> Testimonials are used not only to give apparent substance to the advertising and promotion of relatively worthless products, but also to extend the indications of effective drugs beyond the range of their real utility. They appear either as complete reprints or as priceless quotations in advertisements or brochures. They convince too many physicians that they should prescribe these drugs.
>
> Now the true nature of these testimonials is well known to the industry and its own contempt for them is shown by its vernacular for sources from which they are easily obtained. These are called stables. Still it is an important function, usually of the medical division, to send representatives with generous expense accounts to all parts of the country searching out these sources. The burlesque is compounded by calling the drug trials "scientific studies" and by supporting them with grants which are charged to research cost.[78]

Drug companies and the lay press.—Nor has the lay press been ignored. Most physicians are familiar with the experience of facing patients demanding a prescription for a drug which has been extolled in a pseudo-scientific article in a newspaper or popular magazine. Dr. Perrin Long, professor of medicine, College of Medicine, University of New York, who appeared with officials of American Cyanamid during the subcommittee's hearings on antibiotics, said:

> The question is: Are the sulfa drugs and antibiotics misused?
>
> My answer is: "You bet they are."
>
> By whom?
>
> The doctors who prescribe them and by patients who threaten to fire the doctor who doesn't give them their pet antibiotic when they have a common cold, a viral sore throat, a viral pneumonia or some other type of infection for which treatment with antibiotics is useless.[79]

Dr. Console remarked:

> The patients contribute their share. Too many are unable to accept that the physician in spite of his limitations is still best able to determine the proper treatment. The best doctor is not necessarily the one who gives a shot for every complaint, and the more conservative physician who does not prescribe the latest drug reported in Coronet may be far more competent than the one who does. But fear of disease did not end with the plagues and patients still seek their bag of asafetida. It is this anxiety which leads some to avoid black cats, and most to seek newer, stronger, and more impressive magic from the doctor. Too many physicians respond to this pressure not by dealing with it directly

[78] Hearings, pt. 18, pp. 10371–10372.

[79] Hearings, pt. 24, p. 13770. Dr. Long added: "This happens, gentlemen, far more than you realize. Not long ago a doctor whom I know was called late one afternoon to see the patient of another doctor who was out of town. She had an acute common cold and also chronic asthma.

"She imperiously demanded that she be given penicillin, which my friend refused to give her, because it is not a good idea to give asthmatics penicillin. The patient got very angry, dismissed the doctor, saying, 'I'll get a doctor who will do what I say.'

"She did. He gave her an injection of penicillin, and in less than 5 minutes she died from an anaphylactoid reaction produced by the penicillin.

"This is what doctors all over the country are facing today: patients who want an antibiotic."

but by trying to produce a tangible symbol of the magic. To the pharmaceutical industry this is an open invitation to exploit both the patient and the doctor, and so it claims to have the magic all wrapped up in pretty packages and with a price tag which makes the magic all the more impressive.[80]

A wry observation came from Dr. Weinstein, formerly with the medical staff of Pfizer:

> In addition to the constant stream of promotion applied directly to the physician, there is a rather intense effort made to reach him through the patient.
>
> It is an unfunny joke in the medical profession that the very latest information on new advances in medicine most often appears in the eminent medical journals such as Reader's Digest, Time, and the Wall Street Journal. Some of this is legitimate good reporting. However, much of what appears has in essence been placed by the public relations staffs of the pharmaceutical firms. A steady stream of magazine and newspaper articles are prepared for distribution to the lay press. These may take the form of so-called informative or background articles on conditions such as allergies or edema. Buried within the article, there is often a brief paragraph mentioning that a great drug has been discovered and manufactured by company X and the name of the drug is given. The article does not say that the reader should rush to his physician and demand the drug, but the implication is usually clear. And, of course, there is nothing to show where the article originated.
>
> Along the same lines, it is fascinating to consider how many drugs first become known through the good offices of the Wall Street Journal. The implication of such reports I do not feel entirely competent to discuss. I have wondered, however, what effect such announcements may have on stock market quotations.[81]

Dr. Finland stated the problem in an exchange with Senator Kefauver:

> If the doctors, who are very busy, and perhaps don't have an opportunity to read the Wall Street Journal, or the newspaper on a certain day when the virtues of a certain drug are extolled, before he has had a chance to read his medical journals, and then he is confronted by a patient who shows him this and tells him that, and he calls up the drug manufacturer, or his representative, and he tells him it is a good drug, I think he will probably use that drug.
>
> Senator KEFAUVER. How would you prevent this sort of thing: We see in the Wall Street Journal, or other newspapers and magazines, articles with information given to them by the drug manufacturers, extolling the virtues of a particular drug. Immediately the physician gets advertising material about the drug, and the patient demands it, perhaps changes his doctor if he doesn't get it. How do you think that kind of thing can be checked a little better?

[80] Hearings, pt. 18, p. 10373.
[81] Hearings, pt. 18, p. 10246.

Dr. FINLAND. * * *.

Now, what the intricacies of this would be, I cannot say. But I know there is too great a lag between the time the drug manufacturer perhaps feels convinced he has a good drug, and the time when the clinical investigators are able to present what to their own satisfaction is a proper evaluation, and then from that time to the time when the publication appears.

The question is whether the newspapers, or Wall Street Journal, should be the ones to provide this premature information, or the drug manufacturer who has himself a personal interest in this, rather than the investigator, to the medical public directly. This is what I feel is a defect in our present scheme of things.[82]

A concrete example of the advertising procedure in the case of Sparine, a widely used tranquilizer, was given by Mr. Mike Gorman, executive director, National Committee Against Mental Illness:

Wyeth is American Home Products, which has Sparine. Three years ago they decided at a big cocktail-and-steak party to introduce this wonderful new drug Sparine at the District of Columbia General Hospital. I didn't attend this party because I like to buy my own lunch.

* * * * *

In 1957 at this big Wyeth affair, they were introducing this new drug Sparine and this had a very limited test by a group of doctors at the District of Columbia General. I won't be unkind about them. I say they were not top drawer. Not one of them was top drawer. I had seen this publication, paid no attention to this publication, as did most science writers. Then they got out an immediate flash to all the papers about this thing and then—they also got a flash bulletin to 4,000 or 5,000 doctors about this drug. Then when the doctors protested the premature release of it, they blamed it on the National Association of Science Writers, that the science writers had written prematurely about it. So the science writers wrote a note of protest to Wyeth, made them apologize and the NASW protest was printed in the Journal of the American Medical Association.

It gives you an idea of the powerful pressures that were working. They pushed the doctors on this drug. They quoted this one publication. Then when the articles appeared in the paper, they said, "Well, we didn't announce this to the press. They must have picked it up." But they had a press party for 200 people at which they fed them steaks. Then they said, "Oh, the press is terrible the way they do things."[83]

When Mr. Alvin G. Brush, chairman of the board of American Home Products appeared before the subcommittee, Mr. Dixon questioned him about the allegations and read from the Journal of the American Medical Association a protest from Mr. John Troan,

[82] Hearings, pt. 24, pp. 13938-13939.
[83] Hearings, pt. 16, p. 9012.

chairman, Committee on Information, National Association of Science Writers. Mr. Brush acknowledged his company's errors and said it would not happen again.[84]

Dr. Nathan Kline, director of research, Rockland State Hospital, Orangeburg, N.Y., deplored the steady deterioration of drug-company advertising, maintaining that misleading advertising by one company tends to force others to do likewise. Referring to testimony he had given 3 years earlier before the Legal and Monetary Affairs Subcommittee of the Committee on Government Operations (of which Representative Blatnik was chairman), he stated that he had drawn certain inferences which he now realized were "unwarranted":

> At that time I stated:
> "The occasional excesses to which the industry went in promoting psychopharmaceutical drugs have been followed by a strong counterreaction * * * in recent months there has been a distinct change in the tone of such advertising."

[84] Hearings, pt. 16, pp. 9298–9299; pt. 17, pp. 9505–9506.
Mr. Dixon asked Mr. Brush to comment on exhibit 108, which was read aloud.

EXHIBIT 108

[From the Journal of the American Medical Association 1956]

To the EDITOR:

From time to time, members of the medical profession voice complaints regarding "premature publicity" about developments in the field of medicine. These complaints generally are directed at newspapermen and others employed by lay communications mediums. A full examination of the facts would reveal that such criticism is usually groundless. However, it is unfortunately true that some instances of premature publicity do occur now and then, although the National Association of Science Writers (NASW) feels it is achieving considerable success in its persistent efforts to reduce their incidence. In line with this, the NASW wishes to deplore publicly the indefensible methods employed by a certain pharmaceutical firm in connection with the announcement of a new ataraxic drug on Feb. 20, 1956. Early in February, telegrams were sent, on behalf of this firm, to a number of science writers in the United States, which said in part: "By special arrangements with the chief of staff and chief psychiatrist of the (name of hospital and city) you are invited to attend a staff meeting on the results of the hospital's clinical work with a new potent ataractic drug known as * * *. The date is Feb. 16, 1:30 p.m. sharp, in the medical auditorium of the main hospital building. This is a regular staff meeting to which will be invited physicians from the medical schools of * * * and * * *. Physicians at (the hospital) have done extensive clinical work with the drug and find it most promising. We thought you would be interested in this significant development in the field of chemopsychotherapy and particularly in the clinical studies underway at the hospital. Transportation incidentals and lunch will be provided by our friends at (name of drug house). Luncheon will be served at the Hotel * * * at 11:30 a.m., sharp. Limousines will leave the hotel at 12:45 p.m. for the hospital."

On February 16, a press release was issued on behalf of this drug house. Dated for use February 20, it was 753 words long and began thus: "A new drug which calms and controls acutely agitated mental patients, alcoholics, and drug addicts and facilitates their physical and psychiatric rehabilitation was disclosed here today at a medical staff conference of the * * * Hospital. The new drug differs from others in use in that the calming of patients is not masked with depression. Little or no fall in the patient's blood pressure has been observed. Vasomotor collapse (precipitous drop in blood pressure) has not occurred, nor has the drug produced tachycardia (excessive rapidity in action of heart). There is no evidence of intolerance to intramuscular nor intravenous administration of the drug, no pain on injection, and no tissue destruction at the site of the injection. Jaundice and agranulocytosis attributable to some drugs in the field of chemopsychotherapy has not been observed thus far after administration of the new drug."

Meanwhile, the pharmaceutical house itself was sending confidential letters bearing the name of the firm's president to the profession, which most physicians received on or about Feb. 11. These letters stated in part:

"DEAR DOCTOR: You may have read or may be reading in your newspaper about a potent new ataractic drug called * * *. It is almost impossible to control publicity on an important new scientific achievement. Busy reporters are finding out about * * * in locations where it is being clinically investigated * * *. Because we want you to know about * * * from us, and not from the newspaper, I am writing you this letter to give you the gist of the preliminary findings. Prerelease publicity is unfortunate because we are not quite ready to make * * * available."

The NASW feels such duplicity cannot be condoned. It has no place in medicine or in medical journalism.

JOHN TROAN,
Chairman, Committee on Information, National Association of Science Writers, Inc.

PORT WASHINGTON, N.Y.

At the conclusion of the reading, Mr. Dixon continued:

The company is the American Home Products, Co. and the product was Sparine. Is that correct, sir?

Mr. BRUSH. That is correct.

Mr. DIXON. What comment do you have to make about it?

Mr. BRUSH. We made two serious errors. We have apologized for them, and to the best of my knowledge we have set up a system so that it won't happen again, and I believe the science writers have accepted our apology and to the best of my knowledge the matter is closed.

Later I stated:

"In respect to regulation of advertising it would appear that it is not a matter of 'locking the barn door after the horse has escaped,' but of sending out a posse after the horse has returned of its own accord."

Ordinarily I do not read such promotional literature, but in preparation for these hearings I did look through the current advertising. I must admit that the horse is out of the barn again. Some of the drug firms seem to have adhered to the statement of ethics set up by the Pharmaceutical Manufacturers Association, but others, as Stephen Leacock has put it, "have leapt on their steed and galloped off in all directions."

* * * * * *

Dr. BLAIR. Dr. Kline, would you say that there is sort of a Gresham's law operating here—that bad advertising drives out good advertising?

Dr. KLINE. I would certainly agree with you, Dr. Blair. As an economist, it is unfortunately true.[85]

Need for determining efficacy.—The experts emphasized the imperative need for an objective determination of efficacy of the drug products placed on the market. Dr. Dowling stated:

I should like to make certain positive suggestions for clearing misinformation from the channels of communication, and getting worthwhile information to the doctor. First, the Food and Drug Administration should be empowered to examine the efficacy as well as the toxic effects of all new drugs. It should be obvious to everyone that insufficient knowledge on the part of the doctor regarding the efficacy of a drug can react to the detriment of a patient just as much as a toxic action by the drug, which the Food and Drug Administration now has the power to regulate.[86]

To the same end, Dr. Weinstein described the inadequacies of the present situation as follows:

* * * a number of drugs have been put on the market with efficacy claims based on extremely meager and unobjective observations by people not truly qualified to make such observations. Also, there is absolutely nothing in the law to prevent the manufacturer from completely ignoring unfavorable reports. One company in its advertising for one of its products blithely states that there have been over 200 reports in the literature about this particular drug.

They neglect to say that 60 percent are not entirely favorable or pertinent. The Food and Drug Administration does not determine the qualifications or objectivity of the individuals who provides the data on which new drug applications are based. Very meager and uncritical observations have been allowed to serve as justification for granting permission to advertise and market certain drugs for life-threatening conditions. Such uncritical action is potentially dangerous,

[85] Hearings, pt. 16, pp. 9318-9319.
[86] Hearings, pt. 24, p. 14172.

especially if it encourages the use of an inadequately studied drug to supplant a proven and effective agent.[87]

Several physicians expressed regret that, as the flood of new drugs mounted in the midfifties, the American Medical Association discontinued the practice of testing drugs. Dr. Bean explained the earlier procedure:

> There is a committee of the American Medical Association, I don't remember the title, but on pharmacy and therapeutics, which for a long time had its own testing agency. That is to say, it regularly reviewed the claims and the data upon which drug companies proposed to launch or introduce any remedies. This was discontinued several years ago as an across-the-board review procedure, I suppose because it got to be out of the question to test so many new drugs and so many new things each year.[88]

On this same subject, the following exchange occurred between Dr. Finland and the chairman:

> Senator KEFAUVER. In years past the Council on Drugs of the American Medical Association used to attempt some evaluation, did it not, but they have discontinued that work in recent years?
>
> Dr. FINLAND. Well, they have become what I would call sissy.
>
> * * * * * *
>
> Now, I think the Council on Pharmacy and Chemistry, which was the precedent or the parent of the present Council on Drugs, did do a very excellent job in keeping down the claims of manufacturers and in testing and arranging for the testing of drugs. I do not know what exactly led to their giving up that function on the scale on which they were carrying it out or led to their failure to expand it, which I think it should have done in proportion to the amount of activity that was called for with the increase in the number of drugs. But the Council gave up the testing of drugs and have limited their functions to merely writing a statement about each drug, but I must say that this statement is based upon all the accumulated information which the manufacturer provides.[89]

[87] Hearings, pt. 18, p. 10252. He continued: "It is difficult to find in the medical literature comparative studies of many of the drugs presently on the market. The reason for this is quite simple. It is anathema to most of the drug manufacturers to consider comparative studies. The reasons usually given relate to unfair competition and poor sportsmanship but fundamentally they boil down to the fear that many of our presently popular drugs would not fare very well if compared with established and respected items. Some such studies have been done, a few have even appeared in the literature, and the results have frequently confirmed the reality of such fear.

"The drug efficacy problem is also reflected in promotion and advertising. It is my opinion that the intensity of promotion and advertising devoted to any drug varies inversely with the efficacy of that drug. The tranquilizers are an excellent example of such a relationship."

[88] Hearings, pt. 18, p. 10341.

[89] Hearings, pt. 24, pp. 13941–13942. He elaborated: "Now, I do not think that the drug manufacturer is required to provide all the information available to him as they are to the Food and Drug Administration. It is illegal, I presume, for the manufacturer to withhold information from the Food and Drug Administration, but I am not sure what the Council on Drugs will do if the company presented them with the evidence in favor of a drug and ommitted some evidence which was not the best.

* * * * * * *

"Senator KEFAUVER. In other words, there would be no compulsion to require them to send the unfavorable material?

"Dr. FINLAND. There is no compulsion. Of course, if unfavorable effects occur they may learn about some of them from other sources—they have access to experts, and if they happen to pick experts who have had experience with the drug, and if those experts are unbiased—the individuals whom they consult—they will get that information, and I am sure they do."

Dr. Weinstein proposed that the National Institutes of Health be given the responsibility of evaluation:

> I would recommend that possibly the National Institutes of Health and similar major research centers be given the responsibility of evaluating drug efficacy before the drugs are ever marketed. * * * One of the extremely worthwhile results to be anticipated from such a program would be the very drastic reduction in the number of drugs appearing on the market. This would certainly be welcomed by the physician and the pharmacist. I doubt very much that any really worthwhile drug would fail to be developed because of such a system. This brief delay in marketing which this would entail would never be detrimental and almost invariably would be beneficial.[90]

Dr. Meyers coupled a recommendation that FDA test for efficacy with the proposal that the information on which the FDA acts in releasing a drug should be made available to the entire medical community. In this connection he stated:

> Dr. MEYERS. I think a real evaluation, not just a rough screening for human toxicity, including a comparison with older drugs of the same class, should be required. None of the genuinely new drugs would have had their release delayed by such a requirement. No one is going to be denied the benefit of a penicillin by some requirement that efficacy be demonstrated as well as the absence of toxicity, if indeed the toxicity screen is effective.
>
> The second suggestion is that before a drug is released for sale, the scientific studies, both laboratory and clinical, should be published for study and criticism by the whole medical community. * * *
>
> Mr. DIXON. You mean before it is marketed?
>
> Dr. MEYERS. Yes, sir; at the moment, there is no requirement that any material be available to me at the time I am asked to first use a drug, other than the packaging material, and the scientific studies on which the packaging information is based are not available to me for a more critical reading.[91]

Dr. Barbara Moulton, formerly on the medical staff of the Food and Drug Administration, urged a determination of efficacy. She stated:

> * * * no physician, no one who has ever been responsible for the welfare of individual patients, will accept the idea that safety can be judged in the absence of a decision about efficacy. No drug is "safe" if it fails to cure a serious disease for which a cure is available. No drug is too dangerous to use if it will cure a fatal disease for which no other cure is available.
>
> To attempt to separate the two concepts is completely irrational, and I cannot believe that either Congress or the public will demand or expect greater omniscience on the part of the Food and Drug Administration physicians

[90] Hearings, pt. 18, p. 10254.
[91] Hearings, pt. 18, pp. 10403-10404.

when dealing with efficacy than they do now on safety. Criteria for adequate proof of efficacy would develop gradually, as they have with respect to safety, and the industry would automatically have adequate time to gear itself along these lines.

For a drug firm to object too strongly to such a change in the law should render it highly suspect. In general, drug manufacturers claim that they never market a drug until they themselves think they have reasonable proof of its value. If they have such proof, they should not fear its review by the Food and Drug Administration.

If, as I am afraid is too often the case, they have not attempted to obtain such proof, it is high time that both the medical profession and the public be made aware of that fact.[92]

CHAPTER 11. THE SPECIAL PROBLEM OF DETAIL MEN

According to the opinion survey of physicians conducted for the AMA,[92a] the most important single source of information on new drugs is the detail man. Forty-eight percent of the physicians reported that the detail man was their earliest source of information which leads them to prescribe a drug, as compared to only 20 percent for the next most frequently cited source, direct mail ads. Of the various types of information from which a physician can obtain information about new drugs, no fewer than 65 percent regarded detail men as the "most effective generally."

Their importance is also reflected in the fact that "salesmen's and detail men's compensation and expenses" constitutes the largest single form of sales expenditure by the 20 large drug companies. Amounting to $200 million, the cost of detail men represented nearly two-fifths of their total selling and advertising expenditures.

While conceding that detail men do have a role to play in bringing information to the busy physician's attention, their reliability as a source of information on new drugs was questioned by medical experts appearing before the subcommittee.

PHYSICIANS' COMMENTS

Dr. Maxwell Finland, speaking of detail men, remarked:

* * * perhaps they outdo their instructors in what they do in order to try to promote a drug * * * There was a time when they really tried to instruct me.

Senator KEFAUVER. And instruct you when you know a whole lot more about it than they do.

Dr. FINLAND. Exactly. They came to tell me about a drug I was working on, and they did not know that I was.[93]

Dr. William Bean, professor of internal medicine, School of Medicine, Iowa State University, stated:

Salesmen are interested in sales. If salvation can be gained, too, so much the better. Naturally, special products

[92] Hearings, pt. 22, p. 12040.

[92a] Attitudes of U.S. Physicians toward the American Pharmaceutical Industry, conducted by Ben Gaffin Associates, Inc., and financed by the American Medical Association, 1959.

[93] Hearings, pt. 24, p. 13944–13945.

are praised—those of the salesman's firm—often with a memorized monologue delivered with samples and the accompanying folders. The newer drugs get special treatment. The physician, if he is uncertain of what his fellow physicians may be doing, does not want to be left at the post in any new therapeutic race either. So, with the reassurances he gets, the new therapy is launched. The results are variable but not all according to the spiel.[94]

The limitations of detail men were particularly noted in the handling of new drugs. Dr. Harry F. Dowling remarked on this point:

> It has been said that the majority of practicing physicians obtain their first information about a new drug from a detail man. From extensive personal experience, I can say that this is neither necessary nor desirable. Speed is not an important object in most cases, since most drugs that are newly marketed do not represent anything new. When a drug is really new, information about it spreads with rapidity by word of mouth among the members of the profession and through articles in medical journals.
>
> Furthermore, it is precisely in the case of a truly new drug that the principles upon which its dosage is based and the methods of using it are both likely to be so different from previously used drugs that the practicing physician should get a thorough knowledge of the drug from a competent authority when he first hears about it. Detail men are valuable for the purpose of getting information to physicians and pharmacists regarding the availability and prices of products distributed by their companies, but being salesmen, they cannot be expected to give unprejudiced advice. Not being physicians, they cannot instruct physicians regarding the principles upon which the use of a new drug is based.[95]

Dr. A. Dale Console, on the basis of his experience with a drug firm and in private practice, had this to say of detail men:

> There is a simple maxim, I learned from detail men, which is known to most if not all in the pharmaceutical industry. "If you can't convince them, confuse them." This is a valuable tool in the industry and I have seen it in operation as a guide to detailing as well as to other forms of advertising and promotion of drugs. It operates in what Dr. Lasagna has so aptly called the "numbers" racket with its never-ending barrage of new products, confusing names, conflicting dosage schedules and indications, claims and counter-claims; I have seen it in operation here in statements made by industry spokesmen.[96]

THE NATURE OF THE PROBLEM

The specific problem raised by the detail men is the difficulty, if not impossibility, of checking for accuracy the information which they pass on to physicians. The instructions to the detail man on

[94] Hearings, pt. 18, p. 10336.
[95] Hearings, pt. 24, p. 14172.
[96] Hearings, pt. 18, p. 10368.

what to say to the doctors are given to him in private; the meeting which he has with the doctor is in private. If the physician regards the firm as a "good" company, and if the detail man has built up a "good" relationship between himself and the doctor, the opportunities for the transmission of misleading information are very real indeed. This is particularly true in the case of a new drug which is just being introduced and which has not as yet been the subject of critical and independent investigations reported in the medical literature. And even when journal articles begin to make their appearance, it is extremely difficult for physicians, as they frequently pointed out in the hearings, to keep abreast of the medical literature outside the field of their specialty.

Moreover, if a physician becomes skeptical of a detail man's glowing account of a new drug and reports the matter to the company, the incident is likely to be dismissed as representing nothing more than an isolated instance of overenthusiasm on the part of an overly zealous salesman. Correction can be achieved simply by reprimanding or dismissing the errant employee. The company professes its gratitude for having had the matter called to its attention and promises to take proper steps to prevent its recurrence.

But how often is the misrepresentation a matter of individual overzealousness and how often does it reflect deliberate company policy, codified into specific instructions to the detail man? This is a matter to which there can be no general answer, since it is a rare event indeed when a drug company's instructions to its detail men become a matter of public knowledge. But on a matter in which it was of the greatest importance to the health of their patients that the practicing physicians receive the unvarnished truth, the subcommittee did come into possession of a leading drug firm's written instructions to its detail men. The issue was an exceedingly dangerous side effect, aplastic anemia; the drug was Chloromycetin; and the company was Parke, Davis.

CHLOROMYCETIN: A CASE EXAMPLE

Chloramphenicol, sold exclusively in this country under the trade name, Chloromycetin, enjoys a greater sales volume than any other single trade-name ethical drug and is the second largest selling broad-spectrum antibiotic. It is generally regarded as the drug of choice for typhoid fever, Rocky Mountain spotted fever, and other Rickettsial diseases. In recent years its sales have mounted sharply, as a result of the fact that strains of staphylococci resistant to it have developed more slowly than has been the case of other antibiotics such as penicillin and tetracycline; this in turn is largely the result of a sharp decline in sales during the midfifties, following reports that its use was associated in a relatively small number of cases with the development of blood dyscrasias—particularly aplastic anemia. This is a condition in which the bone marrow ceases to create the white cells, red cells, and other components of the blood; the fatality rate of aplastic anemia is at least 50 percent. The problem is aggravated by a number of other factors. Thus, the condition may develop weeks or even months after the administration of the drug. There is no known method of determining a patient's susceptibility to the drug. Blood studies may reveal the presence of aplastic anemia, but even when recognized the condition is often irreversible. In

many cases, however, the true identity of the ailment is never recognized.

With these characteristics, it can readily be understood why medical circles attached grave importance to reports, beginning in 1950, that aplastic anemia had been observed following the administration of Chloromycetin. The 1951 issue of New and Nonofficial Remedies, published by the Council on Pharmacy and Chemistry of the American Medical Association warned that "changes in the peripheral blood or the blood-forming organs have been reported during the use of chloramphenicol." Furthermore, an editorial in the Journal of the American Medical Association dated June 28, 1952, refers to "additional reports of the effects of chloramphenicol on the blood and bone marrow." These reports must have been made several months earlier. The editorial goes on to say:

> A second and more serious type reaction that has been encountered is production of a true aplastic anemia. In the experience of one group this anemia has occurred in patients who have previously received one or more courses of chloramphenicol without untoward effect. When the drug was subsequently administered, even in small doses, a severe blood abnormality has appeared. Even deaths have been reported.

At the same time the Food and Drug Administration was receiving case histories and, through its Division of Pharmacology was making a study under Dr. Jack L. Radomski, of the toxicity of the drug in dogs; this study, as later presented at the Federated Societies in Chicago in April 1953, showed a significant relationship between blood changes and the use of chloramphenicol.

> Statistical analysis of weekly blood counts revealed a significantly lower granulocyte count during periods of drug administration as compared to recovery periods. * * * Bone marrow changes * * * varied with dosage.[97]

In June 1952 the Food and Drug Administration discontinued the certification of chloramphenicol and referred it to the National Research Council for recommendation as to the future use of the drug. The Council set up an ad hoc committee of physicians who met with officials of FDA and representatives of Parke, Davis. After considering the matter the Council issued its findings and recommendations in August 1952:

> 1. Certain cases of serious blood dyscrasias had been associated with chloramphenicol;
>
> 2. Although this complication had thus far been uncommon, it was considered sufficiently important to warrant a warning on the label of the packages of the drug and in advertisements of the drug and the recommendation that chloramphenicol not be used indiscriminately or for minor infections.
>
> 3. When prolonged or intermittent administration is required, adequate blood studies should be carried out.

[97] Federation proceedings, "Pharmacology and Experimental Therapeutics," March 1953, vol. 12, pp. 358–9. In a later study Dr. Radomski produced further evidence supporting his original finding. ("Antibiotics and Chemotherapy," December 1955, vol. V, pp. 674–678; "Antibiotics and Chemotherapy," November 1954, vol. IV, pp. 1174–1180).

4. Further studies of serious reactions to chloramphenicol and other drugs should be made.

The Food and Drug Administration thereupon acted to implement the recommendations of the National Research Council; it issued a press release on August 14, 1952, announcing that it had decided to permit the drug to go back on the market "under revised labeling that would caution physicians explicitly against its indiscriminate use." The release referred to the National Research Council's consideration of 410 cases of serious blood disorders, of which 177 were definitely known to have been associated with the use of Chloromycetin. The release also pointed out that the labeling would be changed to include the following warning:

(*To appear at top of circular*)

> Certain blood dyscrasias (aplastic anemia, thrombocytopenic purpura, granulocytopenia, and pancytopenia) have been associated with the administration of Chloromycetin. It is essential that adequate blood studies be made when prolonged or intermittent administration of this drug is required. Chloromycetin should not be used indiscriminately or for minor infections.

On the label

> WARNING: Blood dyscrasias may be associated with intermittent or prolonged use. It is essential that adequate blood studies be made.

In announcing the resumption of certification, FDA stated:

> The Administration has weighed the value of the drug against its capabilities for causing harm and has decided that it should continue to be available for careful use by the medical profession in those serious and sometimes fatal diseases in which its use is necessary.

How did Parke, Davis inform its detail men of this series of events? Physicians throughout the country had read of the aplastic anemia problem in medical journals and the lay press could be expected to be anxious to secure more information. How did Parke, Davis describe to its own sales force these actions by the Food and Drug Administration and the National Research Council?

It responded by sending to its detail men a series of communiques, known as "President's" or "Director's Letters", copies of which the subcommittee was able to obtain.[98] As can be seen from a few extracts, these letters ranged from the deceptively misleading to the downright false. An assertion in "President's Letter No. 4," August 12, 1952, is both:

> Chloromycetin has been officially cleared by the FDA and the National Research Council with *no restrictions* on the number or the range of diseases for which Chloromycetin may be administered. [Emphasis in original.]

This statement is false because recommendation No. 2 of the National Research Council states that "although this complication has thus far been uncommon, it was considered sufficiently important

[98] Hearings, pt. 26, pp. 15962-15977.

to warrant a warning on the label of the packages of the drugs and the recommendation that chloramphenicol *not be used indiscriminately or for minor infections.*" [Emphasis added.] Obviously when the National Research Council recommended that chloramphenicol "not be used indiscriminately or for minor infections", it was proposing a restriction "on the number" and "the range of diseases".

The statement is misleading in that it distorts the true nature of the action by FDA and the NRC. What these two bodies did was to permit the continued use and sale of the drug under certain specific conditions, namely, that a warning must be included on the label and the advertisements and that the drug should not be used indiscriminately or for minor ailments. Parke, Davis perverted the permission for continued use under these restrictions into a blanket "clearance" of the drug.

The same letter contains another highly misleading assertion:

> Thus, Chloromycetin has successfully passed three intensive investigations:
> Originally by Parke, Davis & Co.
> Next by officers of the Food and Drug Administration.
> Then by a special committee of authorities in the fields of hematology and chemotherapy appointed by the National Research Council.

If a doctor asked a detail man about this reported side effect of Chloromycetin and he were told that the drug had "passed" three investigations, would he not feel that the changes against the drug had been examined and found wanting? This is a far cry from permission to continue the sale of the drug under circumstances and conditions which, if carried out, would have limited its use, in the words of the FDA, to "those serious and sometimes fatal diseases in which its use is necessary."

In its Director's Letter of September 16, 1952, the self-adulation reaches a new height:

> The recent decision reached by the Food and Drug Administration with the assistance of the National Research Council and a board of nationally known medical experts was undoubtedly the *highest compliment* ever tendered the medical staff of our Company. [Emphasis added.]

The failure of the Government to ban the use of the drug completely is transformed into "undoubtedly the highest compliment ever tendered" Parke, Davis' medical staff. Instead of being instructed to inform the physicians that the FDA and the National Research Council had found blood dyscrasias to be associated with the use of chloramphenicol, had warned that chloramphenicol not be used "indiscriminately or for minor infections" but only for "serious and sometimes fatal diseases", and had required a warning to appear on circulars, labels and even in advertisements, the detailmen were informed that a "compliment" had been paid to the company's medical staff—the "highest" in its history. The passing on of this information to the doctor, while not exactly informative, could certainly be expected to be reassuring.

The most elaborate of the documents sent by Parke, Davis to its detailmen on this matter was its "Director's Letter" of November 20,

1952 which consists of three parts: (a) the letter itself; (b) a detail presentation (planned presentation 10) which, under the general heading of "Ideas and Suggestions", presents arguments and figures designed to enable the detailmen to allay apprehensions on the part of the physician; (c) an attachment to planned presentation 10 which, under the heading "Suggested Details", suggests the exact language to be used by the detailman in presenting his arguments. The covering letter stated:

> Some physicians are of the opinion that Chloromycetin has been taken off the market or its use *restricted*. Some physicians have formed the impression that this antibiotic has been associated with the development of blood dysrasias *in large numbers* of patients and will be amazed when you point out the facts. [Emphasis added.]

The first sentence is another example of the artful use of language to convey a thought which, though technically correct, nonetheless is misleading. True, though the FDA itself did not order its use "restricted," it urged and warned physicians to do the restricting. The second sentence is likewise technically correct, but also misleading. The key phrase is "in large numbers of patients." What is "large"? The number was sufficiently large to impel the FDA and the National Research Council to take the actions described above.

The second item in this package contains the interesting admonition that, "The special detail (PP10) should not be introduced unless the physician brings up the subject or unless you know that he has ceased prescribing the drug." Incidentally, it is difficult to reconcile this position with the company's many self-serving statements to the effect that its policy is to keep the physicians constantly informed of the facts concerning the problem.

The third item contains the following passage which the detailman was instructed to memorize and repeat verbatim to the physician:

> * * * intensive investigation by the Food and Drug Administration, carried on with the assistance of a special committee on eminent specialists appointed by the National Research Council, resulted in *unqualified sanction* of continued use of Chloromycetin for all conditions in which it has previously been used. [Emphasis added.]

The technique is the same; only the phrase is changed. Instead of being the "highest compliment" ever tendered, the decision of the FDA not to ban outright the sale of the product but to rely instead on admonitions and warnings becomes an "unqualified sanction." The qualification of continued use "for all conditions in which it had previously been used" only makes the matter worse, since the drug had previously been used and advertised for virtually all ailments for which the use of antibiotics of any kind is indicated, and many for which their use is not indicated.

Another passage which the detailmen were to memorize and repeat verbatim to the physicians was the following:

> A sensible caution against indiscriminate use, which we have incorporated into our advertising and labeling, is a *welcome addition* to our literature and to the label on Chloro-

> mycetin products, and in our opinion, would be appropriate in those on any potent chemotherapeutic agent. Actually, such caution is an assurance that the full benefits of well-tolerated Chloromycetin will be available and free from misuse. [Emphasis added.]

One can only wonder why Parke, Davis failed to incorporate such a "welcome addition" on the drug from the first day of sale, or why it has not been used by Parke, Davis for other "potent chemotherapeutic agents" sold by the company? Moreover, the phrase "welcome addition" might convey to some physician the impression that this was a voluntary action taken on the part of Parke, Davis itself, rather than a requirement imposed by the Food and Drug Administration.

In carrying out the instructions of FDA on the warnings which are to accompany Chloromycetin, Parke, Davis has followed three levels of compliance—a different one for each of the three principal advertising media. For its advertisements appearing in medical journals (which happen to have editors familiar with FDA requirements) its compliance has been letter perfect. Invariably on such ads it includes the following warning, which is identical with that contained in the FDA press release of August 14, 1952, in which the decision to require a warning was announced:

> Certain blood dyscrasias (aplastic anemia, thrombocytopenic purpura, granulocytopenia, pancytopenia) have been associated with the administration of Chloromycetin. It is essential that adequate blood studies be made when prolonged or intermittent administration of the drug is required. Chloromycetin should not be used indiscriminately or for minor infections.

For the advertisements mailed directly to physicians it has used a modified version, in which, through the insertion of certain phrases and the alteration of verbs, the force of the warning is considerably watered down. A typical example is an ad bearing the date of November 13, 1959, which reads as follows, with the changes from the original italized:

> *Chloromycetin is a potent therapeutic agent* and, because certain blood dyscrasis have been associated with its administration, it should not be used indiscriminately or for minor infections. Furthermore, as *with certain other drugs*, adequate blood studies *should* be made when the patient requires prolonged or intermittent therapy.

With regard to the first modification, Webster's New Collegiate Dictionary defines "potent" in this connection as "highly efficacious chemically or medicinally." Thus, the insertion of the term tends to negate the warning label by conveying the impression that this is a drug which is "highly efficacious"—one which will do the job. Similarly, the insertion of the phrase, "as with certain other drugs" conveys the implication that there is nothing particularly unusual about a recommendation that adequate blood studies be made since this same recommendation should be followed for "certain other drugs," among which, however, are none of the other broad-spectrum antibiotics. Finally, the change from "It is essential" to "should" softens

the force of the warning from the mandatory to the permissive. As Chairman Kefauver put it:

> I am afraid that what you have done here is first to dilute the first part of this warning, which starts off, "certain blood dycrasias have been associated," by putting in front of that "Chloromycetin is a potent therapeutic agent." Then you have diluted the blood study part by saying, "as with certain other drugs." You give the impression that certain other drugs have the same requirement. Then you have diluted "essential" by putting in "should be".[99]

For the third media, Parke, Davis did not bother to soften the substance of the FDA's action. Instead, it adopted the alternative and more aggressive tactic of trying to make a setback appear a victory. Thus, its detailmen were told that Chloromycetin had been "officially cleared"; that it "passed three intensive investigations"; that this represented the "highest compliment" ever tendered its medical staff; and that the investigations had resulted in "unqualified sanction" of the product. And it was able to make these incredible assertions because then, as now, the instructions are known only to three parties—the drug companies who concoct them, the detailmen who memorize and transmit them, and the Nation's doctors who ultimately receive them.

Chapter 12. The Special Problem of Side Effects

The advertising and promotion of drugs is also unique in that frequently it must deal with the problem of side effects. Neither the drug companies nor their advertising agencies can afford to ignore the problem. In his ordinary purchases, say of automobiles, TV sets, and the like, the consumer may exercise whatever expertise he possesses; he can make his own selection and take his chances. If the product which he purchases is of inferior quality, the injury which he suffers is more likely to be financial than physical. At least he has learned not to purchase that particular brand again in the future. Since in ethical drugs the consumer usually does not even know what has been prescribed for him, the doctrine of caveat emptor is meaningless. If he renews his purchase, the responsibility is not on the buyer but on the prescribing physician. The reason why this is and must continue to be the case lies in the fact that many if not most ethical drugs can be dangerous if misused. Therefore, in the interest of protecting the public health, the amateur cannot be permitted to make his own diagnosis and take a fling at self-medication. He must be protected by an individual especially qualified in the field of medicine who can exercise an informed judgment on the need for drugs and the amounts to be used.

Despite the obvious importance of providing the physician on whom this responsibility rests with full and accurate information on side effects, the drug companies in their advertisements have tended to handle the matter in either one of two ways: Ignore side effects entirely or note and then dismiss the subject with some sort of reassuring phrase. When the latter technique is employed the physician is comforted with such language as "virtually free from side effects",

[99] Hearings, pt. 24, p. 14013.

"with few significant side effects", "with low incidence of side effects", "minimum side effects", "unexcelled freedom from major as well as minor side effects", "with no irreversible side effects", "fewer and less severe side effects", "absence of serious side effects specifically noted", "accompanied by fewer and milder reactions", "incidence of side effects is lowest ever reported", "by adherence to [recommended dosages] side effects will be generally infrequent, mild and transient", "without clinically significant side effects", "side effects minimal", "serious reactions have been practically nonexistent", "no serious side effects noted", "relative freedom from untoward reactions", "side effects are fewer and milder", "fewer 'old' and no alarming new side effects", "fewer and milder 'classic' side effects", "with minimal chance of side effects", "minimal incidence of certain side effects", "relatively nontoxic", "untoward reactions infrequent and minimal", "undesirable reactions are seldom encountered or are minor in degree", "lower incidence of severe side effects", "virtually free from side reactions", "side effects few and minor", "side effects generally mild and can be overcome by adjusting dosage", "few side effects to worry about", etc.[1]

The frequent use of such qualifying adjectives as "serious", "significant", "major", "irreversible", "alarming", etc., has of course the effect of making the physician responsible for any ill-effects of consequence that may eventuate. The drug company has implicitly cautioned the physician of the possibility of side effects which are "serious". And who is there to say what is and is not "serious"?

At the request of the subcommittee, the Library of Congress made a survey of drug advertisements appearing in six leading medical journals[2] during the 9-month period, July 1958 through March 1959. The survey covered 34 important brand name products in the principal categories of ethical drugs. In the survey the Library noted each page in which an advertisement for any of the drugs appeared in each of these journals; there were 2,033 such pages. In addition, it indicated whether the advertisement contained any reference to side effects, and if so, the nature of the reference.

In 14 of the drugs the companies followed the approach of ignoring the subject completely. The remaining 20 drugs studied contained at least some reference to side effects. But in 13 of these products the references, when made, were entirely of the type listed above; the language is less of a warning than a reason for prescribing.

Finally there were seven products which went at least somewhat beyond the short dismissal phrase. Although in some cases the warnings were quite limited, at least something was said indicating conditions in which the drug should not be used, cautioning against certain manifestations of unfavorable reactions, naming some of the specific side effects, or making some similar explicit and specific statement which would be of value to the prescribing physician.

To summarize, 27 of the 34 drugs had advertisements appearing in 1,239 pages which either contained no reference to side effects whatever or in which reference consisted only of short dismissal phrases. Only seven of the drugs had advertisements which contained a reference

[1] A variant of this approach which was occasionally used was to name certain specific side effects which, it was alleged, did *not* result from the use of this drug. (Emphasis added.)

[2] "Journal of the American Medical Association," "New England Journal of Medicine," "Lancet," "Medical Economics," "Journal of the American Pharmaceutical Association" (Practical Pharmacy edition), and "Journal of Chronic Diseases."

to side effects that went beyond the typical dismissal phrase. Advertisements of this type appeared in 215 pages, 11 percent of the total number of pages. Advertisements for these same seven drugs which did not contain explicit information on side effects appeared in 579 pages. Added to the preceding figure of 1,239 pages for the 27 drugs, this gives a total of 1,818 pages in which advertisements for the drugs surveyed contained no reference to side effects at all or only a short dismissal phrase; this represents 89 percent of the total pages in which advertisements for these drugs appeared during the 9-month period in the 6 medical journals.

During the hearings, drug company witnesses pointed out that fuller descriptions of side effects were to be found in the "inserts" or "brochures" which are supposed to be placed in the packages containing the drug. The physician who wishes to become informed of the drug's side effects, it was held, need only read these brochures. But how does the overworked doctor get his hands on them? He can write to the drug company and ask for them. Or a detailman might leave a sample package containing the brochure. But the drug companies who employ excellent mailing lists of physicians and who use those lists to flood the doctor with vast quantities of advertising literature have failed for some reason to use those same lists for the purpose of sending out the package inserts. Who then does receive them on a systematic basis? The druggist. When he takes a bottle out of its package, he can, if he has the time and inclination, read the brochure. Since it is the doctor who writes the prescription which the druggist must follow regardless of his own opinion, the busy druggist may be pardoned if he throws the brochure, together with the package, into the wastepaper basket. No matter how conscientious the FDA may be in passing on the wording of these package inserts, the effect of their work insofar as the physician is concerned is largely lost. This practice of sending the document to a party who does not write the prescription, and of not sending it to the individual who needs the information, can hardly be regarded as an acceptable substitute for including adequate warnings in the advertisements.

With more and more drugs being put on the market and particularly with the drug companies using "increased potency" as a sales stratagem, there is an inevitable cumulative increase in the number of highly potent drugs—potent not only in their therapeutic usefulness but also in their side effects. The greater the success of a drug company in allaying the physicians' apprehensions concerning side effects, the greater will be its commercial success and the larger its share of the market. In this connection Dr. Bean remarked:

> The problem as I see it is that the chemistry of medicine is advancing so terribly rapidly that we have available now extremely powerful, potent, and effective drugs. These if misused or sometimes when used properly have an inherent danger. In other words, the dividing line between the successful therapy with a powerful drug and the complication or the side effect, may be very narrow, and certainly is not fully predictable ahead of time.[3]

Furthermore, as many of the witnesses pointed out, serious side effects often do not become manifest in the short period of clinical

[3] Hearings, pt. 18, p. 10340.

testing prior to clearance of the new drug by Food and Drug Administration; often it takes years for the evidence to accumulate gradually with use by hundreds of patients. In this connection Dr. Lehmann pointed out:

> All of this should be documented and one should not make definite claims in the first 6 months or even year of working with the drug because many of the side effects, sometimes the most dangerous complications and side effects of drugs, appear only after the drug has been in use for a year or more. So to make the statement that a drug is not addiction forming or doesn't produce any dangerous side effects within the first year is really quite preposterous and rather meaningless for anyone who knows the field. For a physician who is not a specialist in the field, it may be simply misleading.[4]

Dr. Hans Popper [5] of the Mount Sinai Hospital in New York City made the same point with respect to drugs causing serious liver damage. He informed the subcommittee:

> May I remind you that the number of cases of liver damage of jaundice with most of these drugs is very low. That means probably thousands and thousands of patients must be treated with a drug until such relation can be reasonably established.[6]

In this connection the following exchange occurred:

> Senator KEFAUVER. You say [in your statement]: "Only the physician can decide as to whether the risk should be taken in any individual case."
>
> Would you say then, Doctor, that if the physician is to make that decision, the information which he gets when the drug first comes out is of great importance in enabling him to make up his mind as to whether he should give that drug and as to whether the risk is worth taking in a particular case?
>
> Doctor POPPER. I would consider that the key problem in the prevention of such drug-induced injuries is that the physician has as much information as is available at that time.[7]

Upon being questioned with respect to the incidence of these side effects, Dr. Popper remarked:

> Yes; the incidence of drug-induced jaundice is constantly on the increase. As new drugs are developed, more cases of jaundice are seen.[8]

Senator Kefauver then inquired:

> Doctor, what would you recommend be done to prevent some drug being put on the market and widely advertised

[4] Hearings, pt. 16, p. 9029.
[5] Hans Popper, born 1903, Austria; certified pathology, 1943; M.D., Vienna 1928; Ph. D., Illinois 1944 Director Laboratory, director, department pathologists 1942–57 (all at Cook County Hospital, Chicago); director, department pathology, 1957, Mt. Sinai Hospital. Instructor, department pathology, Illinois, 1940–47; assistant professor to professor, department pathology, Northwestern, 1947–57; professor, department pathology, Columbia Physicians and Surgeons, 1957—. Associations: CAP(F), AMA, ASCP, etc.
[6] Hearings, pt. 18, p. 10361.
[7] Ibid., p. 10355.
[8] Hearings, pt. 18, p. 10361.

as to its positive features—energizing, stimulation of healing, antidepression, and so forth—without mentioning anything at all about the side effects, which may be fatal?

Dr. POPPER. Mr. Chairman, I would feel that we are dealing with, as I tried to point out in my initial statement, a difficult situation. Many of these incidences develop after thousands of patients have received the drug. I could concede perfectly good will and honesty to the drug company in not mentioning it, if they don't know about the cases or if the cases are too sporadic to be sure that there is a causal relation. I would feel that the heavy responsibility lies with the drug companies as soon as this relation has been established to give this information as effectively and as quickly as possible to the medical profession.[9]

THE CASE OF DECADRON

The subcommittee's initial contact with the thorny problem of side effects occurred in the first hearing, which related to the cortical steroids. This involved Decadron, which was introduced on the U.S. market by Merck in November 1958. The basic discovery in this field was cortisone, first marketed in 1950. Following the appearance of prednisone, introduced by Schering in 1955 under the trade name of Meticorten, a number of slight molecular modifications were made by other companies; and rapidly there appeared on the market 6-methyl prednisolone (Medrol) sold by Upjohn; triamcinolone (Kenacort and Aristocort) marketed by Squibb and Cyanamid, respectively; and then dexamethasone sold principally by Merck (Decadron). Though all of these products sell at the same price to druggists and final consumers, the newer ones are more "potent," giving rise to what has been termed a "horsepower race." As contrasted with a 5 milligram tablet of prednisone, the next two drugs contain only 4 milligrams, and dexamethasone (Decadron) only 0.75 milligram.

According to the medical experts who appeared before the subcommittee, the difference in potency makes no appreciable difference in the kind and extent of the side effects experienced by the patient. Speaking of this problem, Dr. Russell L. Cecil, noted authority in the field of cortical steroids, informed the subcommittee:

> Well, the trouble with some of the newer steroids is that they haven't had a large enough group of cases yet to give you really accurate statistics. On the ones that came out 5, 6, or 7 years ago, we have had reports that do cover large groups of cases so that the statistics are fairly reliable. But you take a steroid that has just come out in the last year or two. We have a fairly good line on it, but we can't say for sure just what the occurrence of ulcers or fractured bones and things like that are going to be until they have had several years more to accumulate large and well-controlled groups of cases.
>
> I think at that time my guess would be, purely a surmise, but my guess would be that you will have pretty much the same unfortunate side effects with all of them.[10]

[9] Idem.
[10] Hearings, pt. 14, p. 7985.

The same view was expressed by Dr. Louis Lasagna, a specialist in the testing of pharmaceutical products:

> Adequately controlled comparisons of these drugs are almost impossible to find. By adequately controlled comparisons I mean trials in which a group of patients has been randomly allocated without bias to one of two preparations and then again without bias insofar as this is possible trying to achieve equal therapeutic effects and keeping track of the incidence of side effects. As I say, these kinds of comparisons are almost impossible to find.[11]

Past experience with the side effects of steroids, he thought, requires a cautious approach toward this problem. He remarked:

> The experience with the various steroids that have come along is such that whenever another new one appears, one should, I think, be conservative and assume the worst; that is, assume that one will have the same kinds of side effects as have been seen with previous drugs of this type.
>
> The situation here is analogous to having a powerful but dangerous convict who is a two-time loser and about to be released from prison, and hoping that putting a new hat on or making him go barefoot—my homely analogy to slight modifications of the steroid molecule—that effecting these slight changes will change him radically and will turn him into a good citizen.
>
> One always hopes that this may be so, but it is not realistic to assume that it will be so.
>
> Another point that might be made here is that the history of pharmacology indicates that minor modifications of an original drug do not often provide major therapeutic advantages. I think one can come up with differences in side effects, but major qualitative therapeutic advantages by such modifications are rare.[12]

The need for caution was apparently recognized within the medical department of Merck. In his statement prepared for the subcommittee, which was placed in the record but not read, Dr. Augustus Gibson, director of medical research, Merck & Co., mentioned the problem. Earlier in his statement he said that he would use the word "cortisone" to describe all of its latest derivatives.

> I need not tell you that the beneficial effects of cortisone are unfortunately often accompanied by undesired ones. These may range from simple rounding of the face or easy bruising of the skin to severe mental disorders or spreading of infection. One of the ways the body fights disease is through inflammation of the affected tissues. The steroids suppress inflammation, which is what you want when fighting rheumatoid arthritis. But when infection is present, the

[11] Hearings, pt. 14, p. 8137.

[12] Hearings, pt. 14, p. 8139. He added:

"I would think for example that the chance of coming up with a steroid that would cure arthritis rather than treat its symptoms is probably a remote one. Incidentally experience at Johns Hopkins in the pediatric allergy clinic has shown that perhaps the first steroid, cortisone, may actually be better than the latter ones in some respects.

"For example, most of the newer steroids that have been tried there when given in adequate doses to suppress allergic symptoms in children will interfere with the growth of these children and it would appear—from the experience there at least—that cortisone does not do this, and in this respect perhaps should have been utilized all along instead of trying newer agents as they appeared on the horizon."

result of this suppression may be that the infection travels unchecked throughout the body. This can sometimes be fatal, if not treated.

Although specialists in endocrinology recognized that an excess of hormones of the adrenal glands might have certain undesirable effects, the average practitioner so rarely saw such a case that he did not know what to look for as evidence of overdosage. It became our responsibility, therefore, in introducing cortisone, to educate the Nation's physicians regarding cortisone's undesirable as well as its beneficial results.[13]

In the course of his testimony before the subcommittee Dr. Gibson described the nature of the technical literature made available to physicians in package inserts, brochures, and the like.

But, as was repeatedly emphasized during the hearings, detailed clinical reports tend to be perused carefully only by the specialists in the field. General practitioners, treating a wide range of diseases, simply lack the time for an intensive study of the technical literature in each branch of medicine. In consequence, the subcommittee directed its major attention to the advertising material on Decadron which flooded the medical profession from November 1958, the time of the drug's entrance on the market, to December 1959, the date of the subcommittee's hearings.

The question of the content of these ads was of particular importance because of the tremendous sales inroads made by Decadron in the cortical steroid field. By the end of September 1959, 10 months after its introduction, Decadron had captured 26.9 percent of the prescription market in cortical steroids.[14] Deronil, Schering's brand of the same product introduced some time after Decadron, had acquired another 4.8 percent. Thus, together the two brands of dexamethasone had, within less than a year, secured 31.7 percent of the total corticosteroid market. In contrast, marked reductions in the relative position occurred in Meticorten and the other brand-name versions of prednisone as well as in the other earlier steroids.[15]

Advertising to physicians.—At the request of the subcommittee, Merck supplied copies of all its Decadron advertising. From the very outset of its advertising campaign, Merck emphasized "potency" and minimized "side effects." Its first "Dear Doctor" letter, dated June 1958, stated that Decadron still was "under limited clinical evaluation" and not yet available. It whetted the interest of physicians by saying:

> It is already apparent that it has anti-inflammatory potency many times that of any systemic steroid now in use and that it does not cause salt and water retention. Other clinical attributes, while promising, await further clinical substantiation. It is hoped that with its increased potency there may be a greater separation of anti-inflammatory effects from other metabolic effects than with the older adrenocortical steroids.[16]

[13] Hearings, pt. 26, p. 16503.
[14] Hearings, pt. 14, p. 8175.
[15] Meticorten fell from 30.7 to 13.5 percent; Aristocort from 23.8 to 18.8; Medrol from 18.1 to 17.2; Kenacort from 8.9 to 5.5.
[16] Material in files of subcommittee.

A second letter in September 1958 reiterated the statement that Decadron "does not cause salt and water retention or potassium depletion" and adds:

> The incidence of other undesirable hormonal effects appears to be relatively low.[17]

This letter minimizing side effects states that Dr. Joseph J. Bunim, noted specialist at the National Institute of Arthritis and Metabolic Diseases, refers to Decadron. He did so in a footnote which credits Merck for supplying dexamethazone (Decadron).[18] Bunim himself merely designates the study as "an early report" of interest to other investigators. The clinical trial embraced a maximum period of 12 weeks and covered only 18 patients. Treatment resulted in marked improvement in five patients, moderate improvement in seven and slight improvement in four. No major toxic effects occurred during the *"brief period of trial,"* [19] but there were already manifested minor undesirable side effects in 14. Despite its clearly stated limitations the value to the promotional campaign of this study by a noted authority conducted in and by a prestigious governmental agency can hardly be exaggerated.

In November 1958, at the time of Decadron's release by Food and Drug Administration for sale to the public, Merck informed its physician clientele that the usual adverse side effects for the cortical steroids were absent in Decadron. Its "Dear Doctor" letter stated:

> Muscle wasting and weakness, headache, vertigo, anorexia, weight loss, edema, tachycardia, salt and water retention and potassium depletion have not been encountered. The incidence of other side effects observed in patients under therapy with Decadron was relatively low.[20]

Even in this early period, however, reports of studies by independent experts began to appear, indicating that the side effects for Decadron were no different from those of earlier cortical steroids. Dr. Edward W. Boland, noted authority in this field and one of the first to engage in clinical testing of the drug for Merck prior to its clearance, published an article entitled "Preliminary Observations of Adverse Effects from Dexamethasone" in December 1958 issue of Annals of the Rheumatic Diseases. He remarks:

> The overall incidence of adverse reactions from dexamethasone appears to be about the same as of those from prednisolone when equally effective antirheumatic doses of the two drugs are given.

In the last paragraph of his article he warns that—

> * * * augmented antirheumatic potency alone does not denote superiority, and these clinical trials have been too brief, as yet, to allow us to judge whether dexamethasone possesses therapeutic advantages over prednisone or prednisolone in the management of those rheumatoid arthritic patients who are suitable for long-term steroid therapy.[21]

[17] Idem.
[18] Bunim, Joseph J. et al, "Arthritis and Rheumatism," vol. 1, No. 4, August 1958, p. 313-331.
[19] Emphasis added.
[20] Material in files of subcommittee.
[21] Idem.

It is of interest that this article appears to be one of the many technical reports to which Dr. Gibson refers, which were supplied by Merck to the members of the medical profession. Judging from the rising volume of Decadron sales, however, many physicians failed to note these words of caution amid the heavy flow of Merck advertising material.

Throughout 1959 physicians were being deluged with attractive promotion mailings with the claims for Decadron growing more sweeping with the passage of time—

> * * * has superseded prednisone and prednisolone in the same way that these hormones superseded cortisone and hydrocortisone—in both effectiveness and safety—

that—

> * * * all patients prefer Decadron * * * No worrisome side effects attributable to Decadron have occurred as yet—

that, with Decadron—

> * * * side effects are no longer a serious limitation—

that—

> The unpredictable results, excessive hormonal side effects, and low potency of previous corticosteroids were limitations characteristic of the "growing" period of a new type of therapy. Now Decadron brings the dependability and safety of "maturity" to steroid therapy.

and—

> Now therapy can be established more safely, promptly, and predictably than with any other corticosteroid * * * with *patient need*, not side reactions, *the main consideration* * * * without the handicaps that limited the usefulness of the corticosteroids developed during the transitional period.
>
> By any standard of clinical excellence Decadron stands out as the determinative corticosteroid.[22]

and—

> Decadron marks the end of the transitional product development era and the arrival of mature corticosteroid therapy.

and—

> Therapeutic response highest ever reported.
> Decadron.
> Incidence of side effects lowest ever reported.
> Clinical trials confirm experimental data.[23]

It is of interest that, at the very time Merck's advertising claims regarding side effects were being intensified, the volume of clinical reports by unbiased observers was confirming earlier evidence to the contrary. In a New York Academy of Sciences symposium held in 1958,[24] Dr. Boland again reported with respect to dexamethasone—

[22] All above quotations from material provided by Merck, in files of subcommittee. [Emphasis in original.]
[23] Material in files of subcommittee.
[24] Published Oct. 14, 1959, as vol. 82, art. 4 of "Annals of the New York Academy of Sciences," entitled "A Decade of Anti-inflammatory Steroids from Cortisone to Dexamethasone."

> The overall results in relation to improvement and side effects did not differ significantly from those obtained from prednisone or prednisolone in a group of similar composition and with similar duration of treatment.[25]

Other reports in this symposium contain similar conclusions. An article on British experience with the drug states:

> * * * There is no particular advantage in having a stronger steroid for, to the patient, it is just another tablet to be taken through the day and, for the physician, minor adjustments of dosage are more difficult.
>
> From our short study we conclude that dexamethasone is a potent anti-inflammatory steroid. We consider that it is about six times as strong as prednisolone. In some patients with rheumatoid arthritis better suppression can be achieved with this drug than with prednisolone and, in others, the effect is not so favorable.[26]

A famous blood specialist in this country concluded his report with the remark:

> The introduction of dexamethasone seems to offer no particular advantages over the other corticoids in hematological disturbances.[27]

An article in the Lancet, famous British medical journal, for September 5, 1959 summed up the informed view on both sides of the Atlantic in these words:

> The fact that much the same clinical effect is obtained with a smaller dose, one-fifth, of the new substance is of little practical importance unless the cost is reduced in the same ratio, and this is not the case. The patient on dexamethasone has in fact to take almost twice as many tablets as with any other corticosteroid. It seems likely on the existing evidence that all the same side effects occur with dexamethasone as with prednisolone and prednisone but on this series we can say only that the most frequent and annoying, i.e., gastroduodenal irritation, is no less common * * *.[28]

Testimony of Merck officials.—At the outset of Dr. Gibson's testimony, Mr. John T. Connor, president of Merck & Co., asserted that the medical director of Merck had the final responsibility on all company advertising. He stated:

> I might say, sir, that in our company our medical director has the final say on advertising. To my knowledge Dr. Gibson has never been overruled in his medical opinion either by management or by commercial or advertising people.[29]

[25] "The Treatment of Rheumatoid Arthritis with Adrenocorticosteroids and Their Synthetic Analogues. An Appraisal of Certain Developments of the Past Decade," loc. cit. p. 897.
[26] Dr. Oswald Savage, West London Hospital, "Experience in Great Britain with Steroids (Particularly Dexamethasone) in Rheumatoid Arthritis," loc. cit., p. 909.
[27] Dr. William Dameshek, Tufts University School of Medicine and Blood Research Laboratory, New England Center Hospital, Boston, "The Use of Corticosteroids in Hematological Therapy," loc. cit., p. 937.
[28] Dr. F. Dudley Hart of the Westminster Hospital, London, in the Lancet, Sept. 5, 1959, p. 257.
[29] Hearings, pt. 14, p. 8178.

Dr. Gibson himself described the process as follows:

> Dr. GIBSON. Now, following these discussions, the advertising is written. It is reviewed by a member of my department, and if he objects to the statements in it, they are changed. Now there may be some discussion, but in the final analysis, what we say in the medical department is upheld.
>
> Now, I don't personally see every ad that comes out unless there is some reason to have it brought to my attention.
>
> Senator KEFAUVER. Who writes the ads?
>
> Dr. GIBSON. Ads are not written in my department. They are written by someone in advrtising or for advertising.
>
> Senator KEFAUVER. You do not personally see them all?
>
> Dr. GIBSON. I do not personally see them all, but a physician in my department does see them all, and he acts with authority to disapprove if he feels that they are not medically sound.[30]

Senator Kefauver then raised the question of the accuracy of Merck's advertising of Decadron. Turning to one, he read "Patient need is the main consideration—NO STEROID SIDE EFFECTS," and inquired if this represented Dr. Gibson's view.[31] Mr. Connor replied:

> This particular ad is used by our international division, and we don't have a representative of the international division here, so we will have to get the date of that later and supply it for the record.[32]

Senator Kefauver then inquired:

> * * * you mean you make different claims abroad?
>
> Mr. CONNOR. No, sir.[33]

The Senator read further from the ad:

> "No fluid retention, diabetic action virtually eliminated, virtual freedom from gastrointestinal symptoms, no weight loss, no headaches, drowsiness, nausea, no psychic manifestations, no hypertension, no significant nitrogen imbalance in the therapeutic dosage."
>
> You say in all your advertisements that is true, and yet Dr. Gibson just said that that isn't correct.
>
> Dr. GIBSON. In the first place, I don't believe we do say this in all of our advertisements.
>
> Senator KEFAUVER. I have looked at a number of them here.
>
> Dr. GIBSON. All of those quoted it so happens are from abroad. But as Mr. Connor said, we don't condone false statements either abroad or domestically.[34]

[30] Ibid, p. 8181.
[31] Hearings, pt. 15, p. 8673, exhibit 53 is this ad in full.
[32] Hearings, pt. 14, p. 8182. Merck subsequently supplied the information that this ad was sent out July 13, 1958 (pt. 15, p. 8831).
[33] Hearings, pt. 14, p. 8182.
[34] Idem.

Senator Kefauver then picked up another ad[35] and remarked:

> Here are the exact words:
> "No worrisome side effects attributable to Decadron have occurred as yet."
> Is that statement true?
> Dr. GIBSON. As of today I would say it is not true.[36]

The Senator then summarized the side effects reported in an article in the Canadian Medical Association Journal[37] and inquired of Dr. Gibson:

> Literature like this certainly must come to your attention, doesn't it?
> Dr. GIBSON. Yes; all of the literature on dexamethasone comes to my attention.
> Senator KEFAUVER. This is certainly a far cry from "no adverse side effects developed," isn't it?
> Dr. GIBSON. I don't think we have ever said no adverse side effects have developed.
> Senator KEFAUVER. You said that in your ad here, sir.
> Dr. GIBSON. I don't think that is exactly what was said.
> Senator KEFAUVER. "Have occurred," you said.
> Mr. CONNOR. What are the exact words again?
> Senator KEFAUVER. "No worrisome side effects have occurred as yet. * * *."[38]

During the testimony of Merck officials, Mr. Connor requested the privilege of making later comments on these advertisements. Subsequently, Dr. Gibson filed such a statement which is reproduced in the record.[39] He stated:

> In my opinion all statements in these advertisements were correct in the light of the information on the product then available. The then data had been summarized in two papers, one written by Dr. E. W. Boland and published in June 1958, and the other by J. J. Bunim and published in August 1958.

It is of note that all of the advertisements referred to by Dr. Gibson were issued between July 31, 1958, and January 19, 1959. The symposium of the New York Academy of Sciences was held in 1958, at which time several reports describing the side effects of Decadron were presented by medical experts. It is customary in matters of this kind for authors to send copies of their papers to the company involved before they are given. This is particularly true when the company provides the clinical investigator with his supply of the drug. All of the studies during this period—prior to Food and Drug Administration's release of the drug—could only have been made through Merck's supplying the drug to the clinical investigators.

[35] Material in files of subcommittee.
[36] Hearings, pt. 14, p. 8185. The date of this ad, subsequently supplied by Merck, was Sept. 30, 1958.
[37] Dr. C. H. A. Walton, "Clinical Experience with Dexamethasone," Canadian Medical Association Journal, Nov. 1, 1959. Reprinted in full in hearings, pt. 15, p. 8684 ff.
[38] Hearings, pt. 14, p. 8189.
[39] Hearings, pt. 15, p. 8879.

THE CASE OF DIABINESE

During the hearings the pharmaceutical manufacturers stressed the importance of their promotional activities as "education" of physicians in the uses of new drugs. Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association, informed the subcommittee that "our educational and promotional practices have a vital role in medical care and health."[40] And he listed "doctor education in new drugs" as the first objective of what he termed "competitive education and distribution."[41] He went on to say:

> Indeed, the word "advertising" is perhaps something of a misnomer when it applies to prescription drugs. Our so-called advertising is far different from the customary sales promotion message American consumers normally associate with the word. For the most part, our advertisements are more like scientific treatises, which differ from learned editorial comment in medical journals to the extent that we ourselves write these treatises and pay for the space where they are printed.
>
> Ours are about the only ads in America that tell not merely the good things about our product, but deal exhaustively with the bad ones as well. Toxicity, side effects—all must be exposed in full detail.[42]

One of the major criticisms of the medical experts was the inadequacy of the factual information supplied. Diabinese is a striking example of the failure by a company to disclose to physicians essential information on side effects which it had in its possession. In claiming an absence of side effects as compared to earlier corticosteroids, the Decadron advertisements represent an act of commission; in failing to tell the doctor what the company knew about its side effects, the Diabinese ads constitute an act of omission.

Until the German discovery of tolbutamide in the early 1950's, insulin was the only drug treatment for the diabetic patient. In June 1957 the Upjohn Co., operating under an exclusive patent license from Hoechst of Germany, introduced tolbutamide on the American market under the trade name Orinase. Extensive clinical testing of the product, both in Europe and in the United States, occurred prior to clearance by the Food and Drug Administration. The drug won immediate acceptance with the medical profession, and sales soared.

On August 22, 1958 Pfizer filed with FDA a new drug application for chlorpropamide, a slight molecular modification of tolbutamide; 2 months later this drug was cleared by the regulatory agency, and Diabinese, with much advertising fanfare, made its appearance on the American market at the end of 1958.[43]

Again the element of potency was involved. Whereas Upjohn's Orinase is sold as a 0.5-gram tablet (500 milligrams), the more potent Pfizer product for an equivalent dosage contains half the essential ingredient (250-milligram tablet). Prices are roughly equivalent. At the time of the introduction of Orinase, the patient paid $0.14

[40] Hearings, pt. 19, p. 10699.
[41] Ibid., p. 10700.
[42] Ibid., p. 10702.
[43] Within a year Pfizer captured approximately one-sixth of the market for oral antidiabetic drugs (p. 11168).

per tablet; a price drop which occurred shortly before the subcommittee's hearings resulted in a price of about $0.13 per tablet. Diabinese has sold from the outset at $0.15 per tablet. The typical maintenance dosage for Orinase is two tablets daily. In contrast, Pfizer has stressed in its advertising campaign that Diabinese constitutes an "economical once-a-day dosage." Along this line, Mr. John E. McKeen, president of Pfizer, presented in his testimony a table showing that the Orinase patient spends, on the average, $0.28 daily for medication, whereas the Diabinese patient spends $0.15 for the drug.[44]

As in the case of Decadron, the manufacturer was asked to submit to the subcommittee copies of all Diabinese advertising from the time of its introduction on the market. The material supplied by Pfizer shows that in December 1958 physicians were informed that Diabinese represented—

> the latest word in diabetes control * * * A major advance in oral therapy[45]—

During the ensuing months, the advertising pressures were intensified. Pfizer announced that Diabinese—

> provides the potency essential for predictable, precise response—

that it—

> provides constant activity preventing wide fluctuations of blood sugar and insuring optimum safety—

that it represented—

> More effective control of more diabetics more economically.

The product was urged for—

> Smoother, lower cost oral antidiabetic control—

for—

> More efficient oral control in maturity-onset diabetes.

Diabinese was variously described as—

> The oral antidiabetic most likely to succeed.
> Extending the frontiers of oral antidiabetic thereapy—

and the like.

With respect to side effects, an ingenious device was employed. Most advertisements contained statements averring the absence of side effects for Diabinese, but these were usually placed in quotation marks. Such remarks as:

> Well tolerated with minimal side effects in the therapeutic range of 100 to 500 milligrams.
> Almost complete absence of unfavorable side effects.
> Drug of choice in the sulfonylurea group.
> An active and clinically effective * * * agent more than twice as active as tolbutamide * * * appears to be safe, effective, and well tolerated, with minimal side reactions—

[44] Hearings, pt. 20, p. 11120. Extensive laboratory tests are required in Diabinese therapy.
[45] This and following quotations come from advertisements in the files of the subcommittee.

were taken from the reports of investigators whose critical comments in the same article were ignored. These phrases were excerpted from the early clinical work on the drug. Not only did these investigators usually carefully point out the limited character of their findings from the few cases studied; in many instances they described in some detail the volume and intensity of the side effects experienced by their patients.[46] Particular emphasis in the advertising was given for several months to an article in the West Virginia Medical Journal dated December 1958, which represented one of the earliest clinical studies—of a most favorable character—with only 60 patients.[47]

Opinion of medical experts.—A member of medical experts appearing before the subcommittee in April 1960 testified with respect to serious side effects incidental to the use of Diabinese. Dr. Henry Dolger,[48] eminent authority in this field,[49] stated:

> Although chlorpropamide [Diabinese] is more potent than tolbutamide [Orinase] it seemed to me that the toxicity of the former stood in marked contrast to the safety of the latter. I felt so strongly about this that I repeatedly decried the use of chlorpropamide in publications and medical meetings.
>
> In publications of 1959 and 1960 I stated that "this increase in potency is associated with an increase in serious side effects and toxicity, especially in liver damage. There is no decrease in side effects despite the advertisements."
>
> It seems to me that potency manipulation was comparable to the horsepower race in the automotive industry. In a chronic disease like diabetes where a therapeutic treatment must be administrated for nearly a lifetime, safety becomes paramount in medical treatment. In a letter to the British medical journal, the Lancet, now in press, I stated that in my personal experience with over 3,000 patients treated with tolbutamide I had never encountered a single incidence of liver damage or overt jaundice. On the other hand, out of 400 patients treated with chlorpropamide I have seen 6 develop serious disabling jaundice, 1 of them dying with this toxic picture in New York City in January of this year.
>
> In the past 4 months of this year five publications have appeared in the medical literature describing jaundice from chlorpropamide. During this time I received in the mail the usual biweekly literature for chlorpropamide stating it was "free from significant incident of serious side effects." And again another mail advertisement for chlorpropamide states that "impairment of liver function is only seen in association with use of large doses of 500 milligrams or more and has been reported in 1 percent."

[46] See, for example, Annals of New York Academy of Sciences, vol. 74, art. 3, published Mar. 30, 1959 "Chlorpropamide and Diabetes Mellitus": articles by Drs. S. J. N. Sugar, G. G. Duncan, B. Greenhouse-L. O. Burrell, C. T. Lee, I. Canessa, A. W. Alvi, L. J. Cardonnet, J. J. Lowenthal.

[47] Dr. Wm. M. Sheppe, "Hypoglycemic Drugs in the Oral Treatment of Diabetes Mellitus," West Virginia Medical Journal, vol. 54, No. 12, p. 467, reprinted in hearings, pt. 20, p. 11340.

[48] Henry Dolger, born New York, 1909; certified medicine 1943; M.D., New York University, 1933. House physician 1933–36, chief of diabetes and associate attending physician for metabolic diseases, 1936—, Mount Sinai Hospital. Practice limited to diabetes. Associations: ACP(F), AMA, American Diabetes Association, etc.

[49] Dr. Roberts M. Rees, associate medical director of Pfizer Laboratories, remarked about Dr. Dolger: "Dr. Dolger stated that he was the second investigator for Pfizer with chlorpropamide. It was my understanding that he was No. 1. He was the first man that we contacted and received the first supply in this country" (p. 11163).

> This quote was in an issue that was sent out in the mail in the middle of January.[50]

At the time of the appearance of Dr. Alexander Marble,[51] of the Joslin Clinic in Boston, Senator Kefauver read from a Diabinese advertisement as follows:

> * * * at the lower dosage levels found sufficient in recent clinical reports (100–500 milligrams once daily), Diabinese has been free from significant incidence of serious side effects.[52]

Senator Kefauver then inquired—

> Do you agree that it is free from significant side effects?

In this connection the following exchange occurred:

> Dr. MARBLE. The word "free" is all right. But the important word is "significant." That would be a matter of opinion as to what was the significant incidence * * *.
>
> Senator KEFAUVER. Is any case of jaundice a significant incidence of serious side effects?
>
> Dr. MARBLE. Yes; you would certainly classify that as serious side effect even though it belongs in the so-called benign group which apparently all, or almost all, of these do * * *. One might quarrel with the word "benign," but it is usually a reversible nonfatal process.
>
> Senator KEFAUVER. That is, if the physician recognizes it?
>
> Dr. MARBLE. Yes, sir; of course. Yes, if the drug were continued that would be bad.[53]

Speaking of the same ad, Dr. Samuel D. Loube,[54] a specialist in this field in Washington, D.C., stated:

> I would say that if one patient, if only one patient in a thousand, might have died because of the use of a drug, or if there has been one case of jaundice in a large number that was serious or potentially serious, or one case of severe exfoliative dermatitis which could be traced to the drug, that these constitute, to me, a significant number of serious side effects.[55]

Dr. Loube stressed a point emphasized by the other medical experts, namely, the importance of disseminating to all physicians full information on side effects, particularly because, as he pointed out, diabetic patients are usually treated by general practitioners rather than specialists. He stated:

> I do feel, however, that the side effects are distinctly of sufficient importance to be carefully brought to the attention of any physician who plans to use chlorpropamide in the treatment of his diabetic patients. The large majority of the

[50] Hearings, pt. 20, p. 11146.

[51] Alexander Marble, born Kansas, 1902; M.D., Harvard, 1927. Intern, Johns Hopkins, 1927–28, resident in medicine, Massachusetts General Hospital, 1928–30, Moseley traveling fellow, Harvard, 1930–32; since 1932 in practice of medicine, Boston; now physician, Joslin Clinic and New England Deaconess Hospital.

[52] Hearings, pt. 20, p. 11142.

[53] Idem.

[54] Samuel D. Loube, born Rumania, 1921; M.D., George Washington University, 1943. Intern and resident in medicine, 1943–46, Gallinger Municipal Hospital; senior assistant surgeon, U.S. Public Health Service, 1946–48; resident in metabolism and endocrinology, Michael Reese Hospital, 1948–49; research fellow in diabetes, May Institute for Medical Research, 1949–50; associate in medicine, George Washington University Hospital. Associations: American Diabetes Association, AMA, etc.

[55] Hearings, pt. 20, p. 11188.

diabetic patients in our country are treated by general practitioners who, for many reasons, may not be familiar with the results of carefully developed research studies and the evaluation by experts of such new drugs as chlorpropamide. Rightly or wrongly, they rely on the information passed on to them by the advertising media of the pharmaceutical companies.[56]

Speaking of the promotion material supplied doctors on Diabinese, he remarked:

> Yet many of us feel that too frequently such information is presented in the form of pressure advertising. The physician is inundated with reams of slogans, pretty pictures, graphs, and large print claims such as those that you have just referred to. The physician is human, and busy and, I believe, can be influenced to acceptance and perhaps injudicial use of new drugs before he has an opportunity to familiarize himself thoroughly with the potential disadvantages or hazards of their use. * * *
>
> Senator KEFAUVER. Doctor, the point is that these ads, by themselves do not give all that information that you are talking about. Do you think that in some cases they might mislead a practicing physician?
>
> Dr. LOUBE. Yes, I do.
>
> Senator KEFAUVER. Do you think in view of this finding that it is a fair statement to say that Diabinese is "free from a significant incidence of serious side effects," and that there is "almost complete absence of unfavorable side effects"?
>
> Dr. LOUBE. No * * *. This would certainly mislead me were I not familiar with material such as has been presented here today, or material presented in various analyses in other medical journals.[57]

Dr. Marble complained particularly of the lack of published information on the overall incidence of side effects:

> Senator KEFAUVER. If I may interrupt, you say there has not been an enumeration——
>
> Dr. MARBLE. No published summary.
>
> Senator KEFAUVER (continuing). Of occurrences of jaundice. Shouldn't that be the responsibility of the pharmaceutical company to secure the collection and tabulation of these experiences and give that information to the physician?
>
> Dr. MARBLE. That would be one way of handling it, sir. Such responsibility has, I think, never been firmly fixed in that way, but what you suggest has been done at times; yes.
>
> Senator KEFAUVER. The Food and Drug Administration doesn't do it. NIH doesn't do it. I would think that

[56] Hearings, pt. 20, p. 11185 [emphasis added]. Dr. Loube also stated that the diabetic patient should be fully cognizant of possible side effects in the interest of supplying prompt information to his physician. In this connection the following exchange occurred:

"Senator KEFAUVER. Doctor, in the treating of diabetes, is it important that a patient, in order to cooperate, be aware of these matters so that he understands what side effects might occur and what might be the result? Is that an important part of treatment?

"Dr. LOUBE. Yes. I think nowhere in medicine is there a group of patients who ought to be as thoroughly familiar with every aspect of their disease than the diabetic patients.

"Senator KEFAUVER. You are talking about the patient in saying that nowhere in medicine should there be a fuller understanding of a disease than in diabetes?

"Dr. LOUBE. And its management" (ibid., p. 11190).

[57] Hearings, pt. 20, p. 11186.

there should be some clearinghouse somewhere for the tabulation of experiences of adverse and side effects. I think you have made a very good suggestion. Otherwise, doctors won't know about recent experiences.

Dr. MARBLE. That's right.[58]

If this situation is true for specialists, the plight of the general practitioner in this area is serious. This exchange followed:

Senator KEFAUVER. And if an eminent authority like you doesn't have information about the incidence of the side effects, knowing what the situation is now, how does the average physician?

Dr. MARBLE. He would not be able to know anything that wasn't published or got to him in some way or other; no, sir.

Senator KEFAUVER. You think that is the great need of the time right now?

Dr. MARBLE. I think we need to know that; yes, sir.[59]

In his testimony before the subcommittee, Dr. Hans Popper, a leading expert on liver disorders, pointed out the great difficulties experienced by the attending physician in determining whether a case of jaundice is drug-induced or stems from another source. Among the drugs he listed as inducing jaundice was Diabinese:

* * * recently, several instances of such jaundice are found following the administration of the antidiabetic drug chlorpropamide or Diabinese. It should be emphasized that the so-called cholestatic type of jaundice is usually mild and self-limited. The patients are not severely ill and only very few fatalities have been reported.[60]

Dr. Popper emphasized the necessity for the most informed clinical observation on the part of the attending physician. Pointing out that the usual tool of animal experimentation is of "limited value" since these drug-induced changes do not occur in animals, he added:

I would consider that the key problem in the prevention of such drug-induced injuries is that the physician has as much information as is available at that time.

Senator KEFAUVER. Is it true that when a drug first comes out, frequently the chief, if not the only, information the physician may get will be the information sent to him by the manufacturer when the drug is put on the market?

Dr. POPPER. That is right.[61]

[58] Ibid., pp. 11135, 11136.
[59] Hearings, pt. 20, p. 11142.
[60] Hearings, pt. 18, pp. 10352, 10353.
[61] Hearings, pt. 18, p. 10355.

In this connection Dr. Dolger quoted from the report on Diabinese by the Council on Drugs of the American Medical Association, published in the Journal of the AMA on January 2, 1960, "the margin of safety between doses producing englycemia and hypoglycemia is smaller than with tolbutamide.

"Hence with chlorpropamide as with insulin it is imperative that there be a careful initial adjustment of dosage as well as adequate orientation of the patients concerning hypoglycemic reactions and their control" (hearings, pt. 20, p. 11148) and added: "The conclusion of the Council on Drugs states that there are several disadvantages of chlorpropamide compared with tolbutamide:

"(a) Slightly higher clinical toxicity and smaller margin of safety with respect to hypoglycemia and (b) possibility of jaundice.

"I call your attention to the absence of any mention of these warnings in the deluge of promotional material sent out for chlorpropamide" (ibid., pp. 11148-11149).

Both Dr. Dolger and Dr. Loube were of the opinion that the drug had not been given adequate clinical testing prior to FDA clearance. Speaking of the introduction of Diabinese, Dr. Dolger remarked:

> In contrast with the original investigation on tolbutamide and carbutamide there was no preexisting European experience to take advantage of. In a very limited fashion the exploration of the effects of this particular agent was explored somewhat fitfully and attempts to arrive at appropriate dosage were accompanied by pharmacologic studies which revealed hitherto unknown delayed rates of excretion which made decreasing dosage imperative.[62]

In listing the side effects, he stated:

> * * * the incidence of 1 percent or one-half of 1 percent of jaundice should deter any physician from prescribing this agent when there is insulin or tolbutamide available, both of which never cause liver damage. Since the toxic effect may be due to an idiosyncrasy to the drug, no physician should be condemned for the inability to predict such a reaction.
>
> * * * * * * *
>
> In addition, the toxic or disturbing side effects of severe gastrointestinal disturbance with nausea and vomiting, asthenia, depression, dizziness, and other neurological symptoms appear when chlorpropamide is administered to some patients.
>
> These are secondary side effects. A more serious side effect of chlorpropamide and it may not be a side effect but part of the drug action and should be called perhaps intoxication or overdosage, has to do with its increased potency which produces extremely low blood sugar levels in certain instances.[63]

That Diabinese was not given sufficient clinical testing prior to FDA clearance appears to be indicated by the change that Pfizer made in its recommended dosage of this drug. The hearings disclose that, for almost a year after Diabinese was introduced on the market, the package brochure going to physicians recommended a maximum daily dosage not to exceed one gram. Subsequently, when physicians experienced the kinds of side effects listed by Dr. Dolger, the maximum dosage recommended was dropped to 750 milligrams.[64] This later package insert also states that "Patients who do not respond completely to 500 milligrams daily will usually not respond to higher doses."

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[62] Ibid., p. 11146.

[63] Hearings, pt. 20, pp. 11147-11148. Speaking of this problem relative to the elderly diabetic patient, he said: "This problem could prove more serious in the elderly diabetic patient who is more sensitive to the effects of a low blood sugar. Since the largest portion of the diabetic population is in the elderly group the portent of this phenomenon becomes quite apparent. In 1959 and 1960 I pointed out the danger of chlorpropamide for the 'elderly, senile, arteriosclerotic, diabetic patient who may suffer irreversible brain damage from its prolonged hypoglycemia.'"

[64] Ibid., p. 11222:

"Mr. DIXON. So between November 1958, when the drug went on the market, and up to September 1959, the top dosage recommended was 1 gram. Then in September 1959 the top dosage recommendation was changed to 750 milligrams, is that correct?

"Dr. WARNER. (associate Medical director, Pfizer Laboratories). That is correct."

Dr. Loube also expressed doubt whether Diabinese should be available for general use. It was his opinion that the drug should still be limited to experimental use by clinical tests skilled in the knowledge of its peculiar properties and side effects. When asked if he would approve FDA clearance of the drug, based on his present knowledge, he replied, "Not at this time." [65]

Pfizer data on side effects.—Prior to the subcommittee hearings on Diabinese, Pfizer was requested to supply all of the clinical data submitted to Food and Drug Administration relative to this drug. In response, Pfizer submitted 15 volumes of case studies, each containing reports on over 100 cases. No summary of these data was submitted with the volumes. In an effort to secure an objective evaluation of these reports, the subcommittee turned to outside sources. Dr. Samuel D. Loube, a member of the teaching faculty of George Washington University Medical School and a practicing physician, supervised the compilation, which was made by Dr. Irwin H. Ardam.[66]

After several requests, Pfizer, as the hearings on diabetic drugs began, supplied the subcommittee with a summary of these case reports, prepared by Dr. Domenic G. Iezzoni. This summary, entitled "Diabinese Study Program," was dated August 15, 1958.[67] Questioning during the hearings disclosed that it was among the documents submitted to FDA prior to the drug's clearance by that agency in October 1958.[68] No suitable explanation was given to the subcommittee as to why this report had not been submitted to it at the time the volumes of individual case studies were supplied. Its submission would have made unnecessary the analysis of the voluminous case material prepared for the subcommittee by Dr. Loube. It is worthy of note, however, that the summary findings of both the Loube and Iezzoni reports were in substantial agreement. The result was to substantiate the objectivity and accuracy of both reports.

The Iezzoni summary shows that, of a total of 1,922 cases tabulated, 27 percent reported one or more side effects. The results of the Loube report using a sample of the total were substantially the same.

[65] Hearings, pt. 20, p. 11192. In this connection, the remarks of Dr. William D. Kessenich, Medical Director, Bureau of Medicine, FDA, indicate the agency's awareness of this problem. On Feb. 8, 1960, he addressed the regional meeting of the Pharmaceutical Manufacturers' Association in Chicago, and stated: "A new drug application is made effective on the basis of evidence establishing that the pharmaceutical is safe for use as suggested in its labeling, mainly this very carefully worked-over brochure furnishing physicians adequate information for use of the drug. This brochure is labeling referred to on the label of the drug as 'literature available to physicians on request.' In practice the physician is besieged with literature without his request. Much too commonly the literature mailed and detailed to the profession exaggerates the advantages of the drug and purports to furnish adequate information for its use but fails to state the information concerning contraindications, side effects, and necessary precautions. This volume of information repeated as it is by multiple mailings and appearing in most medical journals, eventually lulls the physician into believing he has been given enough information about a drug and so why request any more. The full story frequently never reaches the physician and this is the problem. Obviously such promotion of new drugs is misleading and dangerous" (hearings, pp. 11168-11169).

[66] A summary is contained in Dr. Loube's testimony, hearings, pt. 20, p. 11175; the full report entitled "Summary of Chlorpropamide Case Reports" prepared by Dr. Irwin H. Ardam, is printed, ibid., p. 11325.

[67] The Iezzoni report may be found in full in hearings, pt. 20, p. 11344.

[68] Hearings, pt. 20, p. 11153.

* * * * *

Of a total of 413 cases, side effects were found in 31 percent of the cases. The comparison is as follows: [69]

	Iezzoni report [1]		Loube analysis [2]	
	Number	Percent	Number	Percent
Total cases	1,922	100	413	100
Side effects	513	27	128	31
Skin	88	4	21	5
G–I (gastrointestinal)	170	9	53	12
CNS (central nervous system)	170	9	35	9
Liver	72	4	15	4
Blood	45	2	5	1
Hypoglycemia	91	4	(3)	
Miscellaneous			41	10

[1] Aug. 15, 1958; table 2A, Cases with sufficient data.
[2] Vols. III–VI.
[3] Included in miscellaneous.

The extent of Pfizer's knowledge of the seriousness of the side effects of this drug is further disclosed in a memorandum by Dr. Iezzoni addressed directly to Mr. McKeen, president of Pfizer, on July 8, 1958. This states in part:

> In the evaluation of Diabinese we have encountered an incidence of toxicity which, at the least, is not less than that seen with Orinase. We have encountered six cases of jaundice. The jaundice in each instance developed after 3 to 4 weeks of chronic daily treatment with Diabinese. In each instance, the jaundice was associated with a skin rash of varying severity * * * It is significant that although jaundice developed in four of these patients while they were on Diabinese in doses of 1.0 gm., and in one patient while on 1.5 gm./day, our most recent case of jaundice developed in a patient on 0.5 gm. of Diabinese daily. It is also significant that subsequent to their jaundice, two of these patients, after being on Orinase for 4 weeks, and one patient, after being on Orinase for 2 weeks, do not, at present, show any clinical or laboratory evidences of liver toxicity or skin rash. A recent report from the Medical Division of Pfizer International listed a patient who developed jaundice after being on chlorpropamide for approximately 3 weeks.
>
> * * * * *
>
> Among the most striking evidences of toxicity associated with Diabinese are three instances of exfoliative dermatitis. This complication developed in patients receiving between 1.0–0.25 gms. of Diabinese after periods of 4 to 5 weeks. One patient who developed a severe dermatitis, just short of becoming exfoliative, received 1.0 gm. of Diabinese for 35 days prior to this complication; when she was challenged with a 250 mg. daily dose of Diabinese subsequently, she developed a recurrence of the skin reaction within 5 days of resuming medication. There have been reported several additional cases of severe skin eruptions with edema and erythema multiforme in addition to the other skin lesions.
>
> * * * * *

[69] Ibid., p. 11370.

The gastrointestinal side effects of nausea, vomiting, and epigastric distress, although less frequent at the lower dosage levels of 0.25–0.5 gm./day, are still more frequent than generally noted with Orinase.

* * * * *

There have been several instances of severe hypoglycemia in patients receiving doses as low as 0.25–0.5 gm./day. No death has occurred from hypoglycemia at these lower dose levels. One patient, however, died of intractable hypoglycemia following Diabinese medication.

Among other complaints still evident at the lower doses are such things as headaches, hazy vision, depression, weakness, and three cases of eosinophilia.

Of the side effects noted with Diabinese medication the jaundice and exfoliative dermatitis are particularly outstanding when one realizes that, to date, there has been no reported instance of either of these complications in patients treated with Orinase.

This is a report only of studies in the United States. Similar types of severe reactions appeared in studies in the international area.[70]

Pfizer's position in hearings.—Since Dr. Iezzoni had been in personal charge of the Diabinese clinical testing program for Pfizer, the subcommittee was particularly interested in hearing his testimony. However, at his first appearance, Mr. McKeen announced that he was accompanied only by Dr. Robert C. Warner and Dr. Robert M. Rees, associate medical directors of Pfizer.[71] On several occasions during the hearings the chairman inquired if Dr. Iezzoni were present. The following exchange occurred:

Senator KEFAUVER. Did you bring Dr. Iezzoni with you today?

Mr. MCKEEN. Mr. Chairman, may I make a brief statement at this time?

Senator KEFAUVER. I am just asking you. The other day when we met—this is on page 5807 of the record—I said that I hope that "any physician—including doctors associated with Pfizer who were here yesterday, also Dr. Iezzoni, who seems to have been in charge of the clinical testing for Diabinese—might also be present."

Apparently, Dr. Iezzoni was in charge of the clinical testing, and I hoped that you might also bring him down with you today.

Mr. MCKEEN. I will be glad to discuss that with you, Senator, although I would respectfully request that I be per-

[70] For full text, see hearings, pt. 20, pp. 11322 ff.

[71] Hearings, pt. 20, p. 11087. At this time the following exchange occurred:
"Senator KEFAUVER. Did you bring Dr. Iezzoni with you?
"Mr. MCKEEN. No, sir.
"Senator KEFAUVER. Was Dr. Iezzoni in charge of the clinical testing?
"Mr. MCKEEN. No; Dr. Warner is currently in charge of the program.
"Senator KEFAUVER. Wasn't Dr. Iezzoni the one who was in charge of it at the time the clinical testing was made?
"Mr. MCKEEN. He had been, Senator. He has developed a very considerable facility in the ability to evaluate new drugs in animals, and then transfer this evaluation over into human pharmacology, and thence into the clinical program, so he is now on other products.
"Senator KEFAUVER. But I thought he might have information about the clinical testing of Diabinese which might be useful to the committee, if he were here.
"Mr. MCKEEN. I think you will find Dr. Rees and Dr. Warner fully informed, able, and willing to answer any questions that may arise."

mitted to make my statement and Dr. Rees make his statement before you close this morning's session, if we may, please.

Now, with regard to Dr. Iezzoni——

Senator KEFAUVER. Just answer the question: Why haven't you brought Dr. Iezzoni?

Mr. MCKEEN. With regard to Dr. Iezzoni, Dr. Warner is now in charge and has been for some time in direct charge of this clinical program. The product itself and responsibility for it has been shifted from the clinical research group over to the Pfizer Laboratories division.

Senator KEFAUVER. When was that shifted?

Mr. MCKEEN. That was just as the product was launched, Senator.

Senator KEFAUVER. I know, but Dr. Iezzoni was in charge of the clinical testing, was he not?

Mr. MCKEEN. Up to that time he was, sir, yes.[72]

Upon questioning, it developed that the physicians accompanying Mr. McKeen had joined the medical staff of Pfizer subsequent to the clinical testing of Diabinese. Dr. Rees entered the Pfizer employ in July 1958 and Dr. Warner in August 1959. Senator Kefauver remarked:

> * * * the man under whose direction all these 15 volumes of clinical tests were made, who analyzed them, who sent you many memorandums which we have here and which we want to ask about, is Dr. Iezzoni.
>
> These physicians with you didn't even get into the picture until after all this was done.[73]

Despite the substantial information known to Pfizer with respect to side effects as early as the summer of 1958, the company made no attempt to supply this essential material to physicians in its advertising. For example, a typical ad dated May 1959—almost a year after the Iezzoni compilation—contained these words:

> Diabinese is "well tolerated with minimum side effects in the therapeutic range of 100 to 500 mg." Its striking effectiveness and "almost complete absence of unfavorable side effects" have led to the prediction that "Diabinese will eventually prove to be the drug of choice in the sulfonylurea group."[74]

[72] Hearings, pt. 20, pp. 11194–11195.

[73] Ibid., p. 11195. Mr. McKeen replied that Dr. Iezzoni's absence was due to his attendance at medical meetings in Atlantic City. Upon questioning regarding Dr. Iezzoni's failure to appear the previous week of hearings, this exchange took place.

"Senator KEFAUVER. Frankly, we have a great deal of material here that Dr. Iezzoni has prepared. Was he at this meeting last week?

"Mr. MCKEEN. No, sir.

"Senator KEFAUVER. Where was he last week?

"Mr. MCKEEN. I don't know, specifically. I assume that he was working on some other drugs. Whether he was in his office, I couldn't tell you, Senator; but I can assure you that these two men that I have with me are fully prepared to answer any questions that you may ask.

"Senator KEFAUVER. I know, but Dr. Iezzoni is the man who wrote these memorandums—who wrote the report, who wrote the diagnoses, a summary of these 15 volumes—and under whose direction all of this clinical testing was done. There is some unusual reason why you haven't brought him here, Mr. McKeen. I am just trying to find out what it is.

"Mr. MCKEEN. None that I know of, Senator. This is a normal set of circumstances that have evolved, and I know of none." (p. 11196).

[74] Hearings, pt. 20, p. 11215. The ad under discussion is reproduced on p. 11187.

In this connection Senator Kefauver inquired why the information known to Pfizer with respect to side effects had not been supplied to prescribing physicians in the United States.

> Let me say this, Dr. Warner, or Mr. McKeen, a doctor is entitled to the fullest information about this drug or any other drug. I can't understand, frankly, when you have made 2,000 tests and you have unquestionably found 27 percent of side effects according to your own Dr. Iezzoni, and a little larger amount, according to the analysis by Dr. Loube that was carefully done, why you wouldn't give that information to the physicians. They are entitled to the best information they can get * * *.
>
> Will you point out one place in your advertisements where you tell what your own medical examiner found to be the truth? [75]

Mr. McKeen replied, "This is a medical question." After remarking "Dr. Iezzoni is really the man who ought to be here to answer," Senator Kefauver stated:

> I am not asking you a medical question, Mr. McKeen. I am just asking a factual question, if you will point out any place in your advertisements where you gave the doctor full information which he ought to have had, which is the truth, that your own medical examiner—who for some reason you won't bring down here, and I can understand why you won't—found that there was 27 percent side effects in these 2,000 cases.
>
> Just point it out in your advertisements.
>
> Dr. REES. There is no reason to put that in the advertising, Senator.
>
> Senator KEFAUVER. It is a factual matter. You have reviewed the advertisements, Mr. McKeen. I am not asking you a medical opinion. I am just asking you for a factual answer as to where you ever said in brochure form or in articles, technical inserts, or whatever you sent to physicians, where did you ever tell him the truth that your own medical examiner found 27 percent side effects? [76]

Subsequent to the subcommittee's hearings on Diabinese, the package insert (informational material accompanying samples of the drug provided doctors) was radically revised at the request of the Food and Drug Administration. The original package insert first sent out in November 1958 began a brief recitation of side effects with the statement:

> Side effects are generally of a transient and nonserious nature.[77]

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[75] Hearings, pt. 20, p. 11216.

[76] Ibid., pp. 11216-11217. Mr. McKeen replied that information on side effects was contained in the individual reports of investigators. The following exchange occurred:
"Senator KEFAUVER. Let's don't get away from the question.
"Dr. REES. May I answer the question again, please?
"Senator KEFAUVER. Let me state the question again.
"Dr. REES. I know the question. May I answer it?
"Senator KEFAUVER. Just a minute, Dr. Rees. You weren't there at the time. Dr. Iezzoni is not here. This was the clinical investigation on Diabinese which you sent to the Food and Drug Administration in order to get your application approved. Approximately 2,000 cases were studied. The tests were made by people that you had selected to do the clinical testing, to report to your own medical examiner on Diabinese, and they found on the use of Diabinese that there were 27 percent side effects."

[77] For full text, cf. hearings, pt. 20, pp. 11296, 11390, 11392.

This remained unchanged until August 1960 when this section was materially revised. The section now reads in part as follows:

> The therapeutic advantages of Diabinese over tolbutamide must be weighed against a somewhat higher reported incidence of side effects. Jaundice, which has been reported in approximately 4 cases per 1,000, is usually promptly reversible on discontinuance of therapy.[78]

The earlier package insert also related undesirable side effects to size of dosage. It stated:

> A decrease in the Diabinese dose usually alleviates these complaints.

The latest package insert states that "the majority of the side effects have been dose-related" but specifically affirms the fact that some cases may be totally unrelated to the amount of the drug taken. The present language reads:

> The majority of the side effects have been dose-related, transient, and have responded to dosage reduction or withdrawal of the medication. However, clinical experience thus far has shown that as with other sulfonylureas some side effects associated with hypersensitivity may be severe and death has been reported in rare instances.

The kinds of "untoward reactions ascribable to the drug, unrelated to the size of the dose" raise serious questions of the usefulness of Diabinese when another drug performs the same functions without similar side effects. The language in the latest package insert goes on to list the more serious side effects which have been associated with its use:

> Certain untoward reactions associated with idiosyncrasy or hypersensitivity have occasionally occurred. These reactions which may include jaundice, skin eruptions rarely progressing to erythema multiforme and exfoliative dermatitis and probably depression of formed elements of the blood show no direct relationship to the size of the dose. They occur characteristically during the first 6 weeks of Diabinese therapy. With a few exceptions, these manifestations have been mild and readily reversible on the discontinuance of the drug. The more severe manifestations which are infrequent may require other therapeutic measures, including corticosteroid therapy. Diabinese should always be discontinued promptly when the development of sensitivity is suspected.

[78] Files of subcommittee.

PART V

GENERIC NAMES VERSUS TRADE NAMES

In addition to patent controls and the vast amounts spent on advertising and promotion, the control of the market by the large drug companies stems from a third source of power; this is their remarkable success in persuading physicians to prescribe by trade names rather than generic names. Where this is done the small manufacturer is automatically excluded from the market, regardless of whether the drugs are patented or non-patented, and the opportunity for price competition disappears. This state of affairs is furthered by anything which causes the physician to be apprehensive of, or have difficulty in, prescribing by generic names.

Chapter 13. The Confusion of Names

The multiplicity of names for products in the drug industry virtually exceeds the bounds of human imagination. First, there is the chemical name which attempts to spell out the structural makeup of the drug; and here a variety of forms of expression is possible. Next comes the generic name which may or may not represent an abbreviation of the more complex chemical name; this is the name commonly used to identify the drug in formularies, the teaching of medicine, etc. Ordinarily a drug has one generic name, but there are cases where two or three are employed. Finally a drug usually has a host of individual trade names used by the various companies engaged in the promotion of the product. In consequence, a single drug product is represented in the market by such a complex body of nomenclature as to intimidate even the initiates in the field. And if one can visualize this situation for a single drug multiplied by the thousands of drugs currently marketed, he can get some impression of the chaos existing in the area of drug nomenclature.[1]

The new so-called synthetic penicillin illustrates the problem. The chemical name for this product is alpha-phenoxyethyl penicillin potassium. This set of syllables is also used as a generic name. In addition, there are two other generic names—potassium penicillin 152 and phenethicillin potassium. Since the product is protected by patent, there are only six sellers, each of whom markets under his own trade name. Thus the prescribing physician is bombarded with promotional material for Syncillin, Darcil, Alpen, Chemipen, Dramcillin-S, and Maxipen. All of these are, of course, the same chemical

[1] Confusion even extends to the names for these general categories of nomenclature. The generic name is often referred to as the nonproprietary name. Recently the American Medical Association has introduced the word "counterpart" with the same intended meaning. The trade name is also variously described as the brand name or proprietary name.

compound. Speaking of this situation, Dr. Charles O. Wilson,[2] Dean of the School of Pharmacy, Oregon State College, and editor of the American Drug Index, informed the subcommittee:

> A new synthetic penicillin derivative now available provides a perfect example of the difficulties which pharmacists and physicians are having. This compound is available by Bristol as Syncillin and by Wyeth Laboratories as Darcil and referred to by both as potassium penicillin 152.
>
> Schering & Co. which sells it as Alpen, E. R. Squibb & Sons which makes Chemipen, and White Laboratories which produce Dramcillin-S all use the generic name "phenethicillin potassium," Roerig & Co. produces Maxipen and refers to it as alpha-phenoxyethyl penicillin potassium.
>
> Here you have three generic names for the same compound in a matter of 60 days.[3]

All six of these products are marketed as distinctive contributions to the medical arsenal. Speaking of them, Dr. Walter Modell,[4] professor of pharmacology and therapeutics at Cornell University Medical College, stated:

> They are colored differently (pink, peach, green, and two shades of yellow) and are advertised as distinctive materials but no effort is made in promotional material to inform the physician who is urged to use them that they are otherwise all identical.
>
> * * * As a matter of fact, it is virtually impossible, even for experts, always to know all the proprietary synonyms which have been created for the nonproprietary names of the drugs they use. Thus, it is possible in a discussion between two specialists in the same field for neither to know that each is talking about the same drug. Imagine the dilemma this can create for those less expert, the student and the general practitioner.[5]

In this example the busy practitioner is confronted with three generic names, six brand names used as the name of the drug itself, and at least five different colors. Thus, there are 14 different identification symbols for the identical drug. In terms of nomenclature, each product stands isolated; indeed, there is an attempt to conceal the identical nature of the drug.

The confusion created with respect to a single drug is further compounded by a failure to disclose the relationship of two closely similar compounds. The generic name often is not related to the chemical family to which the drug belongs. Dr. Wilson remarked:

> In the selection of generic name for related compounds, many times there is no attempt in the generic name to express this relationship. In other words, if you have two com-

[2] Charles O. Wilson, born Washington, 1911; B.S., 1934; M.S., 1935; Ph. D., 1938; University of Washington. Registered Pharmacist, Minnesota, Texas, Washington, Washington, D.C. University appointments: George Washington University, 1938–40; University of Minnesota, 1940–48; University of Texas, 1948–59; Oregon State College, 1959—, dean, school of pharmacy and professor of pharmaceutical chemistry. Associations: American Pharmaceutical Association, American Chemical Society, etc.

[3] Hearings, pt. 21, pp. 11513–11514.

[4] Walter Modell, born Connecticut, 1907; certified medicine 1941; M.D., Cornell, 1932. Intern, Montefiore Hospital 1933–34; teaching staff, Cornell University Medical College, 1932— (now director of clinical pharmacology and associate professor of pharmacology). Associations: ASPET, SEBM, ACP(F); Member, Revision Committee, U.S. Pharmacopoeia XVI; editor, Clinical Pharmacology and Therapeutics.

[5] Hearings, pt. 21, p. 11602.

pounds that differ only by a slight modification, sometimes there is no attempt to show this relationship. In some cases there is a good relationship between two chemical compounds.[6]

Among the examples he cited was the product marketed by Schering under the trade name Chlor-Trimeton. Schering lists the generic name for this product as chlorprophenpyridamine. A slight modification of this compound is available on the market under the trade name Polaramine; it has its own generic name: chlorpheniramine.[7]

Dr. Solomon Garb, professor of pharmacology at Albany Medical College, drew an interesting comparison in the use of nomenclature between the drug and food product industries. He said:

Some typical brand names of food products are Heinz, Beech-Nut, Quaker, Del Monte, Libby, Campbell's, and so forth.

These brand names are used in an adjectival sense to modify the common name of a product. Thus, the usual name, Heinz beans, tells the customer two things: what the can contains, and who made it. There are many makers of canned beans. All use their brand name in an adjectival sense, and all have the common noun "beans" prominently displayed on their labels.

The pharmaceutical industry does things differently. They use two sets of brand names. The one set consists of the name of the company, such as Lederle, Pfizer, Ciba, and so forth. In addition they add a second brand name by inventing a new name for the product and registering it as a private trademark.

Examples are Diamox, Gantrisin, and so forth. This second brand name causes confusion because it is used as the name of the product.[8]

To illustrate the extent of the confusion caused by this practice, he examined the result that would follow if the drug manufacturers moved into the baked bean industry:

To understand fully the extent of the confusion caused by this usage, let us consider what would happen if drug manufacturers took over the manufacture of baked beans.

They would all stop using the word "beans," and each would give the product a new, coined name. Some might use anagrams of beans, like "Sneabs" or "Nabes," and others might call them "Lo Cals," or "Hi Pro's." Picture the confusion in the grocery store if beans were no longer named "beans," but if each maker gave a completely new name to his product. Further, try to imagine what would happen if there were 300 to 500 additional new names of this type in the grocery store every year.

[6] Ibid., p. 11507.

[7] Hearings, pt. 21, p. 11513. Speaking of a similar situation involving another product, Dr. Wilson remarked:

"Real confusion exists with parabromdylamine, introduced as Dimetane by Robins & Co. The American Medical Association used a new generic name, 'brompheniramine,' in the New and Nonofficial Drugs of 1960. Robins & Co. has an advertisement for Dimetane in the Journal of American Medical Association for Feb. 27, 1960, p. 37, and uses the generic name 'brompheniramine.' In the Mar. 15, 1960, issue of Modern Medicine a Dimetane advertisement refers to parabromdylamine. White Laboratories have the dextroisomer available as 'Disomer' and uses the generic name 'dexbrompheniramine.'

"If you can get any more mixed up than that, I would like to find it."

[8] Hearings, pt. 18, pp. 10480–10481.

> This is approximately what is happening in medicine, and it is becoming exceedingly difficult for physicians to keep things clear.[9]

The problem is especially difficult for physicians because of the difference in emphasis in medical schools and in private practice. Whereas the physician, in the conduct of his practice, is bombarded with promotional material urging him to prescribe specific trade-named products, his medical education is in terms of identifying drugs by their generic names. Professors in medical schools appearing before this subcommittee uniformly testified that this practice was essential to acquaint the student with the nature of the drug and its relationship with similar compounds. For example, Dr. Modell of Cornell University Medical College stated:

> Only a name that conveys meaning lends itself to instructive communication.
>
> * * * * * * *
>
> We could never teach pharmacology if we attempted to cope with the confusion created by proprietary nomenclature.[10]

In 1960 the Subcommittee on Generic Terms of the Los Angeles County Medical Association sent a letter to each of the 82 medical schools in the United States. Within 3 weeks 77 responses arrived from departments of pharmacology of these schools answering these questions:

1. Do you teach the prescription of drugs by generic terms?
2. Do you favor the continuation of this practice?

Sixty-four replied they taught only generic terminology; 3 taught both generic and trade names; 10 used trade names under certain circumstances such as when a drug is exclusively monopolized under a patent. The report states further: "The response from the medical schools was enthusiastically in support of the use of generic terms and their simplification."[11]

The remarkable proliferation of new names, as new drugs are brought on the market, many with several trade names in addition to their generic name, was brought out in an exchange between Dr. Modell and the subcommittee's chief economist:

> Dr. BLAIR. * * * at a minimum there are 300 new generic names with which the physician presumably must familiarize

[9] Hearings, pt. 18, p. 10432.

[10] Hearings, pt. 21, p. 11602. The comments from which these sentences were taken follow:

"As a teacher I have used nonproprietary names for drugs because academically this is the only nomenclature useful for the proper teaching of pharmacology and therapeutics. I think that the academic stand is also the practical one. If a subject is to be taught, the materials with which it is concerned must be identified.

"Only a name which conveys meaning lends itself to instructive communication. Only nonproprietary names always tend to identify the nature of drugs and, therefore, as a general rule, only by using them can one communicate meaningfully about drugs and instruct students on the nature of drugs and their effects on the human body.

"If students of medicine do not learn about the nature of the drugs they use, they cannot know how to use them either safely or effectively when they prescribe them for patients.

"In addition, trademark names often introduce confusion in an already difficult and complex subject by providing more than one name for the very same drug; sometimes there are as many as 25 proprietary names for the same thing, occasionally more.

* * * * * * * * * * *

"As a matter of fact, it is virtually impossible, even for experts, always to know all the proprietary synonyms which have been created for the nonproprietary names of the drugs they use. Thus, it is possible in a discussion between two specialists in the same field for neither to know that each is talking about the same drug. Imagine the dilemma this can create for those less expert, the student and the general practitioner."

[11] Report in files of subcommittee.

himself each year, consisting of the dosage forms which are given new names, the combinations, and the new chemical substances.

Now, if there were only on the average 1 seller and thus 1 trade name for each of these new drug applications approved, that would be an average of, say, 300 new trade names for the doctor to familiarize himself with each year.

But, of course, we know that, as in the case of the combinations and the new chemical substances, it frequently happens that there are two or more trade names for one generic name. Consequently, if there were an average of 2 sellers of each of these 300, there would be 2 trade names for each; and that would give us 600 new names for the physician to become familiar with, presumably, each year.

In the course of 5 years that would mean that the doctor would have to have learned some 3,000 new names. Some, of course, would perhaps have a short life, but even though he might not prescribe the drug himself, a patient might come in for treatment to whom another doctor had prescribed the drug by a trade name. So he would have to either have it in his mind or be able to have a ready reference to the name.

Am I correct thus far?

Dr. MODELL. That is right.

Dr. BLAIR. Then, in addition to these 3,000 in 5 years, there would be an unknown number of cases where the Food and Drug Administration approved combinations of drugs already approved separately in past years.

Thus, we are confronted not with the matter of the doctor having to learn just 50 new names a year, but under the fairly conservative assumptions I have outlined here, of having to learn hundreds of names each year, and in a period of a few years of having to either know or be able to identify and familiarize himself fairly quickly with thousands of new names.

Is that a correct statement of the arithmetic of the problem?

Dr. MODELL. It is absolutely staggering. It really is not within the scope of anyone who doesn't attempt to deal with that subject exclusively, and with nothing else, to really begin to understand the problem.[12]

Dr. Modell saw very real dangers to the patient in the drug manufacturers' sales emphasis on their trade names rather than the generic name of the drug:

> The problem in nomenclature thus also relates to the practice of medicine. No one can practice rational medicine unless he knows what he is giving his patient, because he cannot otherwise anticipate all the possible actions from and reactions to the drug. If a physician wants to know at all times what he is prescribing, he will, perforce, use only nonproprietary names.[13]

[12] Hearings, pt. 21, p. 11628. Dr. Modell went on to add that the New York hospital, one of the largest in the world, is "prepared to treat all diseases including the most unlikely to come to our hospitals" with only 359 drugs (Ibid., p. 11629).

[13] Ibid., pp. 11602–11603.

The multiplicity of drug names, according to Dr. Modell, is an ever-present source of confusion:

> The possibility of confusion is something that is always a specter. With the multiplicity of names, there is always a possibility of someone or other getting confused.
>
> So many of the names are so similar, especially in the short, attractive names which compete with the names for detergents and that sort of thing on the market. This is something that worries us greatly.
>
> The fewer drugs we have, the less the chance for confusion.[14]

In addition to the danger of confusion there is also the danger of over-reliance on the detail men. Dr. Modell remarked:

> * * * there are two dangers. One is the danger of not giving the patient the best drug available, and I think that that is a considerable danger.
>
> If one is to take the word of the detail man, then he will prescribe whatever the detail man provides. He will not, therefore, know what the best drug available is, but he will give what he has been instructed to give, so that he may be depriving his patient of the best medication. I consider that a danger.
>
> The other is the danger of confusion. In confusing one drug for another, there is a danger of real accident and disaster. I might say that accident and disaster from treatment is not a rarity.[15]

Dr. Dowling was of the opinion that use of generic rather than brand names would have an educational effect upon prescribing physicians:

> * * * nonproprietary names should be emphasized more than they are at present. The nonproprietary name is usually a shortened version of the chemical name and, therefore, has a meaning which the proprietary name usually does not have.
>
> Senator KEFAUVER. Excuse me, nonproprietary as you use it there is generic?
>
> Dr. DOWLING. The so-called generic name. Generic is really not a correct name for it, but we use the name generic.
>
> * * * * * * *
>
> Furthermore, the nonproprietary names of analogs are usually similar, thus helping the physician to classify the drug in its proper group.
>
> The use of the nonproprietary name is educational as well as regulatory in its function. The physician would thus be put on the alert to determine whether a new modification of

[14] Hearings, pt. 21, p. 11629.

[15] Ibid., p. 11607. Dr. Modell saw "grave dangers" in the "postgraduate education of physicians" by drug companies. He said:

"* * * and I am sure, if nothing is done about it, the manufacturers will be quite happy to take care of it [postgraduate education of doctors] completely. * * * the danger there is that it is as biased as it can be, and, as a result, one not only gets a one-sided picture, but gets a completely uninformative picture of the field.

"One cannot teach about a drug without covering the entire field, and no manufacturer in this detail man's educational program ever discusses anything but his own drug.

"So it gives only a one-sided picture. It is completely biased. It doesn't show the whole field, and it certainly doesn't constitute what we consider teaching" (pp. 11606–11607).

an existing drug was superior to, the same as, or even inferior to the drug already on the market.

He would be less likely to switch to the newest drug in his prescribing, unless the newest drug represented a real advance.[16]

All ethical drugs, whether marketed under generic or trade names, must meet the minimum standards of the United States Pharmacopoeia or the National Formulary. By law, a drug is deemed to be adulterated if, when sold under or by a name recognized in either compendium, it differs from the standard of strength, quality or purity, as determined by the test laid down in the United States Pharmacopoeia or National Formulary.[17]

The U.S.P. compendium of drugs, listed only by generic name, has appeared regularly since 1820; and at the time of the passage of the U.S. Food, Drug and Cosmetic Act in 1906 it was made the official compendium for the enforcement of the act. The U.S.P. also serves the same purposes for similar legislation at the State level.

Dr. Lloyd C. Miller,[18] director of revision, United States Pharmacopoeia, explained the function of his organization as follows:

> The object of a pharmacopoeia was set forth in the preface of the 1820 pharmacopoeia, and remains the same today. In short, the pharmacopoeia over the years has provided a list of those therapeutic substances that reflect the best practice and teaching of the healing arts and has endowed them, in published form, with standards of identity, strength, and purity that are creditable and firmly grounded on scientific fact. The fulfilling of this objective ever more completely in successive revisions has steadily increased the service rendered to the public and the health professions.[19]

It is of interest that the authority for the U.S.P. program rests in the hands of a private, nonprofit organization. The United States Pharmacopoeial Convention, Inc., meets regularly every 10 years; its membership is composed of colleges of medicine, colleges of pharmacy, agencies of the Federal Government, State and national medical and pharmaceutical organizations.[20] At these meetings the members elect a committee of revision consisting of 20 experts from medicine and 40 from pharmacy and the allied sciences.[21] The committee of revision is responsible for drafting and revising the U.S.P.; new

[16] Hearings, pt. 24, pp. 14172-14173.

[17] Cf. sec. 201(j) and 501(b) Federal Food, Drug and Cosmetic Act.

[18] Lloyd C. Miller, born in Illinois, 1907; Ph.D., University of Rochester, 1933. Research fellow, the Upjohn Co., 1933-35; pharmacologist, Division of Pharmacy, U.S. Food and Drug Administration 1935-43; Director of Biological Division, Sterling-Winthrop Research Institute, 1943-50; director of revision, U.S. Pharmacopoeia 1950—. Associations: New York Academy of Sciences (fellow), American Society of Pharmacology and Experimental Therapeutics, APA, ACS.

[19] Hearings, pt. 21, p. 11662.

[20] Hearings, pt. 21, p. 11662. He explained:

"The convention is virtually recreated for each decennial meeting, although the organizations entitled to membership remain substantially the same. These include the 79 accredited colleges of medicine, the 76 colleges of pharmacy, 7 agencies of the Federal Government, the State medical and pharmaceutical associations, and 12 national professional associations and societies in the fields of medicine and pharmacy. Thus, a total of 277 were entitled to representation in the 1960 meeting held recently; of this number, 194 exercised their franchise by sending delegates."

[21] Ibid., p. 11663. He elaborated:

"The 60 members of the committee of revision are elected by ballot from 120 nominees, who need not necessarily be delegates to the convention, who are selected to provide every type of skill and knowledge required in the U.S.P. revision program. Thus, the committee includes specialists in anesthesiology, cardiology, surgery, and other branches of medicine; and pharmacists, bacteriologists, analytical chemists, and other specialists in various branches of the actual practice of pharmacy. The committee is organized into subcommittees, each charged with definite responsibility for some phase of the revision program."

editions appear every 5 years. Speaking of the committee's function, Dr. Miller stated:

> Since the value of the Pharmacopoeia lies in large measure in the selective list of drugs that it presents, the first phase of the revision receives most painstaking attention. It is mainly in the hands of the 20 physicians elected to the revision committee, who are assisted by pharmacists fully familiar with the pharmaceutical forms of the drugs under consideration. The resulting list consists of those drugs and their dosage forms that are believed to represent the best practice and teaching of medicine. This selection process continues right up to press time. Obviously, U.S.P. status is not accorded to every new drug developed.
>
> We come now to the second phase. While the selection phase is still proceeding, the U.S.P. subcommittees concerned with drafting the standards begin their work. Proposed or provisional standards are put to actual laboratory test under the supervision of a member of the U.S.P. Committee of Revision and the final standards are set accordingly.
>
> The work of the third phase, that of the actual publication, is shared as widely as possible by distributing proof copy to the entire revision committee and, in addition, to a large number of other scientific and technical experts. The comments thus received are taken into account in settling on the final text. The task of guiding the text through the various stages of printing is handled from U.S.P. headquarters.[22]

For decades the U.S.P. standards have been held in high esteem both within the medical profession and in the drug industry. This general view is reflected in the following statement made by Dr. Modell:

> * * * There is a level of purity that is consistent with proper application in medicine. These standards are set by the United States Pharmacopoeia or they are incorporated into the National Formulary * * *.
>
> Now there is no purpose in making medication purer than the standards set by the United States Pharmacopoeia. The pharmacopoeia has certain tolerances, and it permits these because this is a practical matter.
>
> Purification beyond these tolerances adds greatly to the expense and adds nothing to the efficacy of the medication and in no way interferes with the medication and causes no reactions.
>
> If these so-called impurities were in any way deleterious, the United States Pharmacopoeia standards would be elevated accordingly. It is a matter of fact that the United States Pharmacopoeia standards are not only high enough, but they are the highest of all pharmacopoeial standards.[23]

He added:

> I don't know of any manufacturer that claims to have purer drugs than the United States Pharmacopoeia standards. But even if they did, I don't see that it would matter. It

[22] Hearings, pt. 21, pp. 11662-11663.
[23] Hearings, pt. 21, p. 11610.

is not a basis for the choice of the drug. It adds nothing to its usefulness.[24]

Similar in character to the U.S.P. is the National Formulary, which is published every 5 years by the American Pharmaceutical Association, the professional organization of pharmacists in the United States. A major function of the N.F. is to carry for at least a 5-year period all drugs which are dropped from U.S.P. This is to maintain standards for drugs removed from U.S.P. but which are still in use in this country.

Chapter 14. The Promotion of Trade Names

Efforts to promote the use of trade names and discourage generic names have been carried out by the drug companies acting individually and in concert. A practice which they individually carry out is the coining of generic names so complex and unpronounceable as to virtually prohibit their use in the writing of prescriptions. Then their spokesmen cite this complexity as a necessary reason for the use of trade names. Thus, a number of witnesses for the major drug companies sought to defend their increased sales emphasis on brand names on the ground of convenience to prescribing physicians. Generic names, it was argued, are often long, complicated and difficult to pronounce; the brand names have all the obvious advantages of simplicity. Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association, asserted that generic names "tax the memory of most of us." These names, he said, are:

> * * * chosen on the request of physicians and others who are interested in proper nomenclature because it has always been contended, by the Council on Drugs, by the United States Pharmacopoeia, and by the International Pharmacopoeia of the World Health Organization that a generic name should indicate in some way the chemical structure of the compound.[25]

The position of other medical experts was to the effect that the generic name is not selected on the basis of "requests of physicians and others who are interested in proper nomenclature" but rather the choice is made by the manufacturer himself; usually it is picked "quite early during the clinical trial before marketing." [26] Dr. Garb placed in the record a letter from the American Medical Association in response to his inquiry Concerning the selection of generic names by the AMA Council on Drugs. The AMA stated that—

> United States pharmaceutical manufacturers are encouraged to submit as early as possible for the council's consideration a name * * *[27]

Dr. Miller of the United States Pharmacopoeia gave a detailed picture of the development of a generic name for a new drug. In the initial

[24] Ibid., p. 11611.
[25] Hearings, pt. 19, p. 10623. He explained further:
"In this way a physician or anyone else, if he reads the label or the literature, will have some way of knowing the nature of the substance and will be able to translate it into terms of therapeutic efficacy. When it comes to prescribing, the trade name on the right is the one that suits his convenience because he too is interested in time and motion, and time and motion is very important when you are seeing 25 or 30 or more patients a day" (pp. 10623–10624).
[26] Hearings, pt. 21, p. 11498 (Dr. Wilson).
[27] Hearings, pt. 18, p. 10589.

period of testing a drug, he stated, usually a code name is used; then, just prior to describing it in the medical and scientific literature, the drug company concocts a generic name which is submitted to the AMA for approval. The AMA Council on Drugs then transmits this name to several agencies, including the United States Pharmacopoeia, for approval.[28] He stated:

> * * * we are given a period of 3 weeks in which to express a view on it, and after that time the name becomes final in the view of the AMA Council.
>
> Then, from that time on, that name is associated with that drug in the publications in the scientific literature, medical, pharmacological and chemical.[28]

It may happen, however, that the drug manufacturer does not choose to submit his proposed generic name to the AMA. The latter acts only upon the voluntary request of the manufacturer. Or, if the manufacturer decides to make his submission and then is dissatisfied with any recommendation that the AMA might make, he is still free to continue with his own selection.[29] No agency of Government has any responsibility in this area; indeed, the Food and Drug Administration does not hear of the selection until approval is sought for marketing of the new drug.

Not only are the generic names creations of the drug companies themselves, but after making them complex and unpronounceable, these same companies proceed to cite their complexity as an argument for the use of their simpler trade names. In this connection Dr. Garb remarked:

> * * * we observed that drug company representatives often tried to claim that the drug companies deserve some special credit for inventing simple brand (coined-product) names. According to them, generic (official) names are so complex and unpronounceable that the companies are doing the doctor a favor by making up simpler names.
>
> I believe a similar argument has been presented before this committee. However, there is no merit to that argument, since the drug company is usually responsible also for the complex generic name.
>
> * * * * * * *
>
> However, since he is largely responsible for the name, it seems unreasonable for him to criticize its complexity.[30]

[28] Hearings, pt. 21, p. 11675.

[29] Ibid., p. 11499. Dr. Wilson stated:

"The American Medical Association will cooperate only if asked by the company, or in conjunction with their New and Nonofficial Drugs or with advertising in one of its journals. In the large majority of the cases, the producer—pharmaceutical manufacturer—determines the generic name.

"When the American Medical Association considers a name for their New and Nonofficial Drugs, it often selects a generic name different from that which was originally used, thus adding to the confusion. I have examples later in the paper.

"The manufacturer does not have to use this new generic name selected by the NND. Experience has demonstrated that the American Medical Association or the U.S.P. have taken very little part in determining generic names and in all fairness, I must say that both organizations are virtually powerless to influence the selection of less lengthy and less unwieldy names."

Cf. also, Dr. Harry F. Dowling, "What's in a Name?", J.A.M.A. Aug. 6, 1960, in which he says:

"The Council on Drugs attempts to obtain the agreement of the manufacturer so that the manufacturer will use the name selected. In most cases the manufacturer is cooperative; sometimes he is not. In the latter event, the council has no control over the name used except in articles and advertisements which appear in publications of the American Medical Association" (reprinted in hearings, p. 11868).

[30] Hearings, pt. 18, pp. 10482-10483.

Dr. Meyers was of the same opinion:

> In any case, the designation of generic names should be taken out of the hands of the drug trade. At the moment, they nominate the names and are in a position to make them as noneuphonious as possible.[31]

When Senator Kefauver stumbled over the pronunciation of some sample generic names, Dr. Meyers said:

> I would say isocraboxazid, prochlorperazine, piperiodolate, thiopropazate, and thioridazine. Even though I am, so to speak, paid by the university to maintain a familiarity with these, I find it much easier to use Librium, Marplan, Compazine, Dactil and Dartal, in spite of the similarity in names, and Mellaril.
>
> * * * * * *
>
> The company nominates the name. It can be reviewed, I think, by the Council on Drugs of the AMA. And there is, I am tempted to say, a nominal review by the World Health Organization. In practice, the industry is pretty much allowed to nominate the name on the basis of a real or fancied relation to the chemical name. They can take syllables from any part of the chemical name.
>
> * * * * *

Dr. Wilson drew an interesting comparison between the development of generic names in pesticides as opposed to the method of selection—or rather, its absence—in the pharmaceutical field. In pesticides, the initiation of a generic name may come from any source, including the manufacturer, formulator, distributor, or noncommercial organizations. However, he stated, the final selection is based on cooperative consideration by the various industrial, scientific, and professional organizations which share a common interest in the employment of a pesticide. Some of the guides they follow are:

> 1. Name should not conflict with other generic brand names.
> 2. Name should be short.
> 3. Name should be distinctive.
> 4. Name should be easily spelled.
> 5. Name should conform to accepted scientific terminology wherever possible.
> 6. Name should apply to the pure basic chemical in order to avoid multiple and dissimilar names for salts, esters, isomers, homologs, dosage forms, and other variations of the parent compound. These latter variations should use the original generic name as a basis for developing new generic names.[32]

In the more significant area of drugs for human use, however, deliberate chaos appears to reign. Here, according to Dr. Wilson, "observations of most generic names in use would lead us to believe"

[31] Hearings, pt. 18, p. 10401.
[32] Hearings, pt. 21, p. 11503.

that the set of guides employed by the drug manufacturers might read as follows:

1. No suggestion as to the chemical formula.
2. No suggestion as to the use of the compound.
3. No relationship to the brand name.
4. Usually have name composed of several syllables.
5. Best if name is long and awkward.
6. Name should be reasonably difficult to pronounce.
7. Name should not be as "catchy" as the registered proprietary name.
8. Name should not be conducive to memorization.
9. Spelling of the name should not be too easy.
10. If similar molecules have a generic name, the generic name for this one should be different.
11. Even if a common name for the substance already exists, a new generic name might be advantageous.
12. When a generic name is available for a compound in the racemic or d–l form, a different generic name might be used for dextra or levo forms; for example, chlorpheniramine, amphetamine.[33]

The drug companies employ a number of other practices which have the effect of minimizing the use of generic names. A common device used in much of the promotion material is printing the trade name in large letters while the generic name is shown in such small letters as to be virtually unreadable. Other devices employed are placing the generic name in an unlikely spot on the ad where it cannot be discovered without careful examination, or omitting the generic name entirely for the full chemical formula.[34]

With reference to these practices, Dr. Dowling said:

> The present food and drug laws provide that the common or usual name of a drug should be given equal prominence with that of the trade name. The Food and Drug Administration has not interpreted this to mean that the nonproprietary name appear in the same size type as the trade name. I believe that the same size type should be required for both names in the label and in the circular accompanying the package, as well as in advertising that is mailed to the physician. This simple measure would help educate the physician as to the proper names of the drugs he uses and could pave the way for editors to establish the same requirements in advertisements in medical journals.[35]

[33] Hearings, pt. 21, p. 11499.

[34] Cf. hearings, pt. 18, p. 10493, where Dr. Garb stated:

"A second abuse is the attempt to imprint the brand name, private product name, on the doctor's mind, while making it difficult for him to discover the generic name. Usually, this involves large letters for the brand name and small letters for the generic name.

"Here is an example which I think is about the average for the industry. The brand name is in very large letters and the generic name is in much smaller letters.

* * * * * * * * *

"In this other ad, sir, I contend that it is difficult to find the generic name, sir, which is a parabromodylamine maleate, and appears in two places. I was only able to find it in one place. Somebody showed it to me in the second place. I think most doctors would have a great deal of difficulty in finding the generic name in that ad."

Cf. also Hearings, pt. 19, p. 10931, where Dr. Austin Smith found it impossible to locate the generic name on an advertisement until aided by a magnifying glass proffered by the subcommittee counsel.

[35] Hearings, pt. 24, p. 14173.

COLLECTIVE ACTIVITIES: THE NATIONAL PHARMACEUTICAL COUNCIL

In addition to individual action to reduce the effectiveness of generic names, the drug manufacturers have engaged in group effort. In 1953 the National Pharmaceutical Council was formed with the support of the leading members of the industry.[36] A number of high-sounding goals were the avowed purpose of its formation.[37]

New concept of "substitution".—One of the first efforts of the National Pharmaceutical Council was addressed to securing a new definition of "substitution." From the earliest days substitution in the drug trade has meant the selling of a wrong medicament—aspirin, say, instead of the antibiotic prescribed. The NPC has been markedly successful in putting over its new concept that substitution exists if another trade name of the identical drug is used in place of the particular trade name prescribed. Dr. George F. Archambault, Chief of the Pharmacy Branch, Division of Hospitals, U.S. Public Health Service, describes the situation as follows:

> Some 28 years ago when I started to practice pharmacy, "substitution" meant one thing—the dispensing of a wrong chemical or drug, one different from that prescribed. Only occasionally did we hear "substitution" then being applied to trade versus official name substances.
>
> * * * * *
>
> Today, a new concept of substitution is being proposed. Its proponents seek legislation to make criminal the dispensing of prescriptions or medication orders of a brand other than that called for on the prescription, even when the physician has given a blanket or prior consent or authorization for dispensing by generic name. In other words, some would say that the physician cannot prescribe by generic name unless he has the pharmacist call him each time, after the order or prescription has been written, in spite of having given prior blanket authorization.[38]

In the furtherance of its "antisubstitution" program, an elaborate "educational" campaign was mapped out by officials of NPC. Much of this was focused upon the State boards of pharmacy who exercise

[36] Abbott Laboratories; Ames Co., Inc. (subsidiary of Miles Laboratories); Bristol Laboratories, Inc.; Burroughs Wellcome & Co. (U.S.A.), Inc.; CIBA Pharmaceutical Products, Inc.; Geigy Pharmaceuticals; Hoffmann-La Roche, Inc.; Lederle Laboratories (subsidiary of American Cyanamid); McNeil Laboratories, Inc.; Mead Johnson & Co.; Merck Sharp & Dohme, Division of Merck & Co., Inc.; The Wm. S. Merrell Co. (subsidiary of Vick Chemical Co.); Ortho Pharmaceutical Corp. (subsidiary of Johnson & Johnson); Chas. Pfizer & Co., Inc.; Pitman-Moore Co. (subsidiary of Allied Laboratories); Schering Corp.; G. D. Searle & Co.; Smith Kline & French Laboratories; E. R. Squibb & Sons, Division of Olin Mathieson Chemical Corp.; The Upjohn Co.; Warner-Chilcott Laboratories (subsidiary of Warner-Lambert); and Winthrop Laboratories, Inc. (subsidiary of Sterling Drug) (hearings, p. 21, pp. 11692–11693).
Neither Eli Lilly nor Parke, Davis has ever been associated with the NPC, and Wyeth Laboratories, once a member, subsquently withdrew (ibid., p. 11715).

[37] Mr. Newell Stewart, executive vice president, stated their purposes are:
1. To benefit public interest by promoting the highest professional standards in the manufacture, distribution, and dispensing of prescription medication and other pharmaceutical products.
2. To benefit the pharmaceutical industry by promoting public relations programs on behalf of pharmacists and others in the industry.
3. To promote the interests of the public, physicians, pharmacists and others in the pharmaceutical industry by encouraging the highest standards of ethics and integrity in the manufacture, distribution, and dispensing of prescription medication and other pharmaceutical products.
4. To collect and disseminate information concerning laws, regulations, and governmental agencies dealing with the manufacture and distribution of prescription medication and other pharmaceutical products as a contribution to the better understanding thereof in the public interest (hearings, pt. 21, p. 11693).

[38] "The Formulary System Versus the New Concept of 'Substitution' ", in Hospitals, Journal of the American Hospital Association, Feb. 1, 1960, reprinted in hearings, p. 21, pt. 11797 ff.

major regulatory powers with respect to pharmaceuticals in the various States. The NPC board of directors formulated its program on December 15, 1955, as follows:

> 1. Interview with State boards of pharmacy relative to their organization, rules of procedure, activities, and authority with respect to substitution under existing law.
> 2. Requesting boards of pharmacy to take action against substitution where the board has the required power.
> 3. Assisting boards in the preparation and recommendation for adoption of legislation to give boards the necessary power if they do not presently have it. In supporting such legislation, the NPC administrators will not engage in lobbying within the meaning of Federal or State legislation.
> 4. Compiling and furnishing to boards of statistics on the prevalence and dangers of substitution.[39]

A campaign was also worked out "to explain the substitution problem" to physicians, pharmacists, pharmacy students, and the public generally.

Mr. Newell Stewart, executive vice president, NPC, and his associates who testified at the hearings insisted that their activities did not constitute lobbying. It developed, however, that staff members, although not formally appearing before State boards of pharmacy, did meet with members privately, conducted an enormous correspondence with them, and achieved a remarkable success in obtaining adoption of regulations in which the NPC definition of substitution appeared verbatim or in a paraphrased form satisfactory to NPC.

Those relations with State boards of pharmacy were summarized thus by Mr. Stewart:

> The representatives of the council do not appear before any legislative committee, nor do we submit statements to such committees. The staff has, however, visited with boards of pharmacy and other groups and has attended meetings and talked about the problem, encouraging pharmacists to cooperate with the board of pharmacy in each State to eliminate this evil.
>
> Our relations with State boards of pharmacy are these. We do not appear before them. We do not file complaints with them or receive reports of decisions from them. We do what we can to urge them to be effective agencies of the State in stamping out substitution and other frauds of pharmacists licensed by them. We try to help them to be good law enforcement agencies.[40]

The extraordinary success of this campaign was disclosed in the subcommittee hearings. At the time of the organization of the NPC in 1953 there were only four States with any kind of antisubstitution laws. By early 1959 the NPC could congratulate itself upon the fact that, "thanks to the efforts of this group," there were now 44 States which have "proper regulations to insure faithful filling of the physicians' prescriptions."[41]

The first success of the NPC was achieved in South Dakota. The June 6, 1955, issue of American Druggist credited NPC with providing

[39] Hearings, pt. 21, p. 11697.
[40] Hearings, pt. 21, p. 11698.
[41] Hearings, pt. 21, p. 11713.

the definition from which the South Dakota regulation was adapted, and described that action as "the first official action at the State level to grow out of NPC's Antisubstitution Committee." It stated that the NPC committee definition would serve as a yardstick to State pharmacy boards and pharmaceutical associations in dealing with the substitution problem. Further, American Druggist said, NPC had received 10 similar requests and was "processing" them.[42]

Mr. Stewart's report to his directors of June 27, 1955, did not describe the South Dakota board's action as an adaptation. He recited the NPC definition which he furnished to the South Dakota board, and says: "This resolution was passed at the last meeting of the South Dakota board." [43]

Another success was in Colorado. In October 1956 an official of the Colorado Board of Pharmacy reported at a convention of the National Association of Boards of Pharmacy and the American Association of Colleges of Pharmacy on the helpfulness of NPC in supplying a definition of substitution and of his board's adoption of it.[44] Quick results also occurred in Arkansas.[45]

Notwithstanding these successes in persuading public regulatory bodies to do what the drug manufacturers desired, the NPC witnesses stoutly insisted at the hearings that they did not lobby.

> Mr. STEWART. We do no lobbying of any kind.
>
> Mr. DIXON. You didn't consider what you were doing lobbying?
>
> Mr. STEWART. No, sir. We weren't appearing before any legislative body.
>
> Mr. DIXON. But you talked to the key people, did you not?
>
> Mr. STEWART. Not in the legislature; no, sir.[46]

The organization, it was asserted, merely conferred with officials of the State boards of pharmacy and various State associations. The conversation continued:

> Mr. DIXON. But in the pharmacy boards?
>
> Mr. STEWART. Oh, yes.
>
> Mr. DIXON. That would make it a request of the legislative body, would it not?

---

[42] Hearings, pt. 21, p. 11817.

[43] The resolution reads as follows:

"The furnishing or dispensing of a different drug, or a different drug product, or a drug product of a different manufacturer or distributor, in place of the specific drug, brand of drug or drug product ordered or prescribed, by any person holding a certificate of registration shall be evidence that such person is incompetent or otherwise lacking in the necessary qualifications to perform the duties of a registered pharmacist and shall constitute grounds for the revocation of such person's certificate of registration." (Ibid., p. 11817.)

[44] The definition was as follows:

"Substitution is the dispensing of a different drug or brand of drug ordered or prescribed without the express permission of the prescribing practitioner."

The Colorado official stated:

"This definition was adopted by the board of pharmacy and we were most grateful for the help given us by the National Pharmaceutical Council, Inc. Previous to this, we did not have a definition of substitution either in our laws or in the form of a resolution. A close examination by the other boards in this district might reveal the same situation that we found and be helpful in amending their resolutions or laws to properly cope with the situation, should they need it." (Ibid., p. 11823.)

[45] The secretary of the NPC wrote the secretary of the Arkansas State Board in August 1955 (hearings, pt. 21, p. 11826):

"As you will recall, we discussed the possibility of your board promulgating a regulation specifically covering "substitution" and you indicated that you would present the matter to the board if we could supply the suggested wording of such a regulation. I am enclosing a proposed amendment to rule 9 of your present rules and regulations adopted June 1, 1953, which may serve the purpose.

"If your board should see fit to adopt this amendment or some other regulation on the subject, will you please notify me so that we can note it on our records."

[46] Ibid., p. 11725.

Mr. STEWART. The boards generally don't make requests of legislative bodies. That is generally done by the State association. The boards of pharmacy are an instrumentality of the State.

Mr. DIXON. But you talk to the State associations.

Mr. STEWART. Certainly, yes.

Mr. DIXON. When you wanted this legislation passed, you went to State associations and urged them to do it; is that correct?

Mr. STEWART. That is right, and still do.[47]

The NPC policy of working through others to obtain desired action from State legislatures was applied in obtaining from the New York Board of Regents the adoption on February 24, 1956, of a new paragraph making unauthorized substitution cause for revocation of the registration of a pharmacist.[48]

Attack on hospital formularies.—Another fertile field that has invited the talents of the National Pharmaceutical Council is the long-established formulary system used in many hospitals throughout the country. Under this practice, hospitals make their purchases in terms of generic names; all physicians making use of their facilities signify in writing their willingness to have such drugs employed on their patients even if prescriptions actually specify trade names.[49] In this country the hospital formulary was adopted at the New York Hospital in New York City as early as 1816. At that time trade names were virtually unknown; the hospital's interest was primarily in insuring a rational drug therapy. This view still prevails.[50]

In addition, with the tremendous expansion in the use of trade names in recent years, another factor has been added. That is the economy that can be effected in the hospital's operation through use of the formulary system. By purchasing in terms of generic names, competitive pricing can often be secured for nonpatented drugs. Both large and small companies vie for this business; and the large manufacturers have found that if they are not to lose out, they must set their prices at the lower level of their smaller competitors. Even aside from patented drugs, on which competitive prices can rarely be

[47] Idem.

[48] The means used to accomplish this and the program for the future, although somewhat complex, were stated with admirable economy by Mr. Stewart:

"The procedure for the approval of the new paragraph originated in discussions we held with Mr. Leslie Jayne, the former secretary of the board of pharmacy. He, together with Mr. Nicholas Gesoalde, secretary of the New York Pharmaceutical Association, presented the idea to the association's executive committee, which in turn referred it with their recommendation to the contact committee of the association, and through them to the board of regents" (hearings, pt. 21, pp. 11821–11822).

[49] Hearings, pt. 21, pp. 11566–11567. Dr. August H. Groeschel, associate director of the New York Hospital, stated:

"In the interest of providing the best possible patient care, the medical staffs of many hospitals have pursued a program of objective evaluation, selection, and use of medicinal agents in the hospital. This is the hospital formulary concept which is the generally accepted method of providing rational drug therapy in hospitals and has been accepted as such over the years by physicians, hospital administrators, and hospital pharmacists.

"A valid hospital formulary program is based upon four things:

"(1) Its approval by the organized medical staff of the hospital;

"(2) The consent of individual medical staff members;

"(3) The functioning of a properly motivated pharmacy and therapeutics committee (sometimes known as the formulary committee) of the medical staff; and,

"(4) Acceptance of the use of official or nonproprietary terminology (sometimes known as generic terminology)."

[50] Ibid, p. 11566. Dr. Groeschel explained:

"Good hospitals try to marshall and organize the best professional skills and judgment available to provide care and treatment of patients. The treatment of these patients in many cases is dependent upon the use of drugs.

"However, the multiplicity of new and unproven drugs available today makes it mandatory that, insofar as medications are concerned, a special program of activity be developed within the hospital to insure that patients receive the best care and protection possible."

obtained, substantial savings are still possible. Dr. August H. Groeschel, associate director of the New York Hospital, estimated that, on total annual purchases of $500,000, another $250,000 would be added to the cost if purchases were made on the basis of trade names.[51]

The NPC recognized that the problem was not an easy one. Conferences were held among representatives of drug manufacturers; appointment was made of a hospital practice committee; and overtures were begun to hospital administrators and hospital pharmacists seeking "cooperation." A memorandum in the NPC files dated February 1957 indicates the extent of the "serious problem" in hospital pharmacies. For one thing, "hospital pharmacists themselves do not consider their practice of supplying so-called equivalents as being 'substitution.'" [52] For another, formularies "are here to stay"; it was realistically admitted that they will "eventually be adopted in all hospitals of any size." The problem of how to tackle this problem in terms of new regulations was a ticklish one; [53] and even the launching of an "educational program" had its difficulties.[54]

Mr. William E. Woods became director of hospital relations of NPC in 1958. His job description throws illuminating light on the functions of this new office:

> To work continually toward effecting the validity of brand name specification and to attempt to make the honoring of brand name specifications an integral part of ethical pharmacy practice in the hospitals;
>
> To slow up, if not to stop, the trend of more and more hospitals adopting a compulsory formulary system; . . .[55]

The methods employed to further these ends are interesting. Dr. August H. Groeschel was asked if "a campaign of threats and intimidation" were employed against hospitals and hospital pharmacists using the formulary system. He replied:

> In my opinion, very definitely. However, if you ask me to produce a threat made against myself or my pharmacist or the hospital pharmacist, it is not done that way. It is done on the basis of these speeches, papers, and so forth.

He cited as an example a booklet containing addresses delivered at the "NPC Pharmacy Education Industry Forum" in Princeton,

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[51] Hearings, pt. 21, pp. 11574–11575:
"Senator KEFAUVER. Can you give us any estimate of the amount of money that might be saved by the purchase of a good formulary drug on competitive bidding rather than having to pay the high price that is charged by some of the companies under trade names?
"Dr. GROESCHEL. Senator, I asked our pharmacist, who is a very able fellow and who has followed this thing very carefully, for a conservative estimate of this.
"We purchase approximately a half million dollars worth of drugs every year. I asked him what it would cost the hospital if we were not to operate our formulary and were forced to use trade names in the manner which has been pushed by the National Pharmaceutical Council. He told me that conservatively it would cost us another quarter of a million dollars a year. This is a lot of money.
"Senator KEFAUVER. In other words, instead of $500,000, conservatively it would cost another $250,000?
"Dr. GROESCHEL. Exactly."

[52] Hearings, pt. 21, p. 11835.

[53] Idem:
"1. Very few State boards of pharmacy have adequate jurisdiction. A study is to be made of all State laws to determine whether NPC should cooperate to obtain more adequate regulation.
"2. Hospital pharmacists apparently prefer regulation by the board of pharmacy and probably would look with favor upon any activity which would elevate their standing and the practice of hospital pharmacy."

[54] Idem:
"1. While there is agreement as to the value of such a program, there is disagreement as to whom should be educated—the hospital pharmacists, the physicians, or the administrators. There is a reluctance to go over the pharmacist's head as often he orders the drugs. However, there is a feeling the physician is not too happy with his position in the middle and does not realize or condone the practices which are carried on in the guise of economy."

[55] Hearings, pt. 21, p. 11760.

N.J., in August 1959: A speech by the general counsel of Hoffmann-La Roche stated:

> As a consequence we are faced with the question—do these formularies constitute substitution? The technical answer, of course, is yes. State boards of pharmacy are becoming increasingly aware that it is objectionable substitution under existing law in many jurisdictions.

And Dr. Groeschel commented:

> I would assume that this would be enough to scare any number of pharmacists.[56]

A speech by Mr. Woods in which he raised questions as to the propriety and legality of generic name filling of prescriptions in hospitals received wide attention in the hospital field, causing uneasiness among hospital administrators and pharmacists. These questions were as follows:

> Does the dispensing of a drug or brand of drug other than the one ordered by the physician, even where a hospital formulary exists, operate to place liability on the hospital or any of its personnel when the personal injury liability is being litigated?
>
> Does the hospital acting through the pharmacy and therapeutics committee have the legal power to authorize a hospital pharmacist to dispense a drug or brand of drug other than the drug or brand of drug prescribed?
>
> How can a board of pharmacy allow hospital pharmacists to dispense a drug or brand of drug other than the one prescribed without the board being accused of using a dual standard for pharmacy law enforcement?[57]

The possibility of a compromise position was outlined in a memorandum of an official of Pfizer in 1957 suggesting that, in view of the fact that the medical staff of a hospital concurred in the use of the formulary, there was a "degree of vulnerability" in the NPC's position that its use constituted substitution. However, he thought the argument could be made to stick against the visiting staff of a hospital, although this compromise should be held off as long as possible:

> This does not apply to the visiting staff in most instances. Since members of the visiting staff are responsible for treating most patients, they represent the largest potential for drug sales. Therefore, it appears that one solution might be agreement to limit the use of the formulary system to the full-time staff, permitting the visiting staff "brand preference." This latter course of action will not be considered until all other possible solutions have been explored.[58]

Punitive action against a hospital pharmacist by the Pennsylvania State Board of Pharmacy brought into focus the controversy over the legitimacy of the hospital formulary system. The case involved

[56] Hearings, pt. 21, p. 11581.

[57] Cf. Hearings, pt. 21, pp. 11797, ff. The questions raised by NPC's hospital pharmacy representative are quoted and discussed in an article in Hospitals, Journal of the American Hospital Association, Feb. 1, 1960, entitled "The Formulary System Versus the New Concept of 'Substitution'," by Dr. George F. Archambault. It is this article which is printed in the hearings, loc. cit.

[58] Hearings, pt. 21, p. 11730; the memorandum is printed in full at pp. 11838 ff.

Joseph V. D'Ambola, a pharmacist at Hahnemann Hospital in Philadelphia. The Schering Corp., a member of the National Pharmaceutical Council, complained to the State Board of Pharmacy that the "hospital pharmacy in question filled physicians' prescriptions not with the trade or brand name drug or drugs called for in said prescription but with other drugs of the alleged identical chemical content." The product involved was Schering's brand of prednisone marketed under the trade name of Meticorten. The State board immediately ordered a 90-day suspension of the pharmacist's license, although later this order was lifted. At the time of the hearings of the subcommittee, the case was still in litigation.

Other "educational" efforts of the National Pharmaceutical Council were designed to raise the implication that hospitals were violating laws by using the formulary system. The legal questions which were raised undoubtedly had the desired effect of producing some concern among hospital officials. Among these were the possibility that the accreditation of these hospitals might be withdrawn by the American Medical Association, the possibility of liability in malpractice suits and infringement of trademarks, and the proposal that a physician's authorization for dispensing generic equivalents of prescribed drugs under the formulary system might be considered void ab initio by reason of coercion.[59]

One of the most ingenious devices employed by the NPC was the widespread circulation of a series of rhetorical questions asked by the then head of the Antitrust Division of the U.S. Department of Justice, Judge Victor Hansen.[60] In view of the source, the questions raised could hardly have allayed the growing concern of hospital administrators when presented to them at their convention in 1957. After prefacing his statement with the remark that his agency "has always shown an interest in antitrust enforcement where the protection and improvement of the people are involved," he asked these questions regarding the hospital formulary:

> * * * does this system provide for competitive bids or negotiated bids? Will this system make it possible for a single manufacturer to achieve a real monopoly of sales in the area where the hospital is located? Will this system actually result in lower prices to the hospital or a monopoly price? Will this system be an interference in the practice of the doctors using the hospital without staff position? Will this system make it possible for the successful manufacturer to create a boycott against his competitors? Will this system have any substantial effect on the sales of a competitor's product, if the hospital's action is construed as a stamp of approval on the product of the successful manufacturer only?[61]

"Educational" pamphlets.—At every opportunity the National Pharmaceutical Council has preached the superiority of brand name products and encouraged doubts as to the quality of products sold under generic names. Staff members traveled widely to carry the message to pharmacists, physicians, hospital administrators, medical, and

[59] Hearings, pt. 21, p. 11858.
[60] Statement presented by Judge Victor Hansen at the convention of the American Hospital Association Atlantic City, October 3, 1957, reprinted hearings, pt. 21, p. 11847.
[61] Hearings, pt. 21, p. 11848.

pharmacy students, faculty members, and the like. Educational forums were organized in the more attractive resort spots of the country. Pamphlets and publications of all kinds were used to give the widest circulation to its point of view.

Their most widely distributed pamphlet entitled "24 Reasons Why Brand Names Are Important to You" [62] was critically examined "reason-by-reason" in the hearings by Dr. Modell of the faculty of Cornell University Medical College. A few examples will illustrate the validity of the "24 reasons." The first reason relates to potency, the brochure stating:

> Insured potency, then, is the first reason why the prescriber should specify the drug of his choice by its brand name.

Since important brand names are in the hands of the large manufacturers, the implication was that the products of small companies are inferior. Speaking on this point Dr. Modell remarked:

> Well, it has nothing to do with the size of the house. It has to do with the care that is taken in the fabrication of a fixed preparation. This is something that can be done by small manufacturers as well as by large ones. As a matter of fact, there are a great many manufacturers of pharmaceuticals which are now very large which started out as being small, and claim to have exercised quite as much care in the very beginning as they do right now.
> It has nothing to do with the size of the manufacturer.[63]

Reason No. 3 related to "purity." Since U.S.P. sets a limited range, it was suggested, levels of greater purity are attained if the manufacturer stays at the upper end of this range. Dr. Modell characterized this argument as "basically nonsense" since any product within the range is entirely satisfactory. He remarked that no health purpose was served by a manufacturer's going above the standard set by the U.S.P.; and if there were anything deleterious in the lower range, "U.S.P. standards would be elevated accordingly." [64]

Furthermore, he pointed out, the human body cannot detect the differences in the U.S.P. range of tolerance:

> The United States Pharmacopoeia provides for these tolerances because it realizes that in manufacturing processes it is not possible to make these things quite as exact as the dosage states; these tolerances are therefore permitted. Now, the tolerance that is permitted is determined to be such that the human body cannot detect the difference. The human response to drugs is not so sensitive, not so delicate, that it can usually detect 5 or 10 percent differences. Where this difference is important, the tolerance is smaller. Where this difference is not so important, or there may be difficulties in the process of manufacture, the tolerance permitted is somewhat larger. But in any event, differences, variations between tablets inevitably occurs in the process

[62] Reprinted in hearings, pt. 15, p. 8637.
[63] Hearings, pt. 21, p. 11609.
[64] Ibid., p. 11610.

of manufacture and the attempt is made to keep these within acceptable limits.[65]

Reason No. 4 relates to sustained-release spansules. Marked differences exist, it was stated; and the "substitution of an 'equivalent' preparation for the brand name drug prescribed by the physician would be a threat to public health." On this point Dr. Modell asserted:

> There was an article about a year and a half ago, a report to the Council on Drugs of the American Medical Association, asserting that none of the so-called sustained release medications were reliable enough to warrant the recommendation of any of them by the Council on Drugs. This is, therefore, a paragraph on a process which is in grave doubt.[66]

Point No. 6 relates to the choice of "vehicle or base" in which the essential drug ingredient is contained. Great variation, it was argued, exists among manufacturers in this area; and this "may well have a considerable bearing on therapeutic efficacy." On this point Dr. Modell remarked:

> But the point is that the business of choosing vehicles and bases is one of the oldest arts of medicine. The vehicles and bases have been with us for many years. It is the drugs that have changed. And so the physician and the pharmacist know a great deal about these matters. It is no secret, and anyone who wants to do it and tries to do it conscientiously could do it properly. Now, it is a fact that two manufacturers are unlikely to produce precisely identical tablets. I don't know what importance there is to that.[67]

Point No. 10 equates the company using brand names with the "conscientious manufacturer" as opposed to the seller who "meets only the minimum requirements" and thus "can produce drug products at a lower cost." It states:

> The temptation for unscrupulous manufacturers to meet only minimum specifications is ever present—at the expense of the public and with the risk of unfavorable effects on public health.

[65] Hearings, pt. 21, p. 11617.

[66] Ibid., p. 11611. FDA actions on sustained-release capsules were discussed in the following exchange:

"Dr. BLAIR. Now, in order to obtain some factual information on the extent to which products that do meet U.S.P. standards, nonetheless for other reasons do run afoul of the Food and Drug Act, the chairman of the subcommittee addressed a letter to Commissioner Larrick of the Food and Drug Administration on Feb. 3. He asked, among other things, for a listing of actions brought during the last 5 years by the Food and Drug Administration against products which did meet U.S.P. standards, or the National Formulary standards, but which were adulterated or misbranded for other reasons.

"Now, in relation to the size of the industry, with manufacturers' sales running in the magnitude of $2¼ billion a year, it is interesting to note that there were in the last 5 years only 31 actions of this type by the Food and Drug Administration.

"That is only a little over six a year.

"Now, of those 31, 17—or nearly half—involved one type of product, the time-disintegrating capsules. Yesterday Dr. Modell was asked for his opinion on the claim which appears as reason No. 4 in the 24 "reasons" of the National Pharmaceutical Council, that reliance should be placed on the larger brand name manufacturers' products on the grounds that a superior kind of disintegrating spansule or capsule would be secured for the patient."

Dr. Modell's response—and I want to read just a few sentences from his reply—is, as follows:

"Well, this is a very special matter. There are a number of patented methods of producing these so-called sustained release medications—and I say "so-called" because there is considerable question whether they are worthwhile using at all" (pp. 11678–11679).

[67] Hearings, pt. 21, p. 11616.

This danger, it is inferred, exists whenever a drug sold under the generic name is used. In this connection Dr. Modell said:

> If he attempted to stay, say, 5 percent on the cheaper side of 100 percent, the question is what would he be saving. In the total cost of fabricating a tablet, if one considers the cost of promotion, the distribution, the excipients and everything else, the cost of the drug itself is a very, very small proportion of the total amount, and if he saves an extra 7 percent on the cost of the drug by giving 95 instead of 102, this is only 7 percent, not of the total cost, but of the very small fraction of the total cost, which represents the drug itself, and it is really a miniscule amount.[68]

Point No. 11 refers to "allergic manifestations" that might arise from an unknown ingredient in a drug. This danger, it was asserted, is alleviated by the practice of using brand name products. Dr. Modell's comment was that, if anything, brand names intensify this very problem. He stated:

> If a patient is allergic to a drug under one trademark name, and the doctor in trying to avoid it gives him the same drug under another trademark name because he doesn't know that the two are identical, he can cause a catastrophe. This is one of the grave dangers of having multiple names for the same drug. Since there are many with as many as 35 names for the same material, it is possible for this sort of confusion to occur.[69]

Other reasons stressed for using brand name drugs relate to irritations that might be caused, the flavor of the medicine, melting point, and the like. But all of these, Dr. Modell reiterated, are in the public domain; "anybody who is interested in it can learn how to take care of this."[70] Point No. 15, relates to "caloric values" which are declared to be a "matter of great moment." On this point Dr. Modell remarked:

> I am amused by it. It is undoubtedly true that it is possible by putting sugar in medication to add some calories to it, but I don't know of many people who have gotten fat from taking medicine. I don't even know that there is enough sugar in many medicaments to upset the control of a diabetic. But if this were a fact or where this is a matter of importance it can be taken care of. Sugar substitutes have been known for a long, long time, and they can be used. Again this is in the public domain. The point that I am trying to make is that this is not a real problem.[71]

[68] Hearings, pt. 21, p. 11617.
[69] Ibid., p. 11619.
[70] Ibid., p. 11621.
[71] Hearings, pt. 21, p. 11621.

Chapter 15. The Substantive Issue of Drug Quality

The subcommittee heard widely varying testimony with respect to the quality of ethical drugs currently sold on the U.S. market. As has already been shown, officials of the large drug companies have been active in disparaging the quality of drugs sold under generic name; their own market for high-priced brand-named products is the vital issue at stake. Were physicians to prescribe nonpatented drugs on the basis of generic names, the small manufacturers would have a chance to have their lower-priced products used.

Medical testimony presented to the subcommittee divided sharply on this issue. Because they are thoroughly familiar with the available literature in their fields and are working intensively with the drugs of particular importance to their specialty, many medical specialists tend to favor wider use of generic name prescribing. In contrast, general practitioners, who use a vast assortment of drugs in the treatment of the myriad ailments of their patients, cannot familiarize themselves thoroughly with all of these products; and the large majority rely heavily upon brand-named products of the major manufacturers.[72]

The problem of objective evaluation is complicated by the fact that actual tests of a conclusive character are conspicuously lacking. Mr. George P. Larrick, Commissioner of Food and Drugs, informed the subcommittee that FDA's "authority to inspect manufacturers of drugs was severely restricted when Congress passed the factory inspection amendment of 1953"; as a result, he stated, "many manufacturers, both large and small, now decline to permit our inspectors to inspect significant phases of their drug operations." He added:

> In these cases we must depend more on the collection and examination of samples from interstate shipment to check on the quality of their output.[73]

However, it appears that FDA is highly selective in its sampling program; Commissioner Larrick asserted that "we confine sampling to drugs which we have reason to believe may be misbranded or adulterated."[74] This practice may represent an efficient use of a regulatory agency's facilities; it also has the effect of spotlighting the violations of that area of the industry upon which enforcement work is concentrated.

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[72] Some of the physicians appearing before the subcommittee appear to rely heavily upon reputable pharmacists for assistance. Dr. Bowes, an obstetrician from Utah, testified that he usually prescribed reserpine instead of Serpasil (CIBA's trade name) because of the marked price difference. He said:

"I use reserpine, and I know it is cheaper, and, therefore, I prescribe it when I have those conditions that warrant it.

"There is a druggist in our city that I buy some of my supplies from, and he has drawn up a list of different drugs according to brand name, and according to generic name, and if we will prescribe the generic name, then he will use his judgment on what brand name to give according to the best buy from his store.

"This does not mean that I send my patients to any one particular druggist, but I also note on that sheet the generic name, and I can write it on the prescription if it is not a long-drawn-out, complicated, difficult thing for the druggist to read" (hearings, p. 18, p. 10467).

Dr. Harold F. Pierce, of West Hartford, Conn., disclosed his method of action in an exchange with Senator Hart:

"Senator Hart. If you are a physician concerned with the economic effect on the patient of the prescription you were giving him, and if the detail man did not tell you what his firm's prices were, and I presume the other detail men did not tell what their prices were, how could a physician intelligently select and order drugs so that the least economic burden be imposed upon the patient?

"Dr. Pierce. I would call up my pharmacist. I have always had a pharmacist that I could trust. There has not been a time in history when a good doctor didn't have a good pharmacist at his elbow. The pharmacist will tell me what I need to know" (hearings, pt. 21, p. 11635).

Some physicians write the prescription in generic terms followed by "ARB" (any reliable brand) (hearings, pt. 18, p. 10268).

[73] Hearings, pt. 22, p. 12113.

[74] Idem.

The FDA head provided the subcommittee with figures showing the number of samples taken per $1 million volume of business for several large and small companies for the 10-year period, 1950–60.[75] It is of interest that in the case of Merck, CIBA, Schering & Carter Products, one sample was taken per $1 million of business; for Smith Kline & French, Lederle (American Cyanamid), Pfizer, and Upjohn the range was from one to less than five samples per $1 million. For the small companies, the situation was strikingly different. Here the samples ranged around 100 samples per $1 million, and in several instances were much higher.[76]

In his testimony Mr. Larrick stated that during the fiscal year 1959 his agency examined 1,513 samples of prescription drugs, of which 123 or 8 percent were violative. Though he did not supply the names of the companies involved, it would not be surprising, in the light of their sampling practices, that many of these violations involved the smaller companies. Apparently all of these cases involved formal legal action by FDA.

The FDA also engages in wide use of voluntary compliance, particularly with respect to the activities of the major drug companies. In this connection Dr. Barbara Moulton, until recently a member of the staff of the Bureau of Medicine, Food and Drug Administration, informed the subcommittee:

> Private conferences between representatives of industry and the Food and Drug Administration staff members are also the rule rather than the exception with respect to regulatory action under the law.[77]

Thus it has been common practice, where a large and so-called responsible producer is concerned, to engage in telephonic communication and get the situation rectified by informal agreement. FDA officials informed the subcommittee that no record is kept for much of this type of informal compliance work. Though there is undoubtedly much to be said for this practice in terms of immediate remedial result, it also means that violations of the large companies handled in this manner do not get reported in the formal statistics of violations. For example, Mr. Larrick informed the subcommittee respecting the fiscal year 1959:

> In addition to the legal actions, 27 drugs were involved in nationwide recall programs, because of very significant violations such as deviation from declared potency, lack of sterility, mixup in the labeling, etc.[78]

He presented a table of "drug recalls" for the 1950–60 period indicating whether recalls were "voluntary" or "requested."[79] An examination of these data shows that voluntary compliance is the accepted practice for the major drug manufacturers.

The statistics of FDA's enforcement activity indicate that most of its effort is focused elsewhere than on the quality of ethical drugs. The subcommittee staff examined the FDA's Notices of Judgment under the Federal Food, Drug and Cosmetic Act for the calendar year 1958.[80] These represent the legal actions brought by FDA in

[75] Ibid., p. 12137.
[76] Hearings, pt. 23, p. 13055.
[77] Hearings, pt. 22, p. 12029.
[78] Hearings, pt. 22, p. 12133.
[79] Ibid., p. 12148 ff.
[80] Hearings, pt. 23, p. 13054.

this field. Of the 281 actions instituted in 1958, 140 involved proprietary (nonprescription) items; and another 123 were cases involving sales of ethicals by druggists without prescription. Only 18 involved the quality of ethical drugs; and 3 of these concerned antibiotics protected by patent monopolies of the large companies. Thus the data supplied by the regulatory agency provide no conclusive showing that there is a real problem of inferior quality, much less its incidence. Indeed this appears to be the view of the FDA Commissioner who informed the subcommittee:

> The only conclusion that can be drawn from these facts is that the coverage being given this industry through inspection and analyses of samples is inadequate and this applies to both large and small firms alike.[81]

Apparently, however, since 1952 the FDA up to the time of the hearings had not considered the situation serious enough to warrant a request to the Congress for stronger inspection and enforcement powers.

Some light was thrown on this whole problem by the testimony of officials of organizations regularly engaged in substantial purchases of drugs under generic name. The Military Medical Supply Agency of the U.S. Government purchases between $30 and $40 million worth of drugs annually.[82] In the interest of achieving economies, all bids for such procurement specify drugs only by generic name. An official of MMSA stated that approximately 20 major suppliers and 80 of the smaller drug houses were involved. In order to bid, all applicants must pass factory inspection and quality control standards of the procurement agency. In this connection the following exchange took place at the hearings:

> Senator HART. In how many instances have you found plants that you were not satisfied with?
>
> Captain FAHLBUSCH. Actually, Senator Hart, there have not been very many. There have been companies which come in on a low bid, but they have been a very small number of companies that we have inspected, because they are all well aware of the inspection which they must undergo prior to the award of a bid, and outfits who know they would not pass do not submit bids.[83]

In addition, tests are made of the drugs upon delivery. The success of the MMSA in securing low bids on products sold by several companies and its failure to do so on patented products has been discussed in chapter 5.

Many of the large hospitals in the country purchase their drugs requirements in much the same way. Purchases are made in terms of generic names, and the company with the lowest price is usually awarded the business. Dr. Groeschel testified that the New York hospital has followed this practice successfully for 144 years.[84]

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[81] Hearings, pt. 22, p. 12113.
[82] Hearings, pt. 21, p. 11563.
[83] Ibid., p. 11562.
[84] Hearings, pt. 21, p. 11578. When asked "How do you determine a reliable product?" Dr. Groeschel replied:

"If there is any question in the mind of the pharmacist and formulary committee, they might very well ask certain departments' research laboratories in our medical college to do this special testing on the drugs.

"They would run not only laboratory tests but also clinical tests to determine whether a drug, for example, met the proper level of potency that it was labeled for, and that kind of thing.

"We do have in that respect, sir, we do have more machinery in the university teaching hospital for doing this kind of thing than the average hospital has. This would be obvious." (pp. 11578-11579.)

He himself, he stated, had taken these drugs in a serious illness involving lobar pneumonia, and he added:

> * * * the drugs that helped me get well were drugs which were purchased in accordance with our formulary and under our generic name basis.[85]

This practice is also generally followed by Federal, State, and local governments purchasing for institutional use. Indeed for most of the smaller companies, selling drugs without benefit of heavy promotional expenditures, this market constitutes a major segment of their business; and the skilled procurement staffs of these agencies have been insistent upon high quality as well as reasonable price. The fact that complaints have been conspicuously lacking by large-scale buyers of drugs would suggest that inferior quality has not been a significant problem.

It is also a growing practice for the welfare departments of the various State and local governments to require that prescriptions for welfare patients be written in generic names. The problems these agencies face is exemplified by the case of Connecticut. Dr. Harold F. Pierce, until recently the medical director of the Connecticut State Welfare Department, testified that economies were essential—

> * * * because the cost of our drugs had become perfectly enormous. It had gone up to $1,300,000 a year. In 5 years it had tripled, although the number of beneficiaries served had increased by only one-sixth.[86]

In consequence of similar urgent financial problems, New York, New Jersey, Michigan, and a number of other States have recently adopted similar programs. In some areas the use of the generic name is limited to a specific group of the more important drugs in current use where a wide disparity in price exists between the large and small companies. In others, a list of approved drugs is prepared, whose therapeutic usefulness has been carefully examined by medical specialists; and prescribing physicians must call for these drugs by generic names.

This trend in the welfare field has been accelerated by a resolution of the American Medical Association in late 1960 recommending the use of generic name prescribing for welfare patients in the interest of reducing drug costs. This resolution has sharply posed the basic problem which Senator Hart, a member of the subcommittee, raised frequently throughout the hearings. Drugs purchased competitively under generic names are used widely in the treatment of hospitalized patients in the country's major hospitals; here they are regarded as safe enough for patients suffering the most severe illnesses. The Veterans' Administration use these drugs throughout their hospitals. The drugs purchased in a similar manner by the Military Medical Supply Agency are used in the treatment of current military personnel of all ranks; indeed, these drugs are given to Members of Congress and high officials of the executive branch who are temporary residents at military hospitals. Now the AMA has recommended that generic name prescribing be used for welfare patients. If, as Senator Hart inquired, these classes of patients have been treated by drugs prescribed under generic name, what does it mean? Are they

[85] Hearings, pt. 21, p. 11585.
[86] Hearings, pt. 21, p. 11637.

being given substandard drugs? Is there one standard for Congressmen and welfare patients, and another for the ordinary citizen? If drugs are substandard, do they have any place at all in our society?

In general, there was a considerable difference in viewpoint among witnesses before the subcommittee on the safety of generically prescribed drugs. A number of witnesses felt that, where a large-scale purchaser subjects the drugs to tests at the time of purchase the problem of safety is nonexistent. The model situation appears to be the MMSA, the world's largest buyer of drugs, which inspects plants and their operations before companies can qualify as bidders; and then, after the award of a contract, tests the material upon delivery. At some midpoint are the country's large hospitals which do some checking on their own, and in addition have available the necessary testing facilities in the event that any doubt exists respecting quality. A number of witnesses, however, drew a distinction between the position of these agencies and that of the individual physician engaged in private practice. Speaking of the private practitioner, Dr. Groeschel of the New York Hospital stated:

> Believe me, I feel for him, because I practiced medicine as a solo practitioner in a rural area for a number of years before the war. I know what I am talking about. You are comparing his situation, a difficult one, with the situation of the doctor in the hospital.
>
> It is entirely different. This I will acknowledge. In the hospital he has the benefit of this entire group studying, appraising, evaluating. When he is out alone, he doesn't have this. It is an entirely different situation.[87]

An interesting contrast in view was presented by two of the subcommittee's witnesses. At the time of the appearance of Dr. Lloyd C. Miller, director of revision, U.S. Pharmacopoeia, Senator Hart attempted to ascertain whether a drug generically prescribed was safe for the patient:

> I am trying to get clear in my own mind, and without attempting to be tricky about it at all, the answer to this practice which we have been told has been recommended by apparently reputable professional sources in this country. I am really trying to find out whether what they recommend for the welfare patient is safe for me, too. If it is safe for him, it is safe for me. If it is dangerous for him, it is dangerous for me, and it is wrong to suggest.
>
> Mr. MILLER. My opinion, sir, is that it is unsafe because there is not sufficient policing of our standards at the present time to insure that the standards are being met.[88]

On the other hand, Mr. O. K. Grettenberger, director of drugs and drug stores, State of Michigan, expressed a contrary point of view:

> I have been director of drugs in the State of Michigan 11-plus years, and in the many samples taken for analytical

[87] Hearings, pt. 21, p. 11588. When asked about the solo practitioner's tendency to rely on major brand products, he remarked:

"I think he would be inclined to do so, and I can remember the days when a whole stream of detail men from pharmaceutical concerns would come in and give me the hard sell for their own particular brand names.

"I think I was perhaps just as susceptible as any other physician trying to do the best for his patients."

[88] Hearings, pt. 21, p. 11681.

findings I have found no supposedly small company representing their labels to be anything other than what was stated thereon.

We have found, however, in our fight against substitution, prior to the *Casden* case, that pharmacists have not always filled the prescription with the particular brand name requested. They have filled it with an unauthorized generic-name product, which substance was always found to have contained within tolerance a like amount of the basic-name medication used in lieu of that particular brand-name product.[89]

Whatever the differences in views may be, the hard fact is that the drug companies have been largely successful in persuading physicians to write their prescriptions in terms of trade names; this is attested by the very small proportion of commercial sales made of generically prescribed drugs. This successful campaign of persuasion by the large firms has been achieved in the face of two obstacles which have made the accomplishment all the more remarkable. The first is the existence of Government inspection, coupled with enforcement powers, designed to assure acceptable quality of all drug products, whether sold by large or small companies. In this industry governmental intervention in the economic process to assure that products of all companies meet similar quality standards is and has long been a reality, dictated by the necessity of protecting the public health. To overcome whatever natural inclination the physician might have to prescribe generically because of this reality, the drug companies have sought to create the impression that the governmental body involved, the Food and Drug Administration, has regrettably been derelict in its duty. The Agency, it is stressed, simply cannot get around to policing all of the companies which make up the industry, and therefore, it is held, the wise physician should rely on those companies whose products he can be sure of. It is a considerable understatement to say that this campaign has in no way been hindered by the Food and Drug Administration.

It is not unusual for an agency to accept and indeed join in the criticisms of its own shortcomings. What is unusual is for it to do so without having grounds to transfer the responsibility elsewhere. It is in precisely this situation that the Food and Drug Administration now finds itself. It can avail itself of neither of the two defenses traditionally employed by Government agencies to excuse their own derelictions—inadequate authority and inadequate funds. In 1952 the agency felt that it needed stronger inspection and enforcement powers to police the drug industry. It sought those powers and was rebuffed by Congress. During the ensuing 8 years it did not renew its request. The shoring up of an agency's enforcement powers is usually accomplished only after the need for the enlarged authority has been clearly demonstrated; this usually and properly takes a period of time. The last important addition to the antitrust laws, the Celler-Kefauver Antimerger Act of 1950, was first recom-

[89] In the *Casden* case referred to by Mr. Grettenberger, a Michigan druggist filled a prescription for Schering's Meticorten with another brand of prednisone sold by Upjohn. Action was instituted against him on the ground that he had engaged in substitution under the theory, widely promoted by the National Pharmaceutical Council, that the filling of a prescription by any brand other than that specifically stated constitutes a violation of the Michigan law. The State court, however, ruled in favor of Casden on the ground that the two products were identical and substitution had not taken place. (Hearings, pt. 31, pp. 11591–11593. The opinion of the court is printed on page 11761 as exhibit 389.)

mended by the Federal Trade Commission in 1927 and following World War II was strongly and annually urged upon the Congress. When an agency fails to renew a request for broader authority, the Congress has reasonable grounds for assuming that the conditions which originally prompted it have disappeared or at least are no longer as pressing.

Nor can the Food and Drug Administration have recourse to the inadequate funds defense. During the period 1952–60 appropriations for the agency were increased by 60 percent. What is more relevant here, the Congress has usually appropriated substantially the amount requested, or more. In every year since 1952, with the exception of 1954, the amount appropriated has been 95 percent or more of the amount requested for the agency. In 3 of the last 5 years Congress has appropriated the full amount requested, while in the other 2 years it has given the agency more than was requested.[90] Moreover, the manner in which the agency apportioned its appropriation on work involving ethical drugs as contrasted to other and perhaps less important types of activities is open to question. This would particularly be the case if the problem of inferior quality of products offered by small firms is as serious as the large companies profess it to be.

The second problem to be overcome, while less well known, is of equal if not greater substantive importance. This is the simple fact that both the small and the large companies, to a very considerable extent, get the drugs themselves from the same sources. As has been brought out in chapter II–1, there is not only high concentration of production but extensive specialization by given companies in particular product areas. It will be recalled that of the 51 products shown on chart 8, more than half of the leading companies actually produce at the most, 1 out of 3 of the products which they sell. The remainder they buy for the most part from other large companies. Insofar as the issue of trade names versus generic names is concerned, this means that, in prescribing the product of a given large company in which he happens to have confidence, the physician more often than not is calling for a drug which was actually produced in bulk form by a

[90] See the following:

Comparison of appropriation requests and congressional action, fiscal years 1952–61

Fiscal year	Request to Bureau of the Budget	President's budget estimate to Congress	House allowance	Senate allowance	Appropriation
1952	$5,852,600	$5,395,000	$5,345,000	$5,172,975	$5,300,000
Supplemental	405,300	361,400	343,300	343,300	326,000
1953	5,897,000	5,637,000	5,600,000	5,637,000	5,600,000
1954	5,975,000	5,663,000	5,000,000	5,400,000	5,200,000
1955	5,206,000	5,206,000	5,100,000	5,206,000	5,100,000
1956	5,484,000	5,484,000	5,484,000	5,484,000	5,484,000
Supplemental	660,000	660,000	660,000	660,000	660,000
1957	6,804,000	6,779,000	6,779,000	6,779,000	6,779,000
1958	10,445,000	9,300,000	9,300,000	9,300,000	9,300,000
1959	10,800,000	9,410,000	9,300,000	9,800,000	9,800,000
1960	13,958,000	11,800,000	13,800,000	13,800,000	13,800,000
Supplemental	332,000	332,000	(1)	(1)	(1)
1961	17,789,000	16,852,000	(1)	(1)	(1)

[1] Now pending before Congress.

different company. Referring to the practice of the large companies in buying and selling from each other, the subcommittee's chief economist stated:

> The claim is made, particularly by the large companies, that their brand names should be trusted by the doctor when he writes a prescription for his patient because of the careful control exercised by the company over each successive stage of manufacture. Certainly the company can logically make this claim in those cases where the company, itself, manufactures the drug. Where it does not manufacture the drug itself, the validity or applicability of the claim is limited to the compounding, packaging, and tableting operation.
>
> Where the company, itself, does not manufacture the drug which it sells, it cannot validly use the argument that the physician should write the prescription in terms of its brand name because of the control which it exercises over all of the stages of manufacture involved in producing the product.
>
> I do not wish to convey the impression that because any of these drug companies does not manufacture a product the quality of that product is in any way questioned. It may well be that Parke, Davis, which produces only 1 of the 20 products shown here, takes steps to assure itself of the quality of the product which it buys from the others.
>
> However, Parke, Davis cannot make the claim that the mere fact that it sells a product means that Parke, Davis, itself, controls the manufacture of the drug.
>
> * * * * * * *
>
> Of course, there is no economic or any other objection to the propriety of this practice. What there may be objection to, however, is the use of advertising which might convey the impression that simply because one of these major companies sold a product, it also thereby manufactured it, and that since it implicitly could be presumed to manufacture it, it did in fact have the type of control over each stage of manufacturing which in point of fact it may have had only over the last stage of tableting and compounding and packaging.[91]

The high concentration of production also means that typically the small manufacturers of drug products obtain the drugs themselves from the large companies. In 45 of the 51 products shown on chart 8, 1 or more of the 15 largest drug companies accounts for 100 percent of the U.S. output. On these products the small manufacturers purchasing from domestic sources must necessarily obtain their supply from a "reputable" large company. Only in reserpine, Orinase, and vitamins A and B_2 does the output of the 15 large companies account for less than 90 percent of the total U.S. production.

Where both a large and a small manufacturer purchase drugs in bulk from the same producer, the only opportunity for variation in quality would be in the secondary stages of tableting, coating, and, if more than one drug is involved, in compounding. In the small as well as the large manufacturer, these operations are highly mechan-

[91] Hearings, pt. 21, p. 11743.

ized, involving the use of automatic tableting machines, revolving circular drums for coating, etc. Then of course the small companies as well as the large are required to make quality control analyses both of the incoming drug in bulk form and of the outgoing manufactured product. This is not to say that differences in the quality of the product at this stage of operations can never arise. But mechanized operations usually offer few opportunities for introducing variations in the quality of the product. Moreover, as Dr. Modell has pointed out,[92] the amount to be saved by skimping on quality at this stage of production is usually so small relative to the price of the product as not to be worthwhile. Also the small drug manufacturers, themselves, appear to be very much aware of the existence of the FDA and of the fact that, as has been brought out earlier, they receive far more attention from that agency, relative to their sales, than do their large rivals.

The fact that the small manufacturers tend to buy their drugs from the large companies, plus the mechanized nature of the subsequent processing stages are undoubtedly the two principal reasons why Mr. Grettenberger was able to say on the basis of his 11 years of experience as director of drugs in the State of Michigan:

> Within the State of Michigan I have yet to find an inferior drug product, as far as generic basic medicinal substance is concerned within tolerance, as labeled, of any yet analyzed. Our analytical work has been done by the Michigan State Department of Agriculture in East Lansing, Mich.
>
> I have the utmost respect for the large corporations manufacturing drugs and also the utmost respect for the small industries manufacturing drugs. As long as the public receives the correct medication in the filling of a prescription, whether it be by brand name or by generic name within the tolerance of the required dose, we have justified our enforcement of the Pharmacy Act as a board of pharmacy and a servant of the public health.
>
> I am afraid that the pharmaceutical industry has overly frightened the pharmacists by implying that everything that is not a brand name is of a poor quality.[93]

[92] Hearings, pt. 21, p. 11617.
[93] Hearings, pt. 21, p. 11592.

APPENDIX

APPENDIX A

STATUS OF PATENT PROTECTION ON DRUGS—18 COUNTRIES

Argentina

Unpatentable: Pharmaceutical compositions.

Australia

Unpatentable: Substances, capable of being used as foods or medicines, which are a mere mixture of known ingredients, and processes producing such substances by mere mixture. General: Any person interested may, after expiration of 3 years from the date of sealing, apply to the commissioner for the grant of a compulsory license on the ground that the reasonable requirements of the public have been satisfied. The commissioner may refer the petition to the high court, if satisfied that a prima facie case has been made out. Where the court is satisfied that the invention is not being worked in Australia on a commercial scale, unless satisfactory reasons are given, or trade or industry in Australia is unfairly prejudiced, or demand not reasonably met, the court may order the patentee to grant licenses on such terms as the court thinks just.

Austria

Patents, 18 years.

Unpatentable: * * * 3. Articles reserved as a Federal monopoly (salt, tobacco, brandy). 4. Articles serving for human nourishment, medicines, and disinfectants. 5. Substances produced by chemical processes insofar as the invention does not relate to a distinct technical process for the manufacture of these products.

Compulsory license: After expiration of 3 years from the date of publication of the grant of the older patent in the official gazette, the holder of a dependent patent may apply for a compulsory license if his invention is of considerable industrial importance. Any trustworthy person may petition for a license if the grant of same is in the public interest. Such a license may be transferred only together with the goodwill of the business. Also after 3 years if failure to work.

Belgium

Patents, 20 years.

"Patents are permitted for any discovery or any improvement susceptible of exploitation in industry or commerce." No exception for drugs.

Brazil

Patents, 15 years.

Unpatentable: 7. Alimentary or chemical substances. 8. Medicaments of any kind. However, processes for obtaining products under 7 and 8 are patentable.

Compulsory license: After 2 years, nonworking.

Canada

Patents, 17 years.

Patentable: Substances obtained by chemical processes, and intended for food or medicine when prepared by the processes claimed.

Compulsory license: If a patent holder charges unduly high prices for a drug, the Government has authority to license another company to manufacture the patented product, with payment of a reasonable royalty. After 3 years any person may apply for an order alleging that the reasonable requirements of the public have not been satisfied and that the patentee refuses to grant a license on reasonable terms. Commissioner may refuse or grant license and appeal may be made to the exchequer court.

France

Until the ordinance of February 4, 1959, pharmaceutical compounds and remedies could not be patented. At present special patents are granted for medicines.

Former law on compulsory license: If not worked and also "at the initiative of the Minister of Public Health" patents relating to the manufacture of pharmaceutical products or remedies may, in the interest of public health, at any time be declared susceptible of the grant of compulsory licenses, if such products are made available to the public only in insufficient quantity or quality or at exaggerated prices. After such decision being published any interested party may apply for a compulsory license.

The new French law (Ordonnance 59–250, dated February 4, 1959) provides that "Special patents shall be granted on medicaments." If it develops subsequently that there is insufficient quantity or the quality of the drug product is below standard, or the prices are excessively high, one may apply to the Minister of Public Health. If he deems it to be in the interest of public health he may require the issuance of compulsory, nonexclusive licenses and, of course, the holder of the patent would be entitled to "equitable remunerations."

Germany (West)

Unpatentable: 2. Foodstuffs, refreshments, and pharmaceutical preparations. 3. Substances obtained by chemical processes. However, processes for the manufacture of substances under 2 and 3 may be patented insofar as they relate to characteristic features. Mere mixtures for pharmaceutical purposes are unpatentable. If a patent has been granted for a process its effect also extends to the products directly obtained by means of this process.

Compulsory license: If patentee refuses consent to use the invention to one willing to pay adequate remunerations, such permission must be granted (if after 3 years) and it is in the public interest. On request by one of the parties the remuneration may be fixed by the Patent Office.

Great Britain

Sixteen years.

Unpatentable (discovery, etc.): 5. Substances capable of being used as foods or medicines consisting of a mere mixture of known ingredients and resulting only in the aggregation of the known properties of the ingredients, and processes for preparing such substances by a mere mixture.

Compulsory license: After 3 years any person may apply for a compulsory license. However, where a product or process patent is in force for a food or medicine, the 3 years delay period for grant of a license does not apply.

Iran

Unpatentable: 3. Pharmaceutical formulas or compositions (processes for the manufacture of pharmaceutical products are patentable however).

India

Patents: 16 years. No restrictions against inventions for food or medicine.

Compulsory license: Under the Indian Patents and Designs (Amendment) Act 1952 compulsory licenses may at any time be applied for under patents on food, medicine, insecticide, germicide, or fungicide, or surgical or curative, device, even where there is no abuse or lack of working.

Italy

Unpatentable: 4. Medicines and processes for their manufacture.

Japan

Patents, 15 years.

Unpatentable: (1) Foodstuffs, beverages, and refreshments. (2) Medicines and methods of compounding them. (3) Substances to be manufactured by chemical processes, but new processes are patentable.

Compulsory license: Only after 3 years where the working and practice of a patented invention cannot be carried out without making use of a patent owned by another party and permission to use such patent or utility model is not granted or cannot be granted by the earlier patentee, compulsory license may be applied for.

Mexico

Unpatentable: (5) Chemical products (processes are patentable but they are limited to the preparation of specific compounds using specific reaction conditions).

The Netherlands

Unpatentable: 2. All substances. * * * (miscellaneous k. According to jurisprudence a substance is a product in which the shape and the dimensions are not in any respect essential, thus a thread of artificial silk was deemed not to constitute a substance).

Compulsory license: After 3 years "the patentee is obliged to grant such licenses as are considered desirable in the interests of the home industry or for other reasons of common interests."

Panama

Medicines are patentable. No compulsory license provided.

United States

"* *o* medicines, pharmaceutical compositions and cosmetics, even if composed of known ingredients are patentable as compositions of matter." No provision for compulsory licensing.

Venezuela

Unpatentable: Beverages, foods, medicines, pharmaceutical medicinal preparations, reactions, and compounds. Processes for the preparation of chemical products and methods of preparation, extraction, and separation of natural substances are patentable.

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APPENDIX B

TABLE A–1.—*Drug company profits,*[1] *compared with all manufacturing, 1959*

	Percent of sales	Percent of net worth
Federal Trade Commission—Securities Exchange Commission "Quarterly Financial Report for Manufacturing Corporations":		
Drugs	10.3	18.1
All manufacturing corporations	4.8	10.5
First National City Bank of New York "Monthly Letter on Business and Economic Conditions":		
27 drugs	11.6	21.9
1,944 manufacturing corporations	5.8	11.6
The Fortune Directory:		
12 drugs	12.3	18.4
500 industrial corporations	6.1	11.0

[1] Net profits after taxes.

NOTE.—See chart 2.

TABLE A–2.—*Rates of return after taxes, identical companies in 3 industries, and all manufacturing 1947–59*

[In percent]

	11 identical drug companies	14 identical motor vehicle companies	25 identical chemical companies	All manufacturing
1947	22.4	17.1	17.2	15.6
1948	21.2	22.5	18.8	16.1
1949	18.8	27.9	18.6	11.7
1950	21.3	30.7	24.0	15.4
1951	18.3	16.8	17.7	12.5
1952	13.4	15.7	15.4	10.3
1953	12.8	15.8	15.3	10.4
1954	14.0	17.5	16.3	9.9
1955	16.4	25.1	20.2	12.6
1956	18.4	14.1	17.7	12.3
1957	20.4	15.5	16.2	11.0
1958	19.9	8.7	13.6	8.6
1959	19.9	16.3	16.9	10.5

Source: FTC–SEC: Quarterly Financial Report for Manufacturing Corporations.

NOTE.—See chart 4.

TABLE A–3.—*Schering Corp.: Purchase price, 1952, and profits after taxes, 1952–June 1957*

[In thousands]

Year	Profits after taxes	
	Annual	Cumulated
1952	$1,729	$1,729
1953	1,729	3,458
1954	1,659	5,117
1955	8,529	13,646
1956	12,305	25,951
1957 (6 months)	6,008	31,959

Purchase price: $29,132,000 in March 1952.

Source: Schering proxy statement, September 1957.
NOTE.—See chart 5.

TABLE A–4.—*Smith Kline & French Laboratories: Net worth Jan. 1, 1949, and profits after taxes, 1949–59*

[In thousands]

	Net profit after taxes			Net profit after taxes	
	Annual	Cumulated		Annual	Cumulated
1949	$5,420	$5,420	1955	$15,999	$49,003
1950	4,864	10,284	1956	18,879	67,882
1951	4,097	14,381	1957	20,553	88,435
1952	4,374	18,755	1958	20,805	109,240
1953	4,913	23,668	1959	25,006	134,246
1954	9,336	33,004			

Net worth Jan. 1, 1949, $10,801,000.

Source: Moody's Industrial Manual and Federal Trade Commission.
NOTE.—See chart 6.

TABLE A–5.—*American Home Products Corp. (entire corporation): Net worth Jan. 1, 1949, and profits after taxes, 1949–59*

[In thousands]

	Net profit after taxes			Net profit after taxes	
	Annual	Cumulated		Annual	Cumulated
1949	[1] $10,231	$10,231	1955	20,537	91,609
1950	[1] 10,883	21,114	1956	31,250	122,859
1951	11,565	32,679	1957	38,618	161,477
1952	[1] 9,089	41,768	1958	42,436	203,913
1953	13,093	54,861	1959	46,662	250,575
1954	16,211	71,072			

Net worth Jan. 1, 1949, $54,166,000.

[1] After downward adjustment for nonoperating income.

Source: Moody's Industrial Manual, Standard & Poor's, and FTC.
NOTE.—See chart 6.

TABLE A–6.—*Carter Products, Inc.: Net worth Apr. 1, 1957, and profits after taxes, 1957–58 to 1959–60*

[In thousands]

Fiscal year	Profits after taxes	
	Annual	Cumulated
April–March:		
1958	$5,595	$5,595
1959	6,968	12,563
1960	8,941	21,504

Net worth on Apr. 1, 1957, $9,526,574 (Prospectus, Carter Products, Inc., July 23, 1957, p. 17).

Source: Moody's Industrial Manual.

NOTE.—See chart 7.

TABLE A–7.—*Leading antibiotics, 1959, percent of market* [1]

NEW PRESCRIPTIONS

Company	Generic name	Product	Percent of market	Cumulative percent
Lederle	Tetracyclines	Achromycin V	22.2	22.2
		Achromycin	5.1	27.3
		Declomycin	3.9	31.2
		Aureomycin	.8	32.0
Parke, Davis	Chloramphenicol	Chloromycetin	14.7	14.7
Pfizer	Tetracyclines	Cosa-Tetracyn	4.3	4.3
		Terramycin	1.6	5.9
		Cosa-Terramycin	1.0	6.9
		Tetrabon V	.5	7.4
	Oleandomycin+Tetracycline	Cosa-Signemycin	2.3	2.3
		Signemycin	.5	2.8
Lilly	Erythromycin	Ilosone	8.7	8.7
		Ilotycin	2.5	11.2

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Lederle	Tetracyclines	Achromycin	10.6	10.6
		Achromycin V	5.4	16.0
		Declomycin	1.2	17.2
		Aureomycin	.4	17.6
Parke, Davis	Chloramphenicol	Chloromycetin	47.1	47.1
Pfizer	Tetracyclines	Terramycin	2.8	2.8
		Tetracyn	2.3	5.1
		Cosa-Tetracyn	2.1	7.2
		Cosa-Terramycin	.4	7.6
		Other	.3	7.9
	Oleandomycin+Tetracycline	Cosa-Signemycin	.1	.1
Lilly	Erythromycin	Ilotycin	3.0	3.0
		Ilosone	2.3	5.3

[1] Other than penicillin, dihydrostreptomycin and streptomycin.

NOTE.—See chart 9.

TABLE A–8.—*Antibiotic prices, broad[1] versus narrow spectrum, 1951–60*

Year	Penicillin bulk, 10 million units	Streptomycin bulk, 10 grams	Broad spectrum[1] price to druggist, 16 250 mgm. capsules
1951	$2.50	$3.24	$5.10
1952	1.15	2.70	5.10
1953	.95	1.70	5.10
1954	.75	1.70	5.10
1955	.44	.90	5.10
1956	.52	.75	5.10
1957	.70	.88	5.10
1958	.70	.88	5.10
1959	.28	.38	5.10
1960 (June)	.21	.36	5.10

[1] Aureomycin, Chloromycetin, Terramycin from 1951; Tetracycline introduced in 1953.

Source of data:
Bulk prices of streptomycin: Open market quotations, June figure, Oil, Paint & Drug Reporter.
Bulk prices of penicillin: 1951–55, Lilly prices compiled by FTC; 1956–60, open market quotations, June figure, Oil, Paint & Drug Reporter.
Broad spectrum: American Druggist Blue Book.
NOTE.—See chart 10.

TABLE A–9.—*Penicillin—Lilly: Bulk prices compared with prices to druggists (per billion units) 1948–60*

Year	Bulk	Lilly's price to druggist					
		Potassium G crystalline (tablet)			V-Cillin (pulvule)		
		Number	Units	Price per billion	Number	Units	Price per billion
November 1948	$800	12	100,000	$3.45×833=$2,875.00			
November:							
1949	330	100	100,000	26.00×100= 2,600.00			
1950	300	100	100,000	12.32×100= 1,232.00			
August 1951	250	100	100,000	9.85×100= 985.00			
December 1952	115	100	200,000	18.99× 50= 949.50			
January 1953	120	100	200,000	10.20× 50= 510.00			
February 1953	[1] 95						
October 1953	90						
January 1954	85	100	200,000	9.90× 50= 495.00			
June 1954	[1] 75						
November 1954	60						
December 1954	50						
July 1955	44	100	200,000	9.90× 50= 495.00			
June 1956	52	100	200,000	9.90× 50= 495.00	50	125 mg.[2]	$9×100=$900
June 1957	70	100	200,000	9.90× 50= 495.00	50	125 mg	9×100= 900
June 1958	70	100	200,000	8.50× 50= 425.00	50	125 mg	9×100= 900
January 1959	40	100	200,000	8.50× 50= 425.00	50	125 mg	9×100= 900
June 1959	[1] 28						
June 1960	21	100	200,000	8.50× 50= 425.00	50	125 mg	9×100= 900

[1] Plotted on chart.
[2] 125 mg. equals 200,000 units USP (approximate).

Source: Bulk: 1948–55, Lilly prices compiled by FTC; 1956–60, open market quotations from Oil Paint and Drug Reporter.
Dosage forms: 1948, Drug Topics Red Book; 1949–60, American Druggist Blue Book. Note that prices to druggist apply to the year as a whole, not to any specific month.
NOTE.—See chart 11.

TABLE A–10.—*Penicillin: wholesale prices by size of company, 1960*

[Potassium Penicillin G, buffered tablets, 250,000 units, 100's]

Size class and company	Price
Under $100,000 Annual Sales: Penburst Pharmacal Co.	$3.30
$250,000 to $999,000: Bryant Pharmaceutical Corp.	2.95
$1,000,000 to $4,900,000:	
American Pharmaceutical Co., Inc.	4.00
Premo Pharmaceutical Laboratories, Inc.	5.20
Rabin Co.	4.60
$10,000,000 to $49,000,000: Vitarine Co., Inc. (West Chemical Co.)	3.60
$100,000,000 to $149,000,000: Abbott Laboratories	11.00
$150,000,000 to $199,000,000:	
Eli Lilly & Co.	12.00
Parke, Davis & Co.	10.98
Over $200,000,000:	
Merck & Co., Inc.	12.00
Chas. Pfizer & Co., Inc.	6.18
E. R. Squibb & Sons Division, (Olin Mathieson Chemical Corp.)	12.00

Source of data: Prices, American Druggist Blue Book, 1960–61; Size (company annual sales), Moody's Industrial Manual 1960, and Companies.

NOTE.—See chart 12.

TABLE A–11.—*Prednisone—Wholesale prices by size of company, 1959*

[Per hundred 5-milligram tablets]

Company annual sales (thousands)	Price	Company name
$0 to $99	$6.95	Penburst.
$100 to $249	12.00	Lannett.
$250 to $999	6.75	Bryant.
$1,000 to $4,999	4.00	Physicians' Drug & Supply.
$5,000 to $9,999		
$10,000 to $49,999	9.33	U.S. Vitamin & Pharmaceutical Corp.[1]
$50,000 to $99,999	17.90	Schering.
$100,000 to $149,999	17.90	Upjohn.
$150,000 to $199,000		
$200,000 and over	17.90	Merck.

[1] Arlington-Funk Division.

Source: Prices: American Druggist Blue Book, 1959–60, and Upjohn catalog. Size: Moody's Industrial Manual, 1959, and Companies.

NOTE.—See chart 13.

TABLE A–12.—*Prednisolone—Wholesale prices by size of company, 1959*

[Per hundred 5-milligram tablets]

Company annual sales (thousands)	Price	Company name
$0 to $99	$7.75	Penburst.
$100 to $249	13.40	Lannett.
$250 to $999	7.50	Bryant.
$1,000 to $4,999	4.85	Physicians' Drug & Supply.
$5,000 to $9,999		
$10,000 to $49,999	9.33	U.S. Vitamin & Pharmaceutical Corp.[1]
$50,000 to $99,999	17.90	Schering.
$100,000 to $149,999	17.90	Upjohn.
$150,000 to $199,999		
$200,000 and over	17.90	Merck. Pfizer.

[1] Arlington-Funk Division.

Source: Prices: American Druggist Blue Book, 1959–60, and Upjohn catalog. Size: Moody's Industrial Manual, 1959, and Companies.

NOTE.—See chart 14.

TABLE A–13.—*MMSA drug procurement: Relationship of number of bidders to MMSA price expressed as percent of commercial price, 1959 and early 1960*

Products	Number of MMSA bidders in period	Lowest MMSA price as percent of price to retail druggist
Sulfas:		
1. Sulfasoxazole tablets	1	42
2. Sulfonamide vaginal ointment	1	61
Antibiotics:		
3. Chloramphenicol capsules	1	37
4. Chloramphenicol injection	1	41
5. Chlortetracycline capsules	1	36
6. Chlortetracycline ophthalmic ointment	1	52
7. Oxytetracycline capsules	1	34
8. Oxytetracycline with Polymixin ointment	1	54
9. Tetracycline capsules	4	47
10. Tetracycline oral suspension	4	50
11. Bacitracin sterile powder	2	31
12. Bacitracin ointment	11	16
13. Erythromycin capsules	2	17
14. Neomycin sulfate tablets	11	16
15. Dihydrostreptomycin sulfate powder	7	19
16. Penicillin G	15	6
17. Procaine penicillin G	8	17
18. Procaine penicillin G with aluminum monostearate, needle unit (Lentopen)	1	53
19. Benzathine penicillin, needle unit	1	57
Poliomyelitis vaccine:		
20. Poliomyelitis vaccine	5	42
Hormones:		
21. Cortisone acetate tablets	10	27
22. Hydrocortisone tablets	5	19
23. Hydrocortisone acetate suspension	10	10
24. Hydrocortisone acetate ointment	10	14
25. Prednisone tablets	17	7
26. Prednisolone tablets	13	8
27. Prednisolone with neomycin ointment	2	34
Diabetic drugs:		
28. Insulin injection (80 units)	2	34
29. Insulin injection, isophane (80 units)	2	24
30. Tolbutamide (Orinase) tablets	1	80
Tranquilizers:		
31. Meprobamate tablets	2	60
32. Promazine tablets	1	58
33. Promazine injection	1	39
34. Chlorpromazine tablets	1	69
35. Chlorpromazine injection	1	72
36. Reserpine tablets	17	1
Vitamins:		
37. Cyanocalbalmin injection	13	3
38. Liver injection, refined	12	11
39. Liver injection, crude	9	23
40. Thiamine hydrochloride tablets	17	8
41. Nicotinic acid tablets	20	17
42. Vitamin K injection [1]	1	68
43. Folic acid tablets	12	13
44. Pyridoxine hydrochloride tablets [1]	13	7

[1] No 1959 procurements reported. Figures are for procurements in last quarter of 1958.

NOTE.—See chart 16.

INDIVIDUAL VIEWS OF SENATOR EVERETT McKINLEY DIRKSEN AND SENATOR ROMAN L. HRUSKA

PREFACE

The majority's views in the report on administered prices in drugs do little credit to the subcommittee for there is no attempt whatsoever to be objective and constructive through judicious evaluation of all the testimony and exhibits presented during the course of the hearings. On the contrary, a reading of the voluminous 500-page mimeographed monstrosity which was submitted to the minority for comment and analysis appears to be nothing more than a calculated review of choice quips, statements, and exhibits presented by biased witnesses whose views were well known to the majority at the time they were called to testify. Thus, the majority's views would appear designed toward misleading and erroneous statements rather than a judicious evaluation of all of the evidence presented.

This is most unfortunate, because a Senate subcommittee report is designed to evaluate the evidence in a concise manner so that the Members of the U.S. Senate can refer to it without the slightest hesitation as to its accuracy and impartiality. Everyone has a right to his own views but also there is an obligation to be correct in the exposition of factual data.

The reason why we speak so strongly at the inception of these minority views is that during the opening days of the hearings on administered prices in drugs some very misleading statements and exhibits were introduced which were misinterpreted by the press and the public to the disadvantage of the drug-consuming public as well as to the manufacturers, wholesalers, and retailers of drugs. Even though at a later time these misleading statements and exhibits were corrected in the record, months later several publications that reached millions of people quoted from the original statements and referred only to those portions completely ignoring the corrected version which was subsequently included in the transcript of the testimony.

Anyone reading the views advanced by the majority would also come to the conclusion that the manner in which it is written furnishes statements and conclusions which will be a boon to business haters and drug industry baiters. These statements will enable them to carry on a vilifying campaign that will destroy the confidence of the people in not only the drug industry but in other businesses, large and small, throughout our economy.

It is surprising that a staff equipped with no special competence in the industries of steel, automobiles, bread baking, asphalt roofing, or the intricacies of the pharmaceutical industry would always reach the same identical conclusion that prices were too high and that the public was being abused by concentrated economic power. In many instances, the reports in each of these industries deal with matters

that are clearly within the province of the individual company managements and can only be mastered by a lifetime of study and acquaintance with the industries in question. In a spirit of kindliness, it is not presumptuous for the minority to state that the staff of the subcommittee has exercised bad judgment in attempting to show its expertise on a series of brief hearings dealing with matters that have occupied the sole attention of industry executives who have been associated throughout their careers with their respective firms which, in turn, has given them a knowledge of the problems at hand.

I. Introduction

The majority's report is a voluminous document which contains 90 chapter headings dealing with such diverse topics as "The Reasonableness of Price," "The Control of the Market," "Patents and Research in Drugs," "Advertising and Promotion of Drugs," and "Generic Names Versus Trade Names."

The vast majority of these topics are totally unrelated to the terms of Senate Resolution 238, 86th Congress, which established the authority of this subcommittee to investigate the antitrust laws and was adopted by the Senate on February 8, 1960, nor Senate Resolution 57, adopted on February 2, 1959.

During the course of the debate on February 8, the chairman stated:

> I think it should be pointed out also that sometimes the exploration of an issue, even though the result is that no bill is reported, may be of greater service to the public than would be the case if some legislation resulted.[1]

If this were the primary function of this subcommittee, we could not in good conscience justify expenditures of public funds and the enormous demands upon private individuals who must prepare material for presentation to the subcommittee. It is to be hoped that American citizens will follow all congressional debates and hearings with interest and understanding, but every hearing must have a legislative purpose and cannot be justified on the basis that it is essential to widen the knowledge of the American people respecting our economic system and its strengths and weaknesses.

In individual views filed by Senator Dirksen in the report on administered prices in automobiles, the following statements were made:

> It is unwarranted effrontery for any Senate committee to undertake to advise the automobile industry how to design its cars, how to secure public appeal for its products, and how best to conduct its business. Yet, throughout the course of the hearings, no hesitancy was shown in suggesting how the industry should be run, how much should be spent for advertising, the types and variety of models that should be produced, and how they should be priced and financed. These are questions which should clearly be left to men of competence, skill, experience, and special training, who have devoted a lifetime exclusively to these matters. In the hard competitive struggle to meet the demands of the American consumer, executives have risen in their respective companies to positions of responsibility. I take exception to the unwar-

[1] Congressional Record, U.S. Senate, 86th Cong., 2d sess., vol. 106, No. 21, Feb. 8, 1960, p. 2032.

ranted attempts by the subcommittee to interfere in the internal operations of an industry. * * *[2]

I firmly believe that the Senate must establish new policies respecting probes and investigations. If they are aimless and without clear objectives, they can and do cause an abuse of the legislative power.

Singularly enough, questions of the cost of these investigations to all concerned are seldom raised. Responsible and busy executives with their staff assistants are immobilized for days on end when they should be actively engaged in their own private and productive enterprises for the well-being of the country. * * *

The preparation of the documents and data which were requested involved the time and effort of many people. Much of this material will receive scant attention. In all candor, the subcommittee's examination of the witnesses was rather disjointed, as it was interrupted with quorum calls and roll-calls. In the very nature of things a full membership was not always in attendance because of conflicting duties and demands. * * *

Reports are filed upon the conclusion of congressional hearings held upon these circumstances as required under the resolutions by which the committee operates. They are usually so lengthy and include so many items of dubious value it is unlikely that they will be widely used or read. * * *

My experience with this particular investigation suggests that other techniques and procedures can be devised to provide the Senate with the necessary information to legislate in the interests of the American people and at far less cost to the Public Treasury. I believe that many Members of the Senate will share this conviction.[3]

These individual views also stated that:

The automobile industry has made mistakes. It will make many more. As long as there are human frailties, this is to be expected. However, competition in the market place insured by a free-enterprise economy provides the discipline to correct them. It is far more effective than gratuitous suggestions from the majority's staff members who are without experience in the practical fields of business.[4]

All of the criticisms which were directed at the procedures followed by the subcommittee in 1958, during the course of its investigation of the automobile industry, are equally valid today, and the need for remedial action is even more acute in order that the American people may have a proper respect for the procedures and methods of the Senate, of which we are proud to be members as it is the greatest deliberative body in the world.

Among the important procedural safeguards which should be protected in future hearings before the subcommittee is the procedure

[2] "Administered Prices—Automobiles," report of the Subcommittee on Antitrust and Monopoly, Committee on the Judiciary, U.S. Senate, 85th Cong., 2d sess., Nov. 1, 1958, p. 213.
[3] Ibid., p. 218.
[4] Ibid., p. 311.

which effects substantial rights of parties when they are called upon to produce records which when revealed could put manufacturers of products at a competitive disadvantage in that cost figures for the manufactured products would be disclosed to competitors.

When a request was made by the subcommittee to the drug manufacturers for information of this character objections were made by the drug companies. Thereafter a letter was directed to the drug manufacturers which included therein this paragraph:

> I assure you that when this material is received, the full subcommittee will be apprised of the nature of the documents and of your views as to how they should be treated. The Antitrust and Monopoly Subcommittee is a duly constituted subcommittee of the Committee on the Judiciary which is concerned with the preservation of free competitive enterprise system. Such being the case, the subcommittee, of course, never discloses any information which might impair competition unless the public interest clearly requires such disclosure.
>
> * * * Your cooperation in making an early return as soon as possible on the subpena will, I assure you, assist the subcommittee in making a thorough examination of the documents and an early determination of your request.

The plain import of the language contained in the letter was that the full subcommittee would pass upon the material furnished to them and determine whether disclosure was necessary. The chairman ruled otherwise and determined that he, as chairman, should decide what records and materials submitted by the drug companies should be treated as confidential.

Senator Dirksen made this observation which appears on page 13618 of the drug hearings:

> Mr. Chairman, we are in a very unhappy position here. I do not like to inject myself into the position where we have to caution publicly by an announcement from the committee table that from here on out counsel and the witnesses better be pretty careful about submitting any confidential data if they are going to receive this kind of captious treatment, and I regard it as slightly captious. We have been through all of this agony before. I thought we had pretty well resolved the matter. Now it comes up all over again, and perhaps we can do no more than protest, but we shall protest, and if we have to, we will make this in the form of a public announcement, that witnesses can expect to receive this kind of treatment by this committee, and that they had better be pretty careful about what they submit by way of confidential information if they expect the confidence to be preserved.

Senator Hruska made this comment, which appears on page 13617:

> Mr. Chairman, on that score, I think one of the most elementary rules of parliamentary law is that individual members of the parliamentary body do not constitute that body. Unless the members are called in a working quorum and sit down together, there is no meeting of the subcommittee.

> There is no subcommittee. Up until that time is reached, they are simply individual members of a subcommittee.
>
> Now the language in the letter of the chairman says: "Your cooperation in making an early return as soon as possible on the subpena will, I assure you, assist the subcommittee in making a thorough examination of the documents and an early determination of your request."
>
> I submit again that when we say "subcommittee," it means "subcommittee," and it does not mean individual members thereof.

It is our view that in passing upon confidential material furnished by manufacturers of products to this subcommittee, the full subcommittee and not just one member thereof should make the determination as to its confidentiality and how it should be treated, particularly when the representation that such would be the case has been made in correspondence to the parties concerned.

The signers of the Declaration of Independence joined forces in fighting a war to establish this country as a free society. While there are many motivations for their actions, they were very much concerned with the development and maintenance of economic freedom for the individual and the development of a society in which individual effort and initiative would receive their maximum recognition. Shortly thereafter, when our Constitution was drafted, these same principles were embodied in our fundamental structure of governmental processes.

It is significant that the Constitution rather than outlining the powers of the Federal Government over the individual, in principle stressed its limitations. The 10th amendment, which is an important article of our Bill of Rights, specifically provides that:

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

Although there were comparatively few specific powers granted to the Federal Government in terms of its relations with individuals, Article I, section 8, provided that the Federal Government should—

> promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.

This was the origin of our patent system. Many historians attribute the inclusion of this provision in the Constitution to Thomas Jefferson. According to an eminent historian, John W. Oliver:

> Jefferson became interested in the science of agriculture at an early age. His agricultural creed was expressed in these words: "Those who labor in the earth are the chosen people of God. Cultivators of the earth are our most valuable citizens. They are the most vigorous, the most independent, the most virtuous; they are tied to their country, and wedded to its liberty and interests by the most lasting ties." [5]

Thomas Jefferson was not only instrumental in providing Federal authority for the creation of a patent system, but he served as Secre-

[5] Oliver, John W., "History of American Technology," the Ronald Press Co., New York, 1956, p. 113.

tary of State in President Washington's Cabinet, later as Vice President, and finally as President of the United States. In all these positions he found many opportunities to continue his scientific studies. When the first patent laws were passed, they were administered by a committee of which the Secretary of State, Thomas Jefferson, was placed in charge.

Again, according to Professor Oliver:

> * * * Jefferson's work in science was, above all else, directed toward utilitarian value. His contributions were practical. He promoted education in science in the University of Virginia, in the founding of which he greatly rejoiced. "Science," he declared, "is more important in a republic than in any government * * * indeed, science is important to the preservation of our republican Government and it is also essential to its protection against foreign powers." [6]

The majority's report attempts to portray Thomas Jefferson as one who had grave doubts concerning granting a monopoly to an inventor. It states that:

> Society may give an exclusive right to the profits arising from them [inventions], as an encouragement to man to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody. Accordingly, it is a fact, as far as I am informed, that England was, until we copied her, the only country on earth, which ever, by a general law, gave a legal right to the exclusive use of an idea. In some other countries it is sometimes done, in a great case, and by a special and personal act, but, generally speaking, other nations have thought that these monopolies produce more embarrassment than advantage to society; and it may be observed that the nations which refuse monopolies of invention, are as fruitful as England in new and useful devices.[7]

In our present contest with the forces of communism, the prophecies of Jefferson are even more applicable than in his own times. Our Founding Fathers obviously have given us a charter of liberties which has not only made America a land of freedom but has enabled her citizens to develop their God-given talents so that we are the leading industrial power in the world today.

It is strange that the majority's report would attempt to find a quotation from Thomas Jefferson that bears so little resemblance to his known views concerning the efficacy of our patent system. For example, in John W. Oliver's book regarding the Patent Act of 1790, he said that:

> * * * To meet these demands the first patent act was passed, and signed by President Washington, April 10, 1790. The act was short, simple, and easy to administer. "Any useful art, manufacture, engine, machine or device or any improvement thereon not before known or used" was patentable. The act was to be administered by a special committee

[6] Ibid., p. 117.
[7] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, Committee on the Judiciary, U.S. Senate, 87th Cong., 1st sess., draft, p. III-65.

> of which the Secretary of State was to be a member. Thomas Jefferson, serving in that position, became administrator of the first patent act. He had great faith in the inventive ability of his fellow Americans and became a strong defender of the rights of the patentee. He declared that, "an inventor ought to be allowed the right to the benefit of his inventions for a certain time * * *, nobody wishes more than I do that ingenuity should receive liberal encouragement." Later in life Jefferson wrote that the Patent Act (1790) had given a "spring to new inventions beyond my conception. * * *" [8]

Our patent system and until recent times a general disposition to leave the conduct of business activities in the hands of those who had demonstrated a fitness in the competitive struggle are largely responsible for our present standard of living and our military strength.

Professor Oliver in discussing Alexander Hamilton's report on manufacturing stated that:

> * * * The introduction of new machines in manufacturing, he declared, would increase production, which in turn would increase employment. Increased employment would insure a steady demand for the surplus products of the soil. Our Nation would never be prosperous said Hamilton, until there was great diversity of labor and a high degree of skills developed. He believed that the labor shortage in this country could be solved, for, "there is in the genius of our people a peculiar aptitude for mechanical improvement." [9]

Prof. Victor S. Clark, in his outstanding work, "History of Manufactures in the United States," said:

> * * * But the promise which our patent system held out to inventors as a reward for their efforts stimulated useful inventions, hastened the perfection of mechanism, caused the early introduction in America of improvements that under different conditions might first have been employed elsewhere, and thus hastened our industrial progress and strengthened us in competition with other nations.[10]

As our society became more complex, Americans were confronted with the hard choice of deciding whether to regulate business activities through the direct intervention of Government bureaucrats or to enforce competition as a means of insuring that the fruits of innovation would be widely shared. This issue was resolved in 1890 through the passage of the Sherman Act which has been supported by both of our great political parties during the intervening 70 years with little deviation. Perhaps its most unique feature lies in the fact that it is general legislation applicable to all industries and citizens, and it does not attempt to establish special rules for any segment of our complex economy.

In recent years there have been numerous efforts to establish legislation that would deal with the particular problems of some restricted segment of our economy. However, the Supreme Court has always

[8] Oliver, John W., "History of American Technology," op. cit., p. 127.
[9] Ibid., p. 128.
[10] Clark, Victor S., "History of Manufactures in the United States," vol. 1, Carnegie Institution of Washington, 1929, p. 314.

looked with disfavor on class legislation. During the course of debate on the original Robinson-Patman Act, this issue was raised by former Senator Arthur Vandenberg, of Michigan, in a colloquy with Senator Marvel M. Logan, of Kentucky, then a member of the Senate Judiciary Committee who had formerly served as chief justice of the Kentucky Court of Appeals, the highest court in that State.

Senator Vandenberg inquired:

> Is it not a fact that this provision was written entirely with the field of retail merchandising in mind, and that it never was contemplated that it was intended to reach into industrial production? [11]

The following colloquy ensued:

> Mr. LOGAN. Really that was my idea about it. However, it had to be general. We could not pick out one particular business.
>
> Mr. VANDENBERG. I understand.
>
> Mr. LOGAN. But I had no idea, until the Senator from Michigan mentioned it, that it had anything to do with the automobile industry. It might have something to do with the industry of mining. It might be that the purchasing power of some manufacturer might be so great that he could buy coal in quantity limits that would enable him to drive out all competitors, and there ought to be some power somewhere—I do not care whether it is in the Federal Trade Commission or where it is—to say to those doing that which would promote monopoly that "through quantity discounts you shall not be allowed to create such a monopoly." I do not know just how it should be done, but this is the best effort I could make at it.
>
> Mr. VANDENBERG. The Senator has been very frank in saying that the proviso was drawn in contemplation primarily of retail merchandising and its related problems.
>
> Mr. LOGAN. While I did not draw the measure, that has been my idea about it, and it is my idea now.
>
> Mr. VANDENBERG. Exactly.
>
> Mr. LOGAN. But I apprehend that if we attempt to make exemptions of particular classes of business we may run into difficulties with the Supreme Court. * * * If we exempt one group, and make the law apply to another, I am afraid we may have some serious constitutional difficulty.[12]

In view of this basic philosophy, a serious question of propriety is raised in the continuing investigation of the detailed pricing practices of specific industries such as steel, automobiles, bread baking, and drugs. Although these hearings were first started in 1957 with a discussion of broad economic issues, they rapidly changed their complexion into a review of specific industry problems.

[11] "Strengthening the Robinson-Patman Act and Amending the Antitrust Law Prohibiting Price Discrimination," report of the Committee on the Judiciary, U.S. Senate, 85th Cong., 2d sess., Rept. No. 2010, July 28, 1958, p. 63.

[12] Ibid., pp. 63-64.

It is significant that 26 volumes of hearings have been produced encompassing 16,505 pages. Of these, the steel industry accounted for 3 volumes; the automobile industry for 2 volumes; asphalt roofing for 1 volume; the bread industry for 1 volume; and drugs for 13 volumes. Furthermore, the drug hearings were started on December 7, 1959, and volume 26 was released by the subcommittee in March 1961. It is difficult to reconcile these procedures with the terms of the resolution under which the subcommittee operates.

Few consumers buy finished steel products. Comparatively few of our citizens buy new cars in any one year. Bread is a relatively small portion of any family's budget. However, drugs have received the subcommittee's principal attention because they are a product which no one normally wishes to buy. In fact, all that one can expect through the purchase of a drug is to be restored to the condition of health which prevailed prior to the onset of an illness, and there is a general resentment on the part of most people toward paying for medical care and drug bills. Any objective study of the antitrust laws cannot be influenced by such considerations.

It is clear to any disinterested observer that steel and automobiles play a far more important role than drugs in terms of income generated, employment levels and taxes paid. However, the emotional impact of the drug business is one upon which the majority's staff has attempted to capitalize.

It might be pointed out that while there are only three major automobile producers, in the ethical drug business there are 28 firms which account for 90 percent of the total business. Hence, there is active competition, and inasmuch as the resolution authorizing the activities of the subcommittee was directed primarily at the prevention of monopoly and not toward the consideration of the prices of particular producers, there is little ground for the type of inquiry which has been pursued.

In previous reports there have been frequent references to the bias of the staff toward our free enterprise economy. It is particularly evident in the drug hearings, and a number of specific instances illustrate that a Government-operated enterprise is immune from traits which would be regarded as objectionable if the same operation under identical management is privately owned and operated for profit.

For example, the Schering Corp. prior to World War II was a German-owned enterprise. It was seized by the Alien Property Custodian when hostilities started, and Mr. Francis C. Brown, its president, was directed by the President of the United States, Franklin Delano Roosevelt, to operate that enterprise in the interests of the U.S. Government. Mr. Brown in his appearance before the subcommittee testified to the effect that his immediate superior was the Attorney General of the United States. From the time that this corporation was seized until 1952 when the Government's investment was liquidated, it was operated by the Alien Property Custodian.

In response to a question by the chairman, Mr. Brown indicated the profits during the period of Government operation as a percentage of

sales. A tabulation of the data included in his statement under both public and private operation is most revealing:

Profits after taxes in percent of sales

Year:	Percent	Year:	Percent
1944	7.3	1952	8.9
1945	7.2	1953	8.4
1946	18.9	1954	8.0
1947	13.4	1955	[1] 18.0
1948	13.3	1956	19.4
1949	11.6	1957	19.0
1950	10.8	1958	16.6
1951	8.9	1959	14.8

[1] Discovery of prednisone and prednisolone.

Furthermore, Mr. Brown, who has operated this property continuously from the time that it was taken over by the Government to the present time has a unique background of service to his country. Mr. Brown was appointed by President Franklin D. Roosevelt as a general counsel for the Federal Deposit Insurance Corporation. He was subsequently appointed by the Alien Property Custodian to operate the Schering Corp. in the interests of the Government. When the property was sold to private interests in 1952, he remained as president.

Mr. Brown, in a colloquy with Mr. Paul Rand Dixon, counsel and staff director for the subcommittee, explained his relationship to the Federal Government during this period as follows:

> Mr. DIXON. I am now talking about the Attorney General's directive and the Executive Order issued by the President.
>
> Mr. BROWN. They are two different things. My responsibility was to comply with the directions which I received from the Alien Property Custodian, the then Attorney General of the United States.
>
> Mr. DIXON. All right.
>
> Then it is very plain that you took your orders from the Attorney General.
>
> Mr. BROWN. This was my boss.[13]

It is also significant that a licensing agreement between the Schering Corp. and a number of other companies in the drug field, which has been the subject of adverse comment in the majority's report, was negotiated during this period of Government ownership with the approval of the head of the Antitrust Division of the Department of Justice as well as a U.S. district court judge. This agreement effected the development of cortisone and a patent was never issued. A similar agreement was negotiated under private ownership for prednisone and prednisolone. In this latter case, although a patent had not been issued, the chairman took exception to the fact that a licensing agreement had been entered into on a product where a patent application was still pending. He said:

> I have forgotten how to be a lawyer sometimes. But speaking just as a lawyer, in regard to efforts to restrict distribution and to collect royalties on a patent which you do

[13] "Administered Prices, Hearings Before the Subcommittee on Antitrust and Monopoly," Committee on the Judiciary, U.S. Senate, 86th Cong., 1st sess., pt. 14, p. 7945.

not have, isn't that a clearcut violation of the antitrust laws? [14]

In this instance there was an obvious interference between a number of firms who had independently developed the same compound, and unless an agreement was made, it would have been impossible to have given the consuming public the benefit of this development for many years while litigation was underway. It is a disservice to challenge an agreement which makes a new development available to the public and improves our general standard of health even though it may add a relatively small amount to the benefits of the company that believes it is responsible for the development in question. In any event, there is no marked difference in the procedures that were followed under private operation in the licensing of prednisone and prednisolone and cortisone under the action of the Alien Property Custodian.

With respect to a patent agreement on a development where the patents were still pending during the period of Government operations, Mr. Brown testified as follows:

> Merck & Co. had completed the first synthesis and furnished the first material used in patients. Therefore, Merck led Schering in making this important compound available. The process was covered by various patents and, to clear the road of all patent obstacles, Merck, Schering, Ciba Pharmaceutical Products, Inc., and Organon, Inc., licensed Research Corp., which held the patents of independent chemical workers, and gave Research the right to license any other applicant, taking such licenses themselves. This arrangement was submitted to the Antitrust Division and to the court which had reserved jurisdiction of an old antitrust consent proceeding to which some of the companies were party. The court authorized execution of the agreement.[15]

Still another sidelight on the character of Mr. Brown is indicated in a telegram sent to the subcommittee by the junior Senator from New Jersey, Senator Williams, who stated that:

> In New Jersey, we are proud of Frank Brown, not only because of his 10 years of excellent service in our Federal Government in 1933 when he served as counsel in charge of drafting the Banking Act of 1935 and continuing during his service as Counsel, Solicitor, and General Counsel to the Federal Deposit Insurance Corporation and as special advisor to the Office of the Alien Property Custodian, but also because, under his leadership during the last 16 years, Schering Corp. has done an outstanding job in the field of drug research and has thereby made a significant contribution to the cause of an improved medical science.[16]

Apparently, those Senators who are most familiar with the operations of this enterprise do not share the biases which were so clearly shown during the interrogation of Mr. Brown by the majority's staff of the subcommittee.

Another example of the confusion evident in the attitude of the majority's staff over the role of an individual who has served well in

[14] Ibid., p. 7931.
[15] Ibid., p. 7850.
[16] Ibid., p. 7849.

both public and private life is furnished by an examination of the careers of those who are responsible for the activities of another important pharmaceutical firm, namely Merck & Co., Inc. In this instance, the chairman of the board is Dr. Vannevar Bush, who, during World War II, was responsible for the Office of Scientific Research and Development, a position to which he had been appointed by President Franklin Delano Roosevelt. He is also honorary chairman of the corporation of the Massachusetts Institute of Technology.

Mr. John T. Connor is presently president of Merck, and he, too, has rendered distinguished public service. In his opening statement he said:

> Before coming to Merck I worked for the Federal Government in various capacities for about 5 years, during and right after World War II: As General Counsel of the Office of Scientific Research and Development, as Marine Corps air combat intelligence officer on active duty in the Pacific, as first counsel of the Office of Naval Research and finally, as special assistant to Secretary of the Navy James Forrestal.
>
> Since then I have served the Government several times in an advisory capacity and at present am a member of the National Advisory Heart Council of the National Institutes of Health.[17]

The following colloquy between the chairman and Mr. Connor is of interest:

> Senator KEFAUVER. You were General Counsel for the Office of Scientific Research and Development. What did you make there?
>
> Mr. CONNOR. Senator, I read George Dixon's column in the Washington Post this morning on the publication of Government salaries, and I agree that Government salaries are shockingly low. My salary when I left the Government service in 1947 was $10,000. * * *[18]

By no stretch of the imagination is there any connection between a person's compensation as a public servant during a period of national emergency with his earnings in free competitive enterprise.

Preceding Mr. Connor's appearance, a telegram from the junior Senator from New Jersey, Senator Williams, was read into the record. It stated:

> In New Jersey, we are proud of John Connor, not only because of his outstanding record of Government service as General Counsel to the Office of Scientific Research and Development, as counsel to the Office of Naval Research and as special assistant to then Secretary of the Navy Forrestal, but also for his leadership of a corporation which has made many significant contributions in the filed of medicine, through expanded research and development.[19]

[17] Ibid., pp. 8013-8014.
[18] Ibid., p. 8131.
[19] Ibid., p. 8012.

Senator Case, the senior Senator from New Jersey, made a personal appearance before the subcommittee and stated that:

> * * * John Connor, president of Merck, is one of my old friends, a person whose veracity, whose social consciousness, whose concern for doing a job not only in a narrow sense for a company or an industry but for humanity, is as great as anybody's I know of.
>
> This is the second time I have had the honor of presenting Mr. Connor to a committee of the Senate this year. Representing his industry, he testified on behalf of the Hill bill which I think you, Mr. Chairman, and I believe the Senator from Wisconsin, and I and many other Senators cosponsored for an international medical research program. * * * [20]

In view of the high character of the witnesses, it is most unfortunate that the proceedings of the subcommittee led to a general characterization on the part of responsible business publications that its proceedings were unfair and designed to place our free, private, competitive enterprise system in a bad light.

For example, the magazine, Printers' Ink, recently published a special report entitled "The Shame of Congress." It is based on articles which appeared in its issues of August 19 and August 26, 1960, in which it urged the need for rules of fair play to guide congressional investigations. If this subcommittee, which has so great an opportunity to promote our free enterprise system at a time when communism is gaining new adherents, is to earn the respect of the American people and the business community, it must cease its attacks on responsible, dedicated individuals. It must also discard its preconceived ideas and beliefs which have long since been disproved by the performance of American industry since the 1930's.

It should be noted that during the 83d Congress the chairman of the subcommittee was the sponsor of a resolution to establish a code of fair procedure for congressional committees. It was supported by 19 other Senators. Among the provisions of this resolution were the following:

1. Approval of full committee required for appointment of subcommittees with less than three members.
2. Selection of committee staff and personnel subject to approval of the majority of committee members.
3. Written notice must be given 16 hours prior to committee meeting, unless waived by committee majority.
4. The resolution setting forth the subject and scope of committee hearings or investigations must be specific and can only be amended by majority vote of full committee.
5. Submission of any official committee report to all members 24 hours prior to its consideration by committee is required.
6. Testimony taken in executive sessions cannot be released by members or staff without prior authorization by majority of full committee. * * *
7. Twenty-four hours' prior notification must be given a witness called by committee, outlining the subject matter on which the witness is to be interrogated.

[20] Ibid., pp. 8011-8012.

8. The right to make an oral statement or submit a sworn statement is given to every witness, and the statement must be included in the transcript of the hearings.

9. Release of statements or material adversely affecting an individual by a member of committee staff is prohibited, unless there has been prior or simultaneous release of rebuttal.

10. Persons adversely affected by testimony taken in public hearings are given the right to cross-examine witnesses in public hearings, be represented by counsel, and subpoena witnesses and documents on their behalf at the discretion of the committee.

11. Persons adversely affected by the release of testimony taken in executive sessions are given the same rights to cross-examine, and so forth, as if the testimony had been taken in public hearings.[21]

The only justification for the vast expenditures which the Senate has granted to this subcommittee is to promote and further American free competitive enterprise. This is the purpose which underlies our antitrust laws and are, of necessity, applicable to industry problems generally. For the past 4 years, a small handful of companies have been subjected to investigatory procedures which would be more appropriate in a criminal action than in a congressional investigation. An examination of the record fails to indicate that the staff recognizes that any of these companies have made any contribution to the welfare of the American people by producing better products, providing employment to millions of our citizens, and supplying the Federal Government with the revenues which their activities make possible. The issues involved are far too important to be treated in this cavalier fashion, and the individual firms have suffered irreparable damage even though they have not been found guilty of any violation of Federal law because of the manner in which the questions were presented during the interrogation of witnesses and in the text of the majority's report.

It would be impossible to attempt to refute the many unsubstantiated and selected portions of the testimony which have been included on drugs for reasons previously stated and, at the same time, meet the test of conciseness and objectivity required of Senate reports. A careful review of the voluminous and extensive transcript, including irrelevant and misleading charts and exhibits, clearly shows that those statements by reputable witnesses disprove the preconceived ideas of the majority's staff. However, they were totally ignored in the preparation of its report. Here is an example. The majority report makes reference to three case histories attacking three specific drugs, namely: chloromycetin, manufactured by the Parke-Davis Co.; decadron, manufactured by Merck & Co., Inc.; and diabines, manufactured by Charles Pfizer & Co.

The minority reiterates its position during the hearings that the Antitrust and Monopoly Subcommittee serves no legislative purpose when it presents merits and demerits of a certain ethical drug. In doing so, the subcommittee not only goes beyond its jurisdiction but it also invades the province of physician-patient relationships; and

[21] "The Shame of Congress," a Printers' Ink reprint of its Aug. 19 and Aug. 26, 1960, special reports, pp. 12–13.

it causes great concern in the user of the named drugs and creates a loss of confidence of the patients using the named drugs in the doctors prescribing said drugs.

It is impossible to refute each of the detailed items contained in the majority report with reference to said drugs which are misleading. The witnesses during the hearings representing the drug companies fully explained their position with respect to the above three named drugs, however, the explanations are not fully reported in the majority report.

One illustration would prove this point: The majority report on page 209, severely impugns the integrity of Merck & Co., Inc., one of the drug companies which testified, in its advertising. The claims made by Merck in promotional literature at the time decadron was introduced were based on the clinical results then available. As further clinical evidence accumulated, these claims were modified to represent the best estimate obtained from a broad program of use. See page 8879 et seq., record of hearings. In an effort to convey a different impression, the majority report fails to indicate that Merck based its claims on the work of more than 390 investigators, as shown in the record on page 8880.

The majority views present a highly distorted image of an industry that has given the American people the best drugs in the world and unsurpassed standards of health. In fact, in the opening statement of the drug hearings on December 7, 1959, the chairman said:

> While this country has the best drugs in the world, it would appear from the great number of letters which the subcommittee has received that many of our citizens are experiencing difficulty in being able to purchase them. * * *[22]

In view of the extreme bias demonstrated throughout the majority's report, it is questionable whether there was any need to hold these extensive hearings. The same basic conclusions could have been drawn on the basis of the preconceived ideas of the staff without the necessity or expense of immobilizing Senators or members of an important industry in order to produce these unwarranted conclusions. In fact, these same views were found in such diverse industries as steel, automobiles, asphalt roofing, and bread.

There are 180 million people in the United States, and the letters received by the subcommittee hardly can be considered a representative sample of public attitudes toward an industry which has lengthened the life span of our population and has restored many hopelessly ill people to good health.

Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association of Washington, D.C., in his testimony stated that:

> Many of us recall from personal experience in our younger days how often we had only prayer and hope when illness struck, and the kindly sympathy of the physician. This has changed, and in the short period of a quarter of a century, disease after disease has been erased from the list of cripplers and killers, and as I will show you later in the presentation, there isn't any disease left to my knowledge that the pharmaceutical industry is not in some way attempting to attack

[22] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14 p. 7833.

today. These discoveries have been made possible in large part by the development of the drug industry and of course with the cooperation of doctors and pharmacists and others who are actively engaged in scientific fields. This is a team project. But when it comes to drug therapy, the pharmaceutical industry has taken the pioneer steps and led the way. * * *

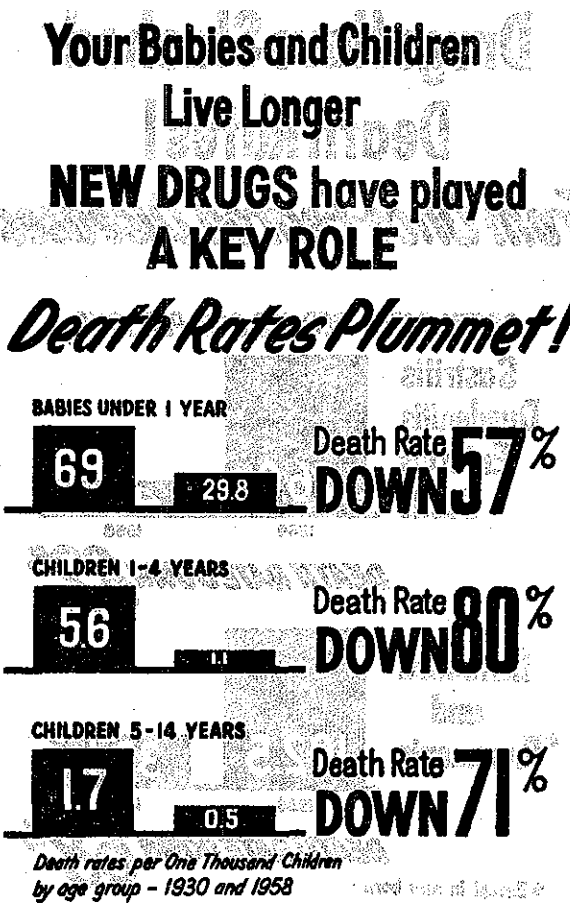
At the turn of the century the life expectancy was less than 50 years. Today it is almost the biblical three score and ten. I have also found that they are interested and impressed when they realize that there are millions of Americans living today who would have been dead if our Nation's death rate, such as existed roughly 25 years ago, had continued.

In fact, statistically in this room this morning, which seems filled, there probably are 11 or 12 people presently alive who would have been dead if our death rate of 1935 still existed. And I cannot help but wonder which of us might have been included in the 11 or 12.

In the next chart there is a presentation of the advances that have been made, and I would like to stress this with full recognition of the fact that this is a cooperative medical team result. You will see that these rates apply to ages that are, shall we say, susceptible to the effects of drugs. These young individuals like the older people are the ones who have diseases so commonly that fall before drugs.

And when we look at this chart and find that babies under 1 year don't die as frequently as they used to, and those a little older less frequently, I think again we have a concrete example of what that may mean to our own families, our own children and our grandchildren also.

CHART 1

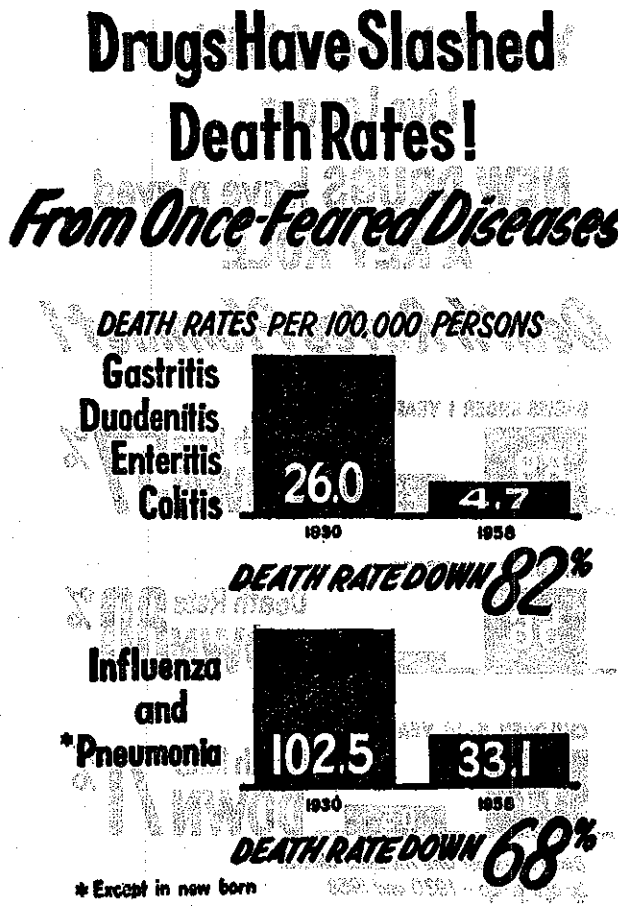


The next chart is a further indication of the way diseases have fallen before the onslaught of modern medicine.

And again I emphasize these because these diseases are ones that are particularly susceptible to the effect of drugs.

* * *

CHART 2



In fact, the National Health Education Committee has reported that in just 1 year the U.S. Treasury gained more than a billion dollars and almost $6 billion was added to the national income as a result of the decline in mortality rates since 1937.[23]

Dr. Smith also stated that:

> Furthermore, there has been no missile gap in pharmaceutical research. While the U.S. pharmaceutical industry has been leading the world in the development of new medicaments, spurred by the incentives of the free enterprise system, the Soviet Union has all but dropped from the race. No single new drug is attributable to Russia in the 42 years that have passed since the October revolution. On the other hand, the U.S.S.R. has freely pirated American developments and is selling identical drugs in world markets at a price advantage, presumably as part of its effort to buy the friendship of uncommitted nations.[24]

[23] Ibid., pt. 19, pp. 10616-10617; charts, pp. 10683, 10684.
[24] Ibid., p. 10680.

A chart[25] was included in the hearings by Mr. Connor which dramatically shows America's progress in pharmaceutical research. It follows immediately:

TABLE 1

DISCOVERY OF CORTICOSTEROIDS
UNITED STATES VS THE SOVIET UNION

CORTICOSTEROID		UNITED STATES	USSR
CORTISONE	(1949)	✓	0
HYDROCORTISONE	(1951)	✓	0
FLUDROCORTISONE	(1954)	✓	0
PREDNISONE	(1955)	✓	0
PREDNISOLONE	(1955)	✓	0
METHYLPREDNISOLONE	(1957)	✓	0
TRIAMCINOLONE	(1958)	✓	0
DECADRON	(1958)	✓	0
	TOTAL	8	0

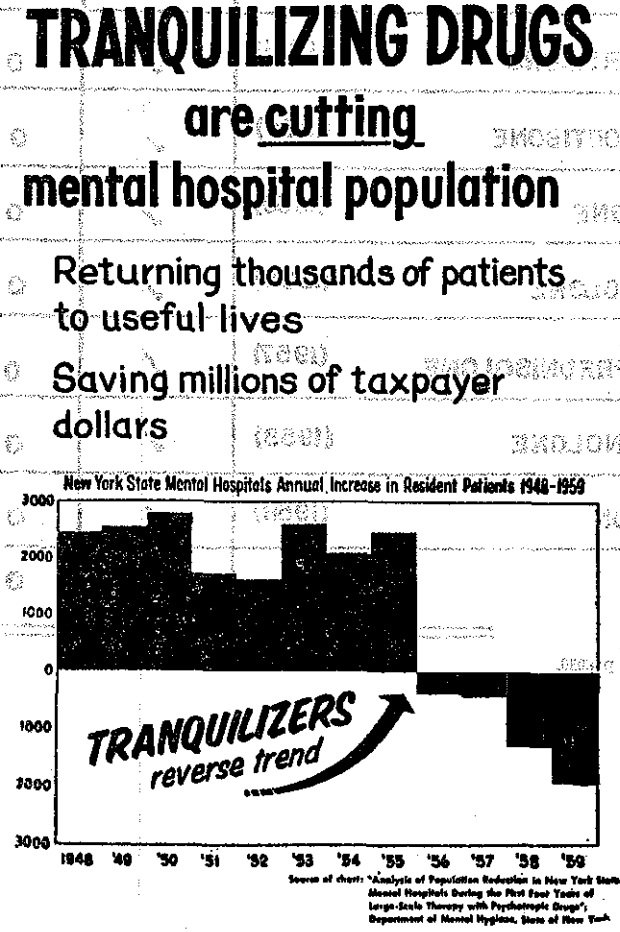
[25] Ibid., pt. 14, p. 8036.

There was a time when the budgets of most States were heavily laden with the expenses of maintaining tuberculosis sanatoriums, and mental hospitals are still a major item in the budgets of most of our States. Irrespective of the charges made by those who have a bias against the pharmaceutical industry, the fact remains that by and large the cure of tuberculosis is no longer a major item in the budgets of most of our States, and rapid progress is being made in finding cures for mental illness.

Dr. Smith also said:

> The next chart [26] is just one example of how these savings come about for the patient suffering and for dollars. You can see what a drug or a group of drugs can do in one field when that field is successfully approached. Instead of the heavy expenditures as suggested above the centerline, we find an entirely different picture or trend below the line.

CHART 3



[26] Ibid., pp. 10617-10618; chart, p. 10686.

Testimony before the subcommittee shows that there are 200,000 practicing physicians in this Nation. Only a handful of witnesses appeared who were critical of the practices of the drug industry. In this regard, during the course of the hearings, Senator Hruska said:

> * * * we have had a series of doctors who are individual members of a profession numbering in excess of 200,000. These witnesses have not been representative, either officially or in fact, of their profession. In the main they have presented nonconforming, antagonistic views, clearly not held by the great preponderance of their professional brethren.
>
> If the drug industry is guilty of any illegal or improper acts, the witnesses called so far, the nature and character of their testimony, and their obvious bias are indeed a poor, unsatisfactory way in which to make acceptable proof.[27]

Among the experts who testified on behalf of the drug industry was Dr. Philip S. Hench, who for 35 years was on the staff of the Mayo Clinic and was awarded the Nobel prize for his work in the treatment of rheumatoid arthritis.

Certainly, in evaluating the testimony of doctors, as with any other profession in our society, the value placed on their achievements by their peers is a major consideration. With few exceptions, those who appeared on behalf of the majority's staff were doctors who had not achieved any substantial recognition by their colleagues. This fact should not be unexpected in view of the character of the witnesses who appeared in opposition to the drug industry, as most of them were comparatively young and had not had an opportunity to achieve distinction in their chosen field of activity.

Unless we are to socialize the entire development of drugs, a profit motive must play a role in the development of new and superior pharmaceutical products. When someone says that profits for the drug industry should be relatively smaller if the corporation recognizes its social responsibility, that person should be in a position to say what constitutes a profit within the realm of recognition of social responsibility.

It is very easy to make sweeping charges as long as it is not necessary to be specific. If the public is being exploited by high drug prices, it is not only a violation of the concept of social responsibility, but competition itself has failed. If a profit is being made to hire people, stay in business, pay dividends to those who put up risk money, and to develop funds for research and modern buildings and increase production, there is no violation of social responsibility. On the contrary, there is a just awareness of business responsibility and the moral obligations of management.

What is apparently completely overlooked by the majority's staff is the fact that investors in this industry have alternative opportunities to use their funds. They are under no compulsion to finance research and improve the health of our people. The record clearly shows that the drug industry in this country has been one marked by a phenomenal growth stemming from developments during World War II. It is also one in which the risks of failure are immense, and any economist is well aware that if an industry has such characteristics,

[27] Ibid., pt. 18, p. 10317.

it normally must operate at a higher profit return than those producing more stable products.

Mr. John T. Connor, president of Merck & Co., in his testimony reviewed his company's experience in pioneering with the development of cortisone. He stated that:

> Our marketing statistics show that in 1950 we had 100 percent of the drugstore and hospital market. In 1951 we still had 99.9 percent.
>
> By 1952 the competition had knocked us down to 76.8 percent. But a harder blow came in 1953. That year our share of the market slid all the way down to 54.8 percent. That lesson in merchandising was one of the factors that led us to merge with Sharp & Dohme, which had something we at Merck did not then possess—a fine sales force specially trained to service the medical profession. * * *
>
> As in other industries, our driving force is profits. But unlike other industries the single most effective way to earn those profits is by making existing products obsolete, including our own.
>
> We do this through research. The result is a rate of obsolescence unknown elsewhere. More than 80 percent of the prescriptions written during the third quarter of 1959 for Merck products could not have been written 10 years ago; the drugs had not yet been born. * * *
>
> As you can see, Mr. Chairman, in this battle of product obsolescence, we are waging war with ourselves as well as with our competitors here and abroad. Our research laboratories are just as busy knocking out their own creative achievements as they are knocking out those of Merck's competitors.[28]

Mr. Connor also said:

> In 1958 we hit what I hope will be the bottom—a new low of 17.2 percent.
>
> Even more significant * * * "Cortone," our brand of the original steroid, cortisone, dropped from 100 percent of all new prescriptions written in 1950 down to 3 percent in 1956 and was off the chart as a separate item by 1958.[29]

All of the evidence adduced during the course of these hearings clearly shows that the modern drug industry is highly competitive and that there are many possibilities not only for productive obsolescence but even the death of a firm itself. Hence, under such conditions, it is to be expected that the rate of return on capital would be higher than in all manufacturing in order to partially compensate for the greater risks that are inherent in any endeavor where scientific advance normally takes place so rapidly.

II. The Drug Industry

No individual enjoys buying drugs per se. However, everyone is interested in increasing his lifespan and remaining in good health. There can be no question of the fact that the development of new

[28] Ibid., pt. 14, p. 8026
[29] Ibid., p. 8027.

drugs, and particularly the antibiotics and other so-called miracle drugs, have supplied the medical profession with new tools with which to improve the Nation's health and general well-being.

A study by the Metropolitan Life Insurance Co. shows that during the calendar year 1911–12, the expectation of life at birth was 46.6 years.[30] In 1960 it is 70.6 years.[31] Even though modern drugs may be expensive, those who are enjoying a full life are more than willing to pay the cost.

Dr. Smith, of the Pharmaceutical Manufacturers Association, previously referred to, during the course of his testimony referred to a study by Dr. Jules Backman, a nationally known economist and professor of economics at the New York University School of Commerce, Accounts, and Finance. In Dr. Smith's prepared statement, he referred to a pointed observation made by Dr. Backman about the price of drugs by stating that—

> "If drug prices had risen as much as other prices since 1939," he said in October 1959, "it would cost the consumer at least another billion dollars to buy the drug preparations now consumed."[32]

Dr. Smith continued:

> Dr. Backman's statement emphasizes a key fact about the prices of the products of this Nation's competitive drug industry in recent years. * * *
>
> In a period of continuing inflation, the wholesale price of drugs consistently since 1948 has resisted upward pressures—rising only 3 percent in the past 10 years. This has occurred, mind you, at a time when wholesale prices of all industrial products were soaring 22 percent. (See chart on p. 286.)
>
> And it has occurred in a period when drug industry costs, far from remaining stable, were spiraling. Drug industry wages went up 70 percent, for example. In the face of great demands for expansion, construction costs shot up 64 percent.
>
> I think I should add, at this point, that several classes of the most effective new drugs produced by the industry were not on the market 10 years ago. They consequently are not included in the BLS figures. But if it were somehow possible to include them, the available evidence on the trends indicates that their inclusion would result in no substantive change in the commendable price performance record of this industry.
>
> This subcommittee is, however, understandably interested—as is the drug industry—in the price the consumer ultimately pays for the product.
>
> Aside from humanitarian reasons, the drug industry has a solid and logical economic purpose behind its interest in reasonable prices for consumers. Successful and profitable business operations, in this industry, are possible only if there is a high volume of sales in drugs. These sales, obviously, will diminish if retail prices are too high—if they prevent the widest possible use of the product by the consumer.

[30] "Statistical Bulletin," Metropolitan Life Insurance Co., vol. 42, January 1961, p. 6.
[31] Ibid.
[32] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 19, p. 10692.

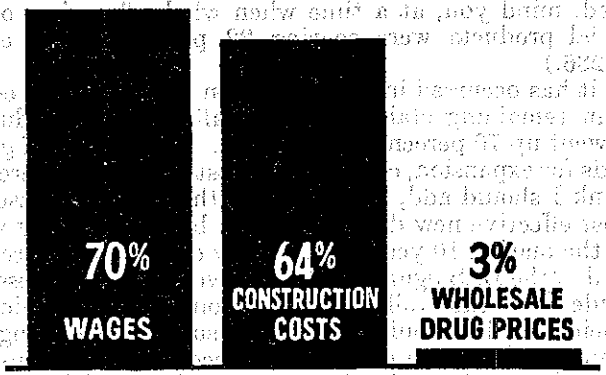
CHART 4

Drug Prices Held Down while Business Costs Soared

1948 1958

WAGES* UP 70%

CONSTRUCTION COSTS UP 64%



* Average hourly earnings, chemicals & allied products

Source: Business Statistics 1959 Edition, U. S. Dept. of Commerce, Office of Business Economics, pp. 32, 43, 75

Additionally, of course, each company is confronted with constant competition from other companies within the industry—each attempting to gain a larger part of the market, each attempting to build sales by a combination of creating better medicinals and broadening their usage through prices that are lower than those other companies charge for similar products.

How do retail drug prices compare with those of other commodities essential to the U.S. citizen for well-being and security?

The fact is that since 1947–49 the retail price of drugs and prescriptions has risen, not more, but somewhat less than other elements of the cost of living (a rise of 21.4 percent compared with 23.7 percent). Rents have gone up 38.7 percent, personal care 29 percent, and transportation 44.3 percent.

The American consumer today, despite all that has been said about drug prices, actually is spending about the same part of his income on drugs as in 1939, before most of our specific high potency drugs were available.

Drug prices, in fact, have increased only about half the extent of fees for doctors and dentists—and only one-fourth as much as the rise in hospital rates. * * *

Interestingly enough, the far more effective drugs of 1960 actually take less out of each individual's health dollar than they did 30 years ago. In 1930, 20 cents of each American dollar spent for health purposes went for drugs and sundries. In 1958 it was 19.9 cents—clear evidence that the price of drugs has not risen relative to the total expenditures for medical care.

These drug prices, incidentally, account for about 1 penny of each person's disposable income. One cent for drugs. Compare that with the 5 cents of every dollar that goes for liquor and tobacco, or the 4 cents spent by the average American out of each dollar for entertainment.[33]

The very fact that many individuals who would have died from pneumonia, diphtheria, or polio at an earlier age are today among the aged is one of the reasons for increasing concern to provide medical care for this group, and this fact has undoubtedly contributed to the interest in the investigation of drug prices.

Any discussion of medical care and drug prices must also include the amazing revelation that modern science has made it possible to cure many diseases that formerly involved a hopeless burden on the patient's family and a terrific social cost. Furthermore, in terms of earning power, there has been a decided economic advantage which has benefited many of our people.

Although medical care is necessarily an expensive item in the average family's budget because it now embraces so many additional features and services that were not formerly available, it is significant that a study prepared by the Joint Economic Committee on November 10, 1959, shows that the entire cost of medical care in 1958 was $16,384 million. Of this, the cost of drug preparations and supplies

[33] Ibid., pp. 10693-10697.

was only $3,261 million, or 19.9 percent of the total.[34] This includes proprietory as well as ethical drugs. All medical care was only 3.7 percent of the gross national product of $441 billion in 1958.[35]

This inquiry is directed primarily to ethical drugs; that is those which are available to individuals on prescription. There are three stages of responsibility to insure that an individual is amply protected:

First, there is the reputation of the supplier.

Second, there is the professional integrity of the doctor. It is generally conceded that there is no group in our society who has to undergo a more rigorous training in order to fulfill his professional responsibilities than those who are practicing physicians. Furthermore, every doctor has to subscribe to the Hippocratic oath, which reads as follows:

> I swear by Apollo the physician, and Asclepios and Health, and All-heal, and all the gods and goddesses, that, according to my ability and judgment, I will keep this Oath and this stipulation—to reckon him who taught me this Art equally dear to me as my parents, to share my substance with him, and relieve his necessities if required; to look upon his offspring in the same footing as my own brothers, and to teach them this art, if they shall wish to learn it, without fee or stipulation; and that by precept, lecture, and every other mode of instruction, I will impart a knowledge of the Art to my own sons, and those of my teachers, and to disciples bound by a stipulation and oath according to the law of medicine, but to none others.
>
> I will follow that system of regimen which, according to my ability and judgment, I consider for the benefit of my patients, and abstain from whatever is deleterious and mischievous. I will give no deadly medicine to any one if asked, nor suggest any such counsel; and in like manner I will not give to a woman a pessary to produce abortion. With purity and with holiness I will pass my life and practice my Art.
>
> I will not cut persons labouring under the stone, but will leave this to be done by men who are practitioners of this work. Into whatever houses I enter, I will go into them for the benefit of the sick, and will abstain from every voluntary act of mischief and corruption; and, further, from the seduction of females or males, of freemen and slaves.
>
> Whatever, in connexion with my professional practice, or not in connexion with it, I see or hear, in the life of men, which ought not to be spoken of abroad, I will not divulge, as reckoning that all such should be kept secret. While I continue to keep this Oath unviolated, may it be granted to me to enjoy life and the practice of the art, respected by all men, in all times! But should I trespass and violate this Oath, may the reverse be my lot!

Before entering into practice every physician must serve an internship and be licensed by 1 of our 50 sovereign States to practice medicine. He is also under the discipline of complying with the ethical

[34] Roberts, Markley, "Trends in the Supply and Demand of Medical Care," prepared in connection with the study of employment, growth, and price levels, Joint Economic Committee, Congress of the United States, 86th Cong., 1st sess., p. 54.
[35] Ibid., p. 52.

standards of his State and local medical societies. There are few other occupations where the public is so well protected from malpractice.

Even though a doctor assigned to a case is licensed and has taken the Hippocratic oath, in those cases where a registered nurse is also employed, she, too, has assumed the responsibility for high professional ethics as indicated in the following code for professional nurses adopted by the American Nurses' Association as revised in 1960.

1. The fundamental responsibility of the nurse is to conserve life, to alleviate suffering, and to promote health.
2. The nurse provides services based on human need, with respect for human dignity, unrestricted by considerations of nationality, race, creed, color or status.
3. The nurse does not use professional knowledge and skill in any enterprise detrimental to the public good.
4. The nurse respects and holds in confidence all information of a confidential nature obtained in the course of nursing work unless required by law to divulge it.
5. The nurse as a citizen understands and upholds the laws and performs the duties of citizenship; as a professional person the nurse has particular responsibility to work with other citizens and health professions in promoting efforts to meet health needs of the public.
6. The nurse has responsibility for membership and participation in the nurses' professional organization.
7. The nurse participates responsibly in defining and upholding standards of professional practice and education.
8. The nurse maintains professional competence and demonstrates concern for the competence of other members of the nursing profession.
9. The nurse assumes responsibility for individual professional actions and judgment, both in dependent and independent nursing functions, and knows and upholds the laws which affect the practice of nursing.
10. The nurse, acting through the professional organization, participates responsibly in establishing terms and conditions of employment.
11. The nurse has the responsibility to participate in study of and action on matters of legislation affecting nurses and nursing service to the public.
12. The nurse adheres to standards of personal ethics which reflect credit upon the profession.
13. The nurse may contribute to research in relation to a commercial product or service, but does not lend professional status to advertising, promotion, or sales.
14. Nurses, or groups of nurses, who advertise professional services, do so in conformity with the dignity of the nursing profession.
15. The nurse has an obligation to protect the public by not delegating to a person less qualified any service which requires the professional competence of a nurse.
16. The nurse works harmoniously with, and sustains confidence in nursing associates, the physician, and other members of the health team.

17. The nurse refuses to participate in unethical procedures and assumes the responsibility to expose incompetence or unethical conduct in others to the appropriate authority.

Third, there is the individual pharmacist who has the same interest as any local merchant in retaining the goodwill of his customers. On this basis alone, there is every reason to expect that the medical needs of every individual will be carefully considered. Those who are too poor to pay for drugs will usually be supplied with the necessary preparations at clinics or through free samples furnished by drug manufacturers to the doctors.

Our primary concern in this study is with those individuals who are in the middle-income group and are burdened with excessive medical costs, but here again there has been little recognition of the fact that in recent years there has been a widespread increase in health insurance of all kinds and many of the more advanced policies also include the payment of the cost of drugs and similar preparations. In many of these cases, the costs of these insurance programs are either met on a contributory basis or they are absorbed entirely by the employer.

It would be tragic to attempt to solve the problem of high drug prices by reducing the number of medications available to sustain life. Our competitive system is the best method of insuring rapid progress.

Dr. W. G. Malcolm, president of the American Cyanamid Co., during the course of his testimony before the subcommittee, reviewed the vast increase in the research and development budget of his company, which in 1939 was $300,000 and had grown to more than $2½ million a year by 1945.[36] By 1959, this amount had risen to more than $14 million.[37]

Furthermore, Dr. Malcolm indicated the vast gamble that any pharmaceutical firm undertakes when it develops new drugs. He testified as follows:

> Twenty-five years ago Lederle was the leading producer of antisera which were then the only effective treatment for pneumonia. You can see that our investment of over half a million dollars in the antisera was nearly wiped out within a year by the introduction of the sulfa drugs.
>
> We immediately went to work in the sulfa field and developed a valuable new sulfa compound, sulfadiazine, which was a potent weapon against a wide range of infections, as well as pneumonia, and had remarkably mild and infrequent side effects.
>
> You may remember how sulfadiazine tablets saved the lives of thousands of wounded soldiers in World War II. But the introduction of penicillin in 1943 made rapid inroads on the sulfas. They still have a role in present-day therapy, but our 1959 sales of sulfadiazine were only 10 percent of what we sold in 1943.
>
> The same story has been repeated again and again with the antibiotics. Our own Achromycin and the other brands of tetracycline largely superseded our Aureomycin. * * *

[36] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 24 p. 13624.
[37] Ibid., p. 13625.

> It was fortunate for us that we were one of those who developed tetracycline, or we would have lost heavily. Since the introduction of tetracycline in 1953, our Aureomycin sales have dropped from $54,500,000 to approximately $15 million a year. The extent to which new competing broad spectrum antibiotics made inroads on this market is vividly illustrated. * * *
>
> How long will our Declomycin remain the most important new antibiotic? All I am sure of is that neither Lederle nor its competitors will relax in their efforts to discover better drugs—if left free to do so.[38]

Although these hearings have directed attention primarily to those drugs that are actually on the market, Dr. Malcolm showed that $37 million have been invested in research in important diverse areas with no significant commercial products to date. This includes $10 million for live polio vaccine, $7 million for cancer research, $3,500,000 for tuberculosis drug research, and $16,500,000 for drugs for heart disease, virus disease, central nervous system, etc.[39]

Everyone who is familiar with the American economy knows that it is impossible to finance a research program of this type unless sufficient revenues are received from commercial products in order to pay these costs. Otherwise, the company will undoubtedly go bankrupt and cease to make any contribution to the welfare of the American people.

Although many individuals regard the drug industry as static, another chart which was introduced during the course of Dr. Malcolm's testimony shows that less than one-half of the drug sales of his company came from products that were more than 5 years old.[40] This fact alone indicates the importance of research and development in terms of maintaining the position of any firm in this industry. If these new products had not been developed, it is certain that by now this company would have ceased to have been an important factor in this industry that affects the health and well-being of every citizen.

No Government agency can possibly be charged with the task of meeting the health needs of the American people as well as a privately operated competitive drug industry.

Dr. Albert H. Holland, former medical director of the Food and Drug Administration, said:

> The naive belief that if the product was not good the FDA would prohibit its sales is just not realistic. FDA labors long and diligently to protect the public but the fact of the matter is that it is completely impossible for FDA to check every batch of every product of every manufacturer that is marketed. Hence the integrity and reputation of the manufacturer assumes unusual significance where drugs and health products are concerned.[41]

The human being is an extremely complex organism, and there are few individuals who react in exactly the same manner to a given drug. This fact alone makes it necessary for both drug manufacturers and

[38] Ibid., p. 13638.
[39] Ibid., p. 13631.
[40] Ibid., p. 13627.
[41] Ibid., pt. 14, p. 8198.

their distribution channels to carry a large inventory of specialized products so that everyone's needs may be met.

It was far simpler in the days when all that was needed was a little aspirin and similar preparations. At the present time it is necessary to produce and stock literally thousands of compounds in order to serve the American public adequately. In many cases, there is very little movement of some of these preparations, and inventory and carrying charges are high. This factor is responsible for the high markups throughout the distribution phase of the drug business. If there were fewer preparations and they were faster moving, it would be possible to effect many economies in distribution that are not possible today.

Furthermore, any careful examination of these hearings shows that every responsible manufacturer is concerned with extensive clinical testing and quality control in order to meet standards that exceed those of the U.S. Pharmacopeia. While it is perfectly true that it would be legal for a firm to sell a product that met the minimum standards, most established organizations attempt to manufacture their product so that they surpass these qualifications by wide margins. On the other hand, there is a maximum limit on the potency of every drug, and this factor imposes inspection processes upon most manufacturers which are not found in other industries. Although every firm attempts to build a reputation for both itself and its products, any company manufacturing drugs where the life and health of our people is concerned has a responsibility that extends beyond that normally expected of any commercial organizations.

Again, Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association, who had also been a trustee of the U.S. Pharmacopeia for 10 years, testified that:

> A generic drug, as you know, is required only to meet the standards of the United States Pharmacopœia, which is published every 5 years, or the National Formulary, which is published at irregular intervals. These list drugs only by generic names and often lag far behind brand names drugs in actual usage. The Salk polio vaccine which has been administered to millions is not yet listed in either publication.
>
> Thus the issue resolves itself to a question. Should seriously ill patients be deprived of the benefits of new drugs developed by manufacturers at their own expense until such time as the formula is available to any drug compounder who cares to use it?[42]

Testimony was also offered by Mr. Alvin G. Brush, chairman of American Home Products Corp., who stated that—

> * * * The United States Pharmacopoeia is published every 5 years, with infrequent supplements, the last of which appeared in April 1959. The National Formulary is published at irregular intervals, not more often than every 4 years. As a result, the newest and often most effective products are not listed in them. As only a minute example of the point, neither of these formularies has yet listed, directly or through supplements, Equanil or Sparine, under

[42] Ibid., pt. 19, p. 10704.

their generic names or otherwise, not have they yet listed poliomyelitis vaccine.[43]

He also said:

> The United States Pharmacopoeia and the National Formulary contain good, but incomplete and general, standards and tests for drugs under their generic names. Our quality procedures impose more stringent and additional standards and tests for constant purity, potency, and therapeutic efficacy. Many doctors prefer to prescribe drugs under their trademarks rather than generic names simply because they believe these extra qualities are desirable.[44]

Unless additional Federal funds of considerable magnitude are to be devoted to this enterprise, it seems highly dubious as to whether the care of patients will be as well met by using a Government publication as through the promotional efforts of manufacturers who are in a position to inform the medical profession immediately of their latest discoveries.

An important and unpublicized activity of the pharmaceutical industry is the fact that they periodically remove from the shelves of druggists merchandise which has lost its potency because it has been on hand for too long a period of time. In spite of adequate labeling and the fact that the product at the time it was produced met the minimum standards prescribed by the U.S. Government, these precautions do not insure that the patient had a drug of adequate potency unless the good name of the manufacturer was also at stake. This is one of the principal elements behind the determination of many members of the medical profession to use only those drugs that have met these standards over a long period of time.

For example, Dr. Eugene N. Beesley, president of Eli Lilly & Co., in his testimony stated that—

> * * * ethical pharmaceutical manufacturers accept a greater burden of responsibility than most other manufacturers. At this moment, for example, Lilly is maintaining huge stocks of polio vaccine which represent potential protection against this dread disease for millions of children and adults. In spite of the fact that little vaccine is being used at present, we feel a continuing obligation to be prepared for sudden increases in demand resulting from threats of epidemic.
>
> * * * Vaccine not used within a 6-month period must be destroyed, and Lilly replaces outdated vaccine with fresh stocks at our own expense. During the past 5 years we have had to destroy the incredible total of more than 14,500,000 shots of outdated polio vaccine, vaccine which was produced with costly and painstaking care. This may or may not be "good business," as that term is normally used, but it is the kind of obligation which, as a pharmaceutical company, we accept.[45]

[43] Ibid., pt. 16, p. 9242.
[44] Ibid.
[45] Ibid., pt. 24, p. 14092.

Mr. Connor, president of Merck & Co., endeavored to explain a few of the more refined quality control processes that are involved in the manufacture of drugs. He testified as follows:

> Indicative of this great effort to insure quality and uniformity are the standards set for each batch of every product we make. The list of different specifications to which our steroid products must conform in order to bear our trademark is a lengthy one. Every imaginable aspect is controlled by inspection and testing. Thus standards are set and tests are required to prove the quality and amount of each substance going into the manufacture of the product. Often the range of the amount of active drug allowed is rather narrow and where an assay procedure itself is known to have an error, say $\pm 1\%-2\%$, an extra amount of drug is used to balance such a possibility. Not only is the amount of each substance controlled but the form of it may be subject to passing the most rigid requirements. Thus in our ophthalmic suspensions which come into contact with the eye, the size of the steroid crystals must fall within narrow limits. A representative specification reads:
>
> "Particle size:
>
> "A. Microscopic: No particles greater than 200 microns. (Occasional fibers should be ignored.) No more than five particles per drop of suspension in the 50- to 200-micron range. Minimum 99 percent (by number) less than 30 microns. Minimum 65 percent (by number) less than 10 microns (tentative)."
>
> This process of testing is pursued endlessly through the manufacturing process. Thus in making one of our ophthalmic solutions no less than 121 separate tests are made before Merck Sharp & Dohme is ready to assign its trade name. Subsequent to manufacture, 750 more separate tests are made to check stability. On this single product 871 separate tests are required to produce the product Merck Sharp & Dohme calls Neo-Hydeltrasol. Incidentally, these tests require at least several hundred man-hours of skilled, conscientious labor, not to mention the most advanced equipment.
>
> The "company conscience" is another name for quality control. The conscience of Merck Sharp & Dohme and Merck operates to give the doctor and the patient exactly what is expected.[46]

Americans may take great pride in the contributions that have been made by the ethical drug industry. Unwarranted attacks on the integrity of firms which have exerted every possible precaution to insure high-quality products diminish the faith of those who are ill and are in need of help, and they seem to forget that many of our citizens are living with the hope that someday someone will find a cure either through therapy or pharmaceuticals for such killers as cancer and heart disease. Such attacks destroy the morale of those who are dedicated to performing a useful task in a highly competitive industry. Although there have been many volumes of hearings, there

[46] Ibid., pt. 14, p. 8198.

is a marked lack of data that indicates any malfeasance on the part of those who are charged with the development of new and superior ethical drugs.

One witness appeared before the subcommittee who claimed to be a competent manufacturer of steroid hormones, and he stated that he employed only five individuals. In view of the fact that on one single product produced by Mr. Connor's organization there are a total of 871 separate quality control tests, there is room for doubt as to the efficacy of preparations that affect the life and health of individuals which are produced without adequate manpower and control equipment.

In making this statement, there is no intent to disparage the efforts of anyone. There are undoubtedly many fields of activity in which small business may play a vital role in the manufacture of drugs and pharmaceutical products, but it is folly to suggest that they can supplant a large integrated producer with research facilities in those advanced areas where every citizen, if given all of the facts, would gladly place his destiny in the hands of the best equipped firm.

While every business in America must earn a profit, those who operate our leading pharmaceutical firms have a high sense of social responsibility. For example, an article appeared in the August 17, 1959, issue of Time magazine which described the difficulties experienced by the Gruwell family of Idaho Falls, Idaho, who had been stricken by an unusual disease known as botulism. The only antidote for this disease that has been proven effective is a development of Lederle Laboratories, which costs about $68 for a 20,000-unit vial. In this instance, Lederle drained the barrel and packaged nearly all of its remaining antitoxin, totaling $9,591, which Lederle marked "Paid" as a public service.[47]

This statement hardly is in character with the often-repeated charges that the drug industry is animated only by profit motives. To be sure, it must earn a profit if it is to continue to serve in our competitive society, but those individuals who have selected a life of service in this field are usually more concenred with the welfare of their fellow man than the average individual.

III. Administered Prices

This entire series of hearings, which has bewildered the business community as well as the minority members of the subcommittee, has been justified on the tenuous assumption that certain industries are characterized by so-called administered prices.

The term "administered prices" was originated by Dr. Gardiner C. Means in the early 1930's. Almost 30 years have elapsed and it has not received any widespread endorsement by economic authorities. An obvious attempt was made in the opening phase of the hearings to equate administered prices—that is, prices which are posted by the seller and remain constant for a period of time—with monopoly prices. Every witness, including Dr. Means himself, was emphatic in stating that administered prices were not necessarily monopoly prices. The mere fact that a seller posts a price does not insure that a buyer will be willing to pay it, nor does it exclude the many other facets of competitive behavior.

[47] Time magazine, Aug. 17, 1959, p. 89.

In his testimony before the subcommittee, Dr. Means stated that:

> Administered prices represent a way of doing business that leads to greater efficiency and higher standards of living. We could not have our big efficient department stores and mail-order houses if prices were not administered. Without this method of pricing, big efficient industry would find it almost impossible to operate. Administered prices are an essential part of our modern economy. The point of my testimony is rather that we do not now know enough about how administered prices actually operate to be able to make good national policy in such economic fields as inflation, full employment, and enforcement of competition.[48]

The following colloquy between Senator Dirksen and Mr. Edwin G. Nourse, former president of the American Economic Association, a former vice president of the Brookings Institution, and Chairman of the President's Council of Economic Advisers under President Truman, is significant:

> Senator DIRKSEN. In your statement you said that administered prices grow naturally and properly?
> Mr. NOURSE. Yes, sir.
> Senator DIRKSEN. Out of the conditions of modern industrialism?
> Mr. NOURSE. Yes, sir.
> Senator DIRKSEN. And I think in one other part of your statement you speak of them as inevitable?
> Mr. NOURSE. Yes, sir.
> Senator DIRKSEN. You regard administered prices as an inevitable concomitant of our industrial setup?
> Mr. NOURSE. I do.
> Senator DIRKSEN. Could you actually operate an industry like the automobile industry without administered prices?
> Mr. NOURSE. I don't see how you could.[49]

The following colloquy between Senator Dirksen and Dr. John Kenneth Galbraith, professor of economics at Harvard University, is also of interest:

> Senator DIRKSEN. It is a fair conclusion then that you and Dr. Means and Dr. Nourse all agree that administered prices in our economy are an inevitable thing?
> Mr. GALBRAITH. I think that is right; yes.[50]

The majority's report refers to Dr. Means' definition of administered prices as prices that are "insensitive to changes in their market." [51] It is of some interest that the Bureau of the Budget made a request of the National Bureau of Economic Research to examine the pricing practices and index procedures of the Bureau of Labor Statistics and the other agencies that produce basic economic data. This report was filed with the Joint Economic Committee on January 24, 1961. One of the principal recommendations of the National Bureau of Economic Research was that "the individual

[48] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 1, p. 75.
[49] Ibid., p. 20.
[50] Ibid., p. 39.
[51] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. vi.

product prices should, where feasible, be collected from buyers (not from sellers, as at present) to get more information on actual transaction prices." [52] This statement, in and of itself, would indicate that even though a posted price is maintained in a catalog, there are seasonal discounts, trade discounts, and other promotional prices which greatly alter the concept of administered prices as set forth by Dr. Means.

Prof. M. A. Adelman of the Massachusetts Institute of Technology is a distinguished and eminent economist who has specialized in antitrust problems over a period of many years. An article entitled "Steel, Administered Prices, and Inflation" by Professor Adelman appeared in the February 1961 issue of the Quarterly Journal of Economics, which is published by the Economics Department of Harvard University under the editorship of Arthur Smithies. It is significant that the associate editors of this publication include such individuals as Otto Eckstein, author of a study entitled "Steel and the Postwar Inflation" under the sponsorship of the Joint Economic Committee when its chairman was Senator Douglas; Dr. John Kenneth Galbraith, a frequent witness before this subcommittee; Profs. Alvin Hansen and Seymour Harris; as well as Carl Kaysen, who was requested by the former Attorney General, William P. Rogers, to make an economic study of the antitrust laws. Each of these individuals has in the past voiced views which are in many respects similar to those advanced by the majority's staff.

Professor Adelman disposes of the mysterious and misleading term, "administered prices," by thoroughly debunking it. In his scholarly article, he stated that:

> The great bulk of prices are administered. They are not observed in the course of an irregular stream of bids matching offers; the seller (or less often the buyer) announces the price by a deliberate act, sometimes after a good deal of internal bureaucratic effort. Yet this is form, not substance; a description of how prices are announced tells us nothing of why they are what they are and not other than they are. * * *
>
> One may question whether the theory of "administered prices" rises to the scientific dignity of error. By an erroneous theory I mean one which is necessary to explain some phenomenon, and which appears internally consistent, operational, and a good fit to the facts; but which is finally proved wanting in one of more respects. The process of disproof brings out what was not previously known, and so knowledge is advanced. "Administered prices" are not a theory, but an evasion of the need for a theory. If prices rise or fall or are at some level because they are administered, then the plays of Shakespeare were written by his pen. The theory of "administered prices" is appealing because it provides a phrase that seems to explain everything. Thereby it liberates us from the need to work at explaining the forces of supply and demand in a given instance, and from the dismal compulsions of supply and demand themselves. There is a deeply felt need for both kinds of freedom. * * *

[52] "Government Price Statistics," hearings before the Subcommittee on Economic Statistics, Joint Economic Committee, 87th Cong., 1st sess., pt 1, p. 6.

> * * * Let the entrepreneur strive and hope as he will for one result, it is no use—he arrives at another. He surely deserves to cover his costs and make at least a reasonable profit—instead, the price is set by market forces, and may be grossly inadequate and "unfair." The resentment is not, however, a simple matter of wanting more. It is also annoyance at being pushed around, at not being the master of one's own fate. It is also a feeling of emptiness, of not having some identifiable human being to blame. Last year, in its issue of April 18, 1959, the New Yorker carried a story from one of its "farflung correspondents" in the Congo. A doctor there explained that in the native belief death never happens by chance, or by natural causes. Some specific human individual is always responsible, either directly or by magic. Even when a man falls out of a tree and breaks his neck, somebody has done him in. We cannot afford to be too condescending about the beliefs of the Congolese.[53]
>
> Enterprise monopoly is within the scope of the antitrust acts. But these laws have never been acts against market power as such, but only against the overt act of collusion. The Assistant Attorney General obviously believes that the fall-in-and-be-counted agreement via the public press is altogether lawful. He is probably right, not only as a matter of law but on broad policy grounds. For to convict people of conspiracy because of statements to the newspapers comes dangerously close to abridging freedom of speech and of the press; to indict someone for charging a price only because other people, over whom he had no control, charged the same price, is too close for comfort to guilt by association.[54]

It appears that the term originally devised by Dr. Means, namely "administered prices," serves as a cloak for every conceivable type of investigation by this subcommittee. If this practice is continued, it will soon render this approach ridiculous to most economists and lawyers.

During the period since this investigation began in 1957 when price levels were generally rising, there was some popular support for this concept. However, it is well to note that Dr. A. A. Berle, Jr., in his book, "The 20th Century Capitalist Revolution," referred to the effect of so-called administered prices in maintaining a stable and lower price level during the period immediately after World War II. He said:

> * * * Again immediately after the close of the war, the American market was hungry for automobiles; a new car could command almost any price the producer cared to ask. The major automobile companies declined to take full advantage of this situation, holding their list prices far below the prices obviously obtainable and actually prevailing in the black market, and did something at least to prevent their less socially minded dealer organizations from overcharging. A somewhat similar price policy—contrary, be it noted, to the dictates of supply and demand—was followed in 1947 by

[53] Adelman, M. A., "Steel, Administered Prices and Inflation," the Quarterly Journal of Economics, Harvard University, Cambridge, Mass., vol. LXXV, No. 1, Feb. 1961, pp. 18-19.
[54] Ibid., pp. 36-37.

> the larger steel companies, and in certain of its lines, by General Electric. * * * [55]

This quotation shows that administered prices may actually have a restraining effect upon the price level. At least it is generally conceded that there is a timelag before a price increase in an industry characterized by administered prices is placed in effect. This is an important factor in restraining inflation and maintaining a more stable economy.

Every witness who has discussed the subject of so-called administered prices in almost any field of activity agrees that they are an inevitable concomitant of our modern society, and by their very nature it is logical that they will pose a resistance to increasing prices faster than necessary to meet increased costs.

In spite of some of the theories that have been expressed before this subcommittee, there is a general agreement among all members of the business community that it is necessary to meet prices of competitors in good faith. Hence, there is no disposition to raise prices to a level that will require a subsequent reduction. In this sense, administered prices have undoubtedly played an important role during the postwar years in restraining those forces which would have led to erratic price changes and probably a generally higher level of wholesale and consumer prices.

IV. Minority Analysis of Majority's Charges

It would be impossible in a document of reasonable length to refute the many erroneous and unsupported conclusions that are contained in the majority's report. However, a number of basic economic facts have been developed in order to set the record straight. In doing so, it is incumbent upon the members of the minority to set forth their view that it is most inappropriate for a subcommittee charged with the investigation and improvement of our antitrust laws to indulge in a discussion of broad economic principles, patents, prices and numerous other topics that have no connection whatsoever with the subject that was assigned to this subcommittee as relevant for its hearings.

POINT 1

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that the drug industry has had a price, profit, and cost structure that was uncompetitive is unfounded and erroneous.

The majority's report states that:

> Again there appears to be a wide margin between production costs and selling price. The 1,000 tablet bottle is offered to druggists by Merck, Upjohn, Schering, and Parke-Davis at a price of $170; a consumer who bought in this quantity would pay a suggested retail price of $283. Yet, it is clear that the drug can be produced, tableted, bottled and packed for shipment to the druggist for no more than $13.61, leaving a margin of 90 percent of sale value to the manufacturer for

[55] Berle, A. A., Jr., "The 20th Century Capitalist Revolution," Harcourt, Brace & Co., New York, 1954, pp. 54–55.

his selling, administrative, and other nonproduction costs and profit.[56]

Throughout the course of the drug hearings and the majority's report there was a persistent effort to impute the costs of products from computations prepared by the staff, based on tables submitted during the course of the hearings. In most cases, the chief economist's exhibits were based on only a small portion of a company's costs, principally materials and productive labor. They completely neglected the costs of selling, distribution, general and administrative expenses, royalty payments on patents, as well as a most important item—Federal, State, and local taxes.

An example of this procedure is provided in the following colloquy between Dr. Blair and Mr. Brown, president of the Schering Corp.:

> Mr. BLAIR. This, of course, translates into a price, into a computed cost excluding selling distribution cost of $1.56 per 100 tablets.
>
> Schering's price for a bottle of 100 tablets of Meticortelone to the druggist is $17.90. * * *
>
> Mr. BROWN. Our price to the druggist is, as you quote here, $17.90 for the bottle of 100.
>
> Now, if we were simply doing the things that you have described on this piece of paper, it would seem to me that your question would be pertinent. But as I have described in my statement, we are doing a great many more things, and these include the informational work, the pioneering work which we did in the development of these compounds, and which we continue to do as the company which originated them. Moreover, the support of the distribution system which we have built up over the years at considerable expense, and the maintenance of the research which we are endeavoring to do to push back the medical horizons for the future.
>
> These are just as much a part of our costs as wastage in production and tableting and bottling.[57]

It is significant that taxes, royalties, research, distribution costs, general and administrative expenses, as well as profits, were not included in this so-called computed cost. These obviously constituted the difference between $1.57 and $17.90. In relating overall profits to the company's financial statement, the following colloquy between Mr. Brown and the chairman is noteworthy:

> Senator KEFAUVER. You mean that research, profit, distribution, and everything else would make up that difference between $1.57 and $17.90?
>
> Is that your testimony?
>
> Mr. BROWN. You have our financial statement, Senator, which disclosed exactly what our performance was. I have also pointed out, if I may interrupt you, that we do not operate on the basis of a single compound alone. We operate on the basis of averages.[58]

[56] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit. Draft, p. 1–19.
[57] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, p. 7858.
[58] Ibid., p. 7860.

A further discussion ensued:

> Senator KEFAUVER. * * * What is the percentage of markup from $1.57 to $17.90?
>
> Dr. BLAIR. Mr. Chairman, it is 1,118 percent markup, roughly 11 times. * * *
>
> Mr. BROWN. If I may be permitted to do so, I would like to say that I consider this not to be the proper relationship, because this does not include the expenses of doing business which I have outlined. This only includes the bare factory production cost.[59]

At a later point in the hearings, the minority counsel, Mr. Chumbris, raised a pertinent point. The following colloquy is of interest:

> Mr. CHUMBRIS. Mr. Brown, on page 10 you list various items in which you consider the costs that go into your products. Let's take this one $1.57 per hundred. Does that include your rent or your plant maintenance or your depreciation? Is that in it?
>
> Mr. BROWN. This, according to the computation as I understand it, this would simply cover the labor charge and I don't know what other items may have gone into it, but it certainly would not include any of the general business expenses.
>
> Mr. CHUMBRIS. Does it include your cost of taxes?
>
> Mr. BROWN. No.
>
> Mr. CHUMBRIS. You have already mentioned selling expenses, distribution, and your research. Senator Kefauver asked you a question. * * * He said assuming that you add 23 percent and 8 percent, that doesn't take much away from your 1,000 whatever percent was used by Dr. Blair.
>
> Senator KEFAUVER. 1,118 percent.
>
> Mr. BROWN. It has to be taken away from 100 percent and not 1,000 percent, Senator.
>
> Mr. CHUMBRIS. So, therefore, if you took into consideration 23 percent and 8 percent and 32 percent, you wouldn't reach a figure anywhere near 1,118 percent, would you?
>
> Mr. BROWN. In the one instance we are talking about, percentages in relation to 100 percent [sic 1,000] and the figure that I gave on selling and distribution expenses being 32.7 percent is in relation to 100.
>
> Mr. CHUMBRIS. In order for the record to be clear, I would like to ask Dr. John Blair to take into consideration these different percentages, and add that to the cost of $1.57 and then compare the markup from that figure to the $17.90 per hundred that he mentioned.[60]

In answer to Mr. Chumbris' question, Dr. Blair evaded the calculation of all proper costs in relation to prices that are normally accepted as good accounting procedure and are accepted by the Internal Revenue Service.

On the second day of the hearings, however, Mr. Brown presented a very lucid explanation of his firm's costs of doing business, which

[59] Ibid., pp. 7858-7859.
[60] Ibid., pp. 7861-7862.

completely refutes the allegation of 1,118 percent markup as represented in the computation included in the exhibit submitted by Dr. Blair. Mr. Brown said:

> We at Schering do not allocate costs on a product-by-product basis, and I am sure that in this industry this is not the case, first, because this cannot be done, and second, because it would serve no useful purpose if it were attempted.
>
> Let me show you a typical cost pattern based on applying the relationship of the various costs shown in our financial statement for 1958, a copy of which I believe is in the hands of this committee, to the prednisolone 5 milligram tablet 100 per bottle, 100 tablets per bottle, that we were discussing yesterday, and I will do this in the way which is customary and accepted both by accountants and economists in business and in Government as well.
>
> In the first place, it was indicated that the drug list price for this item was $17.90 a bottle of 100 tablets. For this, however, we would have received $14.03 after regular trade and cash discounts on sales to wholesalers, and only would have received the $17.90 on direct sales to retailers, which is a smaller part of our business than our sales through wholesalers. * * *.
>
> So in our case the production cost of sales would be $3.05, The selling expenses would be $4.80. The research expenses would be $1.20. The administrative expenses would be $1.22. The royalties and other expenses would be 7 cents, and the income taxes which we pay to the Federal Government would be $1.96, or a total cost of $12.30.
>
> Now, the difference between these costs and what we would get for the product where we sold it through wholesalers, which is the bulk of our sales, would be $1.73, or 12.3 percent of what we received for the product.
>
> Now, this figure would be less than the 16 percent which we derive as overall profit on sales as was discussed yesterday and as is reflected by our financial statements, because we have excluded income and interest, royalty income and interest income from these calculations.
>
> I said yesterday, and I trust you will permit me to repeat, that a 12.3 percent return on sales is a reasonable return, considering the unusual risks involved in this business. These risks, I may say, having recently been recognized in a very important report issued by Her Majesty's Stationery Office for the Queen of England entitled, "The Cost of Prescribing," and known as the Hinchliffe report, in which it lays emphasis upon the fact that in this industry a product can be here today, and gone tomorrow, and that this is a factor which must be recognized * * *.[61]

The procedure in questioning the witnesses by the Majority's staff does little credit to the Senate, since it has no relation to the real world of competitive business. It is purely an academic exercise. In every instance, the published financial statement of the companies

[61] Ibid., pp. 7961-7962.

which have appeared before the subcommittee reveals a reasonable relationship of profits to sales. Certainly, there is no instance where any company which appeared before this subcommittee has informed its stockholders of data which would justify a front-page headline that it was making a profit ranging from 1,000 to 10,000 percent.

It will take many years for the firms who have testified on administered prices in the drug industry to clarify their true positions to the American people. The absence of competition, if such is the case, would have been detected by the enforcement authorities with little difficulty long before profits rose to these fantastic heights if all of the costs had been included in the computations.

A tabulation included in part 14 of the hearings prepared by the Federal Trade Commission shows a comparison of rates of return after taxes in selected industries for the year 1957. In this instance, drugs headed the list with a return of 21.4 percent. This is a far cry from the fantastic figures that have been computed by the staff's chief economist.

Furthermore, the category entitled "Blast furnaces, steelworks, and rolling mills" is shown as having a rate of return of 12.4 percent while "Bakery products" have a return of 11.4 percent. Only a few months ago, these rates of return were also deemed excessive by the subcommittee's majority staff. This same tabulation shows an average for all manufacturing of 11.0 percent.[62]

It is perhaps often forgotten that every average by its very nature must include those industries with a return that greatly exceeds the quoted figure to compensate for those industries that are in a depressed condition or for one reason or another are at the time included in socalled sick industries. Any attempt to use the average rate of return as a fair criteria would, of necessity, so lower the average that this approach would soon introduce new distortions. Hence, a comparison of the returns of any industry with those of all manufacturing is necessarily misleading and meaningless.

In the case of drugs, there is a high degree of obsolescence, as new products are frequently introduced which render the entire investment in patents and research in former products worthless, and hence, if an enterprise is to survive, it must realize a high enough return on those products that it is currently selling at least to insure its survival if obsolescence takes place.

After allowing for the obvious fact that the return on manufacturing is an average that includes submarginal industries, it is important to note that the return on drugs as listed for the 20 companies which appeared before the subcommittee in the majority's report is only 13.1 percent, and in the case of those companies which have not appeared before the subcommittee, it is 11 percent.[63] This is a startling contrast with the many fantastic figures that have been quoted frequently by the majority's staff which indicate a return in excess of 1,000 percent in terms of the prices to druggists in comparison with the actual production costs of the raw materials used in producing the drugs.

[62] Ibid., p. 7874.

[63] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. I-46D-E.

Dr. Frederick L. Thomsen, consulting economist of the Pharmaceutical Manufacturers Association, in his testimony before the subcommittee stated that:

> It has been shown that profits as a percentage of net worth cannot be used to draw significant economic conclusions in relation to possible reductions in prices. It has been shown, also, that profits per dollar of sales (profit margins), although higher for the drug industry than for some other industries, are largely explainable in terms of factors common to all industries. Neither of these measures of profits, on a relative basis, has any significant economic relation to the question of how much drug prices might be reduced by reduction or elimination of profits. However, some light may be thrown on this question by consideration of absolute, as opposed to relative, profit margins.
>
> According to data obtained by your committee from 20 firms for the year 1958, the average profit was 13.1 percent of sales. It has been shown that 1958 was an abnormally high profit year, as was 1957. For the period 1951–55, the Cottle & Whitman figure was 10.1 percent and the Woodward-Adams figure for the larger group of companies was 10.5 percent. For the 10-year period 1949–58, the profit margin was 12.2 percent for the latter group. But this is on manufacturers' sales. Significant costs are incurred after the manufacturer sells the drug to the trade, reflecting the high standards that the consumer demands of the entire medical services industry. Drugs cannot be handled in the trade in the same manner as nails or sugar, and trade markups necessarily are higher than for such staple commodities. Although I have no specific data on this point, I believe it may be said with confidence that the price paid by consumers for prescription drugs, after the wholesaler's and retailer's markups have been added, is at least twice that received by the manufacturer. So it is evident that manufacturers' average profit per retail dollar paid for drugs is roughly 6 percent.[64]

In previous hearings of this subcommittee, many witnesses have testified to the fact that in every instance, profits are overstated because of the fact that depreciation allowances based upon original costs do not return the cash necessary to replace the equipment that has to be purchased at current prices. In this instance, Mr. John T. Connor, president of Merck & Co. of Rahway, N.J., bears out the thesis that has been expounded by Mr. Robert C. Tyson, chairman of the finance committee of the United States Steel Corp., as well as by numerous other witnesses who have appeared before the subcommittee during the last 3 years. Mr. Connor said:

> A recent study of Merck gross additions to plant and equipment for the period 1938–57 illustrates the disparity between original cost and current replacement cost in calculating depreciation. It is significant to note that the

[64] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 19, p. 10767.

> $64 million of depreciation actually charged against income, applicable to the company's total gross additions during this period, falls some $35 million short of recognized current replacement values. Approximately another $10 to $15 million would have to be provided because of inadequate depreciation charged for those additions prior to 1938, which have not been included in this $35 million figure. Thus, under the present tax laws, the company is forced to use some $50 million of reported net earnings to purchase worn-out plant and equipment that cannot be recovered through depreciation.
>
> The failure of the Internal Revenue Code to give consideration to the effects of price-level changes on business income and capital creates the illusion that profits and rates of earnings are much higher today than actually is the case. As the price level rises, revenues or profits represent relatively small current dollars while expenses and invested capital are stated largely in older and relatively larger dollars. This situation creates an upward bias in nominal or apparent rates of return. For example, the rates of net profit return reported by Merck & Co., Inc., to its stockholders for the year 1956 were 11.7 percent on sales and 14.7 percent on net worth. After adjustment of reported net income to provide for adequate depreciation (based on current replacement costs), net profit return on sales is reduced to 10.2 percent and return on net worth is reduced to 12.7 percent. Since 1940 the average return on net sales would decline from 9.9 to 8.2 percent, while the average return on investment would be reduced from a rate of 13.6 to 11.2 percent.[65]

He also indicated that other countries have been aware of this problem and have taken special steps in order to expand their industries and thus create more jobs and produce new end products for the welfare of their people. He testified as follows:

> In the foreign field, the accelerated writeoffs permitted by the other governments, e.g., Great Britain, Sweden, Netherlands, West Germany, and Switzerland, has given our foreign competitors a decided advantage in permitting them to modernize facilities without serious impairment of capital. The efficiency of this newer equipment provides the foreign competition with a decided edge in meeting and underselling U.S. exports.[66]

Any fair evaluation of the actual data in this industry should be on an overall basis rather than an attempt to select the costs of one particular product so that the performance of the entire industry can be evaluated as to its serving the basic interests of the American people. The health of our Nation is far too important to equate it with a few cents added to the price of a particular prescription. If we can extend the lifespan of Americans and reduce the lost production time due to illness, the entire cost of drugs becomes relatively insignificant inasmuch as the ethical drug business, according to the majority's staff, accounts for approximately $2.5 billion, which is only 0.5 percent of our gross national product.

[65] Ibid., pt. 14, p. 8196.
[66] Ibid.

The majority's report shows a preoccupation with the percentage return on investment in this industry as well as the percentage return on sales. It is apparently unaware of the fact that investment in plant and facilities plays a far less important role in this field of activity than a trained and experienced research staff as well as an investment in personnel who are in a position to explain the therapeutic properties of new drugs to the medical profession. As the chairman has said:

> * * * He who orders does not buy; and he who buys does not order. * * *[67]

Under these circumstances, it is obviously necessary that an effort be made to inform those who do the ordering and have a responsibility to their patients which they do not discharge lightly.

An official of a small pharmaceutical company testified before the subcommittee; namely, Dr. Philip Berke, vice president of Formet Laboratories of Roselle, N.J. Dr. Berke explained that his organization only employed five people.[68] It is, therefore, a small business in every sense of the word. In a colloquy which is quoted in the majority's report, he emphasized the importance of research and promotional expenditures as shown below:

> Mr. DIXON. Dr. Berke, if it were possible for you to obtain all the patent rights and facilities to fully engage in the cortical steroid market, what would you say that the investment would take? Would you give me an opinion as to what investment it would take for you, or for a very small business firm, to go into this manufacturing process fully?
>
> Dr. BERKE. Well, of course, that depends on the quantities you want to produce, and if the research has been accomplished, the sum wouldn't be too large.[69]

In other words, it is clearly apparent that research and development are major factors in this business.

The majority's report endeavors to compare the net profits after taxes as a percent of invested capital for a number of companies. However, in almost every instance the amount of invested capital per dollar of sales is far greater than in the drug business whose principal asset is its personnel who have been recruited and trained at great expense to the company. Normal accounting procedures do not place any value on the balance sheet of a firm for this priceless asset.

Although the entire subject of selling costs as a percent of manufacturing costs will be discussed at greater length in a subsequent chapter, it is important to emphasize that any new product, which may affect the health and welfare of our citizens and whose therapeutic qualities require a detailed explanation to members of a trained and learned profession, is necessarily going to require larger promotional costs than would be found in the case of standardized products that have been in use for long periods of time.

In every industry, there are appropriate measures of profitability. However, it is misleading to apply the same criteria to producers

[67] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. viii.

[68] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, p. 8060.

[69] Ibid., p. 8056.

whose cost based on the proportion of payments for wages and salaries in terms of total sales and the capital investment required differ widely.

In the ethical drug industry, the capital costs are relatively low as contrasted with the expense items for salaries of scientists, doctors, and laboratory workers who are developing the new products which have improved our health standards. Furthermore, because the use of these products must be explained to the medical profession, it is impossible to promote them through mass media. Their therapeutic properties must be disseminated in a professional manner to a very select group of highly educated individuals. This is an expensive process. It is also necessary to insure that these products are on the shelves of all local retail druggists so that they are available when prescribed.

A comparison of net profits to sales after taxes in an industry where salaries constitute so large an item is more meaningful than one based on the return on net worth.

The economics involved were presented by Dr. Frederick L. Thomsen, consulting economist for the Pharmaceutical Manufacturers Association, previously referred to. His testimony must be seriously considered by the subcommittee since there has been much confusion as to the degree of profitability in the drug industry. He also deals with the question of the proper correlation, if any, between profits and prices in this field. The following statements are quoted from Dr. Thomsen's testimony and are particularly helpful in understanding the economics of the drug industry:

> Profits stated as so many dollars are meaningless in themselves. Some point of reference is required in order to give such dollar figures significance. In going over the record of the subcommittee's hearings I have noted that a point of reference frequently or even most used has been either net worth or invested capital.
>
> When I see data such as those that have been introduced relating to profits as a percentage of either invested capital or net worth, I wonder whether the effect of some of this testimony will not be to confuse rather than enlighten. Such comparisons may be meaningful to an investment analyst for certain purposes, or to a banker considering credit arrangements for a drug company; but they have no relation at all to the question of how much, if any, drug prices might be reduced by the reduction or elimination of profits.[70]
>
> Profit rates among companies in almost any industry vary widely, due to differences in managerial ability, the caliber of personnel built up over the years, and the other circumstances conditioning their operation. In automobiles, for example, some companies went on to make large profits while many others were dropping by the wayside for lack of profits. Over 90 percent of independent retail establishments are said to fail within a few years, whereas others in the same kind of business prosper. Even farmers differ tremendously in the financial results of their operations. Similar disparities exist in the drug industry.

[70] Ibid., pt. 19, p. 10763.

To use the profit figures of any one company or several individual companies, without taking into account these differing circumstances, as indicative of conditions in the industry as a whole can be as misleading as using the profits of a single product as representative of the operations of a single firm. I realize that the temptation to do so is great, since individual companies, like individual products, furnish striking cases in apparent support of points one would like to make. At least, we can all recognize the danger and try to avoid drawing wrong conclusions or creating misleading public impressions by generalizing on the basis of operations not representative of the industry.[71]

There are many reasons for the great variation in profit margins among industries. Most of these may be included in one of four categories: (1) turnover; (2) degree of risk; (3) circumstances such as growth rate and position on the industry cycle, if any; and (4) external conditions such as the business cycle.

Of these, one of the most important is turnover of both inventory and capital. This may sound surprising to the layman, but not to any businessman or economist who has observed the importance of this factor. Any business with a high turnover may make a very small profit per unit or per dollar of sales and still accumulate a respectable total by income tax time. The same applies to different lines of products.[72]

Contrary to what might be expected without more thorough examination of the industry, ethical drug firms have a relatively slow annual turnover of capital (only 1.30) compared with the lowest of the industries included, copper (0.72) and the highest, grocery chainstores (8.54). In other words, for the ethical drug firms included in the PMA study, annual sales were only 30 percent greater than capital, or it required $1 of capital to support each $1.30 of sales. This serves to explain in large measure the relative position of the ethical drug industry in regard to profit margin.[73]

I believe that even the most ardent critics of the drug manufacturing industry would not have it operate at a noprofit level. Let us presume that they would not object to manufacturers' profits of, say, 3 or 4 percent per dollar of retail sales. Whatever this subjectively determined figure might be, the difference between it and 6 percent would not represent much in terms of retail drug prices, at the most a few cents on a dollar's worth of prescription drugs.

In fact, if the entire profit of drug manufacturers were wiped out completely, buyers of consumer drugs on the average would hardly notice the difference in prices, which could easily be lost in the shuffle. Small changes in wholesale prices frequently are not reflected in retail prices. No, the concern that has been felt over drug prices has not been on the order of a few pennies per dollar, but of fancied

[71] Ibid., pp. 10764-10765.
[72] Ibid., p. 10765.
[73] Ibid., p. 10766.

profits running to many hundreds or thousands of percents, that do not exist in reality because the false measures of costs that have been used to adduce such figures have not taken properly into account all costs, position on the life cycle of the drug, and other conditions that have been dealt with in the foregoing analysis.

A company-by-company approach to the drug industry, and the singling out of the most profitable items in each company's line, coupled with inadequate measures of costs, can produce a totally erroneous impression of the across-the-board possibilities for price reductions through profit elimination. Only a very small reduction in the level of drug prices, and an even smaller percentage reduction in the total cost of a cure, would result if all profits of all the drug companies were wiped out.[74]

In many industries today a salesman is no longer an order taker but rather is a sales engineer. This is true in the case of those who attempt to sell their high-strength steel to an automobile company, a superior cutting oil to a tool manufacturer, and in countless other industries. In fact, many engineering graduates actually become sales engineers rather than technicians in the usual sense. It is impossible to develop and secure the effective application of new and complex products unless their usefulness is explained to those who will ultimately be called upon to make a recommendation as to their effectiveness in meeting the particular need for which they were developed.

The majority's report attempts to compare the earnings of drug producers which also manufacture other commodities with those firms whose activities are confined to the drug industry. It states that:

The subcommittee was unable to obtain from these conglomerate firms data showing net worth devoted to drug operations. Consequently, it is impossible to compute rates of return on net worth for drug operations in contrast with other operations of the same companies. Inasmuch as the capital investment requirements in drugs as compared to the other industries in which these companies are engaged are not particularly high, there are reasonable grounds for assuming that the showings in terms of this measure would also be more favorable for their drug operations than their other activities.

Clearly, since it is the same management which governs the activities of these corporations in all of the industries in which they are engaged, the uniformly more favorable showing in drugs cannot be due solely to the greater efficiency of management in this industry, but must reflect other factors as well, such as the greater control of the market.[75]

This analysis completely overlooks the testimony of witnesses who are in charge of firms that operate in many diversified industries.

[74] Ibid., p. 10767.
[75] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. I-110.

For example, Dr. W. G. Malcolm, president of the American Cyanamid Co., during the course of his testimony, stated that:

> Over the past 10 years we have earned $242 million from our drug operations. We paid out to stockholders some $150 million as Lederle's proportionate share of dividends to Cyanamid stockholders—leaving us $92 million in retained earnings to plow back for future pharmaceutical growth. This is a dynamic industry; under our free enterprise system no business is static—we must move ahead—and I do not think any of us would want it otherwise.
>
> During the same 10-year period we put $75 million into our capital program for Lederle's pharmaceutical plant, property, and equipment and added $24 million to its inventories and accounts receivable to support its growing volume of sales.
>
> Of this $99 million of additional capital required to conduct Lederle's business, $92 million has been financed from retained earnings and the balance drawn from other corporate resources.
>
> Lederle's capital requirements in the years ahead will continue to be heavy. During the current year, for example, we plan to spend more than $14 million, about one-half of which will be required to expand the pharmaceutical facilities in the United States and the other $7 million to construct new plants or add to existing plants overseas. We have no assurance that our future earnings will be adequate to meet Lederle's continuing demand for increases in its capital.[76]

Dr. Malcolm was also emphatic in stating that:

> * * * Each division is autonomous and each division is responsible for its own management and for its own income in the light of the overall corporate picture. And there are no moneys taken from Lederle to support these other divisions. Of course if Lederle does make money, it is thrown into the overall pot, shall we say, for distribution to the stockholders and for reinvestment, but I deny the fact that the Lederle division supports the other divisions.[77]

Many people who are now aged and are experiencing difficulties in meeting drug costs are confronted with a problem that is basically one which is the responsibility of the Federal Government rather than the drug industry. This is demonstrated by the fact that they, like all other citizens, are affected by inflation, rising prices, and Government fiscal policy.

It must be remembered that those who are presently 65 years of age and over, during their productive years, were confronted with the depression of the 1930's. Immediately thereafter, the United States entered into recurring periods of international conflict when taxes were high and a disproportionate share of the income of this particular generation was taken from them. This left little for savings to provide for their years of retirement.

[76] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 24, pp. 13684-13685.
[77] Ibid., p. 13685.

It would seem that the combined wisdom of those who have been elected by the people to represent them is adequate to meet their problem. It will not be solved by socializing or otherwise hampering an industry that has made exceptional strides in meeting our health problems and which has made America a leader in the world today.

POINT 2

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that the drug industry has a permanent control of the market is unjustified, erroneous, and unfounded.

The majority's report states that:

> The extraordinary margins and profit rates in ethical drugs * * * are made possible by the existence of extremely high levels of concentration, with one or at most three large firms accounting for all of the output of most of the industry's products. A correlative condition is the poor position of smaller producers who probably face greater problems in getting their products distributed and used than in any other manufacturing industry. In some lines, small manufacturers are able to put their products on the market; but even though offered at prices substantially below those of the large firms, they usually are able to capture only a very small proportion of the market. There are a few lines, however, in which the price competition stemming from smaller enterprises has been sufficiently important to break down the rigid price structures of the large firms. Such price behavior in in striking contrast to that of similar products sold only by the major companies. * * * [78]

Every firm which develops a new product under our patent laws has temporary control of the market for that particular product, inasmuch as it secures a patent on its development. However, there are few drugs in use where there is not another available substitute which the doctor may prescribe, and under these conditions it is idle to state that a particular firm has an absolute control of the market for a particular product. Any qualified physician always considers the alternative methods that he might use in order to cure an ailment. In this case, the methods not only involve different drugs but also entirely different therapeutic treatments.

There has been a tendency throughout the hearings to imply that firms have a permanent monopoly control over every new development which they pioneer. Obviously, this is not the case. As a matter of fact, testimony during the course of the hearings disclosed that after a period of 5 years most drugs have become obsolete, and any firm which wishes to maintain a permanent position of leadership in this highly competitive field is engaged in a constant race with its own research staff. This is certainly not true in many other types of goods where technological progress and scientific advances are not developed as rapidly.

[78] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. II-1.

Every drug firm in the last analysis must compete in the capital market for the funds necessary for its growth and expansion. This premise is a basic one, and unless the returns from its venture are as attractive as those available to investors elsewhere, it will be impossible for it to secure the funds that are necessary to enable American scientific progress to proceed in curing the sick and ailing. There is apparently a confusion of thought throughout these hearings in that some staff members believe that the drug industry should be treated as a public utility.

The majority's report states that:

> While there is no settled consensus as to the precise profit rate which separates "reasonable" from "unreasonable" prices, most regulatory bodies limit public utilities to profit rates on investment, after taxes, of around 6 percent—or about one-third of the profit rate made by the drug industry. Of course, it may be contended that lower profit rates are appropriate for utilities, since, being necessities of life, they enjoy an assured market. It is not clear, however, why much the same reasoning would not apply to the drug industry.[79]

A similar approach was taken in discussing the profits appropriate for the steel industry by Mr. Otis Brubaker, research director of the United Steelworkers of America. In his prepared statement submitted to this subcommittee during the hearings on administered prices in the steel industry, he stated that:

> It has long been accepted in accounting and financial circles that an average 6-percent net profit rate of return on net worth (stockholders equity investment) represents a fair and reasonable rate of return. * * * * [80]

However, in both industries an important fact has been overlooked. Neither the steel industry nor the pharmaceutical industry enjoys a franchise granted by public authority. Hence, neither is guaranteed a fixed rate of return and both are subject to the competitive forces of the marketplace. A product which is profitable today may become most unprofitable when a new and more valuable discovery is brought forth by one of its competitors. Under such conditions, it is idle even to discuss a comparison of the drug industry with public utilities which are granted a monopoly franchise by governmental authority. It is necessary for every drug firm to be able to compete in the Nation's money markets for funds to enable it to grow and expand.

Although there has been a great deal of discussion on the part of the staff and majority members of this subcommittee concerning the social responsibility of this important industry, it is too often forgotten that it can only be discharged by maintaining a vigorous and thriving organization. This requires that it operate modern facilities and employ skilled scientists who must be secured in competition with other segments of industry. It must also develop an aggressive merchandising force in order that its achievements are widely known to 200,000 individual medical practitioners and that its products are stocked in the millions of drugstores which serve

[79] Ibid., p. I–107.
[80] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 2, p. 529.

our Nation. Unless these steps are accomplished, a discovery which may have valuable attributes in saving lives may lie on the shelf unused for many years largely because of the difficulties in transmitting complex technical knowledge to those who are charged with the responsibility of maintaining the health of their patients.

There are few industries where there is actually less control of the market than exists in the pharmaceutical trade where a host of products with similar therapeutic values are available from domestic producers, as well as from foreign drug houses which have not been idle in their efforts to penetrate the American market. Every manufacturer of pharmaceutical products who is able to show a satisfactory return on sales and on the investment in his plant has performed a valuable service to the medical profession and to all American citizens.

The fact that by and large the return on the more successful firms has been high is attributed to the effectiveness of our research and development activities in this field, and they are reflected in a lowering of mortality rates and in a general improvement in our Nation's health. There are few Americans who would not gladly pay any sum in order to be assured of a permanent elimination of such scourges as cancer, heart disease, and other similar illnesses which cause irreparable injury to the families of those afflicted, not only in terms of the loss of their loved ones, but also from the standpoint of their earning power and a lowered standard of living.

Recently, Dr. Austin M. Brues, director of the Biological and Medical Research Division of Argonne National Laboratory, wrote an article which appeared in the magazine Context, published by the University of Chicago. His article is entitled "Today's Research—Tomorrow's Practice." It is significant in that it clearly shows that there will be new developments arising from our progress in nuclear energy that will make obsolete many products that are presently widely used by the medical profession. Dr. Brues said:

> In the next quarter-century, nuclear technology will have a much greater impact on the practice of medicine than can be appreciated at present. This is a young field in the early "log phase" of growth, where every new concept and technical advance breeds not only its own applications but further concepts and technical developments. We may extrapolate from the last decade or so and then must allow for totally unpredictable developments. Discovery of the Van Allen radiation in space is a recent example of the speed of change.
>
> The impact will be both direct and indirect. It certainly will not be very long before the standard forms of isotope therapy will be available to everyone. What new forms will be developed is a matter for research.
>
> One of the ultimate goals in cancer therapy would be, of course, the discovery of a compound that is attracted selectively to the cancer cell, or—perhaps even better—one that is caught and held in the synthetic "trap" of the tumor cell while it escapes from others.
>
> If such a compound were found to exist, it could then be tagged with the hydrogen isotope, tritium. This is a com-

parative late-comer in the useful isotope field, mainly because of its very short-range beta radioactivity, which made it difficult to measure until newer scintillation techniques were devised. But this very characteristic makes it especially appealing in therapeutic applications, since its average range in tissue is a fraction of a micron, making possible the selective irradiation of individual cells and even of subcellular structures.

One analogous compound, tritiated thymidine, is incorporated into the DNA [deoxyribonucleic acid, the material in the nucleus of every cell which carries the hereditary genes] of growing cells, and in cell cultures is about a thousand times as toxic as the same dose of tritium in water molecules because of its specific localization. It is widely employed in growth research today but holds no therapeutic promise, since it is likewise incorporated into growing nuclei of vital tissues.

Lacking a tumor-specific compound, it is likely that particular tumors can be attacked on the basis of special metabolic characteristics, just as a normal cell population can be, as in the case of the thyroid's affinity for iodine. The somewhat limited success of hormone therapy of cancer, and a good deal of recent research as well, indicates that tumor cells are not so fully independent of the internal environment as we used to believe and that various tumors have specific, unsuspected metabolic features.

We stand on the threshold of considerable developments in external radiation by nuclear devices. It is now possible to produce beams of protons and deuterons of high energy which are deposited at an accurately controllable depth below the surface. Particularly intriguing possibilities are opened by neutron-capture therapy, in which a relatively nontoxic flux of slow neutrons from a reactor activates certain elements such as boron and uranium where they have been deposited, yielding, in the first instance, energetic alpha particles and, in the second, actual fission fragments. This hybrid of localization and directional therapy is being exploited in the therapy of brain tumors, and the indications are that it will be applicable in other cases as well. Meanwhile, physicists are going ahead to develop accelerators approaching cosmic-ray energies, which accelerate large atomic nuceli and produce mesons and a multitude of subatomic bits which even in the terminology of nuclear science are are being called "strange particles."

To leave the realm of pure speculation, we may at least recall that progress in cancer therapy by classical methods has been very real and steady simply through the accumulation of skill and experience and by the improvement of instruments. By this token, with the passage of time and wider use of means such as cobalt-60 teletherapy, small accelerators, and isotopes, the cancer salvage rate will rise several fold in the coming generation. There is the added likelihood that with combined therapy (say, isotopes, hormones, antimetabolites, and radiation-protective agents)

we may achieve remarkable success even if there is no magic isotopic bullet.

The use of isotopes as diagnostic tools is in a brilliant infancy; it is in this field that nuclear science may have its broadest impact on medical practice. Mapping of the thyroid and of iodine-fixing metastases is an accomplished fact. Certain isotopes have the special feature of emitting two radiations at once, in exactly opposite directions; with a little electronic circuitry designed to record these, very precise localization in three dimensions is possible. Blood flow, cardiac output, diffusion rates, and the like are accurately measured by external counting.

The fact that we can label almost any physiological compound with carbon-14 or tritium enables us, potentially, to study many of the features of intermediary metabolism at the bedside. Not only is this likely to revolutionize the diagnosis and therapy of metabolic disorders, but it will make it possible to identify some of the individuals carrying recessive genes for serious heritable disorders, much as we now look for Rh-factor incompatibility. Most of this is now in the realm of research, but today's research becomes tomorrow's practice.

One hesitates to try to discuss the indirect impact of basic scientific advances, even those opened up by isotopes alone, for the very magnitude of the vista. Suffice it to repeat the often-heard analogy to the microscope tracer methods visualize processes that can be seen in no other way. This applies especially to the synthetic processes. Since syntheses and turnover rates have become directly measurable in the living animal, we can look forward in a few years to having a quite complete picture of the formation and destruction of important cell constituents and delineation of their role in disease, and, in addition, we have a fair chance of picking up an anomaly in tumor metabolism that might be exploited.

Of very great importance is the stimulus that has been given to the study of genetics, the aging process, and carcinogenesis by concern with radiation and by the usefulness of radiation research in the study of these things. They are in an exciting state of flux and proliferation of ideas; nuclear science plays a large part in both discovery and exploitation.

Does the future in nuclear medicine entail an inordinate increase in the cost of medical care? One is haunted by the possibility that the panacea might turn out to be an enormous nuclear machine of some sort. For many reasons this seems most doubtful, although electronic equipment for radiation work will become at least as common as electrocardiographic and BMR apparatus, and medical education will include many new and interesting subjects to replace some "drier" ones. If isotopes should win out over high-energy machinery, there might even be an economic gain.[81]

[81] Brues, Austin M., "Today's Research—Tomorrow's Practice," Context, a University of Chicago magazine, vol. 1, No. 1, spring, 1961, pp. 35-36.

Unlike most other industries, the manufacturers of pharmaceutical products are under the strict control of the Food and Drug Administration which must enforce adequate standards of safety before any new product is introduced to the public. There are some who believe that these powers should be expanded to include an evaluation of the efficacy of a drug. However, this involves many value judgments, and it would be preferred to have this determined on the basis of actual clinical evaluation by doctors as long as there is no question that the product might cause harmful effects.

Furthermore, the Federal Trade Commission also has concurrent jurisdiction with respect to any advertising affecting drug products offered directly to the public; i.e., nonethical drugs. Many States have established their own individual methods of insuring that adequate medical standards are maintained.

This subcommittee is casting a serious reflection on the integrity of the Nation's 200,000 doctors who have received special training and are licensed by their respective States. By no stretch of the imagination are they quacks, nor are they willing to foist drugs on their patients which they do not believe will effect a prompt cure for their ailments.

Unfortunately, there is an area in this field where human understanding still leaves a great deal to be desired; but to impugn the motives of those dedicated individuals who have been willing to undergo the rigorous training required to practice medicine and who, in the last analysis, must prescribe all drugs, is a great disservice to the American people. Such attacks aid and abet those in Communist countries who seek to disparage the motives of our free-enterprise economy and attempt to attribute every form of skulduggery to those who are not employed by the state but, on the contrary, must seek their living through competitive endeavors and from the results of their work are required to pay taxes in order to support governmental activities.

Although the subcommittee has been concerned with control of the market exercised by legitimate manufacturers of drugs, it completely ignores the testimony of Mr. Floyd B. Odlum, chairman of the board of the Arthritis and Rheumatism Foundation. He appeared before the subcommittee to protest against the many remedies that were offered to the unsuspecting that could only end in their financial disaster and not effect a cure.

In this connection, the following colloquy involving the chairman, Mr. Theodore T. Peck, special counsel for the minority, and Mr. Odlum is pertinent:

> Mr. PECK. Mr. Odlum, we are all in most sincere sympathy with the position you are taking, and when you mention misleading advertising for phony medicines, I can't imagine anything a great deal more despicable.
>
> However, I would like to know, sir, are the producers of these supposed medicines reputable people?
>
> Who are they? * * *
>
> Are they any of the people with whom we are dealing in these hearings?
>
> Mr. ODLUM. Not at all.
>
> Mr. PECK. I certainly wouldn't think it would be any of the witnesses who are scheduled to appear before us.

Mr. ODLUM. No; these are so-called proprietary medicines as distinct from the so-called ethical medicines. These are medicines that do not have to pass through all of these preliminary researches that I heard explained before on the stand.

Mr. PECK. Might some of these medicines be found in the old covered wagon of the patent-medicine peddler?

Mr. ODLUM. Oh, yes; many are worse. I have been the recipient probably more than anybody in the United States of the drives for these things, because once, I have arthritis and it was pretty well publicized that I had because I was the head of this foundation, and therefore everybody around the United States who either through the goodness of his heart felt that he had a cure for it or who wanted to hook me so in some way I would be sponsoring indirectly a product that they wanted to sell, they would send them to me or write to me, and I have had everything in the world that you can mention written to me about or sent to me to use.

I have used none of them. The last thing I had sent to me was a gallon of tequila from Mexico with a dead rattlesnake curled in it, and if you took a wine glass of that three times a day you were supposed to get cured of arthritis.

Mr. PECK. And a few other things.

Senator KEFAUVER. You would be cured in that you would probably be dead.

Mr. ODLUM. Yes; one of the two.

Senator KEFAUVER. You said a gallon of tequila with a rattlesnake inside of it?

Mr. ODLUM. What they had explained was they had taken the tequila and had dropped a live rattlesnake in it and the rattlesnake had in his death throes thrown out this tequila.

Then they took the rattlesnake out and dried him in the sun and cured it for 2 years and then sold it for $50 a gallon.

Senator KEFAUVER. What did you do with that?

Mr. ODLUM. I put it on the table in my house to let everybody see it for about a month, as to how foolish people can get, and then I threw it away. But I have had alfalfa tea and I have had mushroom things and copper bands and there is a man who claims he has a uranium mine and he is practically ready to sue me because I won't tell him that uranium is good for arthritis.

I happen to have some uranium mines. I wish it were good.[82]

On the basis of testimony from responsible individuals such as Mr. Odlum and his associates in the foundation, including Dr. Russell L. Cecil, of New York, and Dr. Ronald Lamont-Havers, also of New York, it would seem more appropriate for this subcommittee to concentrate its attention on these quack cures if it is really concerned with reducing the cost of medical care.

Mr. Odlum, in his statement—which was confined only to one illness, namely, arthritis—indicated that patients who were seeking

[82] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, pp. 7977–7978.

a cure were spending on fake nostrums and similar potions sold through fake advertising an amount exceeding a quarter billion dollars a year.[83] All of the elaborate statistics that have been arrayed in order to disparage an industry that has served America will fade into complete insignificance after examining this testimony.

POINT 3

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that the patent system has not operated effectively in the pharmaceutical industry is erroneous and unfounded.

The majority's report states that:

> Patents by their very nature restrict competition. The existence of a patent system reflects an explicit or at least implicit decision that the gain resulting therefrom through the promotion of inventiveness more than outweighs the loss resulting from the elimination of competition. For the period covered by the grant the patent holder is a monopolist, immunized from the normal forces of competition. He can, if he so elects, charge whatever price he desires and prevent others from selling his product or using his process.[84]

It also states that:

> Today in the drug industry—as in many other industries—patents are a business device employed by large corporations to stifle competition. The inventor in the large corporate laboratory is an employee of that corporation; at the time of his employment he agrees in writing to assign all of his future inventions to his employer. Thus, at the very outset, his work becomes a pawn in the business struggle; and the nature and quality of his work—including the lines of inquiry he may follow—are largely dictated by the expectation of businessmen, untrained in science, as to what areas appear to hold the greatest promise of commercial gain. If he does fulfill the aspirations of his employer and hits upon a highly marketable product, known in the trade as a "hot" drug, it is the corporation and its stockholders who are the beneficiaries; his reward may be comparatively negligible or nonexistent. Virtually all of the products examined by the subcommittee were those where patent control lay in the hands of drug manufacturing companies.[85]

In other words, drugs are to be segregated from all other commodities in their treatment from the standpoint of patent protection if the majority's views prevail. Before we accept any such thesis, it is imperative that we recognize the fact that American medicine and its pharmaceutical industry are regarded throughout the world as outstanding and that the patent system has certainly played a role in making this achievement possible.

[83] Ibid., p. 7975.
[84] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. III-63.
[85] Ibid., p. III-66.

As has been said so many times, this is an area that normally should be studied by some other committee of the Senate, and not by the Antitrust and Monopoly Subcommittee. There have been legislative proposals that would virtually limit the licensing of patents in many cases or restrict them to a comparatively few products. Furthermore, there have been various proposals made to require compulsory licensing.

Any attempt to treat the drug industry as one that must be licensed by the Federal Government is in complete contradiction to our basic concepts of free enterprise. Prior to enacting any such measures, it is necessary that there be compelling reasons why it is necessary to adopt a sweeping measure which may set a precedent that could well apply to other necessities of life that the average individual requires for his well-being as much as he does the pharmaceutical industry.

Any attempt to apply a different criteria to patents for drugs and pharmaceutical supplies would raise a serious constitutional question as to whether class legislation was being sponsored, and it is doubtful whether a procedure of this type is warranted on the basis of the testimony adduced during these hearings.

America has made an outstanding contribution in every field of applied technology because of its unique patent system which stems from the thinking of Thomas Jefferson. However, there are those who are more concerned with attacking the possible rewards for a successful breakthrough than in promoting the advancement of man's knowledge of his environment which results from stimulating incentives for new inventions.

As an example of this trend, the subcommittee has retained the services of Miss Irene Till, who has devoted a lifetime to challenging our patent system. According to the chairman of the subcommittee:

> Miss Irene Till is one of the leading economists on the subject of patents today. She was coauthor with Dr. Walton Hamilton of the TNEC monograph, "Antitrust in Action." She was the chief economist for Senator Bone's committee, which conducted an investigation of patents.[86]

There is no indication from these statements that Miss Till has ever recognized the usefulness of the patent system in furthering America's economic development or its superiority in technical progress. At a time when we are in mortal conflict with the Russians, it becomes even more important to harness the creative talents of our people, and it would be a small expense for us to pay if our technology in every field was superior to that of all potential enemies. Apparently, this is one of the concepts that has been completely overlooked by the majority's staff, including Miss Till.

The majority's report attempts to segregate pharmaceutical products from other articles and makes the suggestion that no patent should be issued on these items, as they are essential to the health and well-being of our people. It is our view that it is vastly more important to enable them to secure new and advanced drugs than to prevent anyone from deriving a profit through making a contribution to our advanced technology.

[86] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, p. 7917.

The majority's report mentions the fact that in Italy no patents are issued on drug products. However, according to their own chart entitled "Listing of Drugs to Place of Discovery," there are no major drug developments that are attributed to an Italian pharmaceutical scientist. In fact, it is generally known that many of the drugs that are widely used in Italy have been pirated from firms which had undertaken the development of these products in other countries where patent protection was enjoyed. The present Italian law is a product of the Mussolini regime and is hardly one for us to emulate.

The majority's staff has provided the most compelling evidence as to why our patent system has played an important role in furthering American technological progress in this field. A table included in its report lists a series of drugs according to place of discovery, as mentioned above. It includes those developed in countries without product patents as well as those developed elsewhere. It is significant that of all the products listed, there are none that were of sufficient consequence for the subcommittee to consider that were developed in Italy. This list covers a period from 1875 up to the present time.[87]

Dr. Austin Smith, president of the Pharmaceutical Manufacturers Association, in his discussion of the broad problems of the drug industry stated that:

> Earlier in my testimony, I called attention to the intensity of competition in the field of research, and to the benefits gained by mankind from discoveries and products that have stemmed from this effort.
>
> The role of the patent system, in providing incentives for investment of vast sums of money in endeavors which involve such great risks, is one which should be recognized by all who are concerned with the continuation of rapid discovery and the development of new medicines.
>
> The interest of the American people lies in assuring that every feasible and practical means be devoted to the job of finding new answers to the mysteries of disease, to winning new victories in the war against sickness and death. In this, time is of the essence. A new drug discovered tomorrow is too late to save a life lost today. * * *
>
> The patent system works to provide incentive for the many companies, owned by hundreds of thousands of Americans who have invested their savings in drug concerns, to risk the enormous sums required in the gamble that one research project out of thousands will produce a result of benefit to mankind.
>
> Obviously, the system affords no protection against the incredible risks of failure, against the loss of the millions of dollars that are spent on the thousands of research projects that fail.
>
> But it does insure that any reward for research, for development, for contribution to society will go to those who have been willing to risk their savings and to devote their energies to this vital pursuit.
>
> As you know, in the drug field these patents may cover products or the processes for manufacturing them. The

[87] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, pp. III-24-30.

original patent owner, of course, frequently licenses others to use it and receives royalty payments.

This assures, even in cases where substantial additional investments are required for final development, production, and distribution, that the drugs will be made rapidly available. * * *

It also enables, in the case of cross-licensing, the prompt production of new drugs in cases where two or more firms may own patents which affect the production of a single drug.

The patent and licensing system has another advantage. It eliminates a situation in which so many companies would have the right to produce a drug that no single company would have the incentive to invest the sum required to move into production.

And this brings this discussion to a highly important point. A new discovery alone will not cure a single living person of a single known disease. Even the production in quantity of effective medicinals will not affect a cure for one single person. No drug can accomplish anything until it is made available to the patient, until the Nation's doctors know what it can do and how it fits into the medical picture, and are assured it is available at the drugstore.

Thus, the drug industry's job is not done when the discovery is made and when the production machinery is underway. It must devote equal zeal and energy to the task of distribution and education.[88]

Actually, the incentive which a patent provides has been widely acknowledged. For example, in England independent pharmaceutical product protection was reenacted in 1959. It was enacted in France in 1960, and it is currently under discussion in Germany. Although the majority's report attempts to give the impression that a great number of other countries do not issue patents on drugs, a review of the patent systems of 115 countries, including the United States, shows that 66 countries, or 57 percent of the total, recognize independent drug patent protection, while 49 countries do not.

There are obviously a number of variations in patent laws which do not fit into any clearly defined cateogry. For example, the former figure does not include a country such as India where a modified product claim approach exists. India does not grant product protection on basic new drugs but only on a pharmaceutical mixture such as a new injectable mixture of active ingredients, not presently available.

Irrespective of the figures, it is important to recognize that the industrialized nations of the world will play a leading role in this field for many years to come. For example, in Africa there are now 27 member nations of the United Nations, but it is doubtful whether many important medical discoveries will emanate from them.

The fact remains that the most rapid scientific discoveries in the field of medicine have taken place in those countries where patent protection is available. Unless we are ready to abandon a system which extends far beyond the drug field, and includes almost every

[88] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 19, pp. 10698–10699.

aspect of out technology, it is a waste of time to criticize the patent system which has served us so well since the days of Jefferson.

Readers of the majority's report would be led to the belief that they propose legislation to eliminate our patent structure. Any such proposal is not a proper one for this subcommittee to make under the terms of Senate Resolutions No. 57 and No. 238 which authorize investigations of the antitrust laws.

It is equally inappropriate to suggest the imposition of price controls and the elimination of brand names, since such topics under the Senate rules are properly under the jurisdiction of other committees.

There has been a general confusion on the subject of patents, which pervades the majority's report on process patents versus product patents. The majority's report attempts an oversimplified approach to product patents versus process patents protection of inventions relating to pharmaceuticals.[89] This treatment leaves the average reader with an impression which is neither correct nor valid. There is no easy or simplified explanation of this problem. Actually, there are three separate concepts which must be considered:

First, there is independent drug product protection in terms of patents which are obtainable in countries such as Australia, Belgium Great Britain (until 1919 and again commencing January 1, 1959), France (since February 4, 1959), Panama, and the United States.

The second concept is "Derived Drug Product Protection," claiming a product by process claims, for example, in the Netherlands and Germany where the coverage of the only known process, or where available broad process claims, or filing on a series of processes, results in protection virtually equivalent to independent product claims.

The third category is "Process Claims" without recognition of derived product protection (e.g., Argentina and Mexico).

Contrary to the views expressed in the majority's report, Switzerland does grant and has granted patents on fermentation processes for the production of antibiotics.[90]

Actually, the majority's staff shows its ignorance of technology by dismissing process claims in this cavalier fashion. Many products of great usefulness to mankind would only be available at prohibitive prices if a satisfactory process for their manufacture had not first been developed. In a large measure, the success of the American chemical and pharmaceutical industries lies in their ability to develop new processes so as to make the products of inventors readily available to the public at prices which they can afford.

The majority's report makes a disparaging reference to molecular modifications of basic drugs. It states that:

> At the time of the presentation of the Pharmaceutical Manufacturers Association, the subcommittee staff prepared and placed in the record a list of important drugs showing their country of origin. * * *
>
> Subsequently the Pharmaceutical Manufacturers Association submitted its own list prepared by an industry subcommittee. The major difference between the two lists was the fact that PMA included a large number of molecular

[89] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, pp. III-1-2.
[90] Ibid., p. III-1.

> modifications of the basic drug; and many of these modifications were made in U.S. corporate laboratories. * * * [91]

In this connection, it is important to review the testimony of a distinguished scientist, Dr. Philip S. Hench, who played the leading role in the development of cortisone as a member of the staff of the Mayo Clinic. Dr. Hench testified as follows:

> Dr. Lasagna spoke about his opinion that some of these differences were minor, and that pharmaceutical manufacturers should not concern themselves with what he called minor modifications. Again, sir, I would suggest that is also a post hoc determination on his part, because the mistake that Dr. Kendall made between compound A and compound E, the difference is very, very slight, only one little difference in compounds A and E, and yet E does all sorts of things and A does absolutely nothing.
>
> So in talking about a minor modification from the standpoint of chemistry, there is really a minor modification that makes all the difference in the world. You cannot rationalize these modifications. For example, sir, in due time they made a compound called hydrocortisone, and that one simple change made all the difference in the world.[92]

The majority's report makes a partial quote from a document which was written by Mr. Leonard J. Robbins, and which first appeared in the Journal of the Patent Office Society in an article entitled "Pharmaceutical Patents in Foreign Countries."

The majority's report quotes Mr. Robbins as stating that:

> The limitation of protection for chemical products in general as well as pharmaceutical products in particular, to process claims, is essentially a continental European conception, and is tied up with social thinking in the 19th century during the industrial revolution. It became a matter of practically unassailable dogma that if the public is to receive the benefit of new chemical or pharmaceutical products at a reasonable price and in amounts sufficient to meet the demand, that this could only be accomplished by restricting the inventor to his process, so that others will be encouraged to invent new and improved processes which will make the product cheaper and available in greater quantities.[93]

In order to give the full import of the original meaning of Mr. Robbins' statement, additional excerpts are given below which are in marked contrast with the sole paragraph selected for inclusion in the majority's report:

> * * * Probably there was also the fear that with so many closely adjacent countries, product claims would enable the manufacturer in one country to obtain effective control of the entire European market. Switzerland was so fearful of foreign domination, that it adopted the excessively strict requirement that one patent could only cover

[91] Ibid., p. III-22.
[92] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, p. 8172.
[93] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, pp. III-2-3.

the process of making one specific chemical or pharmaceutical product—which has actually resulted in the proliferation of Swiss patents and much benefit to Swiss patent lawyers. However, Switzerland is an exception, and other European countries permit broad process claims when the product is new. These European ideas as regards the desirability of process limitation for pharmaceutical inventions were transplanted many years ago to numerous other regions and particularly to certain Latin American and Far Eastern countries.

The British viewpoint of the 19th century was different and product claims were then permitted. However the process limitation was introduced in 1919, largely as a result of numerous broad product claims for dyestuffs obtained by German inventors before the First World War and the fear of domination of the British industry by German interests. Some of the major British colonies followed suit; some did not. After 30 years, there has now been another about face. In the new 1949 British patent act, independent product claims are again permitted. This dramatic change in British practice has had a profound effect in European patent circles, and in many countries now only permitting process claims—even Switzerland—the desirability of independent product claims in patents for new pharmaceutical products is being most carefully considered on the ground that in view of present conditions and the enormous expansion of the chemical and pharmaceutical industries, limitation to process protection may be outmoded and actually harmful. The number of new compounds that can be created is so great, the spur of competition is so strong, and the cost of research so large, that no manufacturer rests on his oars after placing a new product on the market, and will himself continue to work on improved methods of production. From the viewpoint of the public interest and the commercial utilization of a new product, all the novelty and advantages actually reside in the product itself, and it is immaterial whether the product is produced by an entirely new reaction, or by a conventional reaction. If the reaction process itself is new, this will in turn promote research to utilize it in the production of other new products. It can be vigorously argued that in countries in which patent office practice holds that utilization of a known process to produce a new product is obvious, research is actually stifled. The public benefits from the product and not from the process.[94]

Any careful review of the comments made in the majority's report as contrasted with the text shown above indicates that there is a completely different concept of patent protection abroad than the majority's report attempts to convey.

Unfortunately, there are many individuals who do not realize that it is not necessary for a firm to secure a patent. On the contrary, they could operate a plant and produce a product under a secret process indefinitely. A patent grants a limited monopoly for 17

[94] Robbins, Leonard J., "Pharmaceutical Patents in Foreign Countries," Journal of the Patent Office Society, April 1955, vol. XXXVII, No. 4, Langner, Parry, Card & Langner, New York, pp. 276–277.

years in return for a complete disclosure by the inventor. It furnishes the general public with all of the details of the processes so that after the expiration of the patent period anyone is free to manufacture the product.

American technology has benefited both from the incentive accorded the individual inventory through his limited monopoly for a comparatively few years and from the widespread dissemination of the information contained in all patent applications. Actually, in many of the countries where patent protection simular to our own is not generally available, there is a tendency for far more secrecy in terms of production and processes than exists here in the United States.

Our patent system has not only provided a strong incentive for invention but it has played a dominant role in making America the most powerful industrial nation in the world in the short span of 172 years. If one realizes that most patents have long since become public property, this is a small price to have paid for our eminence in the field of technology and science.

There is still another area that has been badly confused throughout these hearings. This involves the licensing of firms to use processes and manufacture products prior to the time that a patent has been issued. Anyone familiar with the physical sciences knows that it is quite normal for the same idea to be developed simultaneously in a number of different countries without any communication between the inventors responsible for these developments. It then becomes the responsibility of the U.S. Patent Office to determine who was the first inventor in order to issue a patent. In many cases, this involves a long period of searching and perhaps costly and lengthy litigation.

In the case of drugs it would be tragic if a useful or lifesaving product were withheld from the public pending these extended negotiations. Accordingly, it has become the practice in many industries, and particularly in the field of drugs, for manufacturers to license each other on the basis that when a patent is finally issued, a royalty will be paid to the successful inventor. Under this procedure, the public has immediate access to the benefits of most new developments, and they have extended our life span and our general welfare.

An example of this problem was illustrated in testimony before the subcommittee which is described in the majority's report referring to the pending Federal Trade Commission proceeding involving antibiotics, in the matter of American Cyanamid Co., et al., FTC docket No. 7211.[95] Since the majority has seen fit to deal with matters which are an open issue before the Federal Trade Commission, it seems only fair to state the contentions of the respondents, which are contained in briefs in the public files of the Federal Trade Commission, as well as the claims of the Commission counsel. The following is an attempt to do this briefly in respect to the matters referred to in the majority's report.

The majority's report refers to "legal maneuvers" of the companies involved, with the "twofold objective" of assuring the issuance of a tetracycline patent and of securing the patent for themselves.[96] It is the general position of each of the companies—namely Pfizer, American Cyanamid and Bristol—that they independently had the objective of securing a tetracycline patent if it was patentable. Each of them inde-

[95] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. III-81.
[96] Ibid., p. III-79.

pendently could obtain a patent for itself if possible, or, otherwise, obtain a license which would permit it to engage competitively in the production and sale of tetracycline. This is a normal business procedure.

The majority's report refers to the purchase by American Cyanamid of the Heyden Chemical Co.'s antibiotics division for more than its book value, shortly after the Heyden Co. had filed an application for a tetracycline patent.[97] The implication which it attempts to convey is that this was done to remove the Heyden Co. as a potential competitor in tetracycline. Until such time as this case has been concluded and the decision of the Commission has been reviewed by the courts, it is not appropriate for any Senate subcommittee to attempt to pass judgment upon a quasi-judicial proceeding.

Dr. Malcolm, president of the American Cyanamid Co., in his testimony explained that at the time of this agreement, his firm had already embarked on the marketing of tetracycline as its principal antibiotic instead of Aureomycin. He expressed concern that the Pfizer Co. might be found in the interference proceedings to have priority of invention of tetracycline and thus be awarded a patent. If this should occur, it would enable a competitor to block Dr. Malcolm's company from selling its principal antibiotic. Consequently, he agreed to settle the interference proceedings and to give the Pfizer Co. a license under its Aureomycin patent.

The net result of the agreement, Dr. Malcolm explained, was to avert a blocking situation in which the respective parties' patents would have prevented any of them from producing and marketing tetracycline. The net effect of this agreement was that they were enabled to compete, and patients thus had several sources of an important antibiotic. Any fair examination of the entire record shows that there was no desire or motivation to limit the market for tetracycline.

Each of the firms referred to in the majority's report has a responsibility to its stockholders to endeavor to secure a patent whenever possible on any research development which it has financed and pursued to a successful conclusion. Unless this procedure is followed, it would be possible for unscrupulous individuals to file a patent on a product or process which they did not develop and thus make it impossible for the firm which had the original conception to produce and market its own invention. The relative merits of individual processes requires a specialized chemical and pharmaceutical knowledge normally unavailable to the subcommittee's staff.

The important consideration for this subcommittee is that active competition has been maintained in the manufacture and sale of drugs. On the other hand, if the majority's staff believes that substantial evidence has been adduced to show that it is lacking, then there are other remedies to cope with this situation, such as the continuation of the Federal Trade Commission proceedings and a final determination by the courts. In fact, at the present time there are cases pending, and until they are completely terminated it is prejudicial to both the government and the companies for this subcommittee to attempt to pass judgment on the merits of the issues in question.

97. Ibid.

The majority's report makes the amazing statement that:

> * * * If patents are in fact the key to the unlocking of new drug discoveries, why has it functioned effectively in this country only for the last 20 years? * * * [98]

Apparently, the majority's staff is unaware of the fact that prior to World War I, the United States had no chemical industry. In fact, during the period of neutrality before we entered that conflict, German submarines loaded with dyestuffs entered our ports and we were completely dependent upon the German chemical industry. Immediately following World War I, action was taken to develop a chemical industry in the United States, and our patent system has played a vital role in this endeavor.

The animosity toward the patent system upon which the drug industry has been built is clearly revealed in Dr. Blair's book, "Seeds of Destruction," published in 1938. The following statements taken directly from his text clearly indicate how little importance he attached to technological progress. He wrote:

> Perhaps the most striking example of a situation involving the development of monopolies and price fixing against which the FTC is powerless is to be found in our patent system. There monopolies not only for machines and methods, but also names, are in effect granted, and the Commission can only sit back, look at a case, and regretfully announce that while it undoubtedly does involve definite price fixing and a "tendency toward monopoly" in violation of sections 2, 3, 7, and 8 of the Clayton Act, nothing can be done about it because it is a patent monopoly. And patent monopolies are for almost 20 years untouchable by the Federal Trade Commission or by anyone else.[99]

He also wrote:

> Any person acquainted with merely the most basic principles of technology's development knows that inventions and discoveries do not occur overnight. An explosion does not suddenly take place in the inventor's mind, causing him to leap over chairs and tables shouting, "I've got it," thus heralding the seizure out of the blue sky of some discovery never thought of before. An invention in the realm of techniques is almost always merely a new and ingenious application of some specific principle long known to specialists in the field. Inventions are usually the result of decades if not centuries of thought along a certain line. This heritage of mental effort, rather than any definite individual, is the true creator of inventions. Thus to rely upon some cloistered scientist or backyard mechanic to bring into being overnight a revolutionary invention based upon some never-before-dreamed-of principle is to indulge in the fantastic dreaming of an Alice in her Wonderland. We are able to look at existing principles known to man and to reason that from these principles it is possible that new developments within a certain field may be expected to take place within the future. But when we

[98] Ibid., p. III-33.
[99] Blair, John M., "Seeds of Destruction," Covici-Friede, New York, 1938, pp. 127-128.

imagine that capitalism will be saved by something entirely new, we are merely lapsing into wishful thinking.

A glance at some of the records within the U.S. Patent Office verifies this fact, showing that inventions which we today consider extremely modern are really quite old, having behind them decades of constant thought and study.

The handy little gadget known as the zipper goes back to 1893. Since that time it has only been modified in exterior appearance, but it worked almost as well when it was first patented as it does today. That answer to a railroad advertiser's dream, the streamlined train, did not burst into being, full grown, from the minds of modern aerodynamic engineers; a man by the name of S. R. Calthrop obtained a patent on such a train in the Civil War year of 1865. We usually are apt to consider the submarine a product of the 20th century but it so happens that during the Revolutionary War a submarine, powered by a powerful spring mechanism, not only was constructed but successfully went under the surface of Boston Bay, loosed a crude torpedo at a British man-of-war—missing its mark by only a few feet—and then came back up again. The Britisn Government in 1892 granted a patent for an airplane to Sir Hiram Maxim; aviation experts say that this plane, had it been powered by a gasoline motor instead of the heavy steam engine Maxim was forced to use, would have flown successfully, and even as it was, the plane actually did get off the ground. Incandescent lamps possessing filaments of bamboo were successfully used years before Edison ever perfected our modern electric light. And speaking of lighting, the present advertising hullabaloo concerning the advantages of indirect lighting is nothing new, as lamps built on that principle were advertised and sold in 1912. Concerning air conditioning—which by many is regarded as the next savior of capitalism—it is interesting to note that the Empress Theater of St. Louis used in 1913 a form of air conditioning by having air pushed with fans through falling water, and was successful in so doing for temperature was "58° within when it was 90° without." An air conditioner for home use known as the Ozoneator was widely advertised during this period as an "Ozoneator will pull you through."[1]

Without attempting to refute these ludicrous statements, it should be noted that the entire modern drug industry is a product of recent research. If this had not been the case, there would have been no justification for the extended hearings by this subcommittee. Steroid hormones, treatments for diabetics, tranquilizers and the broad-spectrum antibiotics are all recent developments.

Furthermore, the cost of finding these products and then developing suitable manufacturing processes as well as controls to protect the health of those who purchase them has been a staggering expense to the companies involved.

[1] Ibid., pp. 296-297.

Dr. Philip Berke, vice president of Formet Laboratories of Roselle, N.J., previously referred to, in his testimony suggested that:

> If the holder of a patent issues a license or cross license to another firm, and by his own volition gives up his monopoly on the product, then it should be compulsory for him to license all other companies wishing a license regardless of the size of the company.
>
> In order not to retard research and development of new products, I would also suggest mandatory issuance of licenses in the case of compounds that are not to be marked as such, but are to be used as intermediates for the production of other compounds.[2]

Apparently, Dr. Berke attaches little importance to the fact that those firms who have developed these patents have expended funds which otherwise would have gone to their stockholders as dividends. If his proposals were adopted, there would be a serious dereliction of duty on the part of those corporate officers who agreed to grant the licenses he seeks.

In effect, a process patent is an asset of a firm which has expended its funds in order to further their productive abilities. It would be a travesty to license these patents automatically without any consideration of the commercial considerations which should govern any such transaction.

Frequent references have been made to the increase in the net worth of companies engaged in this field. In almost every case, the moneys that were plowed back as retained earnings rather than paid out to stockholders as dividends provided the funds for the research in question, and by every legal standard the stockholders have a right to expect a return on this investment in exactly the same manner as they would if funds had been invested in a plant or some other productive facility.

No one can claim to foretell the future, but it casts a shadow of doubt on the economic ability and intelligence of a staff member—namely, Dr. John M. Blair—who has so little vision that as late as 1938 he was unable to visualize the employment opportunities and the changes in our living standards as the products of the automobile, radio, air-conditioning, air transport and plastic industries were more widely developed.

It is fortunate that America enjoys the services of a few dedicated individuals with scientific imagination who are motivated by an incentive system which has made this country the leader of the free world. Any perusal of the annual reports of many leading American firms will show that more than 50 percent of their total sales may be attributed to products that were not known even 10 years ago. Dr. Blair was obviously unfamiliar with the literature underlying atomic energy and the entire electronics industry which have changed our concepts of defense, imployment, and general economic relations.

Anyone who indulges in the broad dogmatic charges against the American enterprise system that Dr. Blair has used in his "Seeds of Destruction" disqualifies himself from objectively evaluating the pro-

[2] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, p. 8058.

gress of an industry that is saving so many lives and improving the health of our citizens.

General David Sarnoff, chairman of the board of the Radio Corporation of America, in a recent address entitled "Communications and Medicine," stated that:

> At various times, centers like Rome, Berlin, Vienna, Edinburgh, and London have claimed the distinction of being the medical capital of the world. Today, few question that the center of medical learning has shifted from Europe to the United States.
>
> To insure our continued preeminence, we must ceaselessly strive to increase our medical knowledge and to improve its dissemination. * * *[3]

Certainly, the patent system has played an important role in bringing this vital change about.

Although the majority's report is principally concerned with patent protection against competitive firms, it is well known that the most potent source of innovation is a company's own laboratory and research facilities. More good products have been rendered obsolete from internal competition than by any outside threat of a new innovation or development. On the other hand, because other firms may cause the obsolescence of a product, it is necessary for each company to strive for first position in its chosen field.

There has been an effort throughout the majority's report to imply that interference proceedings are secret and that foreign patent licenses are invalid and of dubious value. In the interest of fairplay, it should be added that the State Department was asked to urge the Italian Government to foster a patent law in the pharmaceutical field comparable at least to other European laws. Independently, the British Foreign Office and the Swiss, German, and French Governments similarly urged the principle upon the Italians. The basis was for the protection of growing Italian research and to establish fair treatment in commerce of all inventors of pharmaceutical processes.

The factual situation is that, in all countries except Italy, inventions are published in technical journals soon after patent applications are filed or they are published when patents are granted. Italians, so disposed, are not only free to use such inventions in Italy without an accounting to the foreign inventor, but there is also denied to such inventor any forum in Italy in which to try an issue of infringement and settle the controversy at the source of manufacture as is done in all other patent countries.

If the Italian could show in his own courts that either his invention had priority or his process was not infringing, the issue would be settled in his favor. As it is, the only recourse open to a foreign patentee of any country is to sue for infringement in every country to which the Italian exports under local law. This is an unfair and completely unwarranted burden on American firms engaging in foreign commerce. To sue is a lawful remedy for a legal wrong resulting in government by law—a policy of both the Kennedy and Eisenhower administrations.

Interference proceedings are secret for the same reason that a patent application is. These are secret on the theory that an inventor may

[3] Congressional Record, app., Mar. 21, 1961, pp. A1931-A1932.

either treat his invention as a trade secret or apply for a patent, thereby publishing it. He should accordingly not be required to disclose publicly until his patent issues. The confidential status also prevents a competing inventor from taking advantage of data that would not otherwise be available to him. The Board of Interference Examiners may find that a patent should issue to neither party. The confidentiality of the hearings thus leaves to the parties appropriate aspects of trade secrets. Sworn officers, supervised by the Patent Commissioner, are authorized to make prescribed determinations under rules.

It is true that all pending patent applications are secret, and since an interference involves one or more applications, the interference file, which would disclose such applications, is not made public so long as no patent has been issued. However, after a patent has been issued, the entire application file is open to the public, and the file of any interference in which the application has been involved is likewise publicly available.

The majority's report goes on to describe and criticize "private" settlements of interferences, under which the parties enter into an agreement for their attorneys to examine the evidence respecting priority and try to agree on which party is prior, after which the other party or parties withdraw.[4] The report concludes that this procedure involves an "abdication" by the Patent Office of its statutory function, which takes away safeguards from the public.[5]

The alternative to such a settlement procedure, which the majority concludes would be in the public interest, would of course be to require that all interferences be carried through to completion as adversary proceedings, with the Patent Office making the final determination and awarding a patent to one party. This would mean, of course, that the winning party would receive the 17-year grant of the right to exclude all others which a patent represents, free of any obligation to permit anyone else to practice the invention.

The majority's report does not emphasize, and in fact almost conceals, the fact that the settlements which it criticizes include usually an agreement on the part of the party to whom a patent is issued to license the other parties under such patent. Thus the result of such a settlement, in contrast to the result of a contested interference, is to insure to the public the benefit of competition which might not otherwise occur, if the winning party in the contested interference chose to retain his lawful monopoly and not to license any competitors.

Another benefit which the public may receive from interference settlements is that such settlements eliminate delays in the issuance of patents. Contested interferences are known to be unfortunately protracted. The result is that the issuance of a patent to the party ultimately found to be the prior inventor is held up, and the patent's disclosure of the invention to the public is deferred and the 17-year monopoly period of the patent in effect extended. A settlement, in contrast, results in a quicker disclosure to the public and an advancement of the patent's expiration date, after which anyone may practice the patented invention.

The evils which the majority's report envisage as resulting from interference settlements are not spelled out explicitly but presumably

[4] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. III-96.
[5] Ibid., pp. III-97-98.

the basic evil is that the settling parties are not required to disclose the considerations which led to the decision arrived at between them that one of them should obtain a patent. Since Patent Office procedure contemplates that it will have been determined by a patent examiner that the invention is patentable before an interference is declared, the only decision upon which the settling interference parties need to agree is which of them the evidence shows is the first inventor.

Further, on the issue of patentability as well as that of priority, the facts which might be brought out in a contested interference are not permanently interred by settlement. In an infringement suit, discovery procedures are available to elicit such facts.

The majority's report castigates the U.S. Patent Office in the following statement:

> The U.S. Patent Office is empowered by statute to determine who shall be awarded a patent. Application is made for a patent on the ground of novelty and usefulness of an alleged invention; the function of the Patent Office is to decide whether there is sufficient novelty and usefulness in the claims to warrant the issuance of a patent.
>
> If applications are filed by different parties, all laying claim to the same alleged invention, determination must be made as to which is the "true" inventor. In this case the Patent Office declares an "interference" which in essence is an administrative hearing on the claims of the various parties. However, unlike the ordinary hearing of a trial examiner in an administrative agency such as the Federal Trade Commission, the hearings of the patent examiner are entirely secret, except among the competing inventors * * *.[6]

The majority's report seriously overlooks the fact that licensed attorneys or patent agents, subject to respective discipline, determine priority on the same evidence and under the rules of the Patent Office to the end that a valid patent shall issue to the party entitled to it thereunder insofar as priority is concerned. It serves much the same comparable function as do the Federal rules in litigation, with many suits justly settled as a result of discovery proceedings. The judge in many instances has not "abdicated" nor does he do so when he appoints a special master to determine complex or technical factual situations.

After a party to an interference concedes priority, the senior party must continue to prosecute his application to a final decision by the examiner. To merit a patent he must still demonstrate that his invention is new and useful over all prior art. All that the settlement has determined is that the invention is new over the party which has independently claimed the same invention and has conceded. Given the impetus of intense competition for a lawful monopoly, the presumption can properly be that the conceding attorney has not yielded a determination of priority easily or improperly. If the attorneys cannot agree on a determination of the facts, the matter is ordinarily referred back to the Board of Interferences as the final arbiter. In important cases, royalty is usually payable by the loser. No attorney is going to yield priority and encumber his client with needless expense without sound basis.

[6] Ibid., p. III-93.

There has been a disposition on the part of some to suggest that patent protection in the field of drugs should be handled differently than in other areas. This is largely based on the theory that drugs are an essential to our well-being and hence should not be subject to any special protection. It is difficult to reconcile this theory with the advances we have achieved in American medicine and pharmacology. There are many things that have played an important part in raising the American standard of living above that enjoyed elsewhere, and in each instance there have been patents offered as an incentive to development and also for disclosure of the inventor's development so that in future years these findings will be available to others.

As has been repeatedly stated in these views, the American patent system only grants a monopoly for a limited mumber of years at the price of complete disclosure to the public. American industry operating with a minimum of secrecy and with an open-door policy over the long run offers the average citizen a higher standard of living and more rapid development of technology than any other system that could be devised either through compulsory licensing or the abolition of patents on drugs and pharmaceutical products.

POINT 4

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that contributions by American industry to American research are negligible is erroneous and unfounded.

The majority's report states that:

> What is perhaps most disturbing about the record of inventiveness of the U.S. drug companies is the relative paucity of significant drug discoveries since around the midfifties. Most of the contributions for which the American drug industry is most noted took place in the late forties or early fifties. Among the hormones, newer corticosteroids have of course made their appearance, but cortisone was discovered in 1948 and ACTH 2 years later. Whether the newest steroids represent real improvements over the earlier steroids is very much in question. Since the discovery of tetracycline in 1955, no important antibiotic of American origin has made its appearance; the most widely used of the more recent antibiotics, oleandomycin, accounted in 1959 for only 5.4 percent of the sales to the U.S. drug trade of all broad spectrum antibiotics and only 0.4 percent of sales to hospitals. The U.S. contribution among the oral antidiabetic drugs, phenformin (DBI), is running a very poor third to tolbutamide (Orinase) and chlorpropamide (Diabinese). Among the tranquilizers, the U.S. contributions since the introduction in 1955 of meprobamate have largely consisted of further types of phenothiazine derivatimes, none of which has achieved widespread usage. Of the 42 general drugs shown * * * as having been discovered by U.S. drug companies, only 6 have made their appearance since 1955.[1]

[1] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. III-46.

Those who are acquainted with the facts of scientific research are well aware of the processes of invention and development. Our generation enjoys the accumulated knowledge of all of those who have gone before us. This fact enables a modern research worker to perform miracles that would otherwise have been impossible, but it also imposes a fantastic responsibility upon him if he is to be acquainted with the literature in his field and the current work of his colleagues, not only here in the United States but abroad.

It is a disservice for any individual or organization who is concerned with our health problems to deprecate the efforts that have been made in recent years by private firms which have used stockholders' funds in advancing our knowledge of medical science.

During the course of the hearings, there was a significant colloquy between Senator Dirksen and Mr. Mike Gorman, executive director of the National Committee Against Mental Illness, as follows:

> Mr. GORMAN. * * * But, if I may say this, sir—as a disciple of Thomas Jefferson, if I may say this, sir; I think there is an element of public interest here. The burden of what I have to say, and I think after 15 years of walking the wards and living in these mental hospitals I have a right to say it, the burden of what I have to say, I don't object to their profits. I don't read the Wall Street Journal. It is a bore to me.
>
> Senator DIRKSEN. Mr. Gorman, that is a little beside the point. Now, let me read your statement that you made to the committee this morning.
>
> Mr. GORMAN. All right.
>
> Senatnr DIRKSEN. (reading): "I appear here today because I can no longer remain silent with regard to the arrogant attitude of the pharmaceutical industry toward the working processes of this democracy."
>
> Mr. GORMAN. Yes.
>
> Senator DIRKSEN. Now, you have indicted the whole industry.
>
> Mr. GORMAN. I certainly have, in spades.
>
> Senator DIRKSEN. So, now I quote you Dr. Felix in the field of mental health, and you say he is an authority.
>
> Mr. GORMAN. He is one of a number of authorities.
>
> Senator DIRKSEN. I quoted you Dr. Heller. I quoted you Dr. Farber, and all three of them——
>
> Mr. GORMAN. You quoted Dr. Farber in the cancer area. You quoted Dr. Heller in the cancer area.
>
> Senator DIRKSEN. And Dr. Felix in the mental health area.
>
> Mr. GORMAN. Only in relation to the commercial production of drugs, and I would say——
>
> Senator DIRKSEN. No.
>
> Mr. GORMAN. Senator Dirksen.
>
> Senator DIRKSEN. There was no qualification——
>
> Mr. GORMAN. Senator Dirksen, since we have gotten down to this, let's be frank about this. I have felt that the National Institutes of Health have been derelict in the psychiatric evaluation of drugs since 1954.

Senator DIRKSEN. Repeat that, please.

Mr. GORMAN. They have been derelict in the evaluation of drugs since 1954. Now, I have said this in official testimony. * * *[8]

Everyone has an obligation to make constructive criticisms and to suggest better practices, but on the other hand, it is a gross disservice merely to criticize for the sake of disparaging the work of those who have dedicated their lives to improving the lot of others.

Although many witnesses from drug firms indicated that a fairly modest amount of funds were devoted exclusively to research, the actual cost of developing a new product is far greater as it must include expenses for quality control, engineering, process development, and similar items that are not normally bulked into a research budget. On the basis of the profits that have been so eloquently described in the majority's report, the Federal Government has secured a major share of the fruits of these developments through the corporate income tax.

However, irrespective of these funds, there is so much to be done in this broad field that President Eisenhower recommended budget expenditures for the National Institutes of Health for the fiscal year 1962 totaling more than $332 million.[9] On the basis of a 52 percent corporate income tax, it would require profits from the drug industry before taxes in excess of $620 million, or at least 40 percent of all sales by the ethical drug industry merely to pay for this one item in the budget.

Everyone agrees that this research must be undertaken, and insofar as private organizations are making a contribution in this vital field, it minimizes the need for public funds, and furthermore enables governmental organizations to undertake projects that otherwise might be delayed. Although the funds for the National Institutes of Health have been itemized, there are countless other agencies in the Federal Government—including the Department of Defense, the Veterans' Administration, the Food and Drug Administration, as well as the National Science Foundation and the National Academy of Sciences—which are undertaking important projects in this field.

Actually, it would appall the American people if they were aware of the cost of Government research on health problems, and they would welcome every effort by private enterprise to relieve the taxpayer of some portion of this staggering burden.

No treatment of research would be complete without paying a well-deserved tribute to those private foundations such as the Rockefeller Foundation, the Sloan-Kettering Institute for Cancer Research, the Milbank Memorial Fund, and the important work which is conducted by both privately and publicly supported educational institutions.

There has been a vast amount of cooperation among members of the research staffs of the commercial drug industry and these nonprofit organizations as well as the Federal Government. Any fair-minded individual who has read all of the testimony and exhibits presented to the subcommittee on the subject of drugs would be forced to form an opinion on the work of this industry that would be at sharp variance with that contained in the majority's report.

[8] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 16, pp. 9016–9017.

[9] The Budget of the U.S. Government for the Fiscal Year Ending June 30, 1962, p. 620.

POINT 5

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that foreign prices of drugs are more advantageous to consumers than those here in the United States is unfounded and erroneous.

The majority's report states that:

> A second standard against which the reasonableness of ethical drug prices in the major U.S. market (i.e., sales to the retail drug trade) may be measured consists of prices in other markets—in this case the relation between U.S. prices and the prices of identical products in foreign markets.
>
> Through the good offices of the State Department the subcommittee was able to secure from American consulates abroad the prices of a number of important drug products. The prices were obtained from a leading city of each country in identical dosage forms to those sold in the United States and were as of the spring of 1959. Where the most popular foreign bottle size (in capsules per bottle) differs from that in the United States, the foreign price has been directly adjusted to the U.S. size (e.g., if the available foreign price was in terms of a number of units half that of the U.S. size, the foreign price would be multiplied by 2). For some products the prices reported were for drugs made and sold by foreign manufacturers in their own countries. For others the prices represent prices charged by American manufacturers who conduct partial or complete manufacturing operations in the countries for which prices are shown. And in a number of cases, the foreign prices are quoted for drugs made by American firms in the United States and exported either in bulk (for tableting and packaging abroad) or in finished, packaged form. * * *[10]

The American drug industry has made an important contribution to the image of America in other lands where disease is more prevalent and where fewer resources have been devoted to the development of new drugs and other therapeutic agents.

The majority's report shows a wide disparity in the price charged for the same drug in various countries of the world. However, this can be largely explained by a number of simple factors which it has conveniently overlooked. Among them are exchage controls, tariffs, competition, wages and other employee benefits, taxes, varying costs for detail men, and other promotional expenses, as well as Government regulations.

It has always been known to every economist that if a sale is to be made, it is necessary to meet the prevailing price of a similar product in the marketplace. This fact controls the actions of American firms abroad as much as it does in their sales here at home. American drug producers, in order to assure themselves of wordwide recognition and good relations with the medical profession in other lands, as well as securing a favorable patent position, have had no choice but to exploit their inventions and discoveries wherever possible. Furthermore, those who operate our major pharmaceutical firms have a

[10] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit. draft, p. I–47.

strong personal motivation toward the improvement of health standards wherever possible, and in many cases there is a greater need for these drugs abroad than at home.

The majority's report has attempted to attribute to sinister influences the fact that prices vary for the same product in different countries and that licensing agreements involving patents are not always uniform. It is again easy to criticize but far more difficult to develop a foreign market and build a reputation among the citizens of these countries favorable to American products, their producers, and our Government.

In order to attempt to discredit the efforts of American firms which have engaged in foreign promotional work, there has been a concerted effort on the part of the subcommittee to use the agencies of the executive branch of our Government, including the State Department, to collect data that would present the efforts of American firms overseas in an unfavorable light. This approach is detrimental not only to the drug industry but to the prestige of the Nation as a whole.

There are a number of obvious errors in the majority's report on this subject. For example, a statement appears to the effect that the State Department gathered data on the prices charged by a German subsidiary of an American firm. A table entitled "Comparative U.S. and Foreign Prices of Meprobamate, 1959" shows that in Germany the American Cyanamid Co. charged a price of 69 cents to druggists and $1.33 to consumers for 50 400-milligram tablets.[11] When Dr. Malcolm, president of American Cyanamid Co., appeared before the subcommittee, he was accompanied by Mr. Ernest G. Hesse, manager of their international division. Mr. Hesse took exception to this data and the following statement from the hearings is pertinent:

> I am prepared to comment on that one. I think this is one of the cases where apparently something went wrong with the arithmetic. I have checked this one very carefully and at some expense to my company because I felt that the State Department must know what they are doing. The facts are that we sell 25's, Miltown 25's over there to the druggist at 3.48 deutsche mark and they are sold to the consumer at 5.55 deutsche mark. That, in dollars—this is a stable currency and we don't make the objection we make in the Argentine and Brazil; the conversion we have no quarrel with—is 85 cents for 3.48 deutsche mark and it is $1.33 for 5.55 deutsche mark. The problem here is that they claim they are 50's, and making a conversion for 50's we find by doubling it, times 2 for simplification, which I believe you people approve as a method, the correct figure would be $1.70 to the druggist and $2.66 to the consumer, and not 69 cents or $1.33 as indicated by you in your State Department report.[12]

The entire issue of foreign prices as compared with domestic prices that were so badly distorted throughout the course of these hearings was discussed at length by Mr. Henry H. Hoyt, president of Carter

[11] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. I–53.
[12] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 24 p. 13751.

Products, Inc., during his appearance before the subcommittee. He stated that:

> * * * I do think, in trying to compare foreign prices with U.S. prices, you have to take into consideration all factors involved, such as per capita income, real wages, and so forth. For example, the per capita income in the United States is 13 times as much as in Argentine, 8 times as great as in Mexico, 2½ times more than in Germany. As I said before, it is unrealistic and misleading to try to make direct comparisons on a conversion rate of exchange, because exchange is not based on living conditions. It is based on the flow of money between the countries or it is an artificial fixed rate, and I have been in the export business, and you must get your products down to the scale of living in the foreign countries.[13]

He also said:

> * * * I have a list of the conversions here on a per capita income basis, and I think that if you take the Argentine price, you must multiply by 13, the Australian price by 2, and the Brazil price by 19, Canada by 1½, France by 2½, Germany by 2½, Italy by 5, Japan by 8, Mexico by 8½, the Philippines by 11, Switzerland by 1½, United Kingdom by 2, and I just think that anybody who converts on a rate of exchange basis is not getting the true picture. Just because things are cheaper abroad, that is why we have protective tariffs in this country, because our American industry cannot compete with the lower scale of living abroad.[14]

Another witness, Mr. Alvin G. Brush, chairman of the board of American Home Products Corp., also dealt with this same problem. In his testimony, he said:

> One reason we can sell so low in England—in the first place, we don't sell in dollars in England. We sell in pounds, shillings, and pence. We don't employ Americans in England. We employ Englishmen. These goods are entirely manufactured within the British economy, and the cost of those goods is materially lower than the costs in the United States. A busdriver in London gets £12 a week, which is, roughly, $34. This same man in the United States on the Fifth Avenue bus gets $110 a week. Now that is an exaggerated part of the economy, but we can do business in Britain for about half of what we can do business for in the United States, and our goods in Britain are made in Britain and sold in Britain, and they are produced by British employees, and the whole economy is in pounds, shillings, and pence, and you can't compare that kind of an economy.
>
> We could ship the goods to the United States and let some of our employees out, if that is what would be preferred. But, as I understand, we want to keep our people working in the United States and not have the goods pouring in from these foreign countries who have a distinct advantage over making goods in the United States.

[13] Ibid., pt. 16, p. 9225.
[14] Ibid.

> You can buy transistors in Japan for one-quarter of what you can buy the same thing in the United States. You can can buy shirts made in Japan for practically a third of what you can buy the same shirt for in the United States. You can buy barbed wire in Germany much cheaper than you can buy the same barbed wire in the United States. This isn't only true of the drug industry. This is true of all prices.
>
> The economies of these countries are much lower in prices than we are, and, if we continue to push our prices up, we will price ourselves out of the world markets and we will force ourselves to do business in those local countries by having local operations.[15]

Every firm which is conducting an extensive business abroad is well aware of the problems presented by tariffs, quotas, repatriation of foreign currency into dollars, exchange rates, and numberous factors which do not prevail in the American market. In terms of our overall foreign relations, it would be a gross disservice to discourage the availability of our research discoveries to the medical profession in other lands.

Foreign firms often enjoy tax advantages and in many countries there is a far more realistic approach to the basic problem of depreciating real assets than prevails here in the United States.

POINT 6

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that there have been substantial economies for the American taxpayer in purchasing drugs abroad is erroneous and unfounded.

The majority's report places emphasis on testimony by Adm. William L. Knickerbocker, executive director of the Military Medical Supply Agency. It states that:

> MMSA is required to purchase drugs by generic name at the lowest possible price from what are termed any "qualified suppliers." To provide the best possible medical treatment for patients, who may range from the newest Army recruit to Members of Congress and the President, MMSA insists that suppliers meet exacting standards. Not only must the quality of the particular product being delivered conform to rigid specifications but inspection is made of the supplier's entire operation including the "housekeeping" facilities of his plant, his production and quality control techniques and performance, his records system, the technical proficiency of his staff, and the competency and knowledge of the management itself. In short, every effort is made to assure that any company, large or small, which sells drugs to MMSA is capable of providing pharmaceutical products of fully acceptable quality. Given quality, MMSA endeavors to fill its requirements at the lowest possible cost. * * *
>
> MMSA has had little success in securing price concessions in the patented broad spectrum antibiotics. A case in point is Chloromycetin available only from Parke, Davis.

[15] Ibid., p. 9267.

From May 1954 to February 1958, MMSA negotiated 16 contracts with the company; despite a wide variation in quantities, the price was rigid at $12.50 per bottle. In April 1958, MMSA's purchase officer persuaded Parke, Davis to reduce the price to $11.25; from that date through June 1959 there were 11 additional procurements—all at the same price, although there was again a wide range in quantities.[16]

In order to implement this program, MMSA has frequently purchased drugs from foreign sources, including Italians who enjoy no patent protection. On the surface, if one is only concerned with appropriations, this appears to be a procedure which should save the Government and the taxpayer a substantial sum of money. On the other hand, there are additional factors to be considered.

For example, the employees in the Italian firms do not pay U.S. income taxes, nor do they pay our social security taxes. They are not required to meet the standards imposed by our labor laws and there are, of course, other price differentials which arise from the differences in the two economies over which neither the American nor foreign producer of drugs has any particular control.

In order to place this situation in a responsible frame of reference, Senator Dirksen endeavored to raise a number of questions in interrogating Admiral Knickerbocker that have a bearing on the overall cost of drugs to the American taxpayer. In this connection, the following colloquy is pertinent:

Admiral KNICKERBOCKER. Senator Dirksen, here again I think you were out of the room when I mentioned this subject. I have been in these various Italian plants. I find, generally speaking, in our Danish plant—ours, I mean the plant of our Danish contractor—and the plant of our Italian contractors, that usually they have more handwork and a little less automation than we do in our modern plants over here, sir. As a matter of fact, our contractor in Naples explained that he thought his packaging and packing was costing him as much or more than it did his American competitors because he did have more hand labor. Now in some instances, you will find people sticking labels on bottles that are done by machines over here, find people doing it by hand. It isn't that the equipment is not available. It may be if I have the opportunity to visit the plant again, why I will find out they do have some machines installed. But as Commander Weiss pointed out, the basic product, we do not think labor enters into it very much. In fact, we do not feel actually that labor enters into the cost in these items to a great extent.

Senator DIRKSEN. Admiral, do you know, or are you just speculating?

Admiral KNICKERBOCKER. I am speculating, sir.

Senator DIRKSEN. I thought you were.

Admiral KNICKERBOCKER. Yes, sir.

Senator DIRKSEN. Because your answer was very inconclusive. Now let me ask you another question. I don't

[16] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit. draft, pp. II-43-44.

know anything about the child labor laws in Italy, but do they employ children in these plants?

Admiral KNICKERBOCKER. Not to my knowledge, sir.

Senator DIRKSEN. But do you not know?

Admiral KNICKERBOCKER. No, sir; I do not know.

Senator DIRKSEN. You see, we do have a very stringent child labor law relating to shipments of goods in interstate commerce in this country.

Commander WEISS. But I think, Senator Dirksen, Colonel McMahan, who is sitting behind me, was in constant residence at the Italian plant while the tetracycline was being made. He was in constant residence at the Danish plant while the meprobamate was being made, and I think he——

Senator DIRKSEN. Bless you, maybe the colonel can tell us.

Senator KEFAUVER. Yes, Colonel McMahan, come around.

Colonel MCMAHAN. As the commander has just stated, I was in constant residence at the plant at Farmachimica during the first contract of tetracycline and during the first portion of the contract for meprobamate at Denmark and there were no child laborers at all.

Senator DIRKSEN. Did you find out about the wage scales over there, Colonel?

Colonel MCMAHAN. I did not.

Senator DIRKSEN. Do you know what percentage of the cost of the product must be charged to labor?

Colonel MCMAHAN. I would not be able to intelligently answer that, sir.

Senator DIRKSEN. That was one of the points Lederle made in its presentation this morning and also yesterday, because in this chart they show that labor has gone up 70 percent since 1948. It would be fair to assume that that becomes a very considerable item in the cost of manufacture. Now there is one other item I want to ask about. We collect no taxes, I take it, Admiral, on whatever the profits are on what is manufactured abroad and bought with the people's money out of the Government Treasury for Government account, or do we?

Admiral KNICKERBOCKER. Obviously not, sir. I did not quite understand your question.

Senator DIRKSEN. You see, Admiral, I am just pursuing what has been quite a basic thesis with me for a long time, and it comes about somewhat in this fashion: When, for instance, we bought small narrow-gage locomotives for India through the International Cooperation account, we bought them with money that we sponged out of the pockets of the taxpayers. Some of our contractors and manufacturers were hot on the trail of that contract, but as I recall, it went to Belgium. So when they send you a letter and say, "Look, I am flipping my tax dough into the U.S. Treasury and you guys in Washington are taking it and spending it on contracts abroad that we could very well fulfill and we could manufacture those locomotives," the same thing was true in installing some ovens in some steel mills in Spain. The latest

one was buying some diesel locomotives out in Burma or Vietnam. Those were bought with the taxpayers' money. As strongly as I defended the President's position on foreign aid, that is a hard one to answer when suddenly you discover you have plants back home where they lay off 50 and then they lay off 100 and then they lay off 200, and it begins to make them pretty unhappy.

Now the point I make, Admiral, is this: For the last fiscal year you had $61 million to spend, and out of that $61 million, you had about $42 million to spend for drugs and biologicals; is that substantially correct?

Admiral KNICKERBOCKER. Not quite, Senator Dirksen.

Senator DIRKSEN. You correct me.

Admiral KNICKERBOCKER. We spent, as I recall, $64.8 million, of which——

Senator DIRKSEN. No, I am just figuring the dollar amounts. You had $61 million to spend.

Admiral KNICKERBOCKER. $65.4 million, sir, and 52 percent of that, or $33.7 million, went for drugs and biologicals.

Senator DIRKSEN. Oh, I thought you said here: "In the fiscal year 1960 just completed, grand total for purchases of $65.4 million, and of this total, $33.7 million went for drugs and biologicals."

And in 1959 it was $41.7 million. In fiscal year 1959——

Admiral KNICKERBOCKER. yes, sir.

Senator DIRKSEN. Total purchases——

Admiral KNICKERBOCKER. That is correct, sir.

Senator DIRKSEN (continuing). Amounted to $68.2 million; drugs and biologicals accounted for $41.7 million. Now, you did get this money out of the U.S. Treasury. We appropriated it; did we not?

Admiral KNICKERBOCKER. You certainly did, sir.

Senator DIRKSEN. Yes, sir. And when we do, you do the right thing in trying to run an efficient operation. But I am not forgetting that these people who manufactured competitive items have to throw 52 percent of their take back into the Federal Treasury under the corporate tax statutes. Now when you put it all together, how much did this saving amount to, if you chop it off at one end and it does not get back into the Treasury?

Admiral KNICKERBOCKER. Senator Dirksen, I have not tried to make any such comparisons——

Senator DIRKSEN. Admiral, I know you have not.

Admiral KNICKERBOCKER (continuing). In that respect. I would like to point out, as I did earlier in my presentation, that I cleared our actions with the business people of the Navy, including the Assistant Secretary of the Navy for Material, who was a businessman, and the Under Secretary of the Navy, who is a businessman. I have had the backing of my superiors right through up until this time, and the only thing I am trying to do is to spend my money prudently and get the dollar value for dollar spent, and I do not intend, as far as I am concerned, to waste the taxpayers' money if I can help it in any way.

Senator DIRKSEN. I know that is right. You have told a candid story, but I do not want any misconceptions to get out to the country, because when you try to put it on net balance, and you put in all the factors, all the components, maybe it does not look quite as rosy as you indicated, because you said you bought for $1,700,000 what would have taken, if you bought it here, $1,900,000 more. In other words, you got 3,600,000 dollars' worth of merchandise, so to speak, really for $1,700,000; is that another way to equate it? All right. Did we actually on net gain from the national standpoint save $1,900,000 or did we not? You saved it on your purchases.

The question is what did you do to the tax ledger of this country? What have you done to the income that may not go into the Treasury? What has happened to job displacement, if anything, and all the other factors, because when you talk about net gain—now, that $1,900,000 looks awfully impressive on paper, but that is only a small part of the story. If you can gain that much—this is my final question—then why don't you take the whole $61 million, if you can buy to such advantage, and just throw the whole business abroad, and then come back and tell us, "Well, look, on this deal we did not save $1,900,000, we saved $30 million," and then I want to hear the roar that goes up and start for the timber.[17]

Obviously, the Congress is not solely concerned with the cost of Government procurement, but with its overall effects. It is important that the American taxpayer is charged the lowest price regardless of whether it is accomplished through reduced appropriations or higher tax revenues collected from those in this country who are liable for U.S. income taxes.

Every American is desirous of seeing that American personnel stationed overseas are supplied with the best drugs available at the lowest cost, but it is essential in doing so that we determine what actually constitutes the lowest cost. This may not be the lowest appropriation to the Defense Department, but, on the contrary, a combination of appropriations, income taxes paid by individuals, social security levies, as well as corporate income taxes. Only through a sound and judicious evaluation of this combination is it possible for any informed citizen to reach a sound judgement on this important question.

While the majority of the Government's purchases of antibiotics were confined to the armed services, other agencies—including the Veterans' Administration—were also large purchasers of antibiotics and other ethical drugs.

The majority's report deals at length with the purchases of tetracycline by the Military Medical Supply Agency. It quotes a portion of the testimony by Mr. Lyman Duncan, manager of the Lederle Laboratories Division of American Cyanamid, in which he explained that he had bid $11 for the 100 250-milligram capsules under first MMSA procurement in 1956, because this was the price at which American Cyanamid had been selling Aureomycin to the military.

[17] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 24, pp. 13807–13810.

The majority's report stated that:

> While Admiral Knickerbocker refused to hazard any guess as to the reason for this strange price behavior, an explanation was proffered by Mr. Lyman Duncan, manager of the Lederle Laboratories division of American Cyanamid. According to his testimony the first MMSA tetracycline procurement was announced at a time when Mr. Duncan was still learning the drug business (shortly after his transfer to Lederle from Cyanamid's Organic Chemicals division). As a result, he made a mistake and simply bid for the tetracycline contract at the same $11 price at which Cyanamid had been supplying Aureomycin to MMSA for some months.
>
> "As I recall the circumstances, up to that time I think the buying had been entirely Aureomycin or Terramycin with some Chloromycetin, but the real competing products there were Aureomycin and Terramycin.
>
> "Now what happened there, was, I was not fully aware of this, being new in the business, that the Army had never before bought tetracycline.
>
> "It was brought to my attention that they had an order for tetracycline. Well, I guess I did not give it a great deal of consideration. * * *
>
> "So far as I can remember when this came up, I said: 'Well, I suppose we have been bidding $11 on Aureomycin. It is too low a price, but I guess we might as well bid the same price.' "[18]

The majority's report infers that this was a mistake and points out that on the next MMSA order Lederle bid $19.58 while Pfizer bid $11 and therafter the prices of all bids were higher than the original $11 bids.

The majority's report categorically states that—

> Mr. Duncan's uncertainty as to what Lederle should charge for tetracycline is surprising in view of the fact that for a full 2 years prior to the MMSA procurement his company had been selling the same product to the Veterans' Administration at a price of $19.58, less 2 percent for prompt payment.[19]

Presumably the implication is that there was some sort of understanding regarding these bids. Unless there has been substantial evidence to support such charges, they are unwarranted in any documents issued by a Senate subcommittee.

The majority's report entirely ignores the testimony by Mr. Duncan as to his independent motivations in submitting Lederle's various bids with respect to the initial differences in the prices offered to the Veterans' Administration and the MMSA. Actually, the differences between the bids were easily explained in view of the fact that the earlier VA purchases were for relatively small quantities. Furthermore, the VA awards were not firm contracts but only "hunting licenses."[20] Also, the VA insisted on the privilege of returning merchandise while the MMSA did not.

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[18] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit. draft, p. II-45-46.

[19] Ibid., p. II-46.

[20] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 1, p. 13716.

Still a further factor influencing the prices charged by Lederle to the Veterans' Administration was the fact that it was much closer to the civilian market as there were some 200 scattered installations in which many doctors having private practices were engaged. Mr. Duncan characterized the initial MMSA price as a "special bargain price." [21]

The stress laid in the majority's report on the fact that drugs were sold to Government agencies such as the Military Medical Supply Agency and the Veterans' Administration at prices far lower than those generally available to wholesale druggists appears to indicate to any disinterested observer with a knowledge of fundamental economics as a lack of competition. On the contrary, this fact constitutes an evidence of competition since a large firm engaged in a contract with a Government agency is able to minimize its costs of distribution. It does not have to advertise its product nor send detail men nor does it have any contact with wholesale or retain channels of distribution.

It is feasible to conclude a large sale by a single contact with a responsible purchasing agent acting on behalf of the Federal Government. After the drug in question has been delivered, the responsibility of educating those doctors who will use it is discharged by the Government, and not by the manufactuer. Obviously, any sales of this nature have little similarity to the thousands of transactions involving individual doctors and pharmacists which enables them to discharge their responsibilities to their patients and customers.

An examination of the transcript reveals the true facts. The following colloquy, involving Mr. Myron Pantzer, president of the Panray Corp., removes the misunderstanding which has been generated:

> Mr. PANTZER. * * * There are plausible differences from Ciba. We are different in this respect. We did not seek the business on the product as priced. It came indirectly in ratio to the business originating on an institutional level.
>
> If we were to enter into a program of formal promotion, to gain recognition, credence, and acceptability in prescription writing for our trademark Serpanray on the medical profession level, we would have to charge a much higher price than $2.65. [22]
>
> Mr. PANTZER. Well, briefly, Senator, we do not spend at this moment—and this is the situation for the last 2 years—a single penny to advertise this drug to the medical profession. Our entire business on reserpine today has reduced itself to where the business almost totally comes from competitive bidding. We do a very small business even at this level with the retail or wholesale drug field because we are not doing a significant individual promotion or educational job or a retailing job to the medical profession. [23]
>
> Mr. CHUMBRIS. I think that you stated earlier that you do almost no business with the druggist on this $2.65; you said very little. And, therefore, if you do very little business with the druggist, the consumer would not get it anyway.
>
> Mr. PANTZER. That is correct

[21] Ibid., p. 13718.
[22] Ibid., pt. 16, p. 9366.
[23] Ibid., p. 9367.

Mr. CHUMBRIS. Only through institutions and through the hospitals.

Mr. PANTZER. That is correct.

Mr. CHUMBRIS. And I think you pointed out that when you did advertise, and when you did try to get acceptance from the druggists and the doctors, you charged $21 per thousand; is that correct?

Mr. PANTZER. That is correct, sir.[24]

* * * * *

Well, if we were to promote this purely as a specialty, we would have to use the normal channels of promotion that are used by industry; we would have to first sell and familiarize our trademark to the medical profession; we would have to detail by personal contact the physicians to convince them of our reputation and reliability of production.

This would of necessity have led us to fix a much higher selling price to the druggist. And even at that level we did a very small amount of it. Our price was not too much lower than Ciba's and the druggist did not beat a path to our door.

We were out of our ball park, and we were not capable of doing the tremendous promotional job to the medical profession on a product such as this.[25]

It is evident that if the small manufacturer, in this case Panray, were to compete for retail business with the large manufacturer, the difference in price would not be as great as that implied in the majority's report.

With regard to Government bids, it should be said that it is fortunate that the Government can obtain supplies from the drug manufacturers at such low prices. However, the statement by the chairman does not seem nearly as startling when testimony of the witnesses is examined. Mr. T. F. Davies Haines, president of Ciba Pharmaceutical Products, Inc., said:

> When we bid 60 cents for bottles of 1,000 here, we didn't anything like recover our out-of-pocket cost; we were poorer when we got through with this than we were before we started. I am not talking about overhead, I am talking about the direct labor and material that went into those pills.
>
> In retrospect, it was perhaps a mistake that we did that. I only hope for the sake of my stockholders that we got some benefit out of it, that we got prestige in having our material used by the armed services, that the doctors who used it in the military hospitals saw our name on it, and when they go out and practice in civilian life will remember it so that we get some institutional advertising out of it. I think in retrospect, perhaps, it is a mistake. It hasn't come forcefully to my attention until I prepared myself to come down here. I don't think I would do it any more.[26]

[24] Ibid., p. 9368.
[25] Ibid.
[26] Ibid., pp. 9430-9431.

Again, Mr. Myron Pantzer, president of the Panray Corp., said:

> * * * If we were to take any of those individual competitive bids to the Military Medical Supply Agency or VA out of the total picture, we would find that, if this was the only type of business we could do, we would have a very tough time to exist and grow. But the nature of the beast in this particular case is the following:
>
> We have a plant, sir, that is capable of turning out tremendous quantities of finished tablets, and we like to see our machines rolling at all times, because we like to see people gainfully employed. And the only way to do it is to try to get production on which we can make a fair and reasonable profit, but we make their situation in our picture as part of the whole, not single them out as an individual entity, and this has been an area of reward for us in many instances.
>
> Mr. CHUMBRIS. If you had taken that one particular product and allocated all of the costs of doing business, you would not have made a profit, would you?
>
> Mr. PANTZER. As a single bid, no; but as a regular operation on a multi-mass-production level, yes; but a small profit.[27]

The above statements would indicate that on an isolated secret bid a company may entertain a loss or a small profit. Obviously, a firm that followed such a practice consistently would not be in business very long. In our free enterprise economy, profit is essential if business is to conduct research, expand facilities, or invest in new plants. A review of the transcript impresses the reader with the tremendous progress made by the drug industry in conquering disease. The importance of research has been demonstrated many times in the course of these hearings. As Mr. Pantzer pointed out in his testimony:

> I would like to say on that point that in this wonderful country that we live in, and with this wonderful medical profession that we have, there is no osmotic process that I know by which the physician can absorb the tremendous book of medical knowledge that is daily appearing in the medical journals, and I think the pharmaceutical industry renders an instructional job in keeping the physicians advised. I believe that the entire status of our public health would be thrown into jeopardy if we took the incentive out of new drug development, and if we took the incentive out of trying to vie for the professional medical market.
>
> I think this is a factor of reward that we as citizens and as a part of the industry have the privilege to seek; and I think that we are a necessary part of the whole health process.
>
> I heard this morning, today, a little comment by Dave Garroway before I came here that I would like to mention. On trips to Russia, the public was advised to take your own prescriptions along, because you may have difficulty filling them there.
>
> We in this country don't have to worry about that; we can enter any hamlet in this country with a prescription and have it filled. This is a job that our field is rendering. This

[27] Ibid., p 9365.

> is a job that I think is necessary. It may not be perfect, but I think it has done a wonderful job in lifting the health standards of this country to the highest in the world.[28]

There is an applied inference in the majority's report that the prices that have been quoted to Government agencies should prevail in every distribution channel. If such a practice were followed, it would be impossible to promote new drugs, and the research development in this field would languish. Inasmuch as retail druggists price their products to their customers based on a markup over the wholesale price, it is doubtful if many of them could meet their overhead and remain in business if they were forced to operate in this manner.

Furthermore, eventually the Government itself would be confronted with higher bids on future orders. Hence, any comparison between Government sales and those that normally result in the usual distribution channels is misleading and can serve no useful purpose.

POINT 7

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that selling, promotional, and advertising expenses are excessive is erroneous and unfounded.

The majority's report states that—

> Expenditures for promotion of ethical drugs have reached colossal proportions. Recently Advertising Age estimated an expenditure of $125 million in 1959 for product advertising in medical journals and direct mail alone; and this represents only a portion of total promotion expense incurred by drug manufacturers. According to this same source, these advertising expenditures have been climbing steadily for the industry in recent years; it reports an increase between the years 1953 and 1958 of 219 percent.
>
> The Senate subcommittee secured information from the 22 largest drug manufacturers on their promotion expenses for all types of drugs for the year 1958. In addition to their expenditures for direct mail and advertising in medical journals, these companies were asked to supply data for all other promotion expenses including costs of detail men, samples, and the like. The total reported by these 22 companies for all promotion in 1958 amounted to some $580 million.[29]

The majority's report on administered prices in the automobile industry made a scathing attack on the advertising practices of this important sector of our economy. For example, it stated that on the average, automobile manufacturers spent approximately $75 per car at the manufacturing level for advertising expenditures of all types, including newspapers, magazines, radio, and television.[30]

Actually, while these figures may seem high, they are comparatively low as the entire adult population is exposed to these advertisements,

[28] Ibid., pp. 9370-9371.
[29] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. IV-5.
[30] "Administered Prices—Automobiles," report of the Subcommittee on Antitrust and Monopoly, op. cit., p. 103.

and at one time or another they are prospective buyers of a new car. Marketing experts would regard these expenditures and the broad coverage involved as reasonable.

Those who are charged with the sale and promotion of drugs are confronted with an entirely different problem. At the most, there are only 200,000 physicians in the United States who are trained to read and understand the advertisements for ethical drugs. Hence, not by choice but rather by necessity, all drug manufacturers have had to resort to expensive and limited promotional coverage. It is impossible to use mass media, and detail men—many of whom receive salaries in excess of $7,000 per annum—are required to call on members of the medical profession and explain the new advances which their companies have developed. They are not only expected be to knowledgeable in the therapeutic qualities of those drugs which they are promoting, but they must also have a broad understanding of all of their side effects, some of which may be favorable and others adverse.

Furthermore, there are many medical practitioners who use the detail men to report back to their companies the effects they have encountered in prescribing these drugs to their patients. This provides exceedingly valuable reserach information for their respective companies. The cost of detail men in terms of individual contacts with doctors is necessarily high because they must wait their turn while the doctor is concerned with treating his patients. Any promotional activity of this type is one that is not undertaken except for the fact that experience has proved that it is a vital necessity in meeting the needs of the modern practitioner.

The merchandising of drugs is a highly complex business, and most ethical drug producers would welcome an opportunity to use mass advertising media which were condemned so extensively in the majority's report on administered prices in automobiles. If such techniques could be used effectively, the unit promotional cost per pill would be reduced drastically. Unfortunately, by the very nature of the product this is impossible, and it becomes necessary for this industry to employ a highly specialized and complex distribution system at the wholesale level.

Furthermore, as is well known to every member of the subcommittee, retail druggists are compelled to stock a vast inventory of products if they are to render adequate service to their customers. A drug prescribed today is required at once. A patient will not return to a druggist if he must wait until the product is secured from some distant point, as in the meantime his health may have taken a turn for the worse, or, in an extreme case, he might have died.

The success or failure of any given firm is influenced by the merchandising and distribution of its products. The policies affecting these activities are rendered more complex because of the rapid innovation in this field of science. The majority's report states that—

> The data submitted by the 22 largest drug companies to the subcommittee show that approximately 24 percent of every sales dollar of these companies is expended for promotion * * *[31]

Actually, any fair appraisal of the economics of this business would indicate that this is a conservative sum in order to promote a myriad

[31] "Administered Prices—Drugs," report of the Subcommittee on Antitrust an d Monopoly, op. cit., draft, p. IV-6.

of new and complex products to the medical profession. The majority's report also asserts that—

> It is of interest to contrast this figure of $750 million for advertising with the total budget for this country's medical schools. In 1957 total funds available to all medical schools in the United States for their educational programs were only a little more than one-fourth of this figure—$200 million.[32]

Medical students, of necessity, must be acquainted with the latest advances in the art, and, in a sense, a large portion of these so-called promotional expenses are actually medical education and not merely advertising.

Still a further criticism of the promotional activities of this industry is found in the majority's report and is indicated in the following statement:

> * * * In addition, virtually all who attempt to market some trademarked specialties engage in journal advertising, direct mail, and the supplying of free samples to physicians.[33]

Apparently, the majority's staff is unaware of the fact that many of these free samples have been used to provide drugs for those who cannot afford to purchase them in the regular channels of trade.

POINT 8

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that drug manufacturers do not operate in the normal competitive economy is erroneous and unfounded.

The majority's report states that—

> The difference in the behavior of administered versus market-determined prices, which has been noted in the subcommittee's earlier reports and hearings, is nowhere more dramatically illustrated than in the drug industry. Where the only sellers consist of one or a few of the major companies prices tend to be unchanged over long periods of time, with the different companies selling at identical prices. Where there is an uncontrolled bulk supply to which small manufacturers serving the trade can secure access, not only does the bulk price tend to be flexible, but the drug in packaged form will be offered at widely varying prices. This is true of both of the markets for drug products—sales to the regular trade (i.e., the retail drugstore) and sales to institutional buyers (e.g., governmental bodies, hospitals, etc.). * * *[34]

Most drugs are sold under brand names. However, every doctor who is well acquainted with his patients has some knowledge of their economic circumstances, and it is a totally unwarranted criticism of the integrity of those who have submitted to the arduous training for the medical profession to suggest that they would knowingly prescribe drugs which their patients cannot purchase without seriously jeopardizing their other needs.

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[32] Ibid.
[33] Ibid.
[34] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. sit., draft, p. II-28.

Although prednisone and prednisolone are normally sold under trade names of individual producers, there is testimony included in the record which has been referred to in the majority's report indicating that these products have been made available in Washington at a far lower price by the Dart Distributing Corp., a firm with limited distribution and no national advertising.[35]

At the time when the Congress adopted the Robinson-Patman Act, it was the basic thesis that all competitors in the same general category should be charged identical wholesale prices. Accordingly, for manufacturers to secure effective distribution from those merchants who were in a position to do a superior promotional job, it was necessary to grant higher wholesale prices to many marginal firms than would otherwise have been justified. The Robinson-Patman Act, however, specifically provides that——

> * * * *Provided,* That nothing herin contained shall prevent differentials which make only due allowance for differences in the cost of manufacture, sale, or delivery resulting from the differing methods or quantities in which such commodities are to such purchasers sold or delivered: * * * [36]

The Robinson-Patman Act also specifically provides that any competitor may meet an equally low price offered in good faith in the marketplace. Under present law it has often been necessary to lower prices locally or in a limited marketing area in many instances in order to retain the patronage of a customer. In the absence of fair trade laws, it is necessary that this practice be followed in order to promote competition. Our ideal must be to further the interest of the consumer rather than to preserve the position of any individual competitor.

There has been a marked confusion among the witnesses who appeared before this subcommittee concerning the fact that the prices charged to independent druggists, hospitals, nonprofit organizations, and government agencies differed. In each instance, the firm in question met the price of a competitor in good faith for a particular class of buyer. In no instance was there any violation of the Robinson-Patman Act which states that every buyer in the same general trade classification must be treated equally.

It must be obvious that it costs a good deal less to sell a supply of drugs to a hospital, governmental agency, or a similar institutional buyer than to an individual pharmacist. On the other hand, in order to protect the market position of each competing pharmacist, it has been necessary to establish a price range that will enable even the marginal firm to compete effectively There has been one exception to this broad principle of no price discrimination which provides that it is lawful to meet the competition of another seller in good faith. The act states that—

> * * * *Provided, however,* That nothing herein contained shall prevent a seller rebutting the prima facie case thus made by showing that his lower price or the furnishing of services or facilities to any purchaser or purchasers was made in good

[35] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 17, p. 9662.
[36] Robinson-Patman Price Discrimination Act, sec. 2(a).

faith to meet an equally low price of a competitor, or the services or facilities furnished by a competitor * * *.[37]

This provision of the law has been tested in the Supreme Court on three separate occasions in a case involving the Standard Oil Co. of Indiana. The provision was affirmed.

The following colloquy between Mr. John T. Connor, president of Merck & Co., Inc., and the chairman is pertinent:

> MR. CONNOR. Well, our chart shows what we actually receive from customers, and most of our business is with wholesalers and retailers. But in that line of trade, the waviness of the line is attributable to the fact that our actual prices to druggists fluctuated below the 100-tablet-size price, because of our quantity discounts in effect for retailers, and that we have met and initiated low quotations to hospitals and local government institutions as the competitive situation required.
>
> Senator KEFAUVER. Mr. Connor, I think we would get along a whole lot better if we would stay with druggists. That is what we are talking about here. We will get to the governments and to hospitals and to others later on. I would think that you would be discriminating between druggists, selling to some at $17.90 and making a lower price to some other druggist. If you are doing so, you have been violating the Robinson-Patman Act.
>
> Mr. CONNOR. We are very careful, sir, not to violate the Robinson-Patman law and the quantity prices on Detra were available to all druggists. We do meet competition on sales to hospitals and local government institutions in specific local situations as that competition develops, so that the steady line depicted on exhibit 9 is not in accord with the market conditions.[38]

The marked confusion on the part of the majority's staff in maintaining its two goals, namely, lower prices to consumers and higher prices to sellers is indicated in the following colloquy between Mr. Dixon, counsel and staff director, and Mr. John T. Connor, president of Merck & Co.:

> Mr. DIXON. Had there not been a Syntex Co. and all five companies had lived up to what they had signed and agreed to, how could those small companies shown on the chart on the easel obtain supplies in bulk form in any manner so that they could produce a finished tablet and enter the market and offer it for sale to druggists to the Government and to hospitals and other institutions at lower prices?
>
> Mr. CONNOR. Mr. Dixon, as I have indicated, I don't have the facts as to whether we entered the market before Syntex or not, so it is difficult for me to reply. I will be glad to look up those dates, but I know that our decision to sell in bulk was motivated by other considerations, because our chemical division, which does supply pharmaceutical manufacturers with bulk chemicals, was very desirous of having

[37] Ibid., sec. 2(b).
[38] "Administered Prices," hearings of the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, pp. 8073-8074.

this material made available to their customers in bulk, and that was our consideration

Mr. DIXON. I think small companies that are now buying in bulk would very much like to know this. I would like to know if the happy day ever arrives and the interference is decided and you are the winner, do you intend to license these small companies so that they can engage in the manufacture of prednisone?

Mr. CONNOR. Our record in steroid hormones so far is that we have not denied any patent licenses. Now this does not mean that we won't in the future, because we make these decisions on the facts of specific cases. A lot depends upon the interference situation, and until that is determined we just don't have any general statement.[39]

For several years a measure, S. 11, sponsored by Senator Kefauver and others, has been before the Congress. While it would still permit the meeting of competitive prices in good faith, this defense would not be allowed if such action resulted in harm to competition itself. During the 85th Congress, Report No. 2010 was filed on S. 11, a similar proposal. It included extensive minority views by Senators Dirksen, Butler, Hruska, and Jenner. They said:

> This asserted distinction between a price which "may "lessen competition" and a price which may "injure, destroy, or prevent competition" is not only fine spun and technical, but it seems to have escaped detection by the courts and the Federal Trade Commission in 21 years of enforcement of the Robinson-Patman Act. Only one district court has ever distinguished between these two types of competitive effect and even then only in a theoretical fashion which did not explain the distinction in practice. Numerous Supreme Court decisions and dozens of Federal Trade Commission cases have invariably treated potential lessening of and potential injury to competition as idential and synonymous. Recently, the Federal Trade Commission itself declared: "The difference between the two concepts, if there be one, is slight since the Commission has interpreted 'substantially' as modifying both phrases in this portion of the act" (Purex Corp., Ltd., 51 F.T.C. 100, 116 (1954)). A legal analysis of the bill by the Department of Justice also concluded that no real difference existed.[40]
>
> In the general welter of court decisions, interpretations, and technical discussions of this whole question of competition, it is necessary every so often to reexamine the problem and determine whether the Congress is moving at cross-purposes through the enactment of conflicting statutes from time to time. We speak so freely of our free competitive system. It has become almost axiomatic that competition is the life of trade. The Federal statutes generally are directed toward the preservation of competition.

[39] Ibid., p. 3097.
[40] "Strengthening the Robinson-Patman Act and Amending the Antitrust Law Prohibiting Price Discrimination," report of the Committee on the Judiciary, U.S. Senate, 85th Cong., 2d sess., Rept. 2010, July 28, 158, p. 31.

> Yet, here is a measure which would make the meeting of competition in good faith only a qualified defense where a supplier seeks to hold on to a customer by meeting a competitor's price in the case of food, drug, or cosmetic products, because the instant bill would prevent such action from being an absolute defense if by lowering the price it might be said substantially to lessen competition or tend toward monopoly in commerce in any section of the country. Now this very simple question arises. How does one hold on to a customer by lowering a price without lowering it to other customers and still be certain that the Federal Trade Commission will not consider it as a substantial lessening of competition. Just where is the line and what are the criteria finally by which such action will be judged. It must, therefore, be very obvious that this state of affairs can only add to confusion and bewilderment.[41]

All of the arguments against its passage are equally valid today. Any attempt to apply this legislation to a narrow segment of industry will certainly run afoul of the Constitution which bars class legislation. The minority statement included in Report No. 2010, 85th Congress, stated:

> * * * If this measure were enacted into law, it is a fair presumption that the question of constitutionality would be quickly raised nor would this be surprising.[42]

This subcommittee is primarily and basically dedicated to the preservation of our system of free enterprise. Some individuals imply that unless each producer quotes a different price, this in and of itself is an evidence of monopoly. However, any sound and realistic appraisal of competition clearly shows that there must be a price established that equates supply and demand. Such a price can be set without any overt act, including collusion between the parties themselves. As long as these practices are established, the principles of the antitrust laws have been maintained.

POINT 9

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that inelasticity of demand for drugs under our present marketing arrangements is erroneous and unfounded.

The majority's report states that:

> The drug industry is also unusual in the extent to which the demand for its products is inelastic, i.e., unresponsive to changes in price * * *
>
> The fact that demand is inelastic means that one of the checks which might serve as a possible constraint upon corporate price policies is absent in ethical drugs. When demand is elastic, prices may become so high as to result in a significant reduction in sales volume * * *[43]

[41] Ibid., p. 48.
[42] Ibid., p. 63.
[43] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, p. ix.

The majority's report places great stress on the testimony of Mr. Francis G. Brown, president of Schering Corp., who stated:

> * * * Unlike consumer marketing, Schering cannot expand its markets by lowering prices. Cortisone proved this. After all, we cannot put two bottles of Schering medicine in every medicine chest where only one is needed, or two people in every hospital bed when only one is sick. Marketing medicine is a far cry from marketing soft drinks or automobiles.[44]

Without disputing Mr. Brown's testimony, in terms of the effect of an immediate price reduction, there is a strong elasticity of demand and of supply over an extended period of time. To be sure, it is impossible to place two patients in every hospital bed where only one is sick or to put two bottles of medicine in every medicine chest where only one is needed. However, if the cost of lifesaving drugs is gradually reduced by competition from new products, then the normal forces of supply and demand which control all other markets become effective.

Under such competition, doctors will eventually prescribe a drug which they would not otherwise use because of their knowledge of the financial condition of their patients. Likewise, there is an elasticity of supply in terms of the manufacturers, as they, too, are well aware of the fact that their volume can ultimately be increased if doctors have an incentive to prescribe a product because it will place a lesser drain on their patients' budgets. All of these facts are well known to members of the industry and it is not necessary for a Senate subcommittee to bring them to their attention.

There is every reason to expect that sales will continue to increase contrary to the impressions that have been created throughout the majority's report.

Part 19 of these hearings includes a table showing a 10-company sample of ethical drug companies. This table shows that the sales of the 10 companies have increased from $500,637,000 to $1,263,492,000 during the period 1947–58.[45] These facts provide reputable evidence that there is a marked elasticity of demand for these new products that have saved lives and have contributed so much to the welfare and health of all Americans. Among these new products are the Salk vaccine, penicillin, the sulfa drugs, broad spectrum antibiotics, and many other products that were totally unknown in 1947.

By and large, the medical profession has higher ethical standards and devotes a larger portion of their time to work among the poor and indigent by serving in clinics than any similar group in our professional society. There are serious reflections on the integrity of an important profession which are found throughout the majority's report, and in a spirit of fair play exception must be taken to them.

[44] "Administered Prices," hearings of the Subcommittee on Antitrust and Monopoly, op. cit., pt. 14, p. 7854.
[45] Ibid., pt. 19, p. 10753.

POINT 10

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that new specialized medical preparations are overrated and do not meet the needs of the patients is erroneous and unfounded.

The majority's report states that:

> Until the German discovery of tolbutamide in the early 1950's insulin was the only drug treatment for the diabetic patient. In June 1957 the Upjohn Co., operating under an exclusive patent license from Hoechst of Germany, introduced tolbutamide on the American market under the trade name of Orinase. Extensive clinical testing of the product, both in Europe and in the United States, occurred prior to clearance by the Food and Drug Administration. The drug won immediate acceptance with the medical profession, and sales soared.
>
> On August 22, 1958, Pfizer filed with FDA a new drug application for chlorpropamide; 2 months later this drug was cleared by the regulatory agency; and Diabinese, with much advertising fanfare, made its appearance on the American market at the end of 1958.
>
> Again the element of potency was involved. Whereas Upjohn's Orinase is sold as a 0.5 gram tablet (500 milligrams), the more potent Pfizer product for an equivalent dosage contains half the essential ingredient (250-milligram tablet). Prices are roughly equivalent. At the time of the introduction of Orinase, the patient paid $0.14 per tablet; a price drop which occurred shortly before the subcommittee's hearings resulted in a price of about $0.13 per tablet. Diabinese has sold from the outset at $0.15 per tablet. The typical maintenance dosage for Orinase is two tablets daily. In contrast, Pfizer has stressed in its advertising campaign that Diabinese constitutes an "economical once-a-day dosage." Along this line, Mr. John E. McKeen, president of Pfizer, presented in his testimony a table showing that the Orinase patient spends, on the average, $0.28 daily for medication, whereas the Diabinese patient spends $0.15 for the drug.[46]

Formerly, when medicine was an art rather than a science and most ills were cured by such simple prescriptions as aspirin or other commonly known remedies, the physician had little need to understand the side effects, allergic conditions, and similar disturbances that were characteristic of the individual physiology of his patients.

All of this has changed with the development of the new and more complex drugs which cure or arrest diseases which formerly were often regarded as beyond the scope of our knowledge of scientific medicine. Among these new developments, and one of the most important, is the art of treating and arresting diabetes which once exacted a terrific toll on our population expressed in terms of mortality data or as a loss of productive effort.

During the latter part of April and early May the subcommittee made an extensive review of the activities of those associated with the

[46] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit., draft, pp. IV-115-116.

development of oral antidiabetic drugs. It is human nature that any oral treatment, regardless of the disease, has many advantages over an injection by a hypodermic syringe. Previously, an insulin injection was the only known method of controlling this disease.

One of the firms which played an important role in this new development of an oral preparation was the Charles Pfizer Co. of Brooklyn, N.Y. Mr. John E. McKeen, its president, was introduced to the subcommittee by the distinguished junior Senator from New York, the Honorable Kenneth B. Keating. This company employs over 18,000 people and has more than 60,000 shareholders located throughout the United States.[47]

Senator Keating, in introducing Mr. McKeen, said:

> Mr. McKeen has been associated with the company throughout his professional career. He is one of the distinguished citizens of the State of New York, and as the subcommittee may already have learned, he has a reputation for being very thorough, and I am sure that you will get a full and complete response from him as to any questions which the subcommittee may wish to ask.
>
> It is a great pleasure to me to present him and I know that he will receive every courtesy from you, Mr. Chairman, and from your colleagues on the subcommittee and the members of your able staff.[48]

Dr. Henry Dolger of Mount Sinai Hospital in New York also appeared as a witness to refute the efforts of the medical profession and the pharmaceutical industry to arrest a disease that had baffled his colleagues. He was particularly critical of these oral drugs for diabetic patients. His general discussion of a complex medical problem before a lay audience received wide press coverage and created many problems for the subcommittee. In spite of his experience, he, too, was forced to admit that the drug industry had performed a valuable service to the medical profession. In fact, he said that:

> The pharmaceutical industry cannot be indicted in a blanket fashion. I would like to point out again the superior caution and intensive investigation effort given to the development and promotion of tolbutamide. This represents a fine example of what the industry can do for the ultimate benefit of the public * * *[49]

A flow of telegrams and letters were directed to the subcommittee following Dr. Dolger's testimony because of the widespread press coverage it received. Mr. Peter Chumbris, minority counsel, on behalf of Senator Dirksen raised a basic question as to the procedures that were being followed.

Mr. Chumbris' position was supported in a letter from Senator Dirksen to the chairman of the subcommittee, and relevant portions are included herein, as they clearly indicate the difficulties that the Senate will encounter if it continues with the types of procedures that

[47] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 20, p. 11127.
[48] Ibid., p. 11128.
[49] Ibid., p. 11149.

were used ever since the drug hearings began in December of 1959. Senator Dirksen in his letter to Senator Kefauver said:

> What I refer to is the issue of conflicting medical testimony in open session as to the efficacy of a particular drug. I regard it as a highly delicate issue, first, because it is doubtful whether the Judicary Committee has jurisdiction over matters of this kind; second, because of the possible impact on the faith of the consuming public in a particular drug; third, because of the possible impact on faith in physicians who may prescribe such a drug.
>
> Members of the committee certainly cannot esteem themselves as experts in the field of evaluating the efficacy of any particular drug notwithstanding the testimony which might be presented, and I am genuinely fearful that if the subcommittee proceeds in this direction incalculable harm might result.[60]

For a period of many years, numerous Members of the Congress have been concerned with investigations and have sought to insure that they would fulfill a necessary function of providing our elected representatives with specialized information to enable them to legislate in terms of promoting the general welfare. If nothing else has been learned from these proceedings, at least there has been a reaffirmation of the very principles enunciated by Senator Kefauver during the 83d Congress in his code of proper procedures for any congressional probe. In view of the fact that the present majority leader of the Senate was a cosponsor of Senator Kefauver's resolution, there is is some hope that our procedures will be improved in the 87th Congress.

As time goes on, it is to be hoped that science will find new cures for cancer, diabetes, and other diseases that have sapped the ability of mankind. In the years ahead it is axiomatic that the free world will have less manpower than our opponents, and any advances in our scientific laboratories that enhance our ability to outproduce and outfight our enemies is a potent tool in the hands of those who are dedicated to the preservation of our form of free society with freedom of conscience and expression.

POINT 11

After careful analysis of the testimony adduced at the hearings, the minority finds that the position in the majority's report that the use of trade names in lieu of generic names is erroneous and unfounded. The majority's report states that:

> The multiplicity of names for products in the drug industry virtually exceeds the bounds of human imagination. First, there is the chemical name which attempts to spell out the structural make-up of the drug; and here a variety of forms of expression is possible. Next comes the generic name which may or may not represent an abbreviation of the more complex chemical name; this is the name commonly used to identify the drug in the trade. Ordinarily a drug has one generic name, but it is not uncommon for two or three to be

[60] Ibid., p. 11442.

employed. And finally a drug usually has a host of individual trade names used by the various companies engaged in the promotion of the product. In consequence, a single drug product is represented in the market by such a complex body of nomenclature as to intimidate even the initiates in the field. And if one can visualize this situation for a single drug multiplied by the thousands of drugs currently marketed, he can get some impression of the chaos existing in the area of drug nomenclature.

The situation with respect to the new so-called synthetic penicillin illustrates the problem in one of its simpler forms. The chemical name for this product is alpha-phenoxyethyl penicillin potassium. This set of syllables is also used as a generic name. In addition, there are two other generic names—potassium penicillin 152 and phenethicillin potassium. * * *[51]

It seems rather pointless for this subcommittee to have spent so much time on the subject of brand names as opposed to generic names, inasmuch as there are no laws or rules in most States that in any way limit the use of generic names if doctors and hospitals or Federal agencies wish to use them. For example, a prominent witness who appeared before this subcommittee, Dr. Walter Modell, who is on the faculty of the Cornell University Medical College, stated that:

> At the New York Hospital, which is a teaching hospital affiliated with the Cornell University Medical College, the professor of medicine, the medical board, and the formulary committee require the exclusive use of nonproprietary names for drugs in the hospital because in their considered opinion this is inseparable from the meaningful use of drugs, hence leads to higher standards of medical practice. Prescriptions which do not use nonproprietary nomenclature are not accepted at our pharmacy.[52]

In view of the fact that it is possible for a major hospital that has been in operation for a long period of years to use generic names, it does not seem necessary to engage the Congress of the United States in a dispute over the value of these various types of prescriptions.

It should again be emphasized that this subcommittee has no jurisdiction to review the trademark laws of the United States or to determine whether generic names should be used in lieu of brand names in prescriptions or other medications prescribed by the medical fraternity. If any legislation in this field is enacted, it is one that deserves the most careful scrutiny of the entire Congress, and its implications are effective far beyond the field of antitrust and monopoly.

A portion of the hearings was devoted to the question of using generic terms in lieu of brand designations. The attack on brand names is not a new one. It was proposed with much vigor during World War II as a device to facilitate price controls, and those who have been opposed to our free, private enterprise economy have long

[51] "Administered Prices—Drugs," report of the Subcommittee on Antitrust and Monopoly, op. cit. draft, pp. V–1—V–2.
[52] "Administered Prices," hearings of the Subcommittee on Antitrust and Monopoly, op. cit., pt. 21, p. 11603.

sought to disparge the entire concept of identifying a product of a particular manufacturer.

Any attempt to apply this concept in a practical manner, of necessity, goes far beyond the question of using brand names. It involves advertising, trademarks, patents, and copyrights. Near the close of these hearings, a small group of doctors appeared, who are hardly representative of the entire medical profession. They proposed that all brand names in the drug field be eliminated and, instead, doctors be required to write their prescriptions in generic terms.

Our American economy had been developed on the thesis that a job well done has its proper reward. If products are purchased under a generic name, all drug standards will immediately drop to the lowest tolerance in the United States Pharmacopeia. Any attempt to exceed these standards will be fruitless, as there will be no reward for those who make an extra effort to do so. Furthermore, if doctors do not use brand names in prescribing ethical drugs and undesirable side effects develop, they will have no knowledge as to whose product their patients bought, where to place the blame, or what corrective steps to recommend.

During the interrogation of Dr. Charles O. Wilson, dean of the School of Pharmacy at Oregon State College at Corvallis, Oreg., by Senator Hruska, the following colloquy involving Dr. Wilson, Mr. Dixon, and Senator Hruska took place:

> Senator HRUSKA. And if in his judgment the results he gets from a brand name will achieve a certain result and he knows that for sure, and he doesn't know if he takes one of those seven names which appear on page 12 what the druggist might come up with, what the pharmacist might come up with, might he not out of consideration for his patient's well-being say, "I want that brand name. I know what it will do"?
>
> Dr. WILSON. Very naturally; yes, sir.
>
> Mr. DIXON. Doctor, if the Senator will excuse me for interrupting——
>
> Senator HRUSKA. Surely.
>
> Mr. DIXON. Going back to that example which you discussed on page 12, my specific question is: Would the person coming in with the prescription written in any one of those eight names get the same product, or the same chemical substance?
>
> Dr. WILSON. He should, since all these names are for that substance. They are not for anything else.
>
> Mr. DIXON. So he would get the same substance?
>
> Dr. WILSON. Yes, sir.
>
> Senator HRUSKA. Well, now, Doctor, let's explore that a little bit. If it was a prescription for a given quantity of insulin, and that were taken to a pharmacist, would he get the same product in every instance?
>
> Dr. WILSON. Yes, sir. AU-40 is AU-40.
>
> Senator HRUSKA. Isn't it true that there is some insulin made with a beef base and some insulin made from a pork base, and that some patients are allergic to pork-base insulin and some are not? And he would not get the same product if the prescription simply said insulin?

Dr. WILSON. Well, you are talking about a finished pharmaceutical there.

Senator HRUSKA. It is a generic name by now; isn't it?

Dr. WILSON. Yes, it is official.

Senator HRUSKA. It is a generic name, and if it was so many units of insulin, he would not get the same product, whereas if he said Lilly, he would get an insulin with a beef base; isn't that true?

Dr. WILSON. Yes, sir.

Senator HRUSKA. Well, now, then that would indicate that it is not always true. That by using a generic name, you get the same product, and same medicine in the bottle that is carried away by the customer in a drugstore.

Mr. DIXON. Doctor, it occurs to me that the drug that Senator Hruska has mentioned is a product that is not synthetically made. Insulin, I believe, is made from the pancreas of animals.

Dr. WILSON. He is using an extremely poor example for this particular situation.

Senator HRUSKA. In other words, just to pursue this for a minute, most of these drugs I believe are synthetic, they are synthesized from chemical compounds, and I would assume that they should be the same thing.

Dr. WILSON. Yes.

Senator. HRUSKA. That is the point I wanted to make. They should be, but are they? If a simple layman like myself can pick out—maybe it is true that insulin is different. I wouldn't want to say that the same isn't true of some of these other things. I don't know enough about it.

And goodness knows the fellow who carries that prescription to the drug counter, he doesn't know whether it is a synthetic compound or anything else. All he knows is that the doctor told him to take this medicine, and he goes in and asks for insulin, and it may make him a very sick man instead of a better man, if the doctor so prescribed.

Mr. DIXON. Does Lilly make all of its insulin from beef, Senator Hruska? I don't know.

Senator HRUSKA. I don't know. The doctor apparently thought so because Lilly does have, as I understand it, Lilly does have a beef-base insulin.

Now, whether they make it all or not I don't know. I was led to believe from my informant that they do. I will stand correction on it.

I am not an expert here. I am just a questioner.[53]

A serious doubt arises as to whether firms will undertake research and promotional activities or maintain their quality standards if they are denied the advantages of building their reputation behind a brand name. In this country every individual has been taught from earliest childhood that his most precious asset is a good name and the respect of his fellow citizens. It seems completely out of character for any Senate subcommittee to attempt to destroy this

[53] Ibid., pp. 11511-11512.

concept inasmuch as all of our copyright laws have been enacted to foster a desire on the part of individuals to excel in their chosen lines of activities.

There is a further objection to this proposal which may have very far reaching effects in terms of broad public policy. Most of our news media including our free press, radio, and television are largely supported through advertising by firms which wish to promote a brand name. If the concepts recommended in the majority's report were to be enacted into law, it is doubtful whether many of these media would continue to exist as independent organizations. Under such conditions it would probably be proposed by the sponsors of this legislation that a Federal subsidy of one kind or another should be enacted in order to maintain them. Should this ever occur even though our Constitution guarantees freedom of the press and the free expression of ideas, there are grounds for grave doubts as to whether editors or owners of broadcasting stations who must already depend on the Federal Communications Commission for their licenses would long maintain their political independence. Any objective consideration of the serious consequences that are implicit in these proposals are terrifying to those who wish to maintain the American way of life.

Although ostensibly this inquiry is being confined to drugs, its implications are widespread and will affect our long-standing tradition and our purchasing habits in every field of activity. Those who have advocated these proposals are basically imbued with a desire to change all consumer buying patterns, and any plan to temporize with their philosophies jeopardizes all that we hold dear.

V. CONCLUSIONS

It would be a difficult task to find any industry that presents so many complex technical problems and requires more of a scientific background if an intelligent appraisal of its activities is to be made. Yet, there are few of the majority's staff possessing this necessary training, but this fact did not deter it from pursuing procedures which often bore more resemblance to an inquisition than to an objective investigation to secure information for legislative purposes. These facts are most unfortunate as they cast a shadow of doubt in the minds of those who are ill and are dependent upon the integrity of their local druggists and the firms who supply them in seeking to regain their health.

The resolutions which established this subcommittee were adopted by the Congress in order to insure the maintenance of a competitive free enterprise economy within the United States. Furthermore, it has been the sense of the Congress as expressed in numerous bills authorizing the continuation of the mutual security program that every proper action be exerted to promote the advantages of our economy in other nations of the world.

However, the official publication of a series of hearings and reports which attack respected firms and citizens will do little to enhance our reputation abroad, and it will not accomplish any useful purpose in terms of providing new legislative guides for the Congress.

Although these points have been made before, it is well once again to reiterate the fact that this subcommittee has a limited jurisdiction

which does not deal with trademarks, patents, costs, profits, or the use of generic names. Its standing in the Senate as a legislative body would be enhanced if it confined its activities to those entrusted to it in the resolutions that established it and authorized the appropriations for its investigations.

Actually, it is most interesting that an investigation of the American drug industry would have been undertaken at a time when the 86th Congress adopted a resolution which was enacted into Public Law 86-610, S. J. Res. 41, by President Eisenhower on July 12, 1960. This resolution was accepted by the Senate without any opposition. It established a National Institute for International Health and Medical Research to provide for international cooperation in health research, research training, and research planning, and for other purposes. Among the important provisions was section 4b(3) authorizing the Secretary of Health, Education, and Welfare to:

> make grants or loans of equipment, medical, biological, physical substances or other materials, for use by public institutions or agencies, or nonprofit private institutions or agencies, or by individuals, in participating foreign countries;[54]

Unless the American pharmaceutical and medical professions were held in high esteem in other parts of the world, it is extremely doubtful that other nations would seek our help and assistance in this important new field of science.

Furthermore, during the years since the end of World War II our country has made important contributions to the United Nations through the World Health Organization, the Pan American Health Organization, and the United Nations Children's Fund.

It is also of significance that some of the industry witnesses, namely Mr. John T. Connor, president of Merck & Co., and Dr. W. G. Malcolm, president of American Cyanamid Co., who appeared before this subcommittee were strong supporters of this resolution.

It is imperative that all elected officials maintain the dignity of our Government and insure its respect by every citizen regardless of his station in life. The minority members of this subcommittee sincerely hope that all future inquiries have a clearly defined legislative purpose. Any departure from such a practice will have far-reaching effects that can ultimately destroy the opportunity of our congressional committee to perform a useful service on behalf of the American people.

As those who are well-informed must recognize, the Congress today has been charged with a tremendous workload. During the 86th Congress, appropriation bills totaling more than $80 billion were enacted into law.

Our primary task as Members of the Congress is to conduct our legislative responsibilities. Understandably, there has been a tendency because of the many duties imposed on every Member of the Senate to place the major burden of planning hearings and developing appropriate procedures for their conduct upon their staffs. No subcommittee of the Senate has been granted as large an appropriation nor employs as many individuals as the Antitrust and Monopoly Subcommittee of the Senate Committee on the Judiciary. Senate Res-

[54] Public Law 86-610, 86th Cong., S.J. Res. 41, July 12, 1960, p. 3.

olution 57, which authorizes its activities directs an inquiry toward the preservation of a private-enterprise economy and not its destruction. However, unfortunately, a large portion of the planning for the subcommittee's investigation of the drug industry was delegated to its chief economist, Dr. John M. Blair. Obviously, under such conditions, objectivity as well as a scrupulous concern for developing the truth, whether it coincides with one's preconceived ideas or not, was apparently not a prime requisite. Unfortunately, unlike some other economists who had extreme antibusiness views in their earlier years, many of the theories propounded by Dr. Blair in his book, "Seeds of Destruction," in 1938 apparently still influence his approach to the business community. For example, Dr. Blair wrote:

> How much of this advertising is "reputable" and how much is downright fraudulent, it is impossible to say. Several attempts have been made to estimate roughly the amount of fraudulent advertising which annually floods the land. One of the most conservative of these estimates was made by Chairman Humphries of the Federal Trade Commission, who, while admitting that no mechanism of absolute measurement existed, stated in 1928 that the amount taken annually by fraudulent advertising was more than $500 millions. Unless legislation is enacted to diminish materially the amount of fraudulent advertising, it will, like all other forms of commercial consumer stimulation, continue to grow in response to our principle of the inevitable and continual increase in advertising.
>
> Perhaps another way of viewing the size of modern advertising is through noting the actual amounts which certain small sample groups of advertisers have expended on it. In 1934, 367 advertisers, for example, spent $223,216,520 on newspaper, magazine, and radio advertising. Of this sum, it is interesting to note newspapers received 61.8 percent, magazines 25 percent, and the chain broadcasts 13.2 percent. During the same year 211 national magazine advertisers whose appropriations for this medium alone exceeded $100,000 each, expended a total of $85,422,499. This is indeed rather a large amount to be spent by such a small group of advertisers on a medium which normally receives less than one-quarter of all advertising appropriations.
>
> These groups of advertisers were taken as an illustration not only of how much can be spent by a relatively small number of producers on advertising, but also of another trend in the field of advertising, the trend of concentration. In 1921 advertisers who annually spent between $10,000 and $100,000 contributed 43.8 percent of the total volume, advertisers spending between $100,000 and $1 million expended 51.3 percent of the total and advertisers spending over $1 million a year made appropriations amounting to only 4.9 percent of the total. By 1930 the expenditures of the first group, the smaller advertisers, had fallen to 21.1 percent of the total, the expenditures of the second group or middle-sized advertisers, remained almost unchanged, rising to 55.9 percent of the total volume, but the third group, the few

large advertisers, expended so much in 1930 that their appropriations constituted 23 percent of the total.

Another example of this concentration is disclosed in studies made by the Harvard School of Business Administration which, in investigating the accounts of 564 department stores, found that the average percentage of net sales expended on advertising varied from 2.4 percent for small stores to 3.9 percent for large stores. The conclusion reached was that there existed a general marked tendency for the larger stores to spend a greater proportion of their net sales on advertising than the smaller stores.

The important fact to be gained from this is that since the larger units tend to spend a greater percentage of their turnover on advertising than the smaller units, any trend toward concentration of industry which may be taking place in the United States today will undoubtedly be accompanied by progressively greater expenditures on advertising. If our economy becomes almost completely dominated by large units—and those large units, as we have seen, tend to spend more on advertising—being more sensitive to our "law", then the total advertising bill may well become immense.[55]

Certainly these views support his attack on brand names and his proposals for the use of generic terms. He was also vehement that all prices should be lowered regardless of the consequences to producers or to the Federal Government, which today is a senior partner in every major enterprise. In 1938 Dr. Blair wrote:

> This process of events as outlined above is no mere creation of the imagination. It is what has happened whenever public bodies have tried to set the price at a figure beneficial to the consumer but so low in the eyes of the producer that he would rather produce nothing than try to sell at such a figure. The entire cycle of producers' limiting their output in order to force the established price up, their success in accomplishing that end, the subsequent rush to sell as much as possible at high prices, and the resultant oversupply and fall of prices, is in short the usual history of price-control in those few items such as milk, where public bodies have endeavored to keep prices low without recourse to production control.
>
> All this means that one cannot control prices unless one controls the supply. This is a fact known to all economists and to most businessmen, especially to the successful ones; it is gradually being learned by politicians through experience.
>
> In other words, if it is desired to keep prices down, one must keep the supply up. Production must be stimulated; it must be kept at high levels. But production control itself presents some problems rather difficult of solution.
>
> There has been a great deal of discussion of this matter. Prominent people and various "impartial institutions," lamenting the fact that purchasing power is not "what it ought to be" urge that production be increased, that producers cease their policies of limiting production, that they all

[55] Blair, John M., "Seeds of Destruction," op. cit., pp. 225–228.

produce at or near capacity. As a result, it is maintained, prices will fall, purchasing power will be greatly increased and the weaknesses within the system will be overcome.[56]

He also stated:

> From the standpoint of what is ethically "right" there is unquestionably nothing but truth in arguments of this nature. As such, they can be extremely potent political instruments. "The rich receive so much, the poor receive so little," it is urged, "let us take these vast sums received by the wealthy and divide them among the working people." Many a politician has ridden to power on the strength of this argument, and undoubtedly many more will use it in the future.[57]

During the 23 years that have elapsed since the publication of this work, there has been no public repudiation of any of these views. On the contrary, they have been reaffirmed in other documents, most of which were published at the expense of the American taxpayer. There is an important and serious task before this subcommittee, but it cannot be accomplished if its program is dominated by biases and unsupported charges against the business community. Furthermore, whenever hearings such as those involving major industries such as drugs are conducted, it is essential that a representative sample of witnesses who are fully qualified be asked to testify.

It would be difficult to characterize the doctors who appeared as a representative cross-section of the members of this important profession.

Every member of the subcommittee has a responsibility not only to his constituents but to the country as a whole to insure that it pursues a course of action that will enhance its reputation as a fair-minded judicial body that is seeking to preserve an economy that will provide the sinews of strength for the defense of the free world and also sustain a rise in the standard of living of our people.

These views were expressed by Senator Hruska in a most convincing manner during the course of these hearings. They are of sufficient importance to be included at this point. Senator Hruska said:

> In other hearings I have followed within the Senate Judiciary Committee, the usual and approved format has been to invite and hear the heads of the Federal agencies having jurisdiction over the matters involved; then, the heads or official representatives of the industries or companies involved, and the labor leaders whose unions are interested parties; then, National, State, or regional trade associations, retail and wholesale groups, or professional associations, whether they be medical, legal, engineering, or other. And then such other witnesses who desire to be heard individually and who are within reason and balance as to number and as to nonrepetition.
>
> There is a reason for such a pattern. We should be informed first as a committee of the nature and scope of the field being inquired into. This scope should be placed into

[56] Ibid., p. 390.
[57] Ibid., p. 400.

considered focus and perspective. Differing notions and opinions of representative groups and officials should be gathered so that a balance can be achieved without harmful bias and premature judging. It is a logical, proven method of inquiry.

Such a pattern, however, has been thoroughly disregarded and avoided here. No Federal agency officials have been called so far. With the exception of Dr. Austin Smith of the Pharmaceutical Manufacturers Association, no professional or trade groups have been allowed to appear. No broad and competent basis has been laid for those hearings and for this inquiry.

Instead, we have had a series of doctors who are individual members of a profession numbering in excess of 200,000. These witnesses have not been representative, either officially or in fact, of their profession. In the main they have presented nonconforming, antagonistic views, clearly not held by the great preponderance of their professional brethren.

If the drug industry is guilty of any illegal or improper acts, the witnesses called so far, the nature and character of their testimony, and their obvious bias are indeed a poor, unsatisfactory way in which to make acceptable proof.

In fact, Mr. Chairman, an observer of these hearings has suggested that those in charge of conducting these hearings, being unable to find any support for preconceived views and beliefs from any official, representative, or truly authoritative sources, are forced to resort to the use of witnesses, who, in the main, have a personal "ax to grind," who are nonconformists, who are not representative, often lacking qualified vantage point or competence in the field in which they undertake to testify, and who do not hesitate to recklessly attack constructive efforts of persons with responsibility. It was suggested further that perhaps the lack of such support might also account for the resort to sensationalism, headline seeking, misrepresentation and distortion reflected in much of the testimony and many of the exhibits.

For myself, I shall not judge the situation suggested by this observer until the evidence is in. But, frankly, I find myself wondering why it is that the voices of thousands upon thousands of doctors who rightly credit the drug industry with many solid and remarkable achievements have not already been called in timely fashion. I find it difficult to understand why Government agencies concerned in this field and well versed in it, have not been called to give us the overall picture so that we can fit into their proper places the testimony and stories of individual witnesses. I find myself wondering at the unseemliness of unobjectivity and unfairness displayed so obviously and constantly in the hearings I have attended.

But while I have a desire to be fair with any industry we investigate, I have an even greater and more compelling concern. And that is for the public which has a highly vital

stake in the continued creation, production, and availability of lifesaving and pain-relieving drugs and medicines.

Our citizenry is entitled to a true, balanced, and complete picture submitted in a timely, understandable way. So far, this has been denied them.

In fact, up till now there has been a deliberate attempt, in my judgement, to inflict devasting and irreparable damage upon an indispensable business by trying hard to shatter public confidence in it upon the basis of a biased, distorted, and incomplete record.

It is one thing to make a constructive effort to improve an industry or its operation. But to lead the public erroneously to condemn a necessary industry without any hope of gaining a workable or acceptable replacement for it, is a castastrophe which should not be visited upon the men, women, and children of America.

This subcommittee is rapidly reaching the point of no return in this regard.[58]

All fair-minded citizens who have had an opportunity to examine the voluminous record which has been accumulated over a period of almost 3 years will undoubtedly wholeheartedly endorse Senator Hruska's views.

EVERETT MCKINLEY DIRKSEN.
ROMAN L. HRUSKA.

[58] "Administered Prices," hearings before the Subcommittee on Antitrust and Monopoly, op. cit., pt. 13, pp. 10317–10318.

INDIVIDUAL VIEWS OF SENATOR ALEXANDER WILEY

After more than 2 years of investigations and hearings, the Senate Antitrust and Monopoly Subcommittee has produced its report on the drug industry. This is part of the series of subcommittee reports dealing with administered prices. It is noteworthy that while the report anlayzes most carefully the various aspects and practices of pharmaceutical research, production, promotion, and sales—it nowhere concludes that these practices are in any way in violation of either the letter or the spirit of our antitrust and monopoly laws. Indeed, all of part I of this report—as clearly indicated by its title—deals with "The Reasonableness of Price." Upon reading of the report it becomes evident that the subcommittee's criticisms of the drug industry are leveled not at clearly defined legal violations but at a more flexible concept of "reasonableness," which is subject to different interpretations and coloring depending on the interpretor's point of view.

Our Federal antitrust laws are not generally concerned with the question of price reasonableness. The belief is inherent in our free enterprise philosophy that prices are best adjusted and determined by the free operation of the forces of supply and demand in the marketplace. It is only when these forces are unreasonably restricted by monopolistic practices that the Government must step in. Consequently, the real question before this subcommittee at all times must be the factual determination as to the existence of illegal restraints of trade—not the speculation as to whether prices are reasonable or unreasonable. It is obvious that once we undertake to substitute Government judgment of what is reasonable or unreasonable for the free play of prices in the marketplace—the final product would be a general Government price-fixing program.

This is not to say that the situation in the drug industry requires no public or governmental scrutiny. It has been argued that the drug industry derived a higher rate of return on its investment than other American industries. It has been argued that the pharmaceutical companies have at times exaggerated in their claims for the therapeutic value of certain drugs. It has been argued that the drug companies have spent an unreasonable portion of their budgets in order to indoctrinate doctors so that they would prescribe high-priced trademarked products. It has been argued that the patent provisions and the licensing agreements among drug manufacturers produced concentration of production and power in the hands of a few large manufacturers.

I shall endeavor later to respond in part to these arguments, not in order to protect the drug industry but in an effort to set the record straight. But be this as it may, let me emphasize it again that it is part of a free enterprise system to permit differences in income and profit, to allow free use of advertising and promotion, and to leave

business management to those responsible for it—as long as the public welfare is not directly and immediately threatened. Indeed, it is part of our democratic system that individuals and companies be permitted to try, to experiment and even to make mistakes. It is our belief that it is this opportunity to experiment that is the core of democracy and the true reason for its success. Otherwise, we are destined to follow the example of the totalitarian governments which prescribe to everybody what to do, what to worship, what to produce, and at what prices to sell.

Yet economic freedom is not a license to act contrary to the public interest or to be free from public scrutiny. Governmental scrutiny and reevaluation of the activities of all segments of the population, including business, is an important tool to preserve the national interests. Even the most prominent exponent of free enterprise, Adam Smith, stated in his writings:

> People of the same trade seldom meet together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices.

I do not share this extreme suspicion of business which has been evidenced in many of the documents of this subcommittee. Still, there is often a tendency, on the part of both individuals and of business, to become preoccupied with their own point of view and their own narrow outlook in a manner which is contrary to the best public interest.

I believe that it is the function of the Government, on behalf of the general public, to act as a constant overseer making certain that special interests do not predominate, and that the general welfare is protected. Consequently, I believe that the recent investigation of the drug industry, despite some serious faults, has performed an important public function in making the industry reevaluate its responsibility to the public, in making the public aware of both the accomplishments and the shortcomings of this industry, and in giving Congress an opportunity to examine the need for new legislation. Indeed, any unbiased observer will concede that the investigation of the drug industry has resulted not merely in criticisms but has also provided the industry with an opportunity to convey to the public a picture of its important contribution to American health and welfare.

Reading the conclusions contained in this report on the drug industry, I am not certain that they contain an unbiased evaluation of the economic facts of the pharmaceutical industry and I feel it incumbent upon myself to comment on several issues which I believe have been either completely overlooked or else have been improperly emphasized in the majority views.

THE ROLE OF PROFITS IN THE GROWTH OF THE AMERICAN PHARMACEUTICAL INDUSTRY

The growth of the American pharmaceutical industry in recent years has been phenomenal and required tremendous capital outlays. It is easy, in our search for lower prices, to accuse the drug industry of unconscionable profits and to demand Government controls. But it must be remembered that the Soviet Union, in which the profit motive does not exist and in which the drug industry is completely

regulated, produced no single new drug since the Communist revolution. It must be remembered also that the drug industry is a fairly young industry in this country, and that it has taken large fortunes to build it to the point of its present prominence.

From 1939 to 1958 the American pharmaceutical industry's production grew eightfold. In 1939 the total value of pharmaceutical preparations produced in this country was $386 million. In 1958 it amounted to $2,951 million. In order to keep up with the increasing medical needs of the country, to develop better products and to make more drugs available to an increasing population—the drug industry needed new plants, new research facilities, and new capital. It is the drug industry's success story that provided the necessary capital for the industry's growth.

Before the Second World War we exported only $10 million worth of drugs a year, and we imported over $20 million worth. We now export more than $284 million worth of drug products a year. Between 1939 and 1958 there has been a tremendous increase of 2,800 percent in drug exports. At the same time the exports of manufactured goods generally only doubled. Thus, while competition from other countries has curtailed the expansion of our exports, our drug exports have been constantly increasing. Why is this so? Primarily because our drug industry is advanced and progress-minded and can compete in any market.

The drug industry story is a success story. But success cannot be accomplished through miracles. Unless the drug industry was given an opportunity to reap the harvests of its successes and to invest large portions of it in the development of its facilities and its research, this phenomenal success would not have been possible.

In a period of mere years we became the leading pharmaceutical manufacturers of the world. It was the profit motive which stirred the pharmaceutical industry into further research and growth. It was the profit made by this industry and which was plowed back into it that provided the capital for improvement and growth. Without the profit motive and without the profits being reinvested in the industry—the state of the American pharmaceutical industry today would not be what it is.

True, some may feel that medical research and medical expansion should be subsidized by the Government—but that would also spell out the end of our economic liberty.

In assessing whether the prices of the pharmaceutical industry have been excessive, one must remember that this is a high risk industry, which in 1958, for example, had to test some 14,000 substances before it could produce a mere 40 marketable drugs. This is a high obsolescence industry, where one product can have almost 99 percent of the market 1 year and be reduced to a mere 3 percent 2 years later. It must also be remembered that while wages increased 70 percent between 1948 and 1958, and construction cost increased 64 percent, the increase in the wholesale drug price was 3 percent only.

MONOPOLISTIC TENDENCIES IN THE DRUG INDUSTRY

In analyzing the competitive situation in the drug manufacturing field, it must be pointed out from the outset that more than 1,300 companies are engaged in the manufacturing of prescription drugs—

with no one company accounting for as much as 10 percent of the total sales. This is a field where new drugs may, in a matter of a few years, completely replace drugs which were widely used previously. This is a field where different drugs can be prescribed to take care of a particular medical need—and the final choice is left to the treating physician, as to whether he prescribes one particular drug over another, or whether he chooses the drug of one company over the drug of another.

It is true that new drugs are controlled by the companies responsible for their invention, development, and production. Yet, this is part of the American philosophy which recognizes that the inventor is entitled to the fruits of his invention. This is the philosophy incorporated in our patent and trademark system.

It has been argued before the subcommittee that the pharmaceutical industry has overstressed trademarks and has following restrictive licensing practices—thus, in fact, monopolizing the market. It has been proposed further, that prescriptions by generic name, rather than by trademarked names, would provide the patient an opportunity to buy a cheaper product rather than be limited to the trademarked prescription issued to him.

It is appropriate, therefore, that we remember that by undertaking to do away with trademarks and patents—we would be interfering with the very foundations of our economic system. Trademarks are, indeed, major tools in the promotion of quality, and of competitive economic enterprise. It is noteworthy that while the subcommittee has under consideration the possibility of either eliminating or curtailing the use of trademarks in the drug industry—the Communists, on the other hand, are beginning to appreciate the merits of the trademark. A recent dispatch from Red China tells that—

> Brand names win Peiping backing—labels, many in English, aid bid to improve products.

The story reported by Reuters from Peiping (New York Times, June 4, 1961) states that—

> Communist China has become brand-name conscious, with newspapers supporting the trend in an effort to improve the quality of consumer products.

On the topic of trade names, I should like also to call attention to recent British attitudes and thinking. The British Hinchliffe Committee on the Cost of Prescribing, has concerned itself with problems similar to those before this committee. One of the proposals before that committee was that standard drugs rather than trademarked products, should be prescribed, as a means of reducing prices. It is interesting that the two pharmacist members of the British committee then proceeded to point out that if the practice was spread to do away with prescriptions by brands, and cheaper unbranded generic products were to be generally used—the British drug industry would be unable to recoup its expenditure on research, and Britain will become dependent on foreign countries for new advances in treatment. The same argument would hold true in this country. There will be no motivation for the drug companies to expend large amounts of money on research and development unless the industry is guaranteed patent and trademark protection in order to recoup its investments.

CONCLUSION

I have been in the past, and I still remain critical of the manner in which some of the drug hearings, on which this report is based, were conducted. Likewise, I should like to stress that some of the cures that have been suggested for dealing with the drug evils—real or illusory—are sufficiently drastic to kill not only this particular patient but the whole concept of free enterprise.

Yet, at the same time, the response of the press and the public to this investigation indicates that there is some concern and dissatisfaction with the past practices of the drug industry. We shall be erring seriously if we ignore this.

The essence of the main complaint against the drug industry was the fact of the industry's success. But we must now ask ourselves: Is it a crime to be successful in an economy that believes in free enterprise? After all, one of the major aims of our economy is to encourage success, to promise success to those who enrich society by new discoveries, by improved methods of production and by the use of their genius. Let us not be in too much of a hurry to sacrifice this time-tested economic philosophy. Quite often, in our hurry to correct immediate and present ills we are too ready to sacrifice some of our basic philosophies. Many of the previous congressional investigations have illustrated this danger. Much too often both the public and its representatives unwittingly undertake to accomplish a desired immediate result through the sacrifice of some longstanding principles of government and economics—such principles as government of law and the belief in economic freedom. Yet, we must remember that it was not through price controls and planned economy that this country achieved an economy of plenty and a position of world leadership.

This report is critical of the patent policies applicable to new drugs. It is critical, furthermore, of the industry's use of trade names.

Patents have long been utilized in order to encourage the American creative genius. If we eliminate the incentives under the present patent provisions—would we be doing away with our present motivation for search, exploration and discovery?

In the matter of trademarked drugs, let us likewise be cautious before we substitute Government controls for the professional judgment of trained physicians. To decide by Government fiat that drugs must be prescribed by generic name and thus deny the physician the right to prescribe a brand-named product manufactured by a pharmaceutical house known and trusted by him—may well be destructive to the traditional doctor-patient relationship.

Bearing in mind the dangers of undue interference with our economic system, I do not mean to relieve the drug industry of its responsibilities in this area. As long as thousands of people in this country—old, indigent, and sick—remain unable to pay the high price of drugs, it is the drug industry's moral responsibility—and indeed, the moral responsibility of all others connected with the health and welfare of the Nation—to continue in their efforts to make medical care and attention available to all those that desire them—regardless of wealth and position. We all believe in free enterprise, but free enterprise does not mean selflessness. To me it means public coopera-

tion, widespread moral responsibility, and constant striving for private and public improvements.

Let us remember, in conclusion, that our philosophy and system of economic freedom are not designed to protect the rights of the few, but to foster the interests of the many. The most leading proponent of economic freedom, Adam Smith, stated:

> Consumption is the sole end and purpose of all production.

Let us remember that economic freedom is justified only as a tool for improving the interests of the public at large.