work at all. The State of Kentucky embarked some time ago on a very ambitious program which has met with less than success by any stretch of the imagination. As recently as February of this year there was an article which appeared in the Louisville Courrier Journal and Times which stated that the progress of the generic issue and the formation of a Formulary had really not, in two years, gotten off the ground.

Incidentally, the Chairman of that Kentucky Formulary Council, Robert L. Barnett, Jr., in an interview stated

that he felt that his group would need as much as $100 thousand a year as it expands its drug evaluation system and works out an enforcement program.

Incidentally, in the first two years of operation the Kentucky Formulary group had a budget of $100 thousand - $50 thousand per year. The first year they spend $9,000 primarily for administrative purposes and at the end of 2 years they had added one drug to the Formulary. Subsequent to February I think they have added a few others.

I bring this out to emphasize the possibility of the high cost of embarking on a program, such as called for in the bill before us.

In conclusion, I would like to refer, again - if I may - to the individual who probably has not been given as much attention in the hearings about this bill as he should have been, and that is the patient. The question is, what is best for the patients of New Jersey and who can best make that determination. I am not a pharmacist. I am not a physician. I am a consumer, a layman who has had some exposure to the ethical pharmaceutical industry and I do have some of my own opinions. I do know this, if I were a physician I would like to think that I would have the welfare of my patients uppermost in my mind and this would guide my prescribing habits.

For example, if you were to come to me as a busy, harried businessman and reported some degree of agitation and nervousness and a little bit of sleeplessness, providing everything else checked out well, I probably would prescribe a mild sedative for you - ¼ grain of phenobarbital, two or three times a day, would work out fairly well and probably any good brand of phenobarbital would do the job very nicely. On the other hand, if you were an epileptic patient and you were under my care, phenobarbital

is a drug that is very critical to the welfare and functioning of an epileptic patient. Blood levels of phenobarbital are very critical and can mean the difference between having seizures and not having seizures. In this instance I would insist that you get the very finest quality phenobarbital available, regardless of the cost.

By the same token, if you buy aspirin for household use, any good brand of aspirin probably would serve your purpose fairly well - for headache, backache, minor aches and pains. This would do very nicely for you. But as a physician, if I were treating you for arthritis where you had to take high doses of aspirin and salicylates to keep you mobile and keep you free from pain, I would insist that you get the highest quality aspirin available, regardless of the cost.

The point I am making is, what the Committee should consider is what is best for the patients of New Jersey and who can best make the determination of what is best for the patients of New Jersey. I think that Mr. Weinberger, in his testimony, answers that question for the Committee very nicely. He states - and I quote -

"First, every physician must be free to prescribe whatever medication he believes is most appropriate for his patients. It is not the business of government to tell doctors what market drugs they may or may not prescribe. That is and must remain solely a matter for the professional judgment of the prescribing physician." Thank you very much.

ASSEMBLYMAN BAER: Thank you, Mr. Weeks. Do we have any questions from the Committee? Mr. Herman?

ASSEMBLYMAN HERMAN: Mr. Weeks, isn't the physician permitted to check on his prescription blank, "Do not substitute"?

MR. WEEKS: Here in New Jersey?

ASSEMBLYMAN HERMAN: Yes.

MR. WEEKS: I don't believe that is part of the law yet. If it is, I don't know about it.

ASSEMBLYMAN HERMAN: Notwithstanding whether it is or whether it isn't, that is a very simple thing to check off on the prescription blank assuming it is on it.

MR. WEEKS: It requires a positive action to get a negative effect. You know, it is like belonging to the Book of the Month Club; unless you tell them don't send me a book, you get one.

ASSEMBLYMAN HERMAN: That is very, very simple. It can be done.

MR. WEEKS: Yes, it could be.

ASSEMBLYMAN HERMAN: You don't see it as over-burdensome, do you - the checking of a blank?

MR. WEEKS: I am not a physician.

ASSEMBLYMAN HERMAN: You have given some pretty good medical testimony. As a practitioner of law if you asked us to put a check next to a slip of paper, yes I want it, no I don't want it, you wouldn't see that as overburdensome, would you?

MR. WEEKS: I don't consider it burdensome but I also do not consider it necessary.

ASSEMBLYMAN HERMAN: Okay. Is that in your medical opinion or your lay opinion?

MR. WEEKS: That's my lay opinion.

ASSEMBLYMAN HERMAN: Okay. Are you familiar with Ontario's experience?

MR. WEEKS: No, I am not.

ASSEMBLYMAN HERMAN: Are you aware of the projections up there, based on written reports that that program is saving - according to their estimates - $5 to $8 million a year?

MR. WEEKS: I am not familiar with the program.

ASSEMBLYMAN HERMAN: You didn't cover Ontario?

MR. WEEKS: No.

ASSEMBLYMAN HERMAN: You mentioned that some of the generics were coming on the market as a result of patents expiring.

MR. WEEKS: I think I said that one of the reasons for the increase in generic prescriptions probably was the multiple source of ampicillins and those types of drugs - tetracyclines, etc.

ASSEMBLYMAN HERMAN: Isn't it the usual experience that where a patent expires and you do have "competitive entries into the market" that the patent holder usually experiences a cost reduction in their product? When I say cost reduction I mean a lesser sales price.

MR. WEEKS: Not necessarily. I can speak from experience with my own company, Sandoz, here in New Jersey, along with what Mr. Timberlake was testifying to. We have a product which we don't have a patent on because it is a combination product; you can't patent a combination product. We have this for migraine headache. It is also produced by at least two or three other companies that I know of. Several years ago we used to bid for the armed forces business on a competitive basis. One year we lost the bid; another company underbid us. But a strange thing happened. This company furnished this migraine product to the armed forces and from naval hospitals and army hospitals, air force installations, all over the world came a myriad of complaints that the tablets fell apart. Shortly thereafter the Quality Control people reviewed their specifications, upgraded them, and now we get the contract from the armed forces just about every year.

ASSEMBLYMAN HERMAN: Well, perhaps I am not communicating properly. Let me repeat the same question I believe I did not get an answer to before.

Are you familiar with companies in the market whose patents have expired, where they now have substantial competition?

MR. WEEKS: Yes.

ASSEMBLYMAN HERMAN: And isn't it true in that respect, where there is substantial competition as a result of patent expirations, that those companies who originally held that patent and still continue to produce that product usually sell it for a lesser cost to the retailer than they did before the patent expired?

MR. WEEKS: This does happen, yes.

ASSEMBLYMAN HERMAN: Thank you.

ASSEMBLYMAN BAER: I want to thank you very much for your testimony, Mr. Weeks.

The next witness will be Mr. Martin Johnson, Executive Assistant, Medical Society of New Jersey.

M A R T I N J O H N S O N: Mr. Chairman, Members of the Committee, thank you for the opportunity to give the opinion of the Medical Society of New Jersey, relative to Assembly Bill 1257.

The Medical Society of New Jersey would not and could not stand in the marketplace and deny the use of generic medication if it were possible for the patient to get a generic drug that was equivalent in every respect to the standard and established trade name product if the consistency and the equivalency and lower cost were assured.

Apparently there is no way that this can be proven to date and without this credibility the Medical Society of New Jersey opposes Assembly Bill 1257.

Furthermore the Medical Society of New Jersey is opposed to any infringement on the rights of a physician to practice medicine in the manner in which he is taught and wishes to practice for the best interest of the patient.

Let it further be resolved that should, by legislative action, this freedom of choice of

therapeutics be denied, that some arrangements be made to transfer the liability of malpractice to those who would be usurping the rights of the physician in his free selection of the treatment of the patient. This would include the State government, the legislators who might enact the bill,and any pharmacist who is involved in substitutions without prior concent.

Now, in addition to that, I'd like, with the forbearance of the Committee, to consider the following. Mr. D'Amico, President of the New Jersey Pharmaceutical Association, before this Committee this morning, indicated that the training of pharmacists exceeds that of physicians in the selection of medications. Pharmacists are not admitted into pharmacy school without a high school diploma, but it is my impression that that is their only prior requirement.

Physicians need four years of pre-med, which includes training in four separate years of chemistry and pharmacology and biology before the physician enters medical school.

Following medical school the physician usually gets two additional years of laboratory training in the aforementioned sciences.

I believe that Mr. D'Amico indicated that the training of pharmacists gave them the technical advantage in selecting the proper medication for a patient. The danger in such a statement is outlined by the fact that pharmacists do not have the clinical training that the physician has. The patient may not have a record in the store in which he is buying the medication. Now, this is no reflection on the pharmacist or their training; I think they are doing a very essential job. We very definitely need them and they are well respected professionals. But if you legislate the choice of medication into the hands of someone who is not completely

trained in total patient care, you are preempting the right of physicians to provide such care.

There is no indication that the sharing of liability is covered in Assembly Bill 1257. The way medicine is practiced today a pharmacist can request from a physician permission to switch and if the request is a reasonable one there does not appear to be any difficulty in doing so.

So, Mr. Chairman, the Medical Society of New Jersey finds it difficult to determine why it is necessary to legislate this responsibility. Mr. Chairman, I believe you made mention this morning of the fact that one major company in the pharmaceutical industry manufactures dynamite and that frightens you. That is trinitrotoluene, which is a component of nitroglycerin tablets people stick under their tongue. So whether you want to alleviate their angina pectoris or blow up a building is a matter of choice.

Another company manufactures cosmetics but I think the important thing to mention here is that these are divisions of these companies that are being alluded to and not a sideline of the product.

The thing I'd like to leave you with is that there have been many sincere people who have testified here today and I think they testified to ask your due consideration before you do something overt. There is nothing good that is cheap and there is nothing cheap that is good. The medical industry has been, apparently, under attack since the days of Senator Kefauver and we are going to assume that this Assembly Bill 1257 is intended for the consumer good and not an aggrandizement of any future ambitions and we would like to suggest the Committee go slowly on this.

ASSEMBLYMAN HERMAN: I would say, Mr. Johnson, my wife would resent that because she says she works cheap and she thinks she is good.

(laughter)

MR. JOHNSON: That's something you will have to hack out yourself, barrister.

ASSEMBLYMAN BAER: Do we have any questions?

ASSEMBLYMAN HERMAN: I do. Mr. Johnson, the position which you have stated here today on behalf of the Medical Society of New Jersey, is that a result of a survey of all the physicians in the State, or is it based on a Legislative Policy Commission?

MR. JOHNSON: We have a Council on Legislation which we feel is qualified to speak for the general membership, and that is their opinion, yes.

ASSEMBLYMAN HERMAN: This was not based on a survey of the actual number of physicians in the State?

MR. JOHNSON: This was discussed at our annual meeting. I would have to say that as far as a written survey is concerned, no, Mr. Herman.

ASSEMBLYMAN HERMAN: How many medical doctors are there in New Jersey?

MR. JOHNSON: Approximately 8,500 are members of the Medical Society and there are about 11,000 in general, many of whom are in industry and in State government and, as such, do not belong to the Society.

ASSEMBLYMAN HERMAN: I forgot to ask Dr. Krengel. Do you know how many Osteopathic physicians there are in the State?

MR. JOHNSON: I believe there are about 800 -- no, I cannot speak for them and I shouldn't speak for them. You had your opportunity. The man was here. I am sorry. I can't speak for them.

ASSEMBLYMAN HERMAN: Okay.

MR. JOHNSON: I would say that they are in the minority in comparison to-- I'll give you an approximation.

ASSEMBLYMAN HERMAN: We are not going to hold you to this.

MR. JOHNSON: I would say there are between 800 and 900 Osteopathic physicians in the State.

ASSEMBLYMAN HERMAN: Okay. So, if we were generous we would add on another 1,000, right? We have about 12,000 medical and Osteopathic physicians in the State.

MR. JOHNSON: We consider them physicians by license here to practice medicine and surgery. We don't make any differentiation.

ASSEMBLYMAN HERMAN: Okay. So, there would be a total of approximately 12,000 physicians in this State.

MR. JOHNSON: Yes.

ASSEMBLYMAN HERMAN: The attitude of the Medical Board has come a long way.

MR. JOHNSON: Well, we learn by experience.

ASSEMBLYMAN HERMAN: You have heard me ask this question during the day many times but I feel it is important since you do represent the Medical Society. That is, doctors today have the right to prescribe generically, right?

MR. JOHNSON: That is correct.

ASSEMBLYMAN HERMAN: And many do so?

MR. JOHNSON: That is correct.

ASSEMBLYMAN HERMAN: And in the end, what product is chosen, as to brand - what generic drug - is left to the pharmacist, is that correct?

MR. JOHNSON: If he writes generically and makes no differentiation then that is the prerogative of the pharmacist.

ASSEMBLYMAN HERMAN: That is the law today. You would agree with that? We have been using the example of ampicillin all day today.

MR. JOHNSON: You like that drug.

ASSEMBLYMAN HERMAN: Well, it certainly does serve

as a good example.

MR. JOHNSON: Yes, it does.

ASSEMBLYMAN HERMAN: Now, when a doctor prescribes ampicillin - and I will pick another half dozen if you wish - if he says ampicillin, that leaves it up to the pharmacist as to what brand of that ampicillin he or she will select, is that correct?

MR. JOHNSON: That's correct.

ASSEMBLYMAN HERMAN: Now, do you agree or disagree with that part of our law which permits the doctor to write that way?

MR. JOHNSON: I see -- Wait a minute, I will rephrase that. The Medical Society would not take exception to the physician practicing medicine in the manner in which he wishes.

ASSEMBLYMAN HERMAN: I don't understand.

MR. JOHNSON: Why not?

ASSEMBLYMAN HERMAN: Would you explain to me what you mean by that statement?

MR. JOHNSON: Yes. If he wants to write for generic medication that is his prerogative. What we are concerned about is somebody legislating that he must.

ASSEMBLYMAN HERMAN: All right. I think we now all understand the position of the Medical Society. I have nothing further to ask.

ASSEMBLYMAN BAER: Thank you very much, Mr. Johnson, for your testimony.

The next witness will be Mr. Daniel Vitiello, Pharmaceutical Manufacturers Association.

D A N I E L V I T I E L L O: Mr. Chairman, Mr. Vice Chairman, good afternoon.

ASSEMBLYMAN BAER: Good afternoon. Do you have a prepared statement?

MR. VITIELLO: No, I don't. We weren't advised of the hearing until late Friday and we didn't have time to prepare one.

My name is Daniel Vitiello, I am the Staff Attorney for the Pharmaceutical Manufacturers Association. Our address is 1155 15th Street, Northwest, in Washington, D.C.

ASSEMBLYMAN BAER: This is, then, a national Association, not a State Association, is that correct?

MR. VITIELLO: Right. I will describe the Association for the record.

The Pharmaceutical Manufacturers Association is composed of 110 member firms who manufacture a significant portion of the nation's prescription drug supply and through their research and development efforts have contributed to most of the important advances in pharmacotherapy, diagnostic reagents and vaccines in the past 25 years. More than 20 of our member firms are headquartered in New Jersey and they join with the Association in opposing this legislation.

Mr. Chairman, I would like to address my comments, briefly, on matters that principally have been untouched yet with regard to this bill, if that can be believed. We have done a lot of looking into the theory of this bill, with the idea of a Formulary Council and the idea of a Drug Utilization Review Council - I should say - being able to make determinations with regard to drugs and their equivalency, one to another.

I think it is time that we take a look at the bill, as drafted in its proposed amended version and see what is in the bill because we have been talking concepts all day and now I think it is about time we begin to look there.

I'd like to turn, first, to page 3, Section 3 of the bill.

ASSEMBLYMAN BAER: This is, sir, the proposed

amended version?

MR. VITIELLO: Yes. What is drafted there in the first sentence is what I am most concerned with. That is, the Council shall prepare a list of approved drug products by established names that are determined by the Council to be therapeutically equivalent to brand name drug products.

My question is, one, the word approved -- question: what does the word mean and, two, what will this drug list look like once it is adopted? Are we talking about, one,picking out established names and then allowing that all drugs under that name are equivalent or, two, are we talking about, rather, that manufacturer's versions are equivalent? Again, here, I have to make reference to the reference drug product which is defined in subsection 1 (f). It appears that it was meant that the reference drug product here in section 1 (f) means the product adopted by the Council as the standard. It would appear that what is meant here would be that your list of approved drugs would be the list of drugs which is found to be therapeutically equivalent to the reference drug product, is that correct, Mr. Vice Chairman? Is that what you had in mind?

ASSEMBLYMAN HERMAN: I beg your pardon?

MR. VITIELLO: Is that what is contemplated by this section?

ASSEMBLYMAN HERMAN: I lost the first half of the question.

MR. VITIELLO: Okay. The question is, when the list is finally prepared by the Formulary Council, what would it look like? Will it be a list of equivalent name products to a generic name? In other words, will you say ampicillin and say that all ampicillins on the market are equal or will you take a reference drug

product, as you have in section 1 (f) and say, all right, this is our reference drug product and we are now going to chemically test and therapeutically test all drugs with regard to this reference drug product and then these drugs will be equal to that and will be on the list?

ASSEMBLYMAN HERMAN: I believe my understanding is that it probably could be done either way but the composition of the list itself, I would think, would be a matter as to format and would be best left to the people that have a higher degree of expertise in establishing a criteria as to what should be the best way of listing.

MR. VITIELLO: I would submit to the Committee that the bulk of the testimony that you have received today has been on the basis of, what you will see is a list of drug products whereby you have the reference drug product being used as the standard and from there the equivalency of a drug product will be determined. I think that the bulk of the testimony for your information, basically, would say that to assume that all products of the same equivalent nature are the same--

ASSEMBLYMAN HERMAN: I don't think there is any such assumption.

ASSEMBLYMAN BAER: I don't think that is what Assemblyman Herman said.

MR. VITIELLO: --that the Council could make that determination. In other words, giving that authority to the Council.

ASSEMBLYMAN HERMAN: As to how they would prepare a list? We would be more than happy to give that type of authority to the Council, as to how they will list them.

ASSEMBLYMAN BAER: I think there is a confusion here between two things. One, how the Council should proceed - whether they are going to be making these

determinations of equivalency on a case-by-case comparison basis, and I haven't heard anything to indicate otherwise and, secondly, whether having arrived at all their conclusions they are going to list these equivalencies on a case-by-case basis or whether, where groupings are possible, they will list groupings. But I think you are asking about listings, if I understood you correctly, not about procedure for arriving at conclusions.

MR. VITIELLO: Correct, Mr. Chairman. I am questioning listing and how these will be listed.

We have seen the situation in Massachusetts, to be very frank, were a law was drawn in such a way as to be capable of many interpretations.

The drug list that was adopted in Massachusetts was not - when given the broad authority, as this particular provision would allow - provided with a Formulary of drugs whereby they took, basically, one drug and said, that is equal to all the drugs on the market and they went that route. It was not a listing, let's say, similar to what has occurred in other states. I think the example of Kentucky was given, where they took the term ampicillin by generic name and then went on to list 17 different ampicillins which they believed to be therapeutically equivalent, although they did not have the backing of any - I guess you would say - supporting data other than the manufacturer's submissions.

ASSEMBLYMAN HERMAN: I might add, Mr. Vitiello, that your concern is reasonably answered on page 4 of the bill, under section 3, requiring the Council, in its adoption of rules and regulations, to comply with the Administrative Procedure Act of the State of New Jersey, which requires public hearings, notification, that sort of procedure, which would encompass all of

this, and at the appropriate time, assuming there was a - if I can use the vernacular - better way to fly, or a better way to do things, that those in the industry would be given ample opportunity to - assuming this does become law - present their views.

MR. VITIELLO: Mr. Herman, I believe-- Well, basically, I think it would be submitted by the industry, in any event. The procedure that I have suggested would be the one that I would believe should be legislatively followed.

ASSEMBLYMAN HERMAN: Well, we are happy to hear that. Perhaps if you could be so kind as to address your comments to what you think is better --

MR. VITIELLO: That's exactly what I am suggesting, Mr. Vice Chairman.

ASSEMBLYMAN HERMAN: Okay.

MR. VITIELLO: I am suggesting this just as an improvement of the present language so that this does not fall into the same trap that Massachusetts has.

ASSEMBLYMAN HERMAN: Proceed with your suggestions.

MR. VITIELLO: The next suggestion that I have is with regard to the last paragraph, Section 3. This is something also that has not been looked at by many of the people who have been testifying.

This paragraph reads: "The council shall also have the authority by rule or regulation, to specify the number of times a prescription may be refilled when not specified by the physician, to standardize dispensing quantities and to permit dosage form exchange where the council determines that no substantial therapeutic difference will result."

This is a paragraph which is not aimed at getting into the equivalency of products or the exchange of products, which your testimony today has been directed to.

This is actually getting into the prescribing rights of the physician in treating his patients. You are going to be allowing this council, one, to determine the number of times the prescription may be filled - questionable; two, to standardize dispensing quantities - questionable, particularly when many prescriptions are written to fit the patient. Here you would almost socialize the prescription format for the State of New Jersey by allowing this council to submit rules and regulations. Finally, this would permit dosage form exchange.

I have a son - you may have seen him earlier today, he was in the balcony - and if a doctor prescribed a chocolate flavored ampicillin for him I would take that prescription to the pharmacy and this would authorize that pharmacist to substitute some pills, or some capsules for him to take. I don't believe that this was ever intended by the authors to be included in the legislation. I believe that this whole paragraph should be struck as not being part and parcel of what the bill is concerned about.

I also want to move on to Section 5. This section requires that ". . .where a different brand name or non-brand name drug product of the same established name shall reflect a lower cost to the consumer but is not included in the latest list of approved drug products published by the council. . ." - I'll just delete the next two sentences - ". . .a different brand name or nonbrand name drug product shall be dispensed by the pharmacist, provided, however, that such action by a pharmacist shall be authorized only if in each case the pharmacist notifies the prescriber of the drug product to be dispensed and the name of the manufacturer thereof, and receives the approval of the prescriber to substitute such drug product for the drug product prescribed." This language is very important because

it amends the present substitution law of the State of New Jersey. It will require that in every case where a prescription is made, where there is not a product that is on the Drug Formulary, that the pharmacist will have to call the physician - if there is a cheaper product available - to obtain his consent to substitute a less expensive drug.

The theory of the Formulary is, one, where we are going to be encouraging less expensive drugs of the same therapeutic equivalency to be dispensed.

The theory of this section is that we are going to be encouraging less expensive drugs in all cases, even where they aren't equivalent because you are going to be requiring that pharmacist to go to the physician every time he writes a prescription to request that he dispense a less expensive drug.

I think the theory behind Section 5 is very dangerous and I would suggest that Section 5 be completely revised so that it will allow a pharmacist, at least, to dispense the drug that is prescribed without having to call the physician to obtain his permission to, first, notify him of a less expensive drug and then urge the physician that he not allow him to make the substitution. I think this is going to cause great problems for a pharmacy and for medicine.

I will now go to the last sentence in Section 5. "Whenever the latest list of approved drug products contains drug products of the same established name, section 4 hereof shall be applicable notwithstanding that a brand name or nonbrand name drug product of the same established name as such drug products included on the list would reflect a lower cost to the consumer." I included the "are not", as we discussed earlier.

I would suggest that this sentence still needs

somewhat of a reworking and we would be happy to work with counsel to try to pinpoint what was sought to be achieved. I still think it is capable of numerous interpretations and still is somewhat meaningless when read by itself.

ASSEMBLYMAN HERMAN: Any suggestion, sir, is always appreciated.

MR. VITIELLO: I'd like to go now to the last sentence in Section 6. In here you have the requirement that the pharmacist include on the label of the drug product dispensed, ". . .the established name and the name of the manufacturer if a nonbrand name drug product is dispensed. . ." The full savings, again, would be passed on, from any substitution, to the consumer.

But here you are missing something with regard to the savings and you are missing something with regard to consumer protection as well as the pharmacist's protection, and that is the need to make a record of the pass-on of the savings.

There are no controls in this legislation as it is presently written. How is the pharmacist or the patient to determine the cost of pass-through? Except for the fact that the pharmacist places his price on a unit basis, there is no other way.

We believe that once the pharmacist does make this determination that he should record it on the prescription and on the label, requiring him to show the money saved, indicating to the consumer that he is not being gypped and that the full pass-through is provided.

I think it stands to reason that to enforce this legislation there is something that needs to be put in there with regard to the cost pass-through, otherwise the savings that you would be promising the consumer may not appear.

Finally, I'd like to look at Section 7. In Section

7 you have the problem of it being a criminal statute. We are all familiar with the fact that, with criminal statutes which contain ambiguities, how the pharmacist is to comply with this law must be strictly construed and very plain.

We believe that there are problems with regard to this particular law which leaves the pharmacist in doubt. In one case he is to call the physician; in another case he is to advise him afterwards, keeping up to date between themselves. Enforcement becomes a real problem and the validity of the statute, I think, becomes a real problem here.

Finally, I'd like to address the provision which is not in the bill, and this is with regard to liability. This is something that was touched on previous to my testimony but it is something that I think we really should look at.

Here you have a situation where the State of New Jersey, through a Drug Utilization Review Council, will be selecting certain products which it will find to be therapeutically equivalent and requiring a pharmacist to make substitutions; to dispense a drug product different from the one that the physician selected without the knowledge of the patient. Unless the physician should, by chance, write "do not substitute" on the prescription, or initial the blank, the pharmacist must dispense something else. This is a serious problem for a physician. If he is required to still maintain liability, even though his prescriptions are required to be substituted, I think there is a substantial injustice to him. There is no reason that the physician should maintain that liability if that is the case. He will just be unwilling to cooperate with your law.

The pharmacist in all events will be protected, of course. The pharmacist will be doing the bidding of the

State. The State will be saying to the pharmacist, we want you to substitute a less expensive drug; we want you to dispense another product which we have found to be therapeutically equivalent. So, he will be protected.

In the event of an injury or in the event of a mistake by the Drug Utilization Committee, which, as you saw in Massachusetts, there have been several cases of - each recall, I would say, is a mistake and grounds for a possible law suit - where does the consumer turn to? He can't turn to the physician properly. I don't think any court in this State would hold the physician liable. He can't turn to the pharmacist and he can't turn to the State. You have a State law, which is the State Tort Claims Act - this is under Article 59, Paragraph 3, Subsection 2 - which protects public employees from liability in the performance of a discretionary act where there is no gross negligence involved.

So, we have left the patient without responsibility on anyone's part for the mistake. I think it is incumbent upon you to include in here some provision for the State to maintain liability and, of course, this will go into some sums of dollars and, rightly, should be included in the legislation.

I won't make any estimate as to what that amount should be at this point but I think, possibly, you might be able to develop more information with regard to the hospital costs and things of that nature which a patient might, rightly, sue for.

Mr. Chairman, I have one other area I'd like to touch upon. I have touched upon the bill and I would like now to touch upon the concept of the bill, if I may - as others have. I have had a little bit of a different background than many of the others who have testified before you. I was previously Legislative Counsel, or Staff Counsel, to Senator William Roth of

Delaware. One of Senator Roth's basic theories about government was one where you do not want to create a continual overlap and duplication of government programs or government bureaucracies. This is exactly what this bill would do.

Senator Muskie also feels the same way and has worked constantly through the Intergovernmental Operations Advisory Committee with state governments to reduce overlap and duplication.

You have heard many times today that the Office of Technology Assessment has been doing exactly the same thing which your Drug Utilization Advisory Council is intended to do.

Now I would submit that to pass this legislation, which, admittedly is something you can do, you have the legislative authority to do so-- The question of priority is one, I think, that you, as legislators, have to look at. Do you want to commit your State resources to this type of activity, which is a duplicate of what is being done at the Federal level?

We are familiar in other areas with duplication resulting in waste - where things have had to be scrapped. I could suggest examples of the S.S.T. and other things at the Federal level where we have seen things that have been jumped into too hastily and where we eventually have had to scrap them. Eventually the Federal Government is going to be taking some action in this area. What you do here will probably have to be revised to conform with what the Federal legislation is contemplated to achieve.

I make that suggestion to you so that in your own thoughts you will be able to more or less see that while there are problems in getting into the area, these are being looked at at the very highest levels and is

something, perhaps, that should be left at the Federal level, where the resources are. That concludes my statement.

ASSEMBLYMAN BAER: Thank you for your statement, Mr. Vitiello. There will be a question from Assemblyman Ruane first.

ASSEMBLYMAN RUANE: Could I take you back to Section 3 for a minute - the last paragraph?

MR. VITIELLO: Yes.

ASSEMBLYMAN RUANE: What is the procedure right now? What is the current accepted procedure now?

MR. VITIELLO: Under Section 3?

ASSEMBLYMAN RUANE: Yes.

MR. VITIELLO: As I read this bill the Council shall prepare a list of approved drug products by established names. The Council would just prepare a list of drug products by established names. I don't, basically, understand how that would be implemented.

ASSEMBLYMAN RUANE: Where are you reading from?

MR. VITIELLO: Subsection 3, is that what we are talking about?

ASSEMBLYMAN RUANE: The last paragraph, Section 3.

MR. VITIELLO: Okay, I'm sorry. "The council shall also have the authority by rule or regulation, to specify the number of times. . .", is that it?

ASSEMBLYMAN RUANE: Yes.

MR. VITIELLO: All right. With regard to the number of times a prescription may be refilled, under the Controlled Substances Act there are limitations as to the refilling of prescriptions. For controlled substances, under Schedules 2 and 3, I believe, I don't think any refills are allowed. But there are 6 refills allowed under Schedules 4 and 5 - I think that is correct. I may be wrong on those schedules. Otherwise, there is

no real limitation.

ASSEMBLYMAN RUANE: Isn't it a fact that if the physician doesn't specify any amount of refills on the prescription, that there is just one prescription allowed? Isn't that assumed?

MR. VITIELLO: I would believe so, yes. I am not that familiar with the workings of that particular New Jersey law. I have to defer to someone who might be better able to answer that.

ASSEMBLYMAN RUANE: But you can make a judgment as to deleting this paragraph. You just made a judgment with reference to this paragraph and, yet, you don't understand it.

MR. VITIELLO: The reason I suggested we delete the paragraph was with regard to the standardizing of dispensing quantities, which is something new - the permitting of dosage form exchange - and also because it specifies the number of times prescriptions may be refilled, Mr. Ruane. You have the problem here of this particular bill and this particular council getting into a medical matter and it is outside the province of this legislation and council.

Now, if the State wants to limit the way in which a prescription may be filled, I don't think you have had the testimony on this bill with regard to prescription refills. I don't think this Formulary Council is going to be the body which should be doing this. Really, the suggestion that I am making is that it is outside the scope of this legislation and it shouldn't be involved there.

ASSEMBLYMAN RUANE: Thank you.

ASSEMBLYMAN RYS: I have one question. Mr. Vitiello, I want to go back to where you were talking about the doctor's liability. We have been having these hearings pertaining to doctors and osteopaths and chiropractors for a long time. It has always been

suggested to me that most of these doctors carry an insurance liability policy of $250,000, so what would be the scare there?

MR. VITIELLO: In order for a Formulary to work you must have the support of pharmacists and your physicians. You have that in hospitals on a very limited basis because the Formulary within a hospital is agreed to and revised all the time; it is a very controlled situation.

You are in a community setting here where the ability to control that Formulary will be out of the hands of the physicians who will be practicing under it and will be out of the hands of the pharmacists who practice under it; it will be set by an autonomous group which will be more or less politically motivated.

Now, without the support of these two groups - the practicing pharmacist and the practicing physician - you are not going to have a Formulary that will be operative; you will have an expenditure of money but you will not have a Formulary that will be operative. The physician will be unwilling to utilize a Formulary over which he has no control or approval. The same thing applies to the pharmacist. If he is to be subjected to it, there is no reason why he should accept the liability for it.

ASSEMBLYMAN HERMAN: Following along with that last question, Mr. Vitiello, it sort of raised a question in my mind as to why the Pharmaceutical Association testified in favor of this bill if they have all the concern that you say they have.

MR. VITIELLO: I would submit, sir, that I don't have the figures as to the number of pharmacists the Pharmaceutical Association represents in the State but I would guarantee that it is not 100% and I would guarantee that of the total membership 100% of

them are not in favor of it.

Our people have talked to a number of the county pharmaceutical societies and they have indicated that they are very disturbed that the State Society has taken this action to support this legislation.

ASSEMBLYMAN HERMAN: Are any of these people here today, sir?

MR. VITIELLO: No, they are not, sir. This hearing was only called last Thursday. They would have been here. I would have hoped that these people would have had the chance to come forward - and other county medical societies - to voice their opposition to the proposal that is being suggested here.

We have suggested to you, informally, and I will make this request now, formally, that an additional hearing be held to allow these groups to have the opportunity to come forward.

ASSEMBLYMAN HERMAN: I would like to make one comment for the public record. I don't intend to get into any repertory debate with you but I think it is an interesting comment that should be put into the public record. As far back as two months ago - two months ago - I heard the same hue and cry, the same excuse, the same request for delay of public hearings, whether it be a formalized public hearing or whether it be on a committee basis, every time this bill was listed. This bill has been around and been in the hopper and been in committee for a long time and during the two months that it has been on the committee agenda - or almost two months it has been on the committee agenda - I haven't heard from a number of the people you say urge this concern.

Isn't it also a fact, sir, that throughout the United States most of the retail pharmaceutical state associations backed legislation such as this?

MR. VITIELLO: No, sir.

ASSEMBLYMAN HERMAN: How about the State of Claifornia?

MR. VITIELLO: Exception.

ASSEMBLYMAN HERMAN: How about the State of Michigan?

MR. VITIELLO: Exception, sir.

ASSEMBLYMAN HERMAN: And perhaps we might find another couple of dozen exceptions where this legislation has been introduced?

MR. VITIELLO: Sir, just as recently as this year the New Hampshire Pharmaceutical Association, as an example, suggested that legislation of this character was an excellent idea but that the State should not undertake it because of the amount of expenditures that would be required and that this should be encouraged and be done at the Federal level. This is our position and this is one that I submit should be adopted by this Committee.

ASSEMBLYMAN HERMAN: All right. Let me just ask you two more questions. In regard to malpractice - the shifting of liability - haven't most of the drug cases, based on your professional expertise and knowledge, in the United States, regarding malpractice litigation instituted against physicians as a result of "drug prescriptions" gone to the question of the improper prescribing, basically, of a wrong drug for an ailment?

MR. VITIELLO: Sir, the reason for that is that right now you have sufficient laws on the books.

ASSEMBLYMAN HERMAN: The point is-- I would appreciate, with all due respect - this is not a cross examination - a direct answer to the question I asked. Let me repeat it again, just so we have a mutual understanding. The question, very simply, is, isn't it true

that most of the malpractice, drug litigation, has been instituted against doctors because of alleged improper prescribing of the wrong drug for the ill sought to be cured or treated?

MR. VITIELLO: I have seen no survey, sir, as to whether what is being suggested, that suits that have been brought against physicians up to this point in time, has been on the basis of their prescribing the wrong drug or whether they have prescribed too much of the drug. I don't know of any breakdown or statistics on this.

ASSEMBLYMAN HERMAN: Okay. Let's get into this question of State immunity or sovereign immunity. Aren't there many areas, notwithstanding whether the bill should or should not be amended to include some minimum liability as is done in other tort areas, of discretionary state policy which affect people in all areas of life and which are exempted because of the overriding public considerations? Isn't that the whole doctrine of sovereign immunity?

MR. VITIELLO: Not any more.

ASSEMBLYMAN HERMAN: Not any more? It's a waning doctrine?

MR. VITIELLO: It is a waning doctrine and it is one that courts in state after state have looked at and said the reason for this provision in the law is one that was settled back-- We brought the doctrine of sovereign immunity from England to the United States. It was included in the law to protect the government we were setting up. That situation ceases to exist where the government interferes with the private life of the patient, when he is getting a different drug. I think when a state makes that type of a direct action into the individual personal life of the citizens that the state is the

insurer and must not accept that responsibility if that action is to be taken.

ASSEMBLYMAN HERMAN: It is a point of philosophy to be considered.

Let me ask you this, sir, if I may. Do you think what is being done at the Federal level is good?

MR. VITIELLO: We do not know exactly what is being done at the Federal level, at least as far as the O.T.A. is concerned. We have been advised that by June 30th we will have a report as to whether the equivalency of drug products can be determined with the present knowledge that we have from scientific tools. This is the exact thing that you are going to be giving this Drug Utilization Committee to undertake.

ASSEMBLYMAN HERMAN: Assuming that they can do that, do you think, once again--

MR. VITIELLO: I think that you have seen, sir, the December 19th statement of Mr. Weinberger. You made reference to it earlier today. I think that you will see in that that the Department of Health, Education and Welfare is committed to a policy of drug cost savings. Under that commitment you will see further action taken almost immediately to follow up on any report by the O.T.A.

ASSEMBLYMAN HERMAN: Let me ask the same question. Perhaps we are having difficulty communicating with each other. Assuming that they can accomplish what they say they can - using that assumption - do you think what is being done, or attempting to be done, assuming it can be accomplished, at the Federal level is good or worthwhile?

MR. VITIELLO: I do.

ASSEMBLYMAN RYS: It looks like both of you went to Yale on that one.

ASSEMBLYMAN HERMAN: Sometimes it is difficult to get a direct answer.

MR. VITIELLO: I am speaking personally, however, and not for the P.M.A. on that, just for the record.

ASSEMBLYMAN HERMAN: Just for the record we won't tell them.

Assuming-- You raised a number of points and I appreciate the constructive criticism and comments which you have made regarding the bill. Assuming that all the constructive criticism and comments and input which you have put before the Committee today are met and are incorporated, by way of changes, into this bill, and it comes out in a corrected version which would meet the objections raised by your comments, what is the position of the Pharmaceutical Manufacturers Association to such an amended bill?

MR. VITIELLO: Sir, as I have stated earlier, the position would remain the same.

The amended bill, assuming it were to satisfy all the suggestions that I have made, would remain the same because under the philosophy--

ASSEMBLYMAN HERMAN: What would that be, just for the record, against it or for it?

MR. VITIELLO: It would be opposed on the basis that for a state to undertake something of this magnitude without the resources that the federal agencies have would be folly and one which, without the commitment of the resources, would probably - and I would almost say most certainly - would jeopardize the health of the citizens of this State.

ASSEMBLYMAN HERMAN: Are you familiar, sir, with the basic national statistics, to wit the increase in the number of generic prescriptions that are being prescribed by doctors?

MR. VITIELLO: I heard reference made to them today, sir.

ASSEMBLYMAN HERMAN: Are you familiar with them?

MR. VITIELLO: I don't have a working knowledge of them.

ASSEMBLYMAN HERMAN: Are you familiar with the trend to prescribe generically?

MR. VITIELLO: I am familiar with the fact that there is an increase and I am also familiar with the fact that there are more drugs from which to prescribe generically now on the market than there were previously when the other figures were made up.

ASSEMBLYMAN HERMAN: Is there any indication this is going to be on the wane or is it a reasonable presumption that as the technology increases year to year, as I assume it will, that branded generics will be more prevalent on the market and not less?

MR. VITIELLO: That is speculation, I have no idea.

ASSEMBLYMAN HERMAN: Thank you very much.

ASSEMBLYWOMAN CROCE: Would the pharmaceutical companies be in favor of the posting of prescription drug prices in the store, plus the trade name, generic name, dosage, form, and all cautions about the action and reactions, so that the patient may shop with full knowledge?

MR. VITIELLO: The Pharmaceutical Manufacturers Association has not taken a stand one way or the other with regard to presecription drug advertising or prescription drug posting. We believe this is a matter for the pharmacies and the consumers in the State to determine how best that should be accomplished.

What we have suggested, however, is something a bit similar and a bit down the road as to what I think Mr. Herman is trying to accomplish, which is, cheaper drug prices - I'm sorry, let me rephrase that. - that the patient would get the highest quality product for the lowest possible cost. That is, I think, something that we would -- That is a concept that I think we are in

agreement with, perhaps - perhaps not.

We have suggested to H.E.W. that this be done; that doctors, somehow, get information on drugs with regard to, one, our prices - the pharmacy retail prices - and recalls. I think the doctor is missing this information. The doctor and the pharmacist, for the past several years, have stopped talking to one another. This has created the problem.

This bill here, I think, would be a great help to the pharmacists in the state; it would not help the doctors one bit. It would not help the patients that much. What you need is more communication between physicians and pharmacists, letting the physicians know what the pharmacists are charging his patients so that the doctor can say, I am going to prescribe for you this particular medicine, take it over to this particular guy and you will get a good price for it. He doesn't have that information now. He isn't able to advise his patients. The doctor is the selector of drugs but that is all he is, he doesn't have price information.

You provide the doctor with the ability of getting that price information and information on recalls so that he can best evaluate the, I would say, quality of the product that is being discussed and I think you are going to save that patient money. But under a bill like this, I think you are going to cost the State money and I don't really think you are going to be saving your everyday taxpayer any money.

ASSEMBLYWOMAN CROCE: Thank you.

ASSEMBLYMAN BAER: I think that concludes our questions. Thank you very much, Mr. Vitiello,for your testimony. I would now like to call Mr. Robert Raven.

R O B E R T F. R A V E N: First of all, my name is Robert F. Raven. I am Manager of Government Health Care Programs for Warner-Chilcott, a division of Warner-Lambert.

Mr. Chairman, Members of the Committee, I appreciate the opportunity to speak before you today on an issue that we consider to be of prime importance not only to the pharmaceutical industry but also to medicine, pharmacies and to the consumer.

Before I get into my official presentation, Mr. Chairman, I'd like to state that even though Assemblyman Herman has made mention of this fact, I did not receive notification until Wednesday afternoon of this public hearing. I tried to obtain scientific individuals from our company to come and testify on behalf of our company. All of them were unable to attend. I also made further contacts with other consumer groups and got a similar conflict. I therefore respectfully suggest, Mr. Chairman, that a secondary hearing be held.

ASSEMBLYMAN BAER: May I say at this point that at any rate you are aware that any other scientific witnesses or testimony, or any other thing like that, that you would care to submit in writing can be added to the record in the next 15 days.

MR. RAVEN: I realize this.

ASSEMBLYMAN BAER: This is not just going into the record, this is going to be studied by the members of the committee and carefully reviewed. Do you wish to take advantage of that?

MR. RAVEN: Yes, we probably will.

ASSEMBLYMAN BAER: Would 15 days be sufficient to be able to get that in?

MR. RAVEN: As far as people in my company are concerned, yes. For others, obviously, I cannot go ahead and speak for them. But as you know, Mr. Chairman, one of the advantages of a public hearing is the opportunity to have a question and answer session after the actual presentation and it is because of this that

I would strongly suggest that a secondary public hearing be held. When this will be, obviously, I will leave to your good discretion, Mr. Chairman, to determine the exact date.

In my actual presentation I am in no way going to comment on actual product cost but I will start off by trying to give you some idea of what the pharmaceutical industry is and the importance of research and how it affects the consumer.

Research has been the trademark of the pharmaceutical industry and most of the products that we have on the market today were not even known 25 years ago. Research brought these products into existence and as a result of these products we, in New Jersey and in America, are no longer concerned about such illnesses as polio, whooping cough, scarlet fever, typhoid fever and diptheria.

There are many illnesses that are of concern to us today such as cancer, heart disease, leukemia, cerebral hemorrhage, arteriolosclerosis, and the list can go on and on. Through research, this is the only way these illnesses can be eliminated.

The pharmaceutical companies in the United States since 1947 have been responsible for over 60% of all pharmaceutical products. If these illnesses are to be cured, they must be cured through these same companies.

As a result of this research today our death rates are lower, our lost time in our businesses are less and we have reduced our need for stays in hospitals and our length of stays in hospitals has also decreased.

As an example, in 1950 the average stay for an individual with tuberculosis was 461 days. In 1973 it was 78 days. The use of tranquilizers has resulted in a 51% decrease in the need for hospital confinement.

This all means that an individual, the breadwinner,

is allowed to work and to stay and to be an active member of our society.

Research, however, does not come cheap; it costs money. It costs the New Jersey pharmaceutical companies alone over $400 million a year to carry out their extensive research programs.

You need to know, however, that only one out of every 8,000 compounds tested will ever become a useful medicine and even with this one compound it will take approximately 10 years from the time that research begins until we have a produce approved for market.

At this point, we have no idea whether this product will ever return the money invested in that product. We do not know if the product will ever be a profit to the company.

The pharmaceutical industry in New Jersey employs over 52,000 employees at an annual salary of over $600 million. This is a major industry for New Jersey but what makes a company even more important is its desire to produce a quality product. Quality control is an important aspect of Warner-Chilcott's operations and of a majority of the major companies in the United States.

In the United States, one out of every four or five individuals employed in the manufacturing process is involved in assuring the quality control of that product. Quality control is what assures the successful completion of an illness.

Now, why is Warner-Chilcott objecting to sections of Assembly Bill 1257? We are very much concerned about the creation of a council to determine what products ought to be freely substituted in the State of New Jersey. By the prime sponsor's own admission it will be between 3 and 5 years, in his opinion, before we can ever have, or begin to have, the assurance of therapeutic equivalency of pharmaceutical products.

Such expenditures have been made in 3 other states, Massachusetts, Kentucky and Maryland and in each state, one, there has been no documentation of savings to the consumer and, two, each state's approach has inherent medical and scientific shortcomings. As an example, in Massachusetts, as you heard earlier, 73 drug products were withdrawn from the market due to recalls in 1973. In Maryland all manufacturers of antibiotics were placed on the Formulary but nowhere, at any time, did the State actually do any testing of any antibiotic products. In Kentucky a number of products were placed on the Formulary without evidence of equivalency of any kind. In many cases the actual manufacturer was never even asked to give information to the state.

In fact, there is a third element common in all three states. They have caused the expenditure of taxpayer's dollars without any demonstrated benefit. We would agree that when therapeutic equivalency and bioequivalency of pharmaceutical products can be assured then, and only then, should legislation, such as Assembly Bill 1257, be considered. In fact, it is premature. It assumes a state of the art which does not presently exist. As other witnesses have testified, the Federal Government now, through the F.D.A. in the Executive Branch and the Office of Technology Assessment in the Legislative Branch, and with substantial appropriations - $150 thousand for the O.T.A. alone and God only knows how much money the Food and Drug Administration spent each year on this problem - interestingly enough, through their investigation, they are doing, basically two things:

(a) Establishment of bioavailability standards and

(b) Whether the technology exists to assure equivalency.

Warner-Chilcott believes that action on Assembly Bill 1257 is premature in light of these developments

and are very greatly concerned that New Jersey not fall into the trap of passing this legislation until these Federal studies are completed.

Mr. Chairman, thank you for the opportunity to appear here today.

ASSEMBLYMAN BAER: I want to thank you, Mr. Raven. I would like to see if we have any questions. Mr. Herman?

MR. RAVEN: I would have been disappointed.

ASSEMBLYMAN HERMAN: I would not, even at this late hour, want to disappoint you.

As you know, I have referred, on occasion, to the fine brochure which your company sent all of us Assembly-people.

MR. RAVEN: I am happy to hear that.

ASSEMBLYMAN HERMAN: On page 24 - I think you mentioned earlier that the total investment in research throughout the industry is $400 million.

MR. RAVEN: In New Jersey, that's correct.

ASSEMBLYMAN HERMAN: Can you tell us what that is in relation to gross sales?

MR. RAVEN: No, I'm afraid I could not.

ASSEMBLYMAN HERMAN: I note from your book and I am reading from this fine document - it says, worldwide advertising promotion expenses during 1973 - I am making reference now to Warner-Lambert - were $222,889,000 as compared with $195,107,000 in 1972, an increase of 14%. Approximately $141,723,000 over the 1973 amount was spent for advertising and promotion in the United States. These amounts exclude - and I underscore exclude - promotional sales price reductions which have become a more important part of our marketing effort in recent years.

Perhaps I can stop there for a minute and ask you what is meant by promotional sales price reductions

becoming a more important part of your marketing effort.

MR. RAVEN: I would have to say that, number one, I do not know the answer to your question.

ASSEMBLYMAN HERMAN: Are we talking about discounts and giving people prizes and things of that nature?

MR. RAVEN: No, we are not.

ASSEMBLYMAN HERMAN: Just discounts to try products, product incentive costs?

MR. RAVEN: At this point the only thing I can do is to assume because I do not know the answer to that question.

ASSEMBLYMAN HERMAN: Would you, perhaps, get us the answer to that question?

MR. RAVEN: Yes, I will.

ASSEMBLYMAN HERMAN: I sure would appreciate it. Perhaps you could also get us, if you would, the amount - the dollar amount - that these promotional sales price reductions would be translated into so that we could add it to the total marketing costs to develop a better idea of what's going on.

For the record I would note that the next paragraph goes on to say--

MR. RAVEN: Excuse me, could I ask you one question?

ASSEMBLYMAN HERMAN: Sure.

MR. RAVEN: If I could ask you to go further - I am not sure I understood your last statement before you said you would go on.

ASSEMBLYMAN HERMAN: Just briefly -- Perhaps I will discuss it with you after the hearing.

MR. RAVEN: Okay, fine.

ASSEMBLYMAN HERMAN: Not to take too much hearing time. Just for the record, it is important to note, as your company notes in this report - and I am quoting now - "research and development expenses for 1973 were $64,259,000 as compared to $59,258,000 in 1972, an increase of 8%."

So, if I understand these figures correctly, it would appear that Warner-Lambert spent approximately four times as much on advertising and promotion as it did on research and development in 1973.

MR. RAVEN: As you also know, and have made mention of earlier, Warner-Lambert is a conglomerate company and does make Certs and other products.

ASSEMBLYMAN HERMAN: They are good. I like them.

MR. RAVEN: I have noted you have been enjoying them up here this morning. I sincerely hope it helps.

ASSEMBLYMAN HERMAN: The big question is whom?

MR. RAVEN: That point is up to you to decide.

It does cost substantially more money to promote a proprietary product, such as that, then it would a prescription product. So, we are very, very heavily in the consumer product area and have a number of divisions that are direct consumer and, as a result of that, you would expect a consumer company, such as this, to go ahead and have a larger expenditure, dollar-wise,in this area than you would one that is strictly in the ethical pharmaceutical area.

ASSEMBLYMAN HERMAN: Perhaps you might be able to break that down for us too so the record would be clearer.

Does Warner-Lambert engage in licensing its patents to other pharmaceutical manufacturers?

MR. RAVEN: I cannot speak for Warner-Lambert but I can speak for Warner-Chilcott and the answer is no.

ASSEMBLYMAN HERMAN: How about -- I was just wondering here because it would appear, according to the statement, that there is a large sum that is being taken in from royalties and I assume that that would mean patent distributions.

Does your company engage in the preparation and distribution of branded generics at all?

MR. RAVEN: No, we do not. I am referring, again,

to Warner-Chilcott.

ASSEMBLYMAN HERMAN: How about Warner-Lambert?

MR. RAVEN: I cannot answer that question.

ASSEMBLYMAN HERMAN: Your company does not engage in licensing and cross-licensing of your products?

MR. RAVEN: As far as Warner-Chilcott is concerned, no.

ASSEMBLYMAN HERMAN: And you don't know about the others?

MR. RAVEN: That is correct.

ASSEMBLYMAN HERMAN: Do you know how much your company spends per doctor on marketing and sales?

MR. RAVEN: No, I do not.

ASSEMBLYMAN HERMAN: Do you think you could supply us with that information?

MR. RAVEN: I will try to.

ASSEMBLYMAN HERMAN: I have heard figures on the average of anywhere from $1,750 in the trade all the way up as high as $10,000. I was just wondering.

Just two more questions. Are you familiar with the Ontario legislation at all?

MR. RAVEN: You are talking about the par costs?

ASSEMBLYMAN HERMAN: Yes.

MR. RAVEN: The only information I have on this - I have heard the question a number of times at this point - is I do know that they are currently having some problems with par cost and I asked a gentleman earlier and he indicated that we would be able to supply the committee with more information on par cost and the problems involved.

ASSEMBLYMAN HERMAN: Okay, thank you.

Last question - I believe that you testified that 60% of the new products were as a result of private research.

MR. RAVEN: No, what I said was 60% of the new products on the market to date came from the U. S.

ASSEMBLYMAN HERMAN: Okay. That doesn't take into consideration government patents and products?

MR. RAVEN: No, although the very, very large percentage -- I was looking through my briefcase for this and hoping that I had it because of a question that you asked earlier. I can supply this for you. Hopefully, I can find it again. Private industry is not sponsored very heavily at all by Federal government money.

ASSEMBLYMAN HERMAN: One last question. The patent - how long is your company protected by a patent?

MR. RAVEN: Seventeen years.

ASSEMBLYMAN HERMAN: And if there are modifications there is another 17 years involved?

MR. RAVEN: That's correct.

ASSEMBLYMAN HERMAN: So there is possibly 34 years in which you are protected?

MR. RAVEN: But not too likely. It is usually in the 17 year range.

ASSEMBLYMAN HERMAN: In which you can charge whatever the market would bear?

MR. RAVEN: One thing I would like to emphasize, however, is that 17 years starts with the inception of the research and not upon approval, so if you have 10 years of research put into that, that 17 years already has gone down to 7 years.

ASSEMBLYMAN BAER: I would like to ask, just as a matter of procedure, since there were a number of questions by Mr. Herman that you were unable to answer but presumably can get that information from your company, would you be able to provide that along with whatever other information you are going to provide for the record for us in the next 15 days? Do you need a

list, following the hearing, from Mr. Herman of those questions?

MR. RAVEN: Yes, that would be helpful so we don't have a misunderstanding as to exactly what we are looking for.

ASSEMBLYMAN BAER: Would you be able to provide that, Mr. Herman?

ASSEMBLYMAN HERMAN: I could do that, yes.

ASSEMBLYMAN BAER: Assemblyman Ruane?

ASSEMBLYMAN RUANE: Let me ask you what impact, do you think, would be on research for our drug industry as a whole if they were forced to sell generic drugs as opposed to brand names?

MR. RAVEN: Well, there is no question that if we went to a straight generic type of program, the cost of medication would have to come down and if the cost of medication had to come down, the overall profitability would go down; if the overall profitability went down then the market monies placed in research would have to be less. The second place that it would be lessened would be in the quality control aspect. We would start cutting corners in order to compete. So, it would definitely have an impact on research.

ASSEMBLYMAN BAER: Assemblyman Rys?

ASSEMBLYMAN RYS: I only have one question. This pertains to the salaries of the detail men. A detail man is given a district and I presume that salary that he obtains from the corporation is evaluated as expenses paid for a doctor.

MR. RAVEN: Well, obviously, I am not in the sales area at all.

ASSEMBLYMAN RYS: I just wanted to add that.

MR. RAVEN: I can't comment on the number of criteria that are used to determine the overall salary of detail men.

ASSEMBLYMAN BAER: Thank you for your testimony, Mr. Raven. It was very helpful.

Mr. John W. Hilton, Jr. will be our next witness.

J O H N W. H I L T O N, JR.: Members of the Committee, Ladies and Gentlemen, I am here today as a private citizen and taxpayer. I am a resident of Monmouth County. I do, however, work for the same firm as the gentleman you heard before. Whereas, he is an official representative of the company, I am not. I am here as a private citizen.

ASSEMBLYMAN BAER: What firm is that?

MR. HILTON: Warner-chilcott Laboratories, a Division of Warner-Lambert Pharmaceutical.

ASSEMBLYMAN BAER: Oh. I did not realize that. You are not listed that way. Well, I think I should interrupt at this point. Out of fairness, I think it would be unfair for you to proceed if I were not to allow the others to do so also. Perhaps an alternate means that could be used would be for you to limit your testimony to three or four minutes - because I don't know what questions we are going to have - and then I think I ought to provide that same opportunity to the others, so that the full-sized time slot that we would have provided can be split between the three remaining people who wish to speak. Can you do that?

MR. HILTON: Yes. As a matter of fact, most of the comments that I would have to make have already been made.

I would like to say that I, as a private citizen, am somewhat concerned about Assembly Bill 1257, in that the total health care expenditure in the United States - about 8% of the total health care dollar - is directly related to pharmaceutical and pharmacists expenses for dispensing the drug. That leaves 92% of the total health care dollar

which is not really being looked into. If we take this percentage one step further, the 10% of all pharmaceutical products which are dispensed are generically available or, as we would consider, a multiple source. This somewhat diminishes that percentage once again.

Cost of administration - even though Assembly Bill 1257 indicates a cost, initially, of $7,500 this is going to be totally inadequate for the total administration of this bill.

Some of the things that were mentioned earlier about some way to control the pharmaceutical dispensing, whether or not the savings were going to be passed on to the ultimate consumer, would involve quite a bit of additional expenditure just in the administrative function towards a relatively small portion of the total savings in the health care dollar. As a taxpayer I think the Committee could serve a lot more useful purpose to look into areas where there is more of a substantial amount of dollars to be trimmed from the total health care budget.

At that, I will conclude my testimony. If there are any questions, I will be glad to answer them.

ASSEMBLYMAN BAER: I appreciate your brevity, Mr. Hilton. Are there any questions from the Committee?

ASSEMBLYMAN HERMAN: Just one. What position do you hold with Warner-Lambert and how long have you worked there?

MR. HILTON: I have been employed with the Warner-Chilcott Division of the Warner-Lambert Pharmaceutical Company for the past 8 years. I am presently a Division Sales Manager in the State of New Jersey.

ASSEMBLYMAN HERMAN: Thank you.

ASSEMBLYMAN BAER: Thank you very much for your testimony.

Next we have two witnesses from Merck. Which one

prefers to testify, Mr. Gilligan or Mr. Byles?

D A N I E L B Y L E S: My name is Daniel Byles. I am Corporate Staff Counsel with Merck and Co., Inc. in Rahway, New Jersey. Mr. Gilligan and I conferred and I lost, so I will speak and he won't, how's that?

I will give you a little bit, very briefly, about my background. I am a lawyer and I practice in New York and New Jersey. My entire career of 21 years has been solely as an industry lawyer in the drug industry. By way of other background, as the young lady at my left can well attest, we spent a period of some 5 years studying drug problems in this state when I served as Vice Chairman of the Narcotic Drug Study Commission of the New Jersey Legislature. You will notice in your own files and in the 5 annual reports filed by that Commission, I am not adverse to New Jersey being first in anything. In fact, I think New Jersey should always be first. In fact, we were quite proud of the fact that New Jersey was the first one to adopt a Drug Counterfeiting Act. We were the first ones to update the Narcotic Act. We were the first State to control amphetamines and barbiturates, long before the Federal Government. In fact, some of the Federal legislation and the State legislation we now have, originated with our Commission and our studies.

Incidentally, I might note for the record also that our Commission enjoyed an annual budget of $50,000 which we, in turn, found somewhat less than adequate to conduct our studies with and which makes it somewhat appalling to me that you allot $7,500 for the Council you are establishing.

ASSEMBLYMAN HERMAN: That will be modified.

MR. BYLES: Of course that $50,000 a year goes back some 10 or 12 years and I gather inflation would have increased that.

Let me be very brief. First of all, when your Committee undertook study of this proposed legislation I, for one, believed that you had undertaken, perhaps, a study of the gravest possible legislation to come before the Legislature this session, even more so than the tax problems or the school problems because what you are playing with here - and I don't mean to use the word playing in a derogatory sense - is with the health of every citizen - myself, you and everyone of us. I think it therefore behooves you to give this the most serious consideration.

With that in mind, I would have two very quick comments. One is, I think it behooves each of you to know what you are talking about when you meet in committee session and deliberate on this bill following this hearing and in submission of comments at a later date.

With that in mind, I have already mentioned - and I will restate for the record - that we at Merck in Rahway stand ready at your convenience to have you visit us and see what we are talking about when we say, here is our quality control and our research facilities, here are the scientific inputs into the kind of drugs we are considering. I would strongly also recommend that you not only visit a firm such as ours - whether it be ours or others - but that you also go to the Pharmaceutical Association and get from them, say, one of the generic houses that they seem to be pushing at this moment, and visit that firm too. Make a comparison for yourself. I am not knocking any of those firms, nor am I trying to unduely build up our firm; all I am saying is, go see for yourself before you consider this legislation.

The second point that I'd like to make is that I was a little concerned with Mr. Herman - and I know you didn't mean it that way - when he suggested, or in

his questioning seemed to infer to the Medical Society representative that he was not speaking for the Society because he had not polled the membership. I would respectfully submit that no one, really, has polled the membership of any of the groups they represent here today and I think on a question as serious as this, perhaps it behooves us to poll the membership. Unfortunately, time just won't permit this.

Now, I recognize that the bill is under consideration. Theoretically, all of us have noted it, seen it, and read it. Unfortunately, that is not the case. I think if you were to suddenly poll - have the Society poll - half the doctors of this State and put the question to them in simple form: "Should you, the pharmacists, or a Council appointed by the State, determine who produces the drug that your patient will receive" - that's the question - I think you are going to suddenly find yourself avalanched with responses. I mentioned this at a staff meeting of a hospital in Newark the other night and they literally went through the ceiling. Unfortunately, they were scheduled for surgery, office hours, etc., and they couldn't come down from, what they thought would be, 10:00 to 12:00 this morning.

So, I think it behooves you to do more than leave the record open for 15 days. You should really give the Society a chance to poll its members - the county medical societies, the county pharmaceutical societies. I am not certain that they are all aware of this. The ones we have talked to are not aware of this and they are very much concerned.

This matter is so serious that I think the input from these people is needed. I think 15 days is hopelessly inadequate.

I know everything has been said today that could possibly be added at this late hour, but I would like to just mention one other aspect of this legislation.

What we are saying is that, first of all, every drug has a generic name; that's by law. So, there is no such thing as a generic drug or name brand drug. The sole question is, who determines what drug you will receive - that is,manufactured by whom? In other words, the way it is now, if a doctor writes a prescription for a brand name, the brand name merely states that "I want this drug by this manufacturer". The brand name only denotes the supplier, nothing else. All drugs have generic names. If he prescribes generically, as has come to be the habit, say, with the ampicillins, it could very well be in recognition of the fact that antibiotics enjoy batch certification, where every single batch that is produced by every manufacturer gets certified before it is marketed.

So, there is a difference between a generic prescription for, say, an ampicillin, than might be the case for, say, a non-antibiotic; that could open up a whole new realm of testimony and I don't want to get into that. But it is worth mentioning as one of the reasons for the so-called increase in generics.

ASSEMBLYMAN BAER: I'm sorry, I have to point out that--

MR. BYLES: My time is over?

ASSEMBLYMAN BAER: Yes, you are over your time, so if you could conclude--

MR. BYLES: Let me wrap it up. Every drug is generic. The doctor now decides who gets the drug, who produces the drug, because he knows, from experience, what that manufacturer's product will do with his patient.

I have heard testimony today that says, well, we are now passing this to the pharmacist because of his greater, if you will, training in this area than the physician has. But, yet, the bill doesn't do that.

What it really does is hand it to the Council, who will be under tremendous political and economic pressures to make scientific decisions which shouldn't be made on the basis of policital or economic reasons, and they will compile a list and then we strip the pharmacist of all discretion in that he picks from a list. So, you really don't let the pharmacist exercise his discretion. This concerns me greatly.

In closing, I think this bill deserves a great deal more study and a great deal more publicity and a great deal more time for the health professions of this State to look at it and comment on it. I think we would be doing a disservice if we close this off in 15 days.

ASSEMBLYMAN BAER: Thank you for yout testimony, Mr. Byles. I do want to say this, although I have requested testimony in 15 days so that it can be included in the hearing transcript, that does not mean that communications which may come to us after that will not be considered by the Committee. We do, however, want to have some sort of a cut off point so that the transcribing and printing can begin and so that transcript document will be available. But the Committee will continue to be open and the members will continue to be open to any written material that is submitted either through the Chairman, through the staff director, or to the various members individually. We will continue to be open to that up until whatever point we make a decision, one way or the other, on this legislation.

Are there any questions from the members of the Committee?

MR. RAVEN: An offer was made by Mr. Byles for a tour of a plant. Is the Committee interested in this?

ASSEMBLYMAN BAER: The members of the Committee are going to be discussing that following the conclusion of testimony. We will be discussing that privately and

reaching a determination on that and, perhaps, other procedural matters.

This concludes the testimony for today--

ASSEMBLYMAN HERMAN: Before you do that, would it be proper to make a motion at this time to request the Department of Health as well as notify the Appropriations Committee to reconsider the "appropriation" necessary to fund the bill or does that have to be done in a regular committee meeting? Can that be requested informally at this time, at least to get it started?

ASSEMBLYMAN BAER: As far as the procedural matter that you are referring to is concerned, it can be done under the authority of the Chairman, so it does not require a motion and I think that the action needs to take a slightly different form than what you have suggested. We can work that out.

ASSEMBLYMAN HERMAN: I withdraw my request.

ASSEMBLYMAN BAER: This concludes the testimony for today. I will leave open for a day or two the question as to whether or not I will schedule a further hearing date. I do not want to say anything now that would lead anybody to have the assurance that that would be the case so that you would rely on that as opposed to getting written testimony to the Committee for anything further that you have not presented to us as yet.

I want to thank all the witnesses whose expertise has been very impressive and whose testimony has been very thorough and also the members of the Committee whose questions have been very astute. I think that this is the type of very careful consideration that a measure like this deserves and I am glad it has received this sort of attention.

(hearing concluded)

STATEMENT

BY

CHRISTOPHER M. MARTIN, M.D.

SENIOR DIRECTOR FOR MEDICAL AFFAIRS

MERCK SHARP & DOHME RESEARCH LABORATORIES

MERCK & CO., INC.

RAHWAY, NEW JERSEY

BEFORE THE

NEW JERSEY ASSEMBLY COMMITTEE

ON

COMMERCE, INDUSTRY AND THE PROFESSIONS

TRENTON, NEW JERSEY

JUNE 3, 1974

My name is Christopher M. Martin. I was graduated from Harvard Medical School in 1953, and have served on the staff of the New Jersey College of Medicine as Associate Professor of Medicine and Director of the Division of Infectious Diseases, and on the staff of the Georgetown University School of Medicine as Professor of Medicine and Pharmacology and Director of the Laboratory of Clinical Pharmacology. Later I served as Scientific Director of Georgetown University Medical Division, District of Columbia General Hospital.

My present position is Senior Director for Medical Affairs of the Merck Sharp & Dohme Research Laboratories, a division of Merck & Co., Inc. Merck is a producer of health products and services, primarily prescription pharmaceuticals. We have some 25,000 employees worldwide -- about 3,500 of them at our manufacturing plant and research and administrative headquarters in Rahway.

Mr. Chairman, I appreciate being given an opportunity to comment on certain aspects of A-1257 which would -- under certain circumstances -- require pharmacists to substitute a different product for the medication prescribed by a patient's physician.

From a scientific point of view, I am troubled by the presumption implicit in A-1257 that the therapeutic equivalence of different drug products exists and can be established by a part time unpaid council. Products made by different manufacturers -- using different production methods, different testing and quality control procedures, and frequently, different coatings, binders or other excipient materials -- are different. To suggest otherwise strains rational judgment. Whether these obvious differences cause different results for the patient is a question that has received the most careful attention from pharmacologists and technicians

in a large number of studies. Much evidence has been gathered that in many cases drugs with the same active ingredient made by different manufacturers do give different therapeutic results in use.

Even now, as I am sure the Committee knows, the Federal Office of Technology Assessment is undertaking a study to learn not what drugs may be considered equivalent, but whether or not procedures and modalities can be established which will permit a determination of therapeutic equivalence. This is a logical first step. But we know from long experience that it is not a simple step, and that a simple solution cannot be expected.

With this background, I am concerned as a physician about the additional new variable -- the possibility of different clinical results from what I have learned from experience to expect -- which is introduced if patients are to receive any product other than the particular one prescribed. I'm sure the Committee realizes that the practice of medicine involves judgments covering a vast number of possibilities. Courses of treatment, including medication, are prescribed based on knowledge of and experience with the patient, the condition, and the therapies available. When a drug is prescribed, we expect certain results. If the therapeutic effect is other than we expect, the patient's return to health may be delayed; his suffering prolonged; and the cost for his care increased. And if such an unhappy eventuality should occur only because a so-called "equivalent" product was substituted for the one prescribed, how then has the consumer or his pocketbook been served?

I am a scientist -- not an economist -- and I will leave to others the task of analyzing relative costs to society, but I would suggest that the cost of one more day off the job, or one more visit to the doctor's

office, or one more day in the hospital would surely be far greater than any possible saving from a substitute product, however much lower its price might be. (I might mention by way of illustration that the average sales revenue Merck receives for a day's therapy with our major anti-arthritic product is about 20 cents, and for our major drug product against hypertension it is about 13 cents. In terms of possible added hospital days or added visits to the doctor, reducing those sales revenues to zero would not have an appreciable effect on the total cost of medical care.)

Thus far, I have been speaking of inherent differences in products made by different manufacturers -- differences based on different production techniques, ingredients, etc. I would like also to speak of differences among manufacturers. The state of New Jersey is the home of many excellent pharmaceutical manufacturers, whose 50,000 employees staff first-rate research and development organizations and outstanding production facilities where stringently enforced standards ensure high-quality output. Products discovered by scientists of such companies have saved lives and relieved human suffering to an incalculable extent, and have enabled a great many patients -- who otherwise would be incapacitated -- to lead productive, satisfying lives.

Unfortunately, New Jersey also is the home of some drug producers who do not place so high a premium on quality performance. This latter group of manufacturers supplies only a tiny fraction of the prescription drug needs of New Jersey residents. But newspaper accounts of court proceedings against one such producer indicated bad manufacturing practices continuing over a prolonged period that could cause immediate and irreparable injury to the public. As a physician and as a consumer I would challenge any assumption that products so manufactured are "just as good" as the products I know, and I certainly deplore the suggestion that value judgments based primarily on price should be encouraged by legislation.

My company is one of the manufacturers of brand-name products. The 25,000 people of Merck take pride in a tradition of excellence in research and in a reputation for high standards of quality, uniformity, and consistency in the products of our research. Happily our concern for quality has been shared by prescribing physicians and their patients with the result that Merck has grown, and thus has been able to serve the people of New Jersey and around the world with ever-improving products and services for human health and well-being.

If excellence in performance is our first consideration, it follows that cost must be a secondary, though by no means an unimportant consideration. However, it is perhaps relevant to the issue under discussion that while inflationary cost increases have imposed an onerous burden on all of us during most of the last decade, Merck's selling prices for prescription pharmaceuticals have changed very little up to the present. During the same period, our payroll in New Jersey, the taxes we pay in New Jersey, and the costs of our extensive programs of research and development -- all have increased very substantially.

At Merck, the vast majority of the products we produce and market were discovered in our laboratories, developed by our scientists, manufactured by processes worked out by our engineers and technical people. We have highly skilled production people, and every manufacturing step is subjected to exacting quality control procedures. Our products have been through long years of clinical testing before they are approved for marketing, and we continue to monitor them in use even after marketing approvals have been secured from regulatory agencies. We know our products and we proudly put our name on them. We produce up to the highest standards of quality and performance.

We know -- just as every shopper knows -- that there is hardly a product made that couldn't be cheapened by eliminating some steps or procedure and thus be sold at a lower price. This is not our way, and we sincerely hope it never will be a widespread practice in our industry.

Yet the thrust of A-1257 with its assumption of equivalence and emphasis on price would encourage pharmaceutical manufacturers to produce down to the lowest competitive cost rather than up to the best obtainable quality. Mr. Chairman, I submit that such a thrust is not in the best interests of medicine, the industry, or the public we all serve. We would urge that A-1257 relies on an unsound concept, and that it should not become law.

# # #

MERCK & CO., INC.

RAHWAY, N. J. 07065

PUBLIC RELATIONS DEPARTMENT
AREA CODE 201
FULTON 1-5000

June 10, 1974

Assemblyman Byron M. Baer
Chairman, Commerce, Industry & Professions Committee
420 Lantana Avenue
Englewood, N. J. 07631

Dear Assemblyman Baer:

At the public hearing, June 3, on A-1257, the Committee requested that Dr. Christopher M. Martin, Senior Director of Medical Affairs of Merck Sharp & Dohme Research Laboratories, supply printed versions of the charts he drew during his testimony on bioavailability. The charts are enclosed here -- numbered in sequence to coincide with the order of presentation at the hearing.

Also enclosed is a copy of a related paper written by Dr. Martin when he was Professor of Medicine and Pharmacology and Director, Laboratory of Clinical Pharmacology at Georgetown University School of Medicine. This carefully documented study, conducted by Dr. Martin at the request of the U. S. Food and Drug Administration, demonstrated significant bioavailability differences between chemically equivalent products, and thus raised the very real probability of lack of therapeutic equivalence.

The Committee also asked Dr. Martin and Daniel W. Byles, Merck's Corporate Staff Counsel, if Merck had licensed Parke Davis to produce hydrochlorothiazide; if Merck markets hydrochlorothiazide under license from Parke Davis; or if Merck manufactures hydrochlorothiazide for Parke Davis. At the time, Mr. Byles said that he believed the answer is no to all three questions, but that he would check to be certain. We would like now to confirm that Mr. Byles was correct in his answer to all three questions.

All of us from Merck appreciate the Committee's courtesy in giving us an opportunity to present our views at the public hearing, and to submit this additional and confirming information for the record.

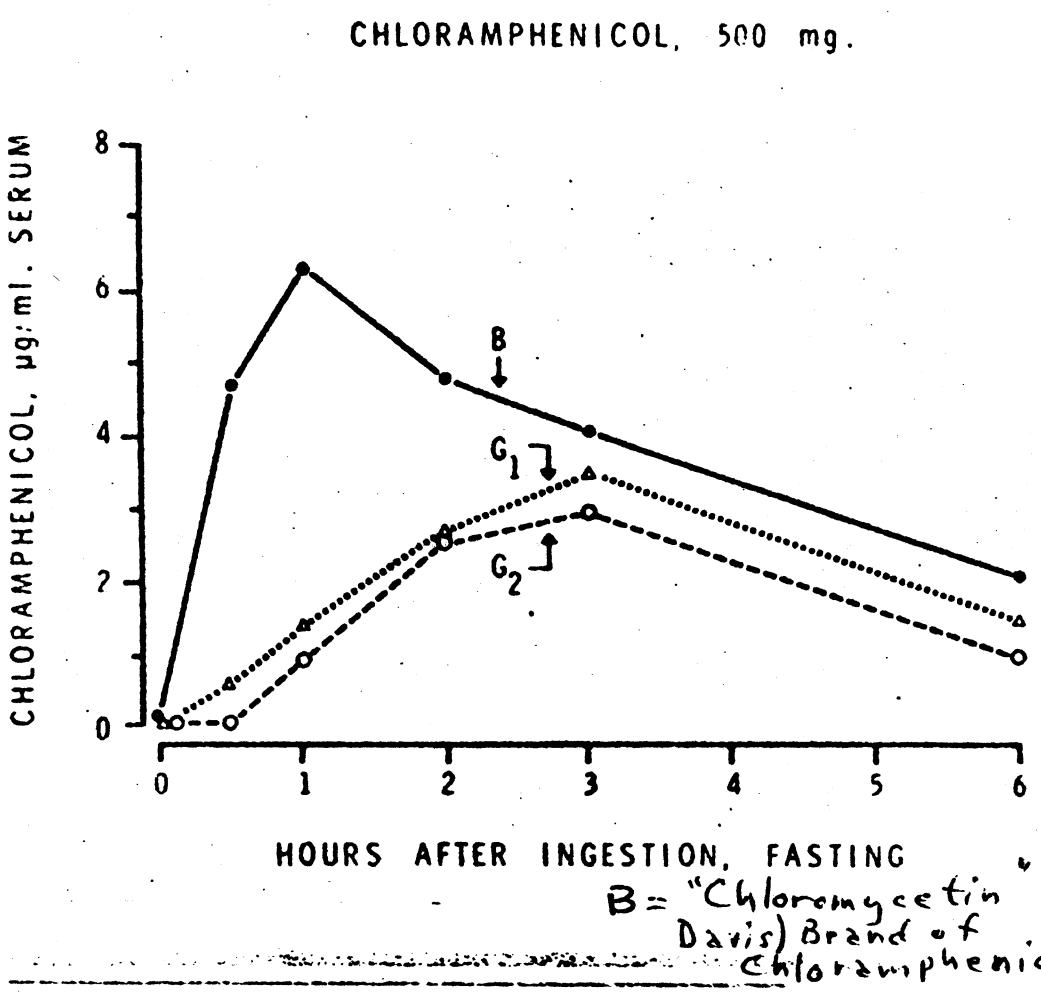
Sincerely,

Thomas C. Daly

AW

cc: Members of Commerce, Industry & Professions Committee
✓Thomas P. Bryan, Committee Aide

CHART 1



B = "Chloromycetin" (Parke, Davis) Brand of Chloramphenicol

CHART 2

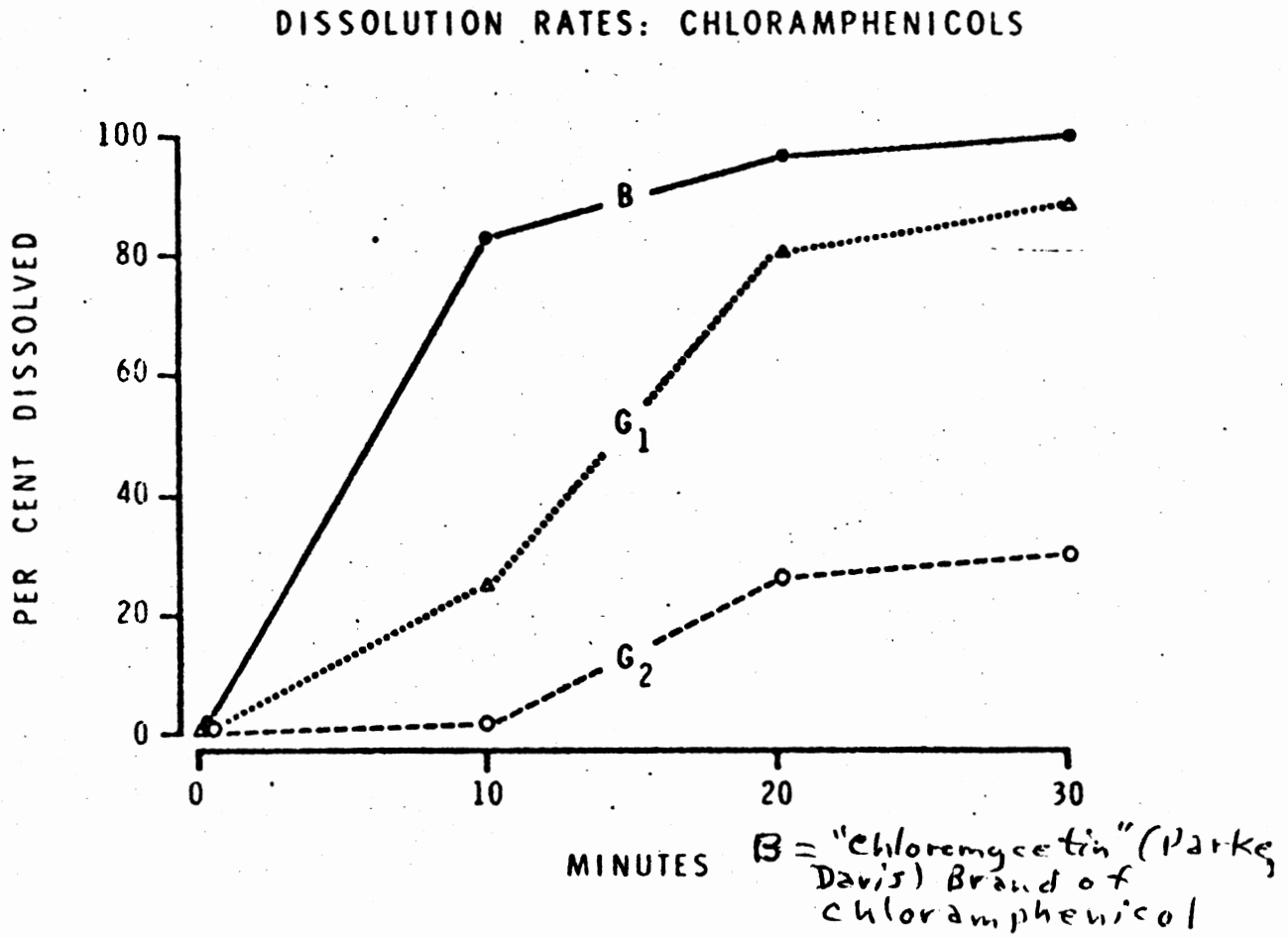
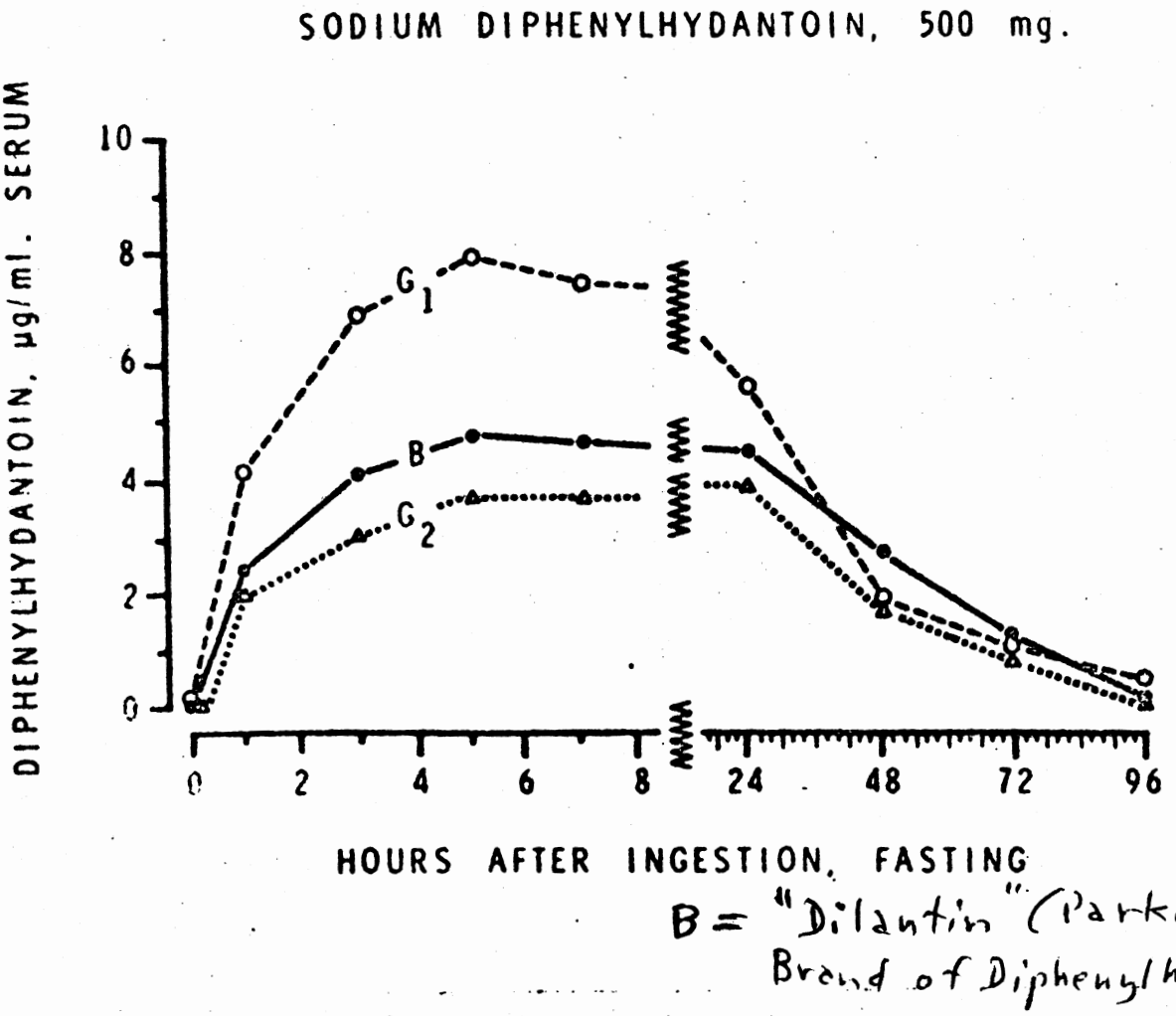

DISSOLUTION RATES: CHLORAMPHENICOLS
PER CENT DISSOLVED
100
80
60
40
20
0
B
G1
G2
0
10
20
30
MINUTES
B = "Chloromycetin" (Parke, Davis) Brand of Chloramphenicol

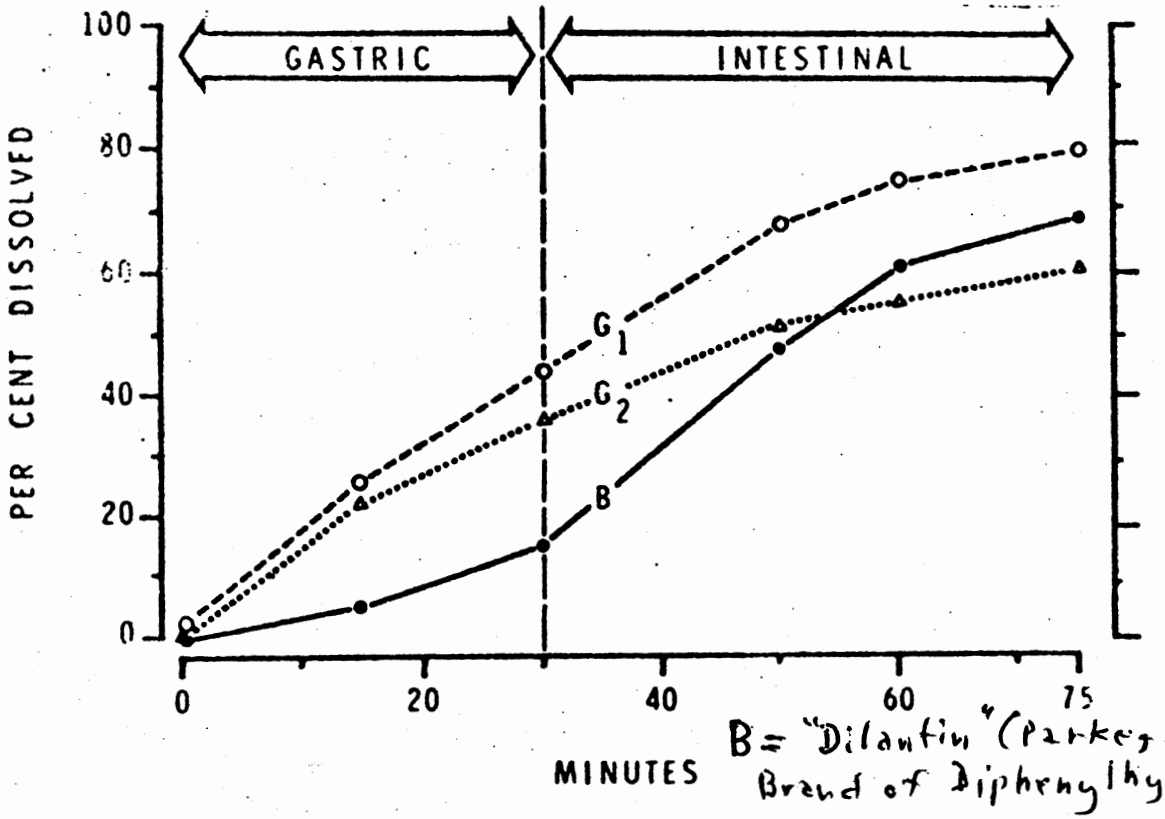
CHART 3



B = "Dilantin" (Parke, Davis)
Brand of Diphenylhydantoin

CHART 4

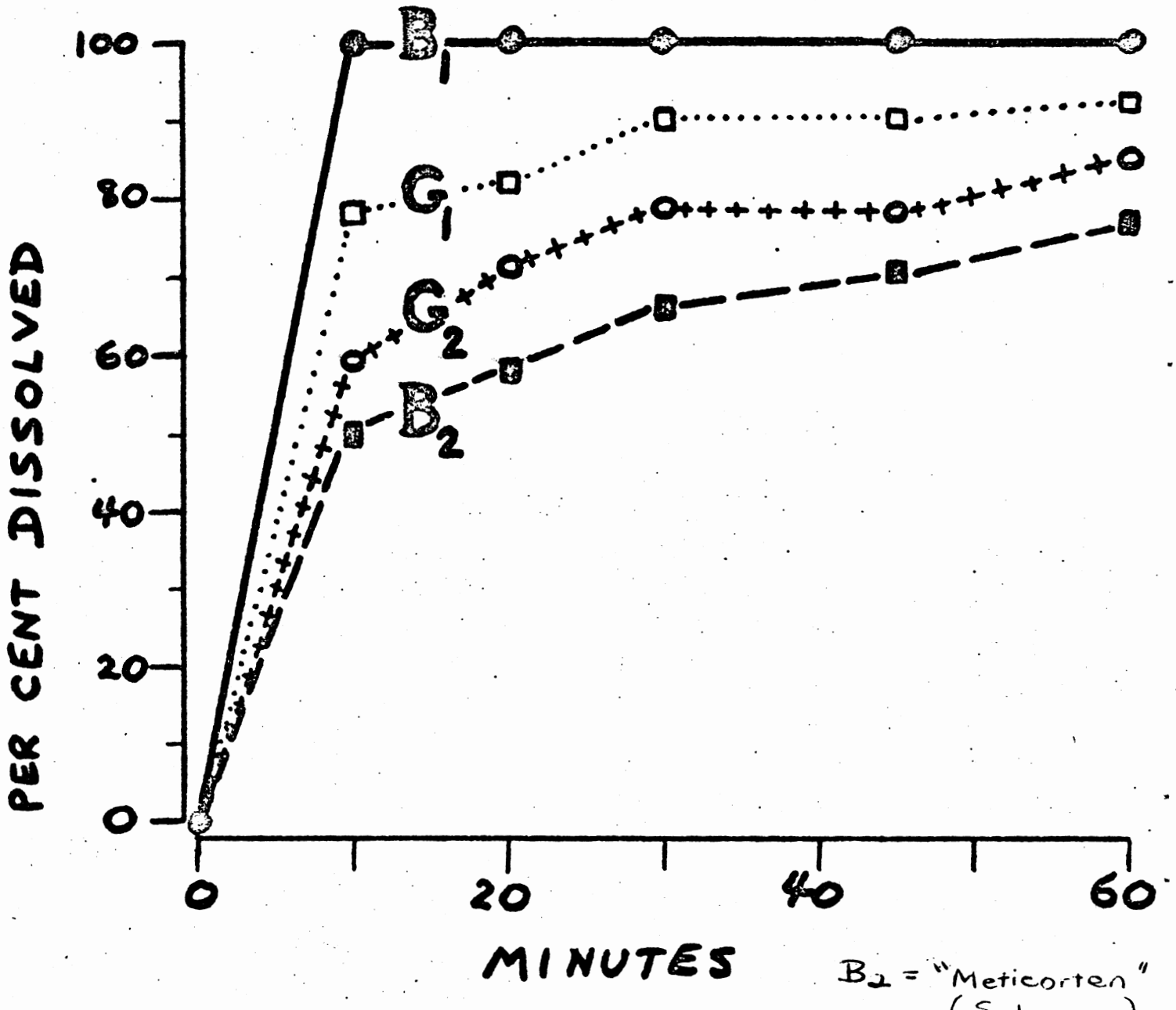
DISSOLUTION RATES: SODIUM DIPHENYLHYDANTOINS



B = "Dilantin" (Parke, Davis) Brand of Diphenylhydantoin

CHART 5

DISSOLUTION RATES: PREDNISONES



B_2 = "Meticorten" (Schering) Brand of Prednisone

CHART 6

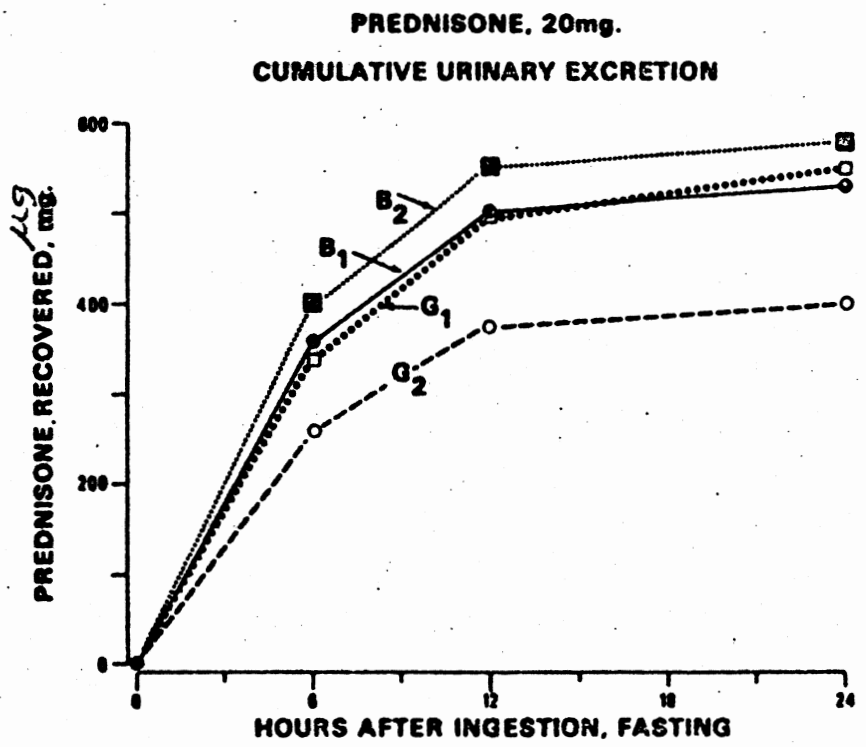


Fig. 11. Mean cumulative urinary recoveries of prednisone after ingestion of 20 mg of each of four prednisone products.

76

B_2 = "Meticorten" (Schering)
Brand of Prednisone

SUBMITTED BY DONALD J. FOLEY, CHIEF, DRUG CONTROL PROGRAM, NEW JERSEY STATE DEPARTMENT OF HEALTH

Mr. Chairman, Members of the Committee:

I am Donald J. Foley, Chief of the Drug Control Program, Division of Narcotic and Drug Abuse Control, New Jersey Department of Health. I am appearing here today in behalf of William J. Dougherty, M. D., the Acting Commissioner of Health. Dr. Dougherty wishes to thank the Chairman and the Committee for the invitation to appear and give testimony regarding the proposed amended version of Assembly Bill 1257.

The Department wishes to state, for the record, that the Department is very much in agreement with the general purpose and concept as presented in Assembly Bill 1257. Legislation which is intended to provide pharmaceutical products and/or services at a reduced cost, or providing a saving to our citizens, deserves our closest attention and consideration. The same attention and consideration are also given to the responsibilities and duties that will have to be assumed or performed by the enforcing agency or agencies charged within the Act.

It is in this context, that the Department wishes to offer comments on some of the provisions, language and duties expressed in the proposed amended version of Assembly Bill 1257.

It would appear to the Department that the proposed Assembly Bill would be intra-Departmental in nature. It provides for a Drug Utilization Review Council established in the Department of Health, whose purpose would be to establish a list of approved drug products by established names that Council determines to be therapeutically equivalent to brand names; and other provisions regulating the practices of pharmacy as it relates to the conditions

wherein a pharmacist may substitute a Council approved drug product for a trade named product in a prescription; such practice of pharmacy being regulated by the Board of Pharmacy, Division of Consumer Affairs, Department of Law and Public Safety.

With this understanding on the nature of the Bill, the Department should like to limit its specific remarks to the Council concept, its functions, duties and budget.

The Department has concern that the Council will have need of technical and clerical personnel as noted in Article 3. The Department feels that printing costs, postage, office supplies and machinery, subscriptions and journals for references, and other expenses would be incurred, sufficient to negate the appropriation of $7500.00. provided in the Act. The Department would request of the Committee and Legislature permission to file a Fiscal Note to adequately provide for the needs and functions of the Council.

With respect to those provisions of the Bill concerning the practice of pharmacy, while the Department is not charged with the enforcement of Title 45, it has reviewed those provisions and would appreciate the Committee's indulgence and latitude by permitting the Department to express some cogent views and experiences gained in the enforcement of other pharmacy related laws.

Again, conceptually, any established rule, regulation, law, practice or procedure deserves review when such review may or will bring about changes that will provide additional benefits to our citizens. It is the stated opinion of the Department that the

provisions and concepts expressed in AssemblyBill 1257 are most favorable to provide such a benefit. However, we have stated our concerns relating to the function of the Council, and we should like to comment on some of the requirements involving the practice of pharmacy.

Article 4 provides a means whereby a pharmacist may substitute a "Council approved drug product" for a trade name drug product, unless the prescriber explicitly states otherwise. Article 5 has a similar provisio but permits a pharmacist to dispense a different brand name or a nonbrand name drug product in lieu of the one noted in the prescription <u>if</u>:

1. A brand name product or a nonbrand name drug product costs less, but is not included in the Council Approved Drug List; or
2. Where in the professional judgement of the pharmacist -
   a. there is no valid proof of efficacy for the product prescribed, or
   b. the pharmacist's patient profile record discloses drug sensitivity, allergies or adverse reactions to the product prescribed, or
   c. there exist a more appropriate drug product than the product prescribed.

In both instances, Article 4 and Article 5 require:

1. Either implied approval from the prescriber (in the absence of an explicit statement "no substitution" or similar notification) as stated in Article 4; or
2. Communication between dispensor and prescriber to obtain

approval prior to the proposed substitution.

The additional label requirements - (typing on the label the brand name of such drug product, or the established name and the name of the manufacturer of a bonbrand name drug product) if not contrary to the prescriber's order, that, the Department believes, the pharmacist can live with and abide by.

Based upon the Department's experience in the enforcement of inventory, dispensing records, maintenance of invoices of purchase, a completion of Federal Purchase Order Forms as required by the Controlled Dangerous Substance Act, and with full knowledge of the added record keeping responsibilities associated with the Patient Profile Records required pursuant to Pharmacy Regulations, the Department takes notice of the requirement set forch in Article 4 and Article 5 requiring communications between the pharmacist and the prescriber, and recommends further deliberation on this requirement.

We, collectively as those regulated and those in enforcement, realize that compliance to a statute is best achieved with a minimum of bureaucratic paper work, senseless report writing and unnecessary correspondence and communications. Such communications required in Article 4 and Article 5 will seriously hamper, if not scuttle the whole concept of providing Council Approved Drug Products to the consumer at a projected great saving.

The pharmacist faced with the prospect of numerous, possibly 50 to 150 daily, telephone calls to the prescriber, not to mention

demands made of the prescriber at the other end of the wire, we can see that both prescriber and dispenser are going to say - "What the hell, its not worth it, I'll not substitute", or "I'll get that pharmacist off my back, every script goes out 'No substitution',". Such actions would defeat the whole concept of the Bill; or if written communications are the elective, you know the status of the postal service today, such communications would be received by the prescriber - when - 2 to 4 days after the fact. What value is such communication? It is therefore the recommendation of the Department that: IF:

1. The prescriber is granted the option to having a particular drug dispensed without substitution, and
2. We really believe that our pharmacists are qualified, Board licensed, experienced, participating in a continuing education program, maintaining patient profiles, qualified in the dynamics of drug interaction, drug incompatabilities and drug reactions and allergies as the New Jersey State Board of Pharmacy certifies they are:

Why not permit, under this proposed Bill, that substitution of a prescribed drug be permissable by the pharmacist in all cases with drugs approved by the Council or under the circumstances set forth in Article 5?

Mr. Chairman, members of the Committee; the Department would again express its appreciation for the invitation to appear. We feel that such legislation is not only needed, but possible long overdue. Faced with the possibility of a National Health Insurance

Act, we feel that such considerations on Assembly Bill 1257 will aid materially in the furtherance of such Federal legislation. New Jersey has always been a front runner in drug and pharmaceutical legislation. The Department believes the concepts expressed in Assembly 1257, with review and further deliberation, will result in a workable, accepted, beneficial proposal to the benefit of all our citizens.

COLLEGE OF MEDICINE AND DENTISTRY OF NEW JERSEY
100 BERGEN STREET / NEWARK, NEW JERSEY 07103

OFFICE OF THE PRESIDENT

June 20, 1974

The Honorable Bryon M. Baer, Chairman
Commerce Industry and Professionals Committee
125 West State Street - State Capitol
Trenton, New Jersey 08625

Dear Assemblyman Baer:

The New Jersey Health Science Group appreciates the opportunity that your Committee has afforded us to testify before it on Bill A-1257.

As per previous understanding, I enclose written copies of the testimony of Dr. Diller Groff and Dr. Duncan Hutcheon for consideration by your Committee.

If the Group can be of any further assistance to you, or your committee, in their deliberations concerning this Bill, please do not hesitate to contact me.

Thank you.

Sincerely,

Stanley S. Bergen, Jr., M.D.
President

SSB:j
Attachments

cc: Mr. Rock
Dr. Groff
Dr. Hutcheon
Dr. Robinson

COLLEGE OF MEDICINE AND DENTISTRY OF NEW JERSEY

MARTLAND HOSPITAL
NEW JERSEY MEDICAL SCHOOL
65 Bergen St. Newark, N. J. 07107

June 11, 1974

Mr. Bob Rock
Johnson & Johnson
501 George Street
New Brunswick, New Jersey

Dear Bob:

I am sorry that I was unable to attend the most recent public hearing concerning the New Jersey Anti-Substitution Bill (A 1257), but I understand that Dr. Duncan Hutcheaon was able to be there to do his usual job. My statement which I would have made at the hearing is as follows:

"I am a faculty member of the New Jersey Medical School in the Department of Surgery and teach the discipline of Pediatric Surgery and conduct my practice of surgery within that context. As a practicing surgeon who writes prescriptions, I can see several very serious problems related to the Substitution Bill. The first relates to the problems of establishing unequivacal bio-availability for various drugs of the same chemical composition but different manufacturer. This is dealt with in detail in the positionpaper of the New Jersey Health Sciences Group, but unless the practicing physician has a list of these drugs for which unequivacal bio-availability is established, physicians will insist upon using the brand name drug with which they are familiar. The practical experience with such drugs as the Tetracyclines and Digoxin has demonstrated that gererically equivalent drugs are not always equivalent biologically. These examples are well known to practitioners, and once burned they are twice wary concerning claims of bio-availability. It is well known that although there are a myriad of drugs available, the individual practicing physician uses only a handful of these regularly, and prefers to use the same brand each time. This helps eliminate some possible variables in each individual patient's treatment.

The second concern I have as a practicing surgeon is the practicality of verbal or written notification by the pharmacist concerning the substitution of medications. Any notification by mail is certainly impractical if the patient has an acute illness. In practice pharmacists will probably be reluctant to spend much time on the telephone looking for physicians to give verbal notification. It would probably turn out that pharmacists did not find it worth their while to try and substitute drugs within the provisions of the present proposed law.

A third aspect which has not been dealt with, to my knowledge, in the discussion of this bill is the extent of the pharmacist's liability in terms of malpractice claims. Although through the bill's safeguards and perhaps by future court decisions, the pharmacist may not be liable for any malpractice suits which arise from patient care cases in which substitution of drugs has taken place, pharmacists may be reluctant to substitute just because they don't want to be involved in any aspect of these possible litigations. Many physicians today practice defensive medicine (ordering examinations and tests to cover all the possible, but not probable, medical aspects of a case) in order to avoid any involvement in malpractice litigation. Certainly unless unquestioned equal bio-availability for generic drugs is established, any lawyer worth his salt is going to implicate a substituted drug in any malpractice litigation.

From the practicing physician's point of view, I would say that despite commendable motivation, the pharmacy and medical professions are not quite ready for the law which has been proposed in bill A 1257."

I have to apologize for getting this off so late. In the rush of things it inadvertently received a lower priority than it should.

Sincerely,

Diller B. Groff, M.D.
Director
Division of Pediatric Surgery
Associate Professor of Surgery

DBG/rf

COLLEGE OF MEDICINE AND DENTISTRY OF NEW JERSEY

NEW JERSEY MEDICAL SCHOOL
100 Bergen Street
Newark, New Jersey 07103

May 14th, 1974

The Honorable Martin A. Herman
State Capitol
125 West State Street
Trenton, New Jersey 08625

Dear Mr. Herman:

As I mentioned after the hearing on Bill 1257 last Thursday, I am a pharmacologist engaged in studies of the actions and toxicity of drugs in man. I am communicating with you at this time on behalf of the New Jersey Health Sciences Group which, as you know, is deeply concerned with achieving the highest standards of health care for our State. The New Jersey Health Science Group appreciates the importance of your work and wishes to compliment you on your efforts to improve health care delivery in New Jersey.

Most of the discussion at the May 9th hearing involved making prescription drugs more economical. It is, of course, even more important to protect the consumer against the sale of impure, ineffective and toxic drugs. Furthermore, the New Jersey legislation should not conflict with pending Federal regulations which are expected to be published in the near future.

In view of the above, I would like to recommend certain changes in the wording of Bill 1257:

1. Expand Section 1 para e (page 2) to include a statement ensuring chemical and biological purity of drug products manufactured and marketed in New Jersey.

2. I feel it may be false security to include procedural details of bioavailability studies in Section 1 g (1) (b). Such procedures are applicable to some marketed prescription drugs but not to others. Furthermore, quantitative chemical assays of blood concentrations of many long-established drugs are presently unavailable or are only in the developmental stage.

3. The New Jersey Health Sciences Group would like to recommend that at least one of the two physicians on the Council should have experience in clinical pharmacology and that one of the pharmacists be employed in the field of biopharmaceutics.

Standards for therapeutic equivalency are now being prepared by both HEW and the Senate Health Subcommittee. At Senator Kennedy's request, the Office of Technology Assessment has established a panel of scientists to study the issue and report its findings to Congress by June 30, 1974. We therefore believe it would be wise to have the recommendations of this panel before reporting out the New Jersey bill to the Legislature. In this way conflicting and incomplete legislation in the New Jersey Act may be avoided.

If you have any questions on the proposed changes, representatives of the New Jersey Health Sciences Group would be happy to meet with you at your convenience to discuss them.

Sincerely yours,

Duncan E. Hutcheon, M.D., D. Phil.
Professor of Pharmacology

DEH:oy

cc: Assemblyman Byron M. Baer
Dr. Stanley S. Bergen
Dr. Robert J. Robinson

COLLEGE OF MEDICINE AND DENTISTRY OF NEW JERSEY

NEW JERSEY MEDICAL SCHOOL
100 Bergen Street
Newark, New Jersey 07103

June 18, 1974

The Honorable Bryon M. Baer
State Capitol
125 West State Street
Trenton, New Jersey 08625

Dear Assemblyman Baer:

I am writing this letter to supplement my testimony presented at the public hearing on Bill A-1257 on June 3, 1974. I would appreciate having it written into the record as representing the position held by the New Jersey Health Sciences Group.

The Federal legislation passed by Congress since 1906 has been for the primary purpose of protecting the public against the misuse of toxic, habit-forming and ineffective drug products. The initial Food and Drug Act was passed as the result of excessive adulteration and misbranding of drugs. The subsequent amendments in 1938 and 1962 were enacted following the tragedies resulting from the inadequate testing of the new drug preparations.

It is important to continue this policy of consumer protection for prescription drugs. New legislation should not weaken existing laws by providing an opportunity for marketing substandard and biologically or chemically impure drug products in the name of economy.

Bioavailability studies on a mounting number of drugs have demonstrated wide variability in blood levels after administration of different pharmaceutical preparations of the same drug. The enclosed table represents a partial list of drugs and vitamins for which bioavailability studies have been reported. For some drugs the difference between various formulations of the same drug have been so great that certain preparations have led to toxicity whereas other products containing the same quantity of active drug have produced very low blood levels and therapeutic failure.

Furthermore, State as well as Federal laws regulating prescription drugs must be strictly enforced. Qualified professional personnel with complete laboratory facilities such as provided by the FDA must be available for surveillance programs. Drugs marketed in New Jersey require constant monitoring. Manufacturers of cheap drug products must be prevented from cutting their costs by marketing preparations which fail to meet USP standards for purity and safety.

The therapeutic equivalency problem is presently being studied by the Department of Health Education and Welfare. A panel has been set up under the Office of Technology Assesment to determine whether the same drugs supplied by different manufacturers produce equivalent therapeutic results.

The State of New Jersey depends heavily on the Federal agencies to regulate the marketing and dispensing of prescription drugs. It is, therefore, felt that Bill 1257 should not be reported out to the Legislature until such drug cost-quality questions have been resolved by the Office of Technology Assesment and the Department of Health, Education and Welfare. Legislation proposed for the State of New Jersey should consider the OTA reports in order to avoid any incompatibility with expected changes in Federal regulations controlling prescription drugs.

Sincerely yours,

Duncan Hutcheon

Duncan E. Hutcheon, M.D.,D.Phil.
Professor of Pharmacology

DEH:gw

cc: Dr. Stanley Bergen
Dr. George A. Condouris
Mr. Richard Hastings
Mr. Robert Rock

Bioavailability Data Reported by Drug Research Laboratories
Health Protection Branch, Ottawa*

Drug (dose)	Type	Urinary excretion	Blood level	Bioavailability %
Riboflavin	Compressed tablets			11 to 112
NaPAS	Compressed tablets	x		10 to 102
Salicylates	Enteric coated	x		23 to 116
Riboflavin	Enteric coated			29 to 81
Riboflavin	Sustained release	x		15 to 64
Riboflavin	Chewable	x		30 to 125
and Thiamine				85 to 116
Riboflavin	Spaced release	x		13 to 77
and Thiamine				28 to 98
and Niacinamide				27 to 122
Riboflavin	Sugar coated	x		12 to 98
Iron	Sustained release		x	24 to 103
PAS and Salts	Various	x		42 to 99
Acetaminophen	Tablets and elixir	x	x	78 to 103
Sulfadiazine	Compressed tablets	x	x	42 to 124
Sulfisoxazole	Compressed tablets	x	x	75 to 101
Sulfamethizole	Compressed tablets	x	x	92 to 111
Nitrofurantoin	Compressed tablets	x	x	70 to 117
Hydrochlorthiazide	Compressed tablets	x		88 to 113
Phenylbutazone	Sugar coated		x	61 to 104

*Cook, D. History of Bioavailability Testing at the Food and Drug Directorate. Rev. Canad. de Biol. 32 (Suppl):157, 1973

ELI LILLY AND COMPANY

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

EASTERN REGIONAL OFFICE
277 PARK AVENUE
NEW YORK, N. Y. 10017

May 15, 1974

MEMORANDUM IN OPPOSITION TO:

A-1257 (Herman, et al.) Amended

An Act concerning prescription drugs, authorizing substitution of drugs under certain circumstances, establishing a Drug Utilization Review Council, providing penalties for violations and making an appropriation for the purpose thereof.

The above proposed legislation would drastically change the existing state law which specifically prohibits any substitution or deviation from the terms of a prescription written by a physician, or other licensed practioner who is qualified to write prescriptions.

Major areas which should be examined before the New Jersey Legislature endorses such a radical change:

1. The formation of a Drug Utilization Review Council to prepare a list of therapeutically equivalent drugs, raises the question of State liability - the legal rights of the patient would be complicated and adversely affected.

2. There is no guarantee in the bill that the consumer will receive quality medication in the product substituted, since the F. D. A. cannot guarantee quality of most drugs. (Congressional Record - Senate May 1, 1974) (The Federal Register, January 5, 1974)

3. Recent experiences with Drug Formularies in Kentucky and Maryland have not been successful - the appropriation of $7,500 for the formation of the Council to implement the Act is insufficient.

4. Present laws of New Jersey permits a pharmacist to obtain the physician's consent to substitute another drug - thus, the legislation in the Act is not necessary.

5. The problem of equivalence is being studied at the Federal level. The Office of Technology Assessment has received an appropriation of $150,000 just to develop the Committee to study the feasibility of drafting regulations and technology for assuring bioequivalence in the future. (Congressional Record-Senate May 1, 1974.)

6. The fiscal implications for the State of New Jersey in developing a mechanism to approve drug product equivalencies could prove to be prohibitive.

7. There should not be legislated a mandatory requirement for a physician to indicate on his prescription that no substitution be made. This is an infringement on his basic rights in the practice of medicine.

Generic substitution is a subject which demands, and deserves, the most thoughtful consideration. Only an orderly, valid, scientific evaluation, product class by product class, will find the facts. The scientific resources of government, our academic institutions, and industry should be mobilized to answer this compelling question. The OTA (Office of Technological Assessment) is attempting to solve this controversy.

Eli Lilly and Company urges defeat of A-1257.

Respectfully submitted,

PHARMACEUTICAL DIVISION
ELI LILLY AND COMPANY

Albert G Mercuri

Albert G. Mercuri
Manager of Regional Services

AGM/bed

PHARMACEUTICALS
PFIZER INC.

June 3, 1974

From the desk of: Dan Minicucci

To: Thomas P. Bryan
Committee Aide, Assembly
Commerce, Industry and
Professions Committee

At this public hearing on A-1257, Pfizer Pharmaceuticals wishes to go on record as opposing said bill.

Attached is a copy of the original memorandum in opposition , dated May 15, 1974.

I respectfully request that the attached be made a part of the record of this public hearing.

Sincerely yours

Daniel M. Minicucci, R.Ph.
Government Relations

May 15, 1974

TO MEMBERS OF THE ASSEMBLY COMMERCE, INDUSTRY & PROFESSIONS COMMITTEE

Very briefly, I ask that you consider the postponement of further action on A-1257 for the following reasons:

1. Central to the implementation of A-1257 is the question of equivalent prescription drug interchange. The question is widely recognized as a very difficult one. In recognition of this fact, Senator Kennedy, through the Office of Technology Assessment (OTA), has caused to be convened "a blue ribbon panel to try to resolve the drug bioequivalence dilemma raised by Health, Education & Welfare's Secretary Casper Weinberger's announcement before the Health Subcommittee last December of a new drug reimbursement policy". 1/

   To involve the State of New Jersey in a duplicative effort would result in a needless expenditure of time, effort and State funds. If the objectives of A-1257 are valid, then the OTA study will certainly so declare and document, and at no cost to the New Jersey taxpayers.

2. Senator Kennedy's drug bill, Title IV 2/ - NATIONAL DRUG COMPENDIUM:

   A) requires the Secretary to prepare and publish a compendium of all approved drugs, with price information

   B) requires arrangement of drugs by therapeutic classification as determined by the Secretary.

   C) to be sent free to all practitioners. Supported by Federal funds.

3. Recognizing the validity of the Federal government's approach and the substantial savings of taxpayer's money, the Pharmaceutical Society of the State of New York has voluntarily requested New York Assemblyman Levine and Senator Dunne that they withdraw their related bills "until the OTA study has been completed". 3/

Respectfully submitted,

Daniel M. Minicucci, R.Ph.
Government Relations

DMM:ejd

1/ Congressional Record, May 1, 1774, pages S 6812-13

2/ FDC Reports "PINK SHEET", May 6, 1974, page 22

3/ PSSNY letter to New York Assembly and Senate members (copy attached)

Pfizer PHARMACEUTICALS
PFIZER INC.

DANIEL M. MINICUCCI, R.Ph.
GOVERNMENT RELATIONS

235 East 42nd Street
New York, New York 10017
Office: (212) 573-2688

3776 Charles Court
Seaford, New York 11783
Home: (516) 785-3216

Draft - incomplete 3-21

PHARMACEUTICAL SOCIETY OF THE STATE OF NEW YORK

117-119 East 69th Street, New York, N. Y. 10021 • 212-879-5100

RE: A. 9446A
S. 8338A

AN ACT

To amend the education law, in relation to allowing apothecaries, pharmacists and druggists to substitute a less expensive generic or other brand name equivalent drug for the brand name drug originally prescribed and to amend the public health law in relation to the duties of the department of health relating thereto.

Since the Federal Government is currently studying the entire matter of generic substitution of prescription drugs, it is the opinion of the Pharmaceutical Society of the State of New York that the New York State Legislature should take no action on these bills until the matter has been resolved by Federal Statute.

It is quite possible that there is no way to assess accurately the generic therapeutic equivalancy between certain brand name and generic drug products. It is a complicated, highly technical process. The Office of Technology Assessment, an advisory body appointed by the Congress, has been authorized to make a study of the subject by compiling relevant factual data and testimony to make a determination of facts and necessary procedure.

In any event, since definitive federal action rests on the outcome of this study, the Pharmaceutical Society of the State of New York respectfully requests that the New York State Legislature take no action on the bills at present, or until the OTA study has been completed.

perennial quest for more funds. For the past six years, they have been turned away with less in real terms than they got the year before. But this year for a number of reasons, some having little to do with national defense, their persistence may pay off. And the outcome over the next few years could be a shift in national resources from domestic programs to defense.

The Pentagon says it needs additional funds to improve the nation's readiness for military emergencies, to modernize its weapons systems and to cover costs boosted by inflation. The Administration seems prepared to buy these reasons, because they comport with one of its own—to give a sluggish economy a spring tonic. Historically, it has seldom proved good economics to give an economy a fiscal shot in the arm by upping defense outlays. Yet Congress—mindful of mounting unemployment and aware there is no political edge to be gained these days from dovish gestures—may go along, even though chances are the boost will come at a time when it could rekindle the fires of inflation.

In the program outlined in the 1975 budget, defense spending is scheduled to turn sharply upward after declining to $74 billion in fiscal 1973—$5 billion below the level of spending at the height of the Vietnam war in fiscal 1969. And a $4.5 billion supplemental increase in outlays booked for late 1974 is expected to be followed by successive increases of $6 billion each in fiscal years 1975 and 1976.

This rise may not appear very strong when inflation is taken into account—and inflation is severe enough to make comparison in real terms a necessity. Even in real terms, however, this increase represents a switch from negative to positive yearly percentage changes in defense spending. Moreover, the budget is more expansionary than the numbers would suggest. While the rise in manpower and operations expenditures in the budget reflects the soaring of prices and wages, long-range plans for procuring materiel, laid out in 1975 Report of the Secretary of Defense, suggest a strongly rising trend in real defense spending over the rest of the decade. Although forecasting defense expenditures is perilous since their levels are dictated less by economic considerations than by changing perceptions of the international and domestic political scene, the rise in the cost of defense over the next five to six years could well be as rapid as the rise in gross national product.

Domestic politics also shape the course of defense spending, since governments sometimes vacillate between fiscal constraint and surges of spending.

TARDY STIMULUS

Obligations—commitments to spend in the future—are slated to rise much faster than expenditures in fiscal 1974. The Pentagon plans to step up awards of procurement of hardware of all sorts, ranging from tanks to sophisticated missiles and including ammunition which is expendable rather than durable. Obligations are scheduled to reverse dramatically from an 11% decline in fiscal 1973 to a 22% increase in 1974.

Congressional approval of the supplemental defense funds for fiscal 1974 would be unlikely to have much effect on the economy before the end of the second quarter of calendar 1974. More than half—$3.3 billion out of a total of $6.2 billion requested—is to pay for pay and pension increases that took effect during 1973 and in January of this year, so that fiscal stimulus has already been felt. Most of the rest of the supplemental is to buy more military hardware and to maintain equipment. Even if this legislation were passed in time to increase obligations in May or June, the higher level of economic activity would not be felt until the second half of the year because of the delay between incurring obligations and the new hiring and purchasing. Thus the fiscal push would not come until after the forecasted upturn from the recessionary trough.

The desire to boost the economy is not the only reason the spending level for defense is being pressured upward. Inflation is pushing up costs for the Pentagon just as it is for businesses and individuals throughout the country, and part of the increase in manpower costs comes from that factor. Moreover, the Defense Department says that spending constraints in the last few years have forced it to operate on a barebones budget. During fiscal years 1970–73, a time of controversy over the Vietnam conflict, Congress slashed defense budget requests by an average of about 4% per year—much sharper cuts than the approximately 1% a year cuts that were made in the 1960–69 period. Historically, defense expenditures always have fallen after wars. But the fall in current dollars has never been back to prewar levels. And now, because inflation has caused real outlays to lag, the Defense Department wants to hold its own.

Other factors leading to increased requests come from within the department itself. Manpower costs are higher because of the volunteer army, the comparability pay principle and climbing retirement costs stemming from the growing number of retirees and their higher salary base. The cost of weapons also is going up, not only from inflation but because the expense of increasingly sophisticated technology squeezes the funds available. It is difficult to assess to what degree inflation affects the total amount spent for unique and experimental equipment that may have no other market than the Defense Department. Many military purchases require exquisite and painstaking hand tailoring to meet changing requirements, and the result often is low productivity and cost overruns. However, the Pentagon argues that modernization is needed and that weaponry must be upgraded.

TO MARKET, TO MARKET

If it gets the money, the Pentagon has a long shopping list of items needed to achieve these goals. For the remainder of 1974, it wants funds to replace weapons shipped to Israel, to accelerate buying of weapons and equipment that proved particularly effective in the October war and to make up "deficiencies . . . that were made apparent by the Middle East hostilities." Included on the proposed list for late 1974 are antitank missiles, M–60 series tanks and armored personnel carriers. The Pentagon would also increase purchases of supplies "to improve readiness and increase airlift capability," according to the report of the Secretary of Defense.

In its plans for 1975, the Administration wants to spend its money on a number of research and development projects, as a hedge both against failure of the Strategic Arms Limitation Talks and the possibility of increasing Soviet military capability. In addition, the Administration carries on its push for modernization of strategic equipment—the Trident sea-based missile system, completion of the program to replace the Minuteman I missiles with advanced missiles that can carry three independently targetable warheads, and a half-billion-dollar continuation of the five-year development effort on the B–1 bomber. Also, the Army plans to continue buying M–60 tanks and antitank missiles and the Navy has asked $143 million as a downpayment on a $1 billion program to build sea control ships to provide protection for sea-based aircraft, amphibious groups and convoys. The Navy is also planning to continue the purchase of antisubmarine-warfare aircraft, destroyers, frigates, missiles and nuclear-powered attack submarines. The Pentagon also would continue to enlarge its fleet of F–14 and F–15 fighter planes, develop close-support aircraft and to expand the Air Warning and Control System.

FUTURE BUYING

If the Defense Secretary's programs go forward as planned, beyond fiscal 1975 a number of programs now in the research-and-development stage will be ready for a buy-no buy decision. The purchase of these weapons and equipment items along with ongoing procurement plans would involve an investment of well over $50 billion, according to estimates of the Brookings Institution. These purchases by 1979 could raise real spending by as much as $5 billion above current levels. The key items on this list are:

Strategic forces: Conversion of the 450 Minuteman II missiles to an MIRV version, the actual purchase of B–1 bombers and modernization of air defenses. Development of the cruise missile—a new kind of strategic missile for submarines—and a new mobile land missile to suceed the Minuteman. The spending for these last two weapons would depend on the outcome of the SALT negotiations.

Ground forces: Battle tanks, mechanized combat vehicles, surface-to-air missiles and transport and attack helicopters.

Naval general purpose forces: Purchase of more aircraft carriers, patrol frigates and sea control ships.

Tactical air forces: Buying more F–14 and F–15 fighters and acquiring close-support aircraft.

There is a good chance the Pentagon's shopping list eventually will be adopted—unless the present political climate changes. The Secretary of Defense himself has said that the department was allowed higher expenditures last year than it might have been under previous "tight money" budgets. This could be an omen of a turnabout in the outlook for the budgetary process, and the beginning of an era when the trend in real defense spending is rising rather than falling sharply. If this happens, it seems obvious that pressures will be brought to bear on nondefense spending—or, conversely, on any loose talk of lower taxes.

DRUG BIOEQUIVALENCE DILEMMA

Mr. KENNEDY. Mr. President, the Office of Technology Assessment has convened a blue ribbon panel to try to resolve the drug bioequivalence dilemma raised by HEW Secretary Caspar Weinberger's announcement before the Health Subcommittee last December of a new drug reimbursement policy.

This distinguished group of scientists is chaired by Dr. Robert Berliner, the dean of the Yale Universty School of Medicine.

I ask unanimous consent that the accompanying summary of the committee's charge, and its request for technical documentation be printed in the RECORD.

There being no objection, the summary was ordered to be printed in the RECORD, as follows:

OFFICE OF TECHNOLOGY ASSESSMENT, DRUG BIOEQUIVALENCE STUDY

The Office of Technology Assessment, Congress of the United States, has been directed by the Health Subcommittee (of the Senate Committee on Public Welfare) to examine the scientific aspects of the drug bioequivalence issue. A panel, chaired by Dr. Robert Berliner, Dean of the Yale University School of Medicine and approved by OTA, has been formed to issue a report based upon a review of available technical information. (A list of panel members is provided below.)

The panel invites interested individuals

and organizations to submit written technical documentation related to the study charge as presented in the following sections. Given the report's due date of June 30, 1974, the panel requests that all information be submitted no later than May 20, 1974 to: Drug Bioequivalence Study Staff, 1910 K Street, N.W., 8th Floor, Washington, D.C. 20006.

BACKGROUND

The Health Subcommittee (of the Senate Committee on Labor and Public Welfare) is conducting a series of hearings on the pharmaceutical industry. Testimony has been presented on a number of issues including drug safety, Federal regulatory functions, drug costs, physician prescribing and drug utilization.

Wednesday, December 19, 1973, HEW Secretary Weinberger appeared before the Committee and recommended a new Federal drug purchasing policy. In brief, he proposed that "in absence of demonstrated differences in uniform quality and therapeutic equivalence, there is no reason why the Government should pay more for a drug than the lowest price at which it is widely available."

The Secretary reasoned that most chemically equivalent drugs are also clinically or therapeutically equivalent. The Secretary's recommendation was further based on the observations that "It has been shown in recent years that in a few instances two or more chemically equivalent drugs, even though they meet all official standards, produce significantly different blood levels when administered to man. In scientific terms they differ in bioavailability or, to use another term, they are lacking in bioequivalency."

The Secretary went on to say that "all evidence to date indicates that clinically significant differences in bioavailability are not frequent." In those few instances when chemically equivalent drugs are not clinically equivalent, these differences may be measured by additional bioavailability data. Therefore, the Secretary was proposing to advance the national interest by a policy of paying for "lowest priced" chemical equivalents.

In a subsequent hearing on February 1, 1974, the Subcommittee received testimony from representatives of the pharmaceutical industry. They stated that in terms of quality and therapeutic equivalence, significant differences among chemically equivalent drugs have been shown. Further, Mr. C. Joseph Stetler, President of the Pharmaceutical Manufacturers Association, argued that "inequivalency unproven is not equivalency assured".

Thus, the hearings developed differences of opinion on the frequency with which chemical equivalents will be found to differ in therapeutic equivalence.

CHARGE

The overall charge to the panel is to examine the relationship between the chemical equivalence and therapeutic equivalence of drug products. The panel will evaluate the extent to which technology short of therapeutic trials in man can be used to determine whether drug products that meet the same official standards of chemical composition but that are produced at different times or under different manufacturing processes and that may contain different inert ingredients can be expected to produce comparable therapeutic effects.

The panel recognizes that chemically equivalent drug products can produce measurably different therapeutic effects. The panel will therefore focus its attention on whether such differences in therapeutic effect can be predicted from measurable differences in bioavailability. The panel will also examine whether such differences in bioavailability can be correlated with different responses to *in vitro* tests.

To make these judgments the panel's assessment of the state of the technology will include:

1. An evaluation of currently available methods for determining in man the bioavailability of the active ingredient of drug products. Included will be analytical methodology, the influence of disease states on bioequivalence, and the assessment of bioequivalence, and the assessment of bioequivalence in the instances in which there are no methods known. To be specified are:

a. the target populations under consideration

b. objective standards as to what may be considered to constitute comparable bioavailability.

2. An assessment of current technology for drug product formulation as it relates to continuing assurance of adequate bioavailability. This should include:

a. evaluation of data on batch to batch variations over time in bioavailability of drug products manufactured by current production methodology

b. the extent to which continuing bioavailability can be related to in-process formulation, excipient effects, shelf life characteristics, etc.

3. An assessment of whether present and future compendial *in vitro* tests can be used to predict bioavailability. Also, the panel's assessment of whether *in vitro* tests in species other than man can be used to predict bioavailability.

The conclusion of the panel will be based on current technology as well as technology that the panel believes will become feasible over time. The report will also include a consideration of the need and potential for new research relevant to the problems under consideration.

TECHNOLOGY STATEMENTS

The panel considers several definitions necessary for this study:

Chemical Equivalents: Drug products from different sources which contain essentially identical amounts of the identical active ingredients, in identical dosage forms, and which meet existing physicochemical standards in the official compendia. (Inert ingredients in chemical equivalent drug products need not be identical.)

Therapeutic Equivalents: Chemical equivalents, which when administered to a specified population in the same dose regimen and schedule, will provide essentially the same therapeutic and/or toxic effect as measured by the control of a symptom or disease.

Bioavailability: The extent and rate of absorption from a dosage form as measured by the time concentration curve of the active ingredient in the system's circulation.

Drug Product: A total dosage form containing an active therapeutic ingredient(s) along with other substances required in the manufacturing process. The composition of the active ingredient(s) is specified within certain tolerances established in the official compendia. When administered, the drug product releases the active ingredient(s) in order to produce a therapeutic effect.

For the purposes of this study the panel will focus its attention on solid formulation drug products administered by mouth in order to produce a systemic effect. The therapeutic effect of such drug products is assumed to be a function of its availability in the general circulation as measured by blood level or urinary excretion curves of the active therapeutic ingredient(s).

The panel will be concerned primarily with the principles and methodology involved in comparing therapeutic effects of chemically equivalent drug products. The panel will attempt to identify categories of drug products for which bioavailability measurements may be critical to assuring therapeutic equivalence. When appropriate the panel will also refer to specific examples of drug products within these categories.

The panel will focus its attention on categories with the following criteria:

Drug products used for treatment or prevention of a serious illness, rather than for the alleviation of temporary symptoms.

Drug products which have step dose-effect curves.

Drug products which have unfavorable therapeutic indices.

Active ingredients which are relatively water insoluble.

Drug products which have previously been the subject of reported or suspected nonequivalency or therapeutic failure.

Drug products which are available from multiple sources for national distribution and have been identified by recognized sources as being among the most heavily prescribed.

The panel will not undertake indepth studies of individual drug products. Rather, it is the intent of the panel to bring to the attention of HEW, compendial and industrial interests those categories to which the methodological principles should be applied on a priority basis.

OFFICE OF TECHNOLOGY ASSESSMENT, BIOEQUIVALENCY DRUG STUDY PANEL MEMBERS

1. Robert Berliner, M.D., Dean, School of Medicine, Yale University, 333 Cedar Street, New Haven, Conn. 06510. ✓

2. Leighton E. Cluff, M.D., Professor and Chairman, Department of Medicine, College of Medicine, J. Hillis Miller Health Center, University of Florida, Gainesville, Fla. 32610.

3. James T. Doluisio, Ph.D., Dean, College of Pharmacy, The University of Texas at Austin, Austin, Texas 78712.

4. Kenneth Melmon, M.D., Chief, Division of Clinical Pharmacology, University of California, San Francisco Medical Center, San Francisco, Calif. 94143.

5. Alexander S. Nadas, M.D., Chief, Cardiology Department, Children's Hospital Medical Center, 300 Longwood Avenue, Boston, Mass. 02115.

6. John Oates, M.D., Professor of Medicine and Pharmacology Department of Pharmacology, Vanderbilt University, Nashville, Tenn. 37232.

7. Sidney Riegelman, Ph.D., Professor of Pharmacy and Pharmaceutical Chemistry, Chairman, Department of Pharmacy, University of California, San Francisco, Calif. 94143.

8. Fred Shideman, Ph.D., M.D., Professor and Head, School of Pharmacology, 105 Millard Hall, University of Minnesota, Minneapolis, Minn. 55455.

9. Marvin Zelen, Ph.D., Professor of Statistical Science, Director of Statistical Laboratory, Statistical Laboratory, SUNY at Buffalo, 4230 Ridge Lea Road, Amherst, N.Y. 14226. ✓

Frederick Robbins, M.D., Exofficio Member, Member of OTA Advisory Council, Dean, Case Western Reserve Medical School, Case Western Reserve University, 2119 Abington Road, Cleveland, Ohio 44106.

Stanley Kleiner, Pharm.D., Staff Executive Director, 1910 K Street, NW., Washington, D.C. 20006. (203) 293-2370.

Carl Taylor, Congress of the United States, Office of Technology Assessment, Washington, D.C. 20510. (202) 225-0737.

INFLATION

Mr. HOLLINGS. Mr. President, I would like to bring to the attention of my colleagues in the Senate three resolutions sent to me from Aiken, Saluda, and Bishopville, S.C.

I share the concerns which are expressed in these resolutions, and I ask unanimous consent that they be printed in the RECORD.

SUBMITTED BY A. G. WEEKS

ASSEMBLY BILL - 1257

WILL THERE BE A SAVINGS?

CASPER WEINBERGER, SECRETARY OF HEALTH, EDUCATION AND WELFARE, IN HIS STATEMENT OF DECEMBER 19, 1973, STATED THAT BY ADOPTING THE POLICY OF PAYING FOR THE "LOWEST COST GENERALLY AVAILABLE" PRESCRIPTION DRUGS, SAVINGS OF 28 MILLION DOLLARS WERE PROJECTED FOR THE MEDICAID PROGRAM IN FISCAL 1974. BASED ON A TOTAL PROJECTED EXPENDITURE FOR MEDICAID OF 534 MILLION, THE SAVINGS REPRESENT 5.5% OF THE TOTAL EXPENDITURE. LET US PROJECT WHAT THIS MEANS TO THE CITIZENS OF NEW JERSEY, BASED ON FACTS THAT WE KNOW TO BE TRUE. APPROXIMATELY 49 MILLION PRESCRIPTIONS WERE FILLED IN NEW JERSEY IN 1973. (SOURCE: 1971 AUDIT BY MARKET STATISTICS, NEW YORK. PRESCRIPTION COUNTS 1973 BY LEE ASSOCIATES.) APPROXIMATELY 10% OF THE TOP 200 MOST FREQUENTLY PRESCRIBED DRUGS ARE MULTIPLE SOURCE, THAT IS, MORE THAN ONE MANUFACTURER MARKETS THE PRODUCT. THESE MULTIPLE SOURCE DRUGS WOULD BE THE GROUP THAT PHARMACISTS COULD SUBSTITUTE FOR UNDER PROVISIONS IN ASSEMBLY BILL 1257. THIS MEANS 4,900,000 PRESCRIPTIONS WOULD BE SUBJECT TO SUBSTITUTION. THE AVERAGE COST OF A PRESCRIPTION IS $4.50. DEDUCT FROM THIS THE PHARMACIST'S FEE OR MARK-UP FOR FILLING THE PRESCRIPTION, AND THE INGREDIENT COST IS ABOUT $2.50. MULTIPLY THIS BY 4,900,000 PRESCRIPTIONS AND YOU GET A TOTAL OF $12,250,000. REDUCE THIS BY 5.5% (THE AMOUNT HEW PROJECTS WOULD BE SAVED), AND THE AMOUNT "SAVED" BY ALLOWING SUBSTITUTION WOULD BE $664,950.00. SPREAD OVER NEARLY FIVE MILLION PRESCRIPTIONS, THIS BOILS DOWN TO ABOUT THIRTEEN CENTS PER PRESCRIPTION.

IS THIS LEGISLATION WORTH IT? LET'S LOOK AT ANOTHER STATE THAT PASSED A BILL SIMILAR TO ASSEMBLY BILL 1257 AND WHAT PROGRESS IT HAS MADE. MORE IMPORTANT, LET'S LOOK AT THE COST TO THE TAXPAYERS.

ASSEMBLY BILL - 1257
WILL THERE BE A SAVINGS?
PAGE TWO

THE STATE OF KENTUCKY PASSED A LAW IN 1972 ESTABLISHING A "DRUG FORMULARY COUNCIL". AFTER TWO YEARS (AS OF 2-17-74) AMPICILLIN WAS THE ONLY PRODUCT ON THE FORMULARY. OTHER PRODUCTS HAVE SINCE BEEN ADDED, NOTABLY ERYTHROMYCIN.

ROBERT L. BARNETT, JR., AN ASSISTANT PROFESSOR OF PHARMACY AT THE UNIVERSITY OF KENTUCKY AND CHAIRMAN OF THE FORMULARY COUNCIL, STATED THAT THE COUNCIL HAD TAKEN ON A MAMMOTH TASK THAT MIGHT BE BETTER ACCOMPLISHED ON A NATIONAL LEVEL.

ACCORDING TO THE LOUISVILLE COURIER TIMES, THE SLOW START OF THE FORMULARY COUNCIL IS POINTED UP BY THE FACT THAT IT SPENT $9,000.00 OF ITS APPROPRIATION FOR THE LAST YEAR - I MIGHT ADD, TO PUT ONE PRODUCT ON THE FORMULARY. MR. BARNETT SAYS THE COUNCIL MIGHT NEED AS MUCH AS $100,000.00 A YEAR AS IT EXPANDS ITS DRUG EVALUATION SYSTEM AND WORKS OUT AN ENFORCEMENT PROGRAM.

INCIDENTLY, COPIES OF THE KENTUCKY FORMULARY ARE AVAILABLE TO THE PUBLIC AT A COST OF FIVE DOLLARS. IT LISTS ONLY THE DRUGS, NOT THE PRICES.

GIVEN THE FACTS ABOVE, ASSEMBLY BILL 1257 IS NOT IN THE BEST INTEREST OF THE CITIZENS OF NEW JERSEY AND SHOULD BE DEFEATED.

A. G. Weeks
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Rt #10
E. Hanover, N.J.