

Testimony

United States Senate

Select Committee on Small Business
Monopoly Subcommittee
Hon. Gaylord Nelson, Chairman

Senator Nelson and Members of the Committee:

I am grateful for this opportunity to appear before your committee to present my views regarding some of the matters you have under consideration, particularly the responsibilities of practicing physicians in the prescribing and administration of drugs, biologicals and chemical agents in the treatment of patients and the relationships between physicians and organizations of physicians and the drug industry.

I am the president of the American Society of Internal Medicine, an organization of approximately 10,500 specialists in the field of Internal Medicine. On February 4, 1969 I mailed to you a copy of the By-Laws of our organization, several copies of our monthly Newsletter, a pamphlet entitled "Aims and Purposes of ASIM", and a brief biographical sketch of myself. I have brought with me today a few of the pamphlets and other publications of our Society as well as a roster of our membership and a list of our Committees and Councils.

All our active members are Doctors of Medicine who have completed an internship, 3 years of special training in Internal Medicine and 2 years of practice in the specialty. Our basic goal is to assure that high quality medical care is rendered to all. We are especially concerned with the working domain of medical practice, and with the professional, socio-economic and political conditions under which such practice is carried out, whether in the hospital, the physician's office, the patient's home or elsewhere. Our efforts have to do primarily with the practical aspects of how to translate medical science and knowledge into the day to day care of sick patients in the most efficient, effective and economical way possible without sacrificing any of the quality of such care.

Inasmuch as the specialty of Internal Medicine has to do with the diagnosis and treatment of diseases and disorders by non-surgical means, you would know that my training, experience and interest have been in the use of drugs and related materials in the practice of medicine. While I have had some experience in the clinical investigation of drugs both in my private practice and in connection with my teaching of students at the University of

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Nebraska College of Medicine, my principal knowledge and experience have been gained in the study and use of drugs and related materials in the day to day practice of medicine with private patients.

I served for many years on the Pharmacy Committee of the Nebraska Methodist Hospital in Omaha, Nebraska, on the Executive Committee for 10 years, and was Chief of Staff for two years. In these positions I gained some knowledge as to the practical problems involved in operating a pharmacy in a large, private, general, metropolitan hospital.

My father was a pharmacist, so I know something, too, of the private druggist's problems from his side of the counter.

I have been active in several organized medical societies for many years, including the American Therapeutic Society, an organization which has to do with the scientific study and practical application of the use of drugs in clinical medicine, the American Diabetes Association, the American Rheumatism Association, the American Heart Association and others. These activities have naturally brought me in contact with many pharmaceutical companies and their representatives in scientific matters as well as in business matters having to do with arrangements for meetings, contributions for clinical research and similar joint projects.

With respect to the internal organization and operation of medical societies themselves, I have had experience as an officer in many of them at the state and local level. For the past 6 years I have been a member of the Board of Trustees of the American Society of Internal Medicine and president this past year. In this position I have necessarily become familiar with the financial as well as all other aspects of the operation of these organizations. As the principal liaison officer, I have spent a great deal of time with the officers of other professional organizations in the health care field as well as with governmental agencies having to do with health care matters both at the national and state level.

I have been interested and active in the health insurance field for many years. This, of course, involves the insurance considerations related to the use of drugs as well as other matters pertaining to health care insurance. I am Associate Medical Director of Mutual of Omaha and their consultant on Medicare. Mutual is one of the fiscal intermediaries for the Department of HEW in this program as well as for the Department of Defense in the CHAMPUS program, formerly known as Military Medicare. I will be in Baltimore at SSA headquarters the next two days for a regional meeting of medical directors and consultants of the fiscal intermediaries for the Medicare program. One of the

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important subjects we will discuss is the use of drugs and related materials in the program.

I have read many of the press releases and some of the official testimony given to this committee. If I can make any contribution which might be of help to you I believe it would be in the area of the relationship; between the drug industry and organized medical societies and in the areas involved in the practical translation of medical scientific knowledge to the care of patients. I will be glad to answer any questions that I can.

Physician Responsibility

With respect to the prescribing drugs, I believe it is the physician's responsibility to be fully informed about any of the drugs he prescribes -- the dose, the expected pharmacologic effects, side effects, toxicity and all similar matters. It is equally important for him to know his patient because the identical drug may produce an entirely different pharmacologic effect in one person than another. Dosage requirements and tolerances may vary widely in different patients and even in the same patient at different times. Treatment with drugs, as with all other modalities, should be highly individualized.

Physicians have an economic responsibility to their patients too, and some consideration should be given to the cost of drugs prescribed so long as cost is not the sole determining factor. If a cheaper drug will not accomplish the desired result, then obviously it is not cheaper at all but really more expensive and the delay in obtaining the desired result might be harmful to the patient. Naturally, no prescribing physician should have any secondary financial gain in prescribing one drug or one brand as compared with another. He should always be guided by what he believes to be best for his patient.

Relationship of Professional Medical Organization; to the Pharmaceutical Industry

It is not only natural and inevitable but highly desirable that there be a close relationship between the pharmaceutical industry and the medical profession. This is essential in the public interest and necessary in order for us to provide the best care and treatment that we can for our patients. That is what we all want in the final analysis. We are providing professional

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services to our patients in the course of which we use drugs, biologicals, instruments and supplies of various kinds. We need to know something about the companies that provide these materials.

At the same time, the drug, instrument, appliance and other producers of materials used in health care need to know a good deal about the problems we practicing physicians have in using these materials in the care of patients. They need to know how and when and under what circumstances we use their products: and what the results are -- both good and bad.

There is no way for us to find out what we need to know from each other without a continuing dialogue and exchange of information between us, in person as well as in writing. This necessarily takes place at an individual level, such as between the individual physician and the individual manufacturer's personal representative, and at an organizational level. The latter is particularly important because of the complex matter of logistics. There are more than 300,090 physicians and several hundred manufacturers. To provide the necessary exchange of information on an individual basis obviously would be impossible. To try to do it on the basis of a single publication or even a few would be as impractical as to try to do it on the basis of a single meeting. Each of us has to get our message to the other in many different ways.

The science of medicine, particularly as related to drugs and instrumentation as well as techniques, has advanced so far and so rapidly in the past 20 years: that no one method of disseminating information, acquiring information, or translating it to the care of sick patients can suffice. It has become necessary for many different techniques and many different organizations to be developed to do the job.

Just as we are all dependent on each other in the philosophic and scientific sense in the pursuit of our common goal, it necessarily follows that there is a certain amount of financial interdependence too. It costs money to do research, to produce a drug or an instrument, to publish literature, and to have a meeting. It seems natural and logical that a manufacturer of drugs would provide information about his products in a magazine or journal published and read by physicians. In the same journal, of course, medical scientific information is transmitted from one physician to others. So long as the advertising and the medical scientific information in the articles written by the physician-authors is ethical, accurate and honest then the best interest of the public are being served.

It is not the advertising campaign of the drug manufacturers.. nor their contributions to medical organizations for scientific or

social affairs that convinces the practitioner of the virtues or safety of a new or old drug, but only his own personal experience gained from listening to and examining his patients and his knowledge of the experience of his colleagues.

I hope that this very sincere and dedicated committee will not be diverted in its efforts to help identify and solve some of the troublesome socio-economic problems related to the health care field by those few persons who presume to see some sort of collusion between the drug industry and practicing physicians which they believe exists to take unfair advantage of the public. Believe me, gentlemen, there is no exchange of material goods or services or money that I know of which is contrary to moral or statutory law or ethics.

National Drug Compendium

The matter of publication of a national drug compendium has been discussed at length and in detail by medical, governmental, and other organizations for several years. The consensus of opinion of practicing physicians generally is, I believe, that such an effort would not be desirable, practical, useful, or in the public interest. If such a book were to be all-inclusive, several volumes more than 3 inches thick would be required. It would have to be loose-leaf and up-dated regularly and frequently. It would have to be compartmentalized for the best use of the different medical specialties, yet there is sufficient overlap in all that there would have to be some duplication of entries. It would indeed be difficult to find any agency or group of physicians, however knowledgeable, who could put such a mass of information together in readily useable form. By the time it was published and distributed, much of the information would be outdated. The editors would not dare put in anything too new, yet much of the new is very good and useful as time and experience later prove. It would be difficult to leave out some of the old, yet much of it is outdated or so very well known generally that it would be in the way. However much disclaimed, if published by or with the approval of government, the material contained in it would be interpreted as having legal federal sanction. Then if a drug were used in the treatment of a condition not listed in "the book", or in a different dosage range, the physician might be presumed guilty of malpractice. Conversely, if a drug were listed as useful for a certain condition and the attending physician did not use it even for very good and acceptable reasons, then he might also be presumed guilty.

A further disadvantage would be its use as a lever to impose compulsory prescribing by generic name. This simply cannot be

handled by the majority of practicing physicians. All of us prescribe some drugs by generic name, but we cannot possibly remember all of the generic terms for all the drugs we are accustomed to prescribing. To be required to look them up in "the book" would use up too much valuable time and would further aggravate our existing health-manpower shortage. Further, and more importantly, a compendium would further confuse the question of generic equivalence. We have already found out, as has the FDA, that drugs identified as being the same generically are not always the same clinically.

Gentlemen, the last book on therapy has not yet been written. What person, or committee, or agency is to say with finality that this or that vitamin is better than another, that this or that antibiotic should or should not be used, that the dosage range of this or that drug is from here to there but no less and no more, that this or that drug is very good for this condition but must never be used for that: I can think of nothing worse for the health and care of the American public than for individual physicians to be compelled, directly or by implication, to treat their patients according to a majority vote of a committee of other physicians or scientists, however honest, capable and sincere the members of that committee might be.

Treatment must be individualized and scientific areas where preciseness of measurement is almost non-existent should not be highly regulated. Pharmacology, toxicology, absorption factors, excretion factors, blood levels, bacterial sensitivity studies in the test tube and the like fail to inform us really of what drugs do at the cellular level. Until we have better methods for making such determinations, these studies, while necessary and important, are only gross guides for drug therapy. There are no "standardized" patients and I do not believe there can be any "standardized" drugs to meet their needs.

Previous testimony before this committee indicates that more than 90% of prescriptions filled called for 3 product by brand name or the product of a particular manufacturer in whom the physician had placed his confidence. It also has been stated here that 86% of the dollars spent by the federal government went for the purchase of products of brand name manufacturers when all the testing and elaborate screening procedures were completed. Physicians, depending on manufacturer integrity to secure the highest quality medicines for their patients -- and government, refusing to accept anything except scientific proof of quality -- both arrived at the same drug counters to secure healing agents for those for whom they were responsible.

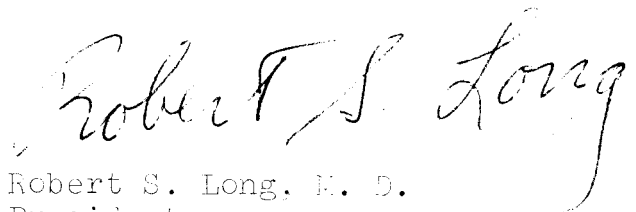
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Drug Labeling for Patient

The matter of labeling prescription drugs dispensed to a patient is a highly individual matter and often involves medical judgement which only the attending physician who knows his patient should exercise. I hold no brief for the physician who labels a bottle of medicine "take as directed", unless those directions are given in writing to the patient by the physician. This is necessary in certain situations. It is my own practice to identify the name of the drug, the dosage schedule, and the purpose for which it is prescribed in most instances. Even here, there are exceptions. For example, there are certain patients who develop so much anxiety from seeing the name of a drug on the bottle when the possible harmful side effects of that drug have been discussed in recent newspaper and magazine articles, that it is better for them just not to know the name of it. Again, the doctor has to know his patient and act accordingly. A patient should almost never be given the usual "package insert" to read. They already have enough anxiety about their condition without being frightened by reading information which they cannot possibly interpret properly without a medical background.

From the testimony given here previously, I believe most witnesses and also this committee recognize the advantages and disadvantages of generic prescribing and everyone is generally agreed that the attending physician has the privilege and the duty to prescribe what he believes to be best for the particular patient in the particular circumstances which exist at the time the decision must be made and that dispensing pharmacists should never make substitutions for the specific preparation prescribed.

I will be glad to answer any questions I can. Thank you for your kind attention.



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