COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

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HEARINGS

BEFORE THE

SUBCOMMITTEE ON MONOPOLY

OF THE

SELECT COMMITTEE ON SMALL BUSINESS

UNITED STATES SENATE

NINETIETH CONGRESS

FIRST SESSION

ON

PRESENT STATUS OF COMPETITION IN THE PHARMACEUTICAL INDUSTRY

PART 4

OCTOBER 31, NOVEMBER 9, 15, 16, AND 28, 1967

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COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

TUESDAY, OCTOBER 31, 1967

U.S. SENATE,
MONOPOLY SUBCOMMITTEE OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10:15 a.m., in room 318, Old Senate Office Building, Senator Gaylord P. Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson and Hatfield.

Also present: Benjamin Gordon, staff economist; James H. Grossman, minority counsel; Susan H. Hewman, research assistant; and William B. Cherkasky, legislative director, staff of Senator Nelson.

Senator NELSON. We will now open the hearings of the Monopoly Subcommittee of the Small Business Committee.

Our witness is Mr. George Callahan, of the American Telephone & Telegraph Co., who will discuss medical communication systems and their potential application in transmitting drug information as well as other medical information. This will include methods of acquainting the practicing physicians with new drugs, their uses, limitations, contraindications, side effects, and their relative efficacy. In addition, such a system could be used to alert physicians, pharmacists, and the public about dangerous, adulterated, or mislabeled drugs.

As I understand it, Mr. Callahan, you propose to manage the presentation of the various kinds of communications equipment and techniques; is that correct?

STATEMENT OF GEORGE E. CALLAHAN, SALES PROJECTS MANAGER, AMERICAN TELEPHONE & TELEGRAPH CO., NEW YORK, N.Y.

Mr. CALLAHAN. Yes, sir.

Senator NELSON. Then at the appropriate time Dr. Meyer, from the University of Wisconsin, will present what he has to present and Dr. Nobel will make his presentation?

Mr. CALLAHAN. Yes, sir.

Senator NELSON. Go ahead.

Mr. CALLAHAN. Thank you, Mr. Chairman.

The need for recognition of the role that communications can play in assisting the medical profession has never been greater. The information explosion that is taking place in medicine is like a deluge to the practitioner trying to keep abreast of his discipline. Still, he must often wait hours, even days, to get information he dearly needs. Meanwhile, the population continues to soar and the hospital population soars faster as programs like medicaid and medicare extend the opportunity for medical service to millions more.

Nurses also are caught between a growing avalanche of paperwork and patient care. While the average nurse devotes 40 to 60 percent of her time to clerical work the number of nursing school graduates falls further and further behind the need. The computer, with its incredible memory capacity and processing speeds, offers the only hope for managing the flood of medical information now being generated. But only those with access to the computer will be able to use it and its communications growing in capability apace of the computer, which will extend the real benefits of the computer age to medicine as to others. These, I think, are two mighty tools, the computer and communications. Each reinforces the value of the other.

The marriage of the computer, with its ability to digest, manipulate, store, sort, and articulate mountains of data over any distance, and communications, with its ability to move these mountains of data over any distance at any speed in practically every form using the Nation's communications system, is a truly awesome union.

Throughout the Nation, a great effort is underway to harness the capability of the computer and communications to medical objectives. In my report I will describe several examples of how this is being accomplished.

In addition to computer data communications, I have selected examples of how voice, video, and simple data systems are also being used. In all, 12 actual systems will be described. These cases include the transmission of electrocardiograms and other medical data by telephone——

Senator NELSON. The purpose of this is to transfer an electrocardiogram that has been taken under the direction of a physician someplace to a cardiologist in some other part of the country for assistance and diagnosis? Is that the kind of thing you are talking about?

Mr. CALLAHAN. Yes, sir; exactly.

Senator NELSON. So, a doctor in some remote part of the country at his small hospital who may think he needs assistance or advice in diagnosing an electrocardiogram that he has taken, can instantly transmit it and get an answer back?

Mr. CALLAHAN. Yes, sir.

Senator NELSON. Where is the transmission equipment going to be?

Mr. CALLAHAN. Well, the transmission equipment may be in the doctor's own office. There is portable equipment which he may carry with him to use even in the patient's home and, of course, the receiving equipment would be located either in the cardiologist's office or in a medical center, where the services of a cardiologist or other heart specialist would be available to assist the local doctor.

Senator NELSON. There is small portable transmitting equipment that a physician might have?

Mr. CALLAHAN. Yes, sir, and we are going to demonstrate that equipment today, also.

In addition to discussing the transmission of electrocardiograms, we are going to explain and show an automatic hospital emergency alerting system, and to describe the use of telephone in operating rooms; we are going to describe a computerized cancer treatment planning system, an automated medical laboratory and medical record system,

a computerized arrangement for taking medical histories directly from the patient.

Senator NELSON. Is this the technique of using a machine to interview the patient?

Mr. CALLAHAN. Yes, sir. The patient sits at a teletypewriter, which is connected to a computer at the distant location and the computer, which has been programed to take a medical history, actually works directly with the patient in the role that frequently consumes many hours of the doctor's time.

Senator NELSON. This can be done by just the machine and the patient?

Mr. CALLAHAN. Yes, sir.

Senator NELSON. With the patient being interviewed by the machine; is that correct?

Mr. CALLAHAN. That is right; yes, sir.

We will also discuss applications of Telelecture and tape libraries and television in continuing medical education. We will discuss a concept for a drug information system.

Senator NELSON. With regard to drug information, are you talking about some system of furnishing information by phone or otherwise to physicians who call a center of some kind?

Mr. CALLAHAN. That would be part of it, sir. We will be describing a system which will make it possible to get information out promptly to the physicians all over the United States when there are some urgent needs to recall a drug, for instance, or any other information, possibly about an adverse reaction which has been discovered and there is an urgent need so that all who might prescribe or dispense that drug will know about it quickly.

Senator NELSON. In other words, so far as the drug information system is concerned, if a physician had prescribed a drug for a patient and suddenly the patient had a dramatic reaction to it, the doctor could call the center, describe the drug and the reaction, and have an expert advise him immediately as to what to do about it?

Mr. CALLAHAN. Yes, that could also be incorporated in the system. But primarily the system we will describe would be for providing information which has been developed in research or has been reported by physicians who have learned about some unknown side effect or other adverse reaction to the doctor through a central controlling point. The system would permit dissemination of that information all over the country so that those who need to know about it, not only physicians but druggists and others, would know about this and still would be protected from the general public learning about it.

Senator NELSON. Is there a need for a source of information for the doctor about drugs of which this would only be part? Supposing the doctor wants to know what type of drug to use for a certain kind of situation. Is there a value in having a bank or an information bank he can call and find out?

Mr. CALLAHAN. Well, we're going to talk about that kind of a tape library in use at the University of Wisconsin, Mr. Chairman. Whether or not there is a need or a value for that, being a communications man,

I am not really qualified to answer, but I would be glad to ask one of the doctors with us today if they might wish to comment on that.

Senator NELSON. Go ahead.

Mr. CALLAHAN. Finally, we are going to demonstrate several new services which have promising potential for medical applications, specifically telewriting, Touch-Tone telephones, and Picture Phone service.

As I mentioned, since I am a communications man and not a medical man, I have asked the professional medical people who are familiar with several of the systems that we are going to describe here to discuss the medical aspects and to make any evaluatory comments. Two of these gentlemen are here with us, and four others will speak to us by telelecture, which is an amplified telephone call.

I would like to introduce at this point Dr. Joel J. Nobel, director of the Graduate Pain Research Foundation in Philadelphia.

Dr. Nobel——

Senator NELSON. Glad to see you, Doctor.

Mr. CALLAHAN (continuing). And Dr. Thomas C. Meyer, associate dean of the University of Wisconsin Medical Center.

Dr. Meyer——

Senator NELSON. Dr. Meyer.

Mr. CALLAHAN (continuing). Addressing the committee by telelecture will be Dr. Cesar A. Caceres of the U.S. Public Health Service in Washington, D.C.; Dr. John S. Laughlin of the Memorial Hospital for Cancer and Allied Diseases, New York; Dr. Hugo C. Pribor of Perth Amboy General Hospital in New Jersey; and Dr. Cecil L. Wittson, of the University of Nebraska College of Medicine. The communications equipment you see displayed will be used in live demonstrations of several of the systems we shall discuss.

In concluding, I will briefly discuss the function of communications in the developing concept of regional medical centers.

If it pleases you, Mr. Chairman, I will proceed now to discuss the first communications system, which is the transmission of electrocardiograms by telephone.

Senator NELSON. Go ahead.

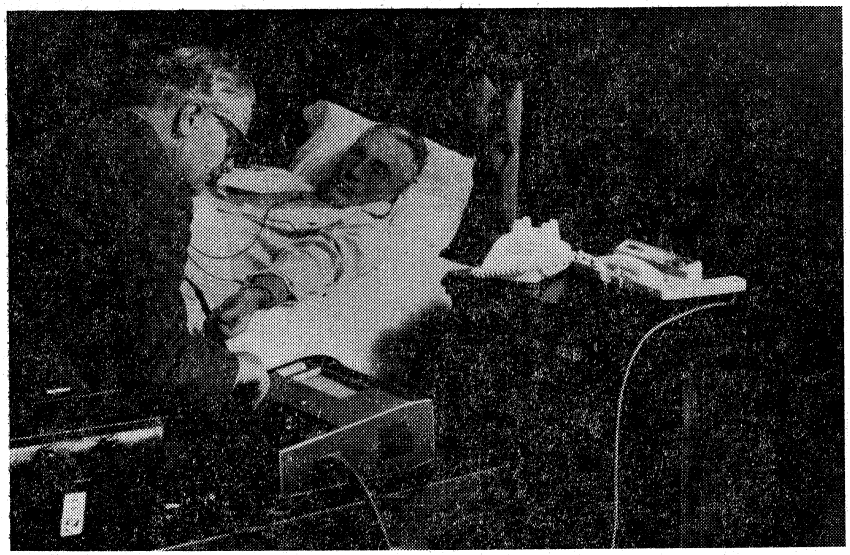
Mr. CALLAHAN. During the time it takes us to present this program, hundreds of persons in the United States will die of coronary occlusions. How many of these could have been saved if proper means of diagnosis were available is problematic, but if the answer turns out to be one or more, then surely these prompter means must be found.

One of the most widely recognized tools for the diagnosis of heart ailments is the electrocardiogram, which is commonly referred to as an EKG. By taking note of the relative amplitudes, durations, shapes, and relationships in time of the wave forms of an EKG tracing, a cardiologist can tell much about the condition of a heart.

Data-Phone data sets are now being used to transmit EKG tracings over the regular telephone network, thereby permitting maximum utilization to be made of qualified specialists and skilled personnel in analyzing EKG's. A Data-Phone data set is a telephone which en-

ables machines to talk to machines and, of course, it can also be used as a regular telephone for verbal communications.

(The Data-Phone sender illustration referred to follows:)



Mr. CALLAHAN. There are three types of data sets that are used in the transmission of EKG's. The sender, which is normally used in a small hospital or a nursing home, from where a number of EKG's would be sent regularly, is permanently installed like a telephone. There is a portable sending set that is used with a portable EKG machine and can be used with almost any telephone, whether it be in a hospital, a doctor's office, or even in the patient's home.

The Data-Phone receiver would be located in a cardiologist's office or a hospital or regional medical center.

In a typical transmission of electrocardiograms over a telephone line, a doctor, technician, or hospital staff member prepares a patient for a regular EKG examination. But before the examination begins, a phone call is dialed to a heart specialist. Before the EKG is transmitted, certain personal data about the patient is provided verbally—his name, his age, his sex, height, and weight. The examination takes about 5 minutes with both the transmitting and receiving locations getting simultaneous recordings of the tracing.

Once the electrocardiogram has been sent, the specialist can analyze and discuss the interpretation with the sending location.

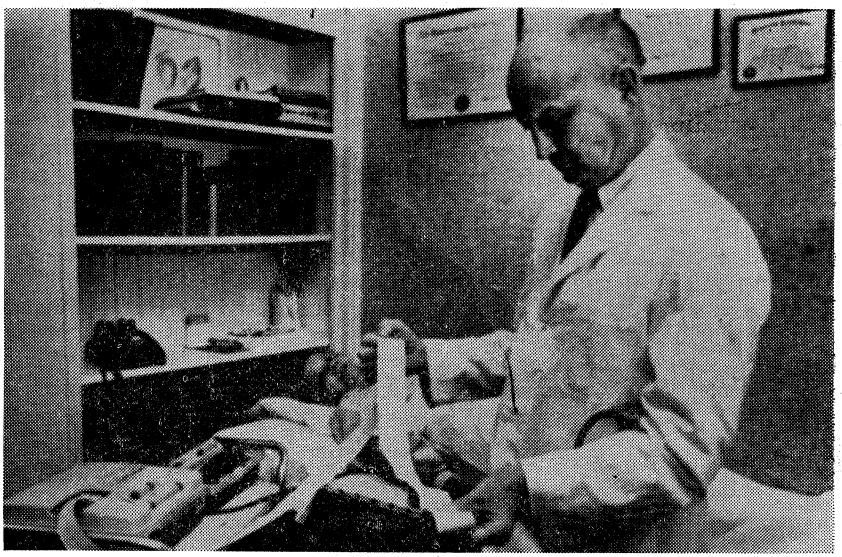
Several medical centers are using Data-Phone service to provide EKG service to doctors and hospitals in their region. For instance, there are 29 hospitals and doctors' offices located in Nebraska, Iowa, and South Dakota which send EKG's to Creighton University School of Medicine's cardiac laboratory in Omaha.

In the picture we have on the screen now, an EKG is being received at Creighton University of a patient in a rural hospital, suffering from a severe heart disturbance. As a result, the patient was moved to a larger hospital, where he could receive proper treatment.

(The Data-Phone receiver illustration referred to follows:)

Mr. CALLAHAN. In his office in a small town in Iowa, a doctor reads a patient's electrocardiogram while, simultaneously, it is being sent over the ordinary telephone lines to Creighton's cardiac laboratory for interpretation. In this case, the portable data set is used by the local physician.

(The illustration referred to follows:)



Mr. CALLAHAN. In the third illustration, a technician sends the patient's EKG from the patient's bedside to the center.

Illustrating the flexibility of this service, the director of the Creighton Cardiac Laboratory receives EKG tracings in his home. At night, electrocardiograms are sent to him in the absence of a staff cardiologist or for consultation.

At this point, with the assistance of my associate, Mr. Richard Murray, we will demonstrate the transmission of an EKG, using a mechanical heart for a patient. We have the equipment over on this table.

Now, at his office or home or at the patient's home, the physician has a portable EKG machine about the size of a tape recorder, and he also has a portable EKG Data-Phone set. He attaches the leads of the EKG machine to his patient. In this case, that is a mechanical heart we will use to be the patient.

He then calls a cardiologist or medical center, using any telephone that happens to be convenient.

Upon receiving an answer, he describes the case and gives the name, age, height, weight, and sex of his patient. He then places the telephone handset in the Data-Phone data set and both he and the receiving location switch the Data-Phone over to an EKG transmission mode from the voice mode.

Now, he starts his EKG machine and simultaneously he and the doctor at the receiving location receive a tracing, an EKG tracing.

Senator NELSON. So the cardiologist who is being consulted 500 miles away, or 200, or whatever, is receiving this electrocardiogram on his machine at the same time that the local physician is receiving it on his machine?

Mr. CALLAHAN. That is right; exactly, sir.

Senator NELSON. Then you are going to tell us how he makes his diagnosis and responds back to the consulting physician?

Mr. CALLAHAN. Yes, sir. Normally, this transmission would run 4 or 5 minutes, because there are quite a number of body leads, but we are going to end it here. We have sufficient tape to show what the doctors would have in their hands at each location.

Then, depending on the circumstances, they could either proceed with an immediate discussion, analysis, and interpretation. Or if it is a routine diagnosis, the cardiologist would call back and discuss his interpretation with the local physician back in his office.

Senator NELSON. Now, the cardiologist is not on the telephone all this time, taking the electrocardiogram; is he?

Mr. CALLAHAN. No, sir; the telephone handset is actually over there in the Data-Phone data set, which makes the connection between the EKG machine and the telephone network. By this means the signals can be transmitted to the distant end.

Senator NELSON. Then if the cardiologist determines from his examination of the electrocardiogram that there is a serious matter here and he ought to discuss it with the physician who transmitted the information on his patient, what does he do?

Mr. CALLAHAN. After he sends the EKG tracings, he then takes the handset——

Senator NELSON. Who takes it?

Mr. CALLAHAN. Both the local doctor and the specialist. They can tell when the tracing ends. Then both the receiving end and the local doctor take the handsets, switch into a voice mode again, and discuss the case at hand before hanging up.

Senator NELSON. So they are connected all the time?

Mr. CALLAHAN. Oh, yes. Therefore, as you said, if there is an indication of an immediate need, they can make that analysis and interpretation right away and take appropriate action.

Senator NELSON. I see.

Is this being done anyplace now?

Mr. CALLAHAN. Yes. In addition to Creighton, we know of at least 17 other locations in the United States where such groupings are in operation.

Senator NELSON. I know, but are they using this equipment?

Mr. CALLAHAN. Oh, yes, sir. This is now standard equipment which is available to all of the Bell telephone companies, and there are installations in various parts of the country—New York, New Jersey, a number of them—out in Wyoming and West Virginia and Illinois; and almost weekly, there are new groups. By groups I mean you have to start with a regional center or a cardiologist, who then arranges the service with other local physicians in his area for whom he will do the specialist work.

In this communications system I have just described, the medical data is interpreted and analyzed by a specially trained person. It is apparent that the processing of millions of EKG's annually in the fight against heart disease imposes a tremendous burden on these specialists.

A research program presently sponsored by the U.S. Public Health Service is proving the feasibility of applying modern data communications and data processing techniques to the rapid, accurate interpretation of electrocardiograms and other medical signals by computer. A computer is being used to analyze electrocardiograms transmitted over telephone lines from cooperating hospitals and Government clinics to the U.S. Public Health instrumentation field station.

Senator NELSON. Are you saying that the computer does the analysis without the intervention of a doctor?

Mr. CALLAHAN. Yes.

Senator NELSON. Will that not upset what the medical profession is always worried about, the physician-patient relationship?

Mr. CALLAHAN. Well, in this case, it is an analysis and interpretation, but it is not telling the doctor what to do; it is telling him what the condition of the heart is, which can be, as is being effectively demonstrated by the U.S. Public Health Service, very dependably performed by the computer.

Senator NELSON. Is that kind of analysis of an electrocardiogram by a computer being done in practice now anyplace?

Mr. CALLAHAN. Yes.

Senator NELSON. Where?

Mr. CALLAHAN. We will show you some interpretations which yesterday were transmitted from the Hartford Hospital in Connecticut to the U.S. Public Health Service computer and the analysis and

interpretations which were sent back to Hartford Hospital. We will show you copies that we have here today. It is actually a working system.

Senator NELSON. Does it just interpret normal electrocardiograms, or does it also interpret or analyze disease situations?

Mr. CALLAHAN. It does all of the analysis and interpretative work which would normally be performed on an EKG tracing by a specialist. It actually removes the burden of that interpretative work from the cardiologist or specialist.

Senator NELSON. What does the cardiologist do with this information? Does he use it?

Mr. CALLAHAN. The hospital then acts upon that information just as if they had received the interpretation from a cardiologist.

Senator HATFIELD. Do I understand that the hospital actually will receive a monitor signal to be seen on their encephalographs or cardiographs?

Mr. CALLAHAN. Yes, Senator.

This question really does get over into the field of medicine more that communications, and, if it pleases you, I would ask Dr. Meyer of the University of Wisconsin if he would care to make some comment to describe that more clearly.[1]

Dr. MEYER. Thank you, Mr. Callahan.

Senator NELSON. Dr. Meyer, of the University of Wisconsin, we are pleased to have you here today.

Dr. MEYER. Thank you very much.

With an electrocardiogram, there are a great number of measurements, and a great number of judgments that have to be made, that can be done mechanically. The actual judgment of what the implication of this is to the patient cannot be done by a computer. This has to be done by somebody who knows the history and what they have found on physical examination. It is a synthesis of all the data that can only be done by the physician. But the mechanical reading of the electrocardiogram can quite easily be automated.

Senator NELSON. I still do not understand it very well. What has it done that the cardiologist does not have to do over again? The cardiologist gets the machine's mechanical analysis. How does that save the cardiologist from repeating himself, and what good does it do him?

Dr. MEYER. It saves him a tremendous amount of time in doing all these basic measurements that have to be done. It gives him these measurements in a form in which he can interpret from them what this cardiogram means to the patient, knowing the background of the patient, knowing the symptoms and the physical signs of the patient. A cardiologist spends perhaps, oh, 8 to 10 minutes looking at a cardiogram and taking these measurements and this data from this.

Senator NELSON. You are talking about actually——

Dr. MEYER. Physically doing this.

Senator NELSON. Measuring in terms of centimeters and so forth?

[1] See complete prepared statement of Dr. Meyer, p. 1204, infra.

Dr. MEYER. It is usually in millimeters, and if one wishes to do any research on this, if you have this accurately measured and put down into retrievable form, in due course, this is going to cause a tremendous advance in the reading of electrocardiograms.

Senator NELSON. Well, it reduces his time—if you say it takes 10 to 15 minutes for the doctor to do the measurements and evaluate an ordinary one, how much time is this going to save him?

Dr. MEYER. I would think it would save him 50 percent, 60 percent of the time he spends actually on that tracing, and he would then look at that tracing for 4 or 5 minutes instead of 8 to 10 minutes.

Senator NELSON. Then a cardiologist in a medical center could, in effect, in servicing the whole surrounding countryside for many miles, could double the number of diagnoses that he could make per day? Is that what you are saying?

Dr. MEYER. Yes, sir; or he would be free or freer to discuss with the referring physician the implication of this particular tracing to the patient, and he would then have the opportunity to talk and to teach the person who is transmitting the EKG.

Mr. CALLAHAN. Mr. Chairman, we also have Dr. Caceres of the U.S. Public Health Service, speaking from the Medical Systems Development Laboratory here in Washington, will be describing his program to us by Telelecture in a moment. He is on the line now. If you wish, I am sure Dr. Caceres will be able to give you more information on this subject.

Senator NELSON. Proceed. Any time the questioning interferes with the mechanical presentation of something you planned here, just interrupt Senator Hatfield or me.

Mr. CALLAHAN. Yes, sir.

I believe the discussion as a result of your questions has brought out the additional comment that I was about to make. Therefore, I would like at this point to introduce to the committee, Dr. Cesar A. Caceres of the U.S. Public Health Service, who is directing this program.

Dr. Caceres, are you on the line with us now?

STATEMENT OF DR. CESAR A. CACERES, CHIEF, MEDICAL SYSTEMS DEVELOPMENT LABORATORY, HEART DISEASE CONTROL PROGRAM, NATIONAL CENTER FOR CHRONIC DISEASE CONTROL, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, WASHINGTON, D.C.

Dr. CACERES. Yes; I am.

Mr. CALLAHAN. Would you go ahead and make your presentation?

Dr. CACERES. In a very short time there will be more human beings alive at one time than have populated the world since the beginning of man.

The need to provide for this sudden huge population growth creates new medical problems. Entirely new concepts of medical analysis and treatment—not merely improvements of existing ones—must be de-

veloped to maintain the quality of medical care needed for the rapidly increasing mass of human beings.

In routine physical examinations and in the diagnosis and treatment of heart disease, physicians in the United States spend part of their scarce time analyzing some 50 million electrocardiograms per year, for example, as one of the things they have to do.

These tests and many more can now be done on a mass scale—quickly, reliably, and inexpensively—by automated systems using computers.

Just as automation in a thousand industries has jumped up production while saving time and money and conserving manpower, it can now be used in medical care. To be of greatest effectiveness, automation requires extensive communication facilities.

Automation is a giant step in the battle against heart disease, with its annual mortality in the United States alone of well over 700,000—against stroke, with an annual mortality of approximately 200,000—against other killer diseases of the cardiovascular and cardiopulmonary systems.

The growing number of physical and laboratory tests required by our increasing and aging population, the shortage of physicians and other health personnel, and our awareness of the need for raising the quality of medical practice for all our citizens, force us to utilize the precision and rapidity of computers and communications systems. These systems can be tools in medical practice to help us keep up and not fall behind in our vital battle to preserve the health of our people.

Delegation of routine duties to automated systems is an ideal way in which the physician can find more time for development and exercise of higher professional skills and to provide leadership to the medical teams required in today's concept of comprehensive health care.

Since a computer system can increase the effective use of the physician's time, he can concentrate more on his needs for further education to maintain awareness of day-by-day scientific advances.

The computer can, for example, relieve the heart station physician, the industrial physician, and the physician in group or hospital practice, of the tedium of reviewing predominantly normal electrocardiograms. The physician-time thus saved can be reflected in better care of patients.

The digital computer in this way can help solve today's problem of the shortage of medical manpower.

To make this major advance, research and demonstrations have been conducted the past several years in the use of computers and modern electronic systems to interpret electrocardiograms and other medical signals.

System Development

Several steps were necessary to develop a functional system. First, a new electronic instrument was engineered to take an electrocardiogram. The unit, which can be operated by any EKG technician, is called a data acquisition console. Slide No. 1 shows an example of this.

(The illustration referred to follows:)

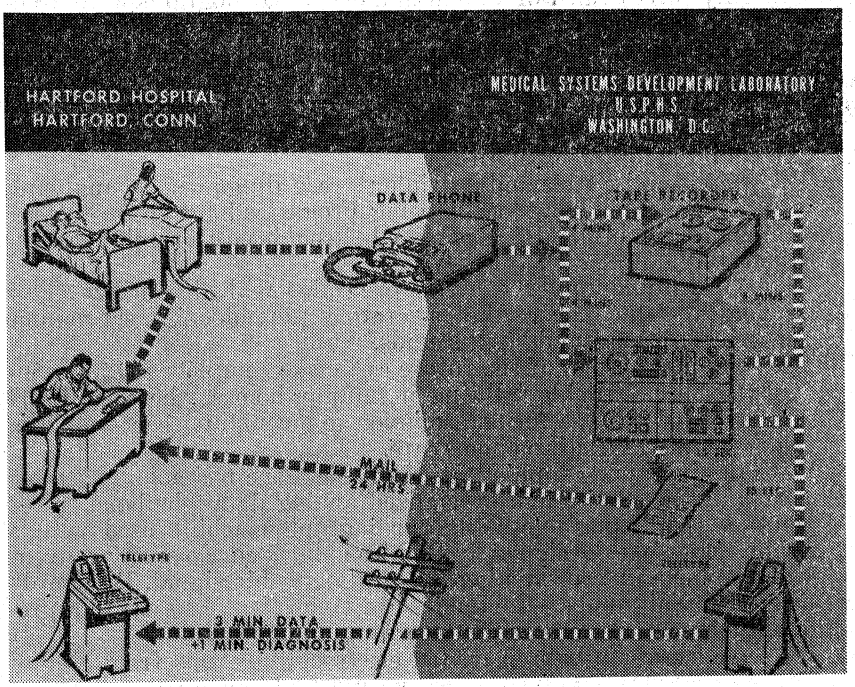
Dr. CACERES. It is similar to conventional electrocardiograph machines. The technician connects the leads in the usual manner. The console unit is essentially a tape recorder plus a conventional EKG machine.

The data acquisition unit provides many unique features—in addition to the standard tracing. Among these features is a system for coding to identify the EKG and to identify the patient and record certain of his physical characteristics, such as age, sex, height, and weight. An automatic timer is provided to meter standard lengths of recording. A side panel provides for the electrocardiogram and additional physiological inputs such as electroencephalography, phonocardiography, and spirometry. The unit is operated in the same manner as ordinary EKG machines.

The patient and lead-identification codes are recorded both on the visible tracing and on analog magnetic tape, which can serve as the input to the computer system.

In the second slide, we see an example of a service being provided today. The signal or the magnetic tape recording of the electrocardiogram or other signal can be fed through a telephone from Hartford by use of data-telephone systems, which sends the signal to the computer center, however distant. The slide shows you the diagrammatic presentation of what we are doing. There, the individual in bed, in the out-patient department or the emergency ward, can have an electrocardiogram recorded by telephone. This can be sent to the Public Health Service field station in Washington, D.C., where the telephone data is received and, if necessary, re-recorded on analog magnetic tape. This tape is fed into an analog-to-digital converter.

(The illustration referred to follows:)



Dr. CACERES. This device samples the continuous EKG waveform 500 times per second. Each sample is thus tagged so that a computer program can identify the peaks and valleys of the wave complex. A method to determine the amplitudes and durations of the P, Q, R, S, and T waves, as used in present-day electrocardiography, has been programed into many thousand individual instructions.

Each lead is monitored for several seconds. Within 15 seconds after the computer has recognized the waveforms of all the leads, it associates the values and can print out an interpretation, such as the physician would receive from an electrocardiographer.

Storage of the processed data for later retrieval for comparison, followup, or statistical analysis can also be made from the processed data stored on digital magnetic tape. Within a few seconds, results can be fully processed and returned to the physician or to the hospital.

High-speed teletype machines and printers, which make out reports for delivery by wire, can also serve in situations where rapid screening of large numbers of people is necessary.

With this routine processing system, the Public Health Service has established less than 1 percent error in the computer system. This is far less than any human system can possibly produce. There is a high agreement between cardiologists and computer interpretations. Moreover the computer helps the physician avoid missing any significant data.

The field trials conducted by the heart disease control program have been highly successful. Forty thousand electrocardiograms were processed in the first year of routine operation, using only one-third of the system's capability. For example, computer-analyzed electrocardiograms have been routinely employed for the past 2 years at the Hartford Hospital.

Records are processed in the evening and are available routinely at the hospital the following morning.

Two-step exercise tests and continuous recordings will be analyzed, as well. Our computer system is being programed for these, to take advantage of the information obtained through post-exercise electrocardiography.

In the future computer analysis programs will also utilize other physiological data, such as the respiratory test, blood vessel volume changes, brain waves, and heart sounds.

The computer system of the future can make complete electrocardiography service available full time in nursing homes, where the EKG can be recorded on tape for transmission to a computer center or in a patient's home while he is on home care.

With the increasing sophistication of telephone technology, signals can be transmitted through specialized analog data-telephone transmitters. A small, portable electrocardiograph machine used with a telephone interface developed by Bell Telephone employs any conventional telephone in transmitting the cardiographic signal. By simply dialing a special number, the sender can transmit the signal to a predetermined computer center for recording and analysis.

We have successfully transmitted electrocardiograms from France to Washington, D.C., for computer analysis and immediate return, using telephone, RCA communications, and satellite transmission.

System advantages

The public health or home care nurse can keep the hospital, health department, or heart center aware of the patient's condition.

The increasing costs of medical service, the considerations raised by regional medical programs on heart, cancer, and stroke, make the role of computer systems even more essential in large hospitals, and in programs involving cooperative arrangements in a group of hospitals. It is also a practical way of coordinating outpatient services, nursing homes, and home care with medical centers.

Computer analysis of medical signals will reduce the cost of individual patient care, while at the same time increasing the number of patients who can be seen and effectively treated. If emergency situations dictate, interpretations can be made rapidly and continuously.

Computer analysis will speed the physician's diagnostic procedures to shorten hospital time and to alleviate crowded conditions.

The Medical Systems Development Laboratory of the U.S. Public Health Service has processed over 15,000 electrocardiograms for a National Institute of Health-sponsored study across the seas in Israel. Computer analysis is being used in a spirometry study in Ohio and another in Wisconsin. There is routine use of telephone and teletype transmission of EKG's from several Washington clinics.

Within a few short years, large populations of the United States can obtain electrocardiograms through computer analysis, making possible early detection and aiding in the prevention of heart disease, our major cause of death.

Discussing our Nation's urgent medical needs, and the effect of computer systems in medical practice and in research, the Public Health Service's Surgeon General has said:

> However much we may do to build schools and train more physicians, there is an immediate urgency to use the available human resources in medicine to the highest degree for which they have been trained. The physician should delegate as many of his duties as possible and reserve his time for the exercise of his highest professional skills.

Computers and telemetry help him achieve that goal.

Thank you very much.

Mr. CALLAHAN. Thank you, Dr. Caceres.

Would you now transmit to us by teletypewriter a sample of the report that you would send back to a hospital after a computer analysis and interpretation?

Dr. CACERES. Fine. It should begin to arrive now.

Mr. CALLAHAN. In the meantime, we have distributed to the committee copies of the reports which you sent yesterday.

Mr. Chairman, the Telelecture Service is two ways, so that using the microphone before you, if you care to ask questions of Dr. Caceres, it is as if he were in the room before us.

Senator NELSON. Thank you.

Dr. Caceres, this is Senator Nelson. Also with us is Senator Hatfield of Oregon.

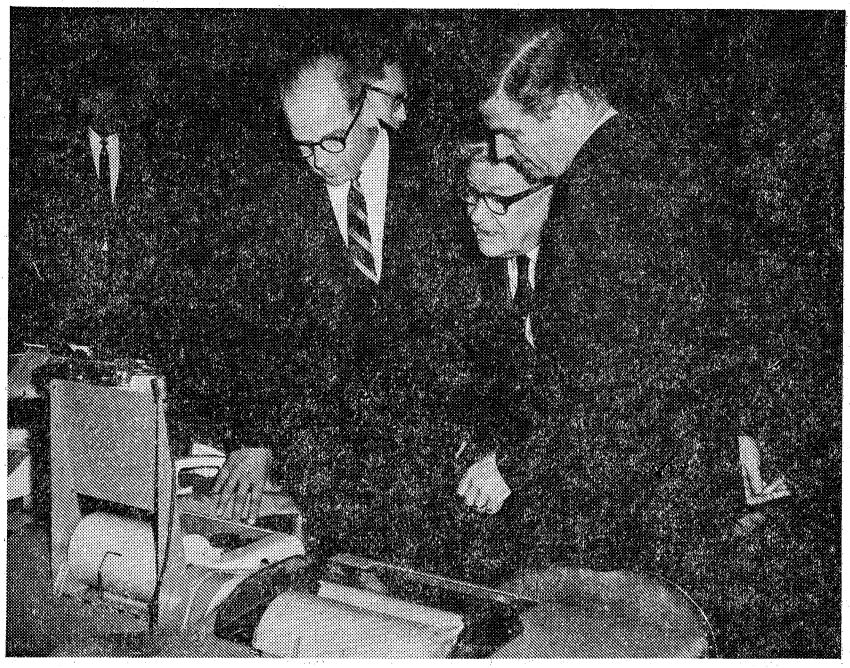
Do I understand you are going to transmit an electrocardiogram——

Mr. CALLAHAN. Yes.

Senator NELSON (continuing). Which is going to come out on this teletypewriter here in this room?

Mr. CALLAHAN. The teletypewriter is now answering the call, just as if it were located in the hospital. Then we will receive a copy of the analysis and interpretation, just as it would be received in a hospital.

(The illustration follows; printout appears on facing page.)



Senator NELSON. How is the information put in the transmitter at your end, Dr. Caceres, so you can put it in the teletypewriter?

Dr. CACERES. After the computer has performed the analysis, it puts out a punched paper tape that is used as the input to a teletype. It could be done electronically, by passing the punch paper tape. That will be done in the future.

Mr. CALLAHAN. Dr. Caceres, this is Mr. Callahan. Senator Nelson and Senator Hatfield were over at the teletypewriter and watched the printout come through. Do you have any additional comment you would like to make now?

Dr. CACERES. Only that we would like to have this sort of service made available as soon as possible, to hospitals, clinics, and physicians, so it can help them improve the quality of patient care.

Senator NELSON. I could not hear all of your original statement, so this may be repetitious. As I understand it, a physician with the proper equipment can transmit an electrocardiogram by telephone into some center?

Dr. CACERES. Yes.

Senator NELSON. And then the analysis of that electrocardiogram would be done by machine, interpreted by a cardiologist, and then sent back to the doctor in the same fashion that you have just sent it into this hearing room; is that right?

INSTRUMENTATION FIELD STATION HEART DISEASE CONTROL PROGRAM
COMPUTER PROCESSED ELECTROCARDIOGRAM
G. HEART STATION

NAME DIAGNOSIS
NUMBER 315560 TAPE 637 OPTION 087 DATE 2-16-67 TIME 02--18--27
HEIGHT 71 WEIGHT 162 AGE 42 MALE MEDS UNKNOWN
BP UNKNOWN

LEAD	I	II	III	AVR	AVL	AVF	VI	V2	V3	V4	V5	V6	
PA	.09	.06	.03	-.09	.05	.08	.03	.04	.00	.04	.05	.07	PA
PD	.09	.06	.07	.10	.05	.10	.04	.07	.00	.06	.07	.06	PD
QA	-.07	.00	.00	.00	-.06	.00	.00	.00	.00	.00	-.10	-.08	QA
QD	.03	.00	.00	.00	.02	.00	.00	.00	.00	.00	.02	.02	QD
RA	.46	.38	.04	.05	.30	.18	.17	.48	.54	1.25	1.66	.80	RA
RD	.04	.03	.02	.02	.05	.05	.04	.05	.05	.05	.04	.04	RD
SA	-.14	-.36	-.33	-.41	.00	-.29	-.64	-.79	-1.25	-1.12	-.56	-.23	SA
SD	.03	.04	.05	.03	.00	.03	.06	.05	.06	.04	.03	.03	SD
R'A	.00	.00	.00	.15	.00	.00	.00	.00	.00	.00	.00	.09	R'A
R'D	.00	.00	.00	.03	.00	.00	.00	.00	.00	.00	.00	.00	R'D
ST	.10	.09	.12	.11	.12	.10	.12	.12	.12	.12	.12	.07	ST
STO	-.01	-.09	.01	.02	-.04	-.04	.00	.01	.08	.06	.01	.02	STO
STM	.03	-.04	.00	-.01	.01	.00	.04	.16	.27	.24	.14	.06	STM
STE	.07	.00	.02	-.06	.01	.02	.07	.40	.75	.71	.38	.07	STE
TA	.18	.19	.12	-.22	.06	.16	.10	.64	1.10	1.21	.74	.33	TA
TD	.13	.13		.14		.15						.18	TD
T'A	.00	-.08	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	T'A
T'D	.00	.14	.00	.00	.00	.00	.00	.00	.00	.00	.00	.00	T'D
PR	.12	.12	.13	.13	.11	.14	.12	.11	.00	.11	.11	.10	PR
QRS	.10	.07	.07	.08	.07	.08	.10	.10	.11	.09	.09	.09	QRS
QT	.34	.30	.34	.34	.30	.33	.30	.35	.37	.36	.36	.35	QT
RATE	77	78	83	84	73	79	80	83	75	75	81	84	RATE
CODE	2	4	4	2	3	3	4	3C	4	4	3	3	
CAL	100	100	100	100	100	100	100	100	100	100	100	100	CAL

AXIS IN	P	QRS	T	Q	R	S	STO				ST-T	QRS-T
DEGREES	54	-38	33		20	265	210				177	71

8311 QRS AXIS RANGE -10 TO -59 . LEFT AXIS DEVIATION
6171 TALL T WAVES V LEADS . CONSIDER HYPERKALEMIA OR POSTERIOR
. WALL ISCHEMIA
.

Dr. CACERES. With one exception; the analysis is all done by machine. The patient is at the recording end, the computer receives the data from the patient, and the answer goes back to the physician requesting it without ever having gone through a cardiologist's analysis. The physician cardiologist caring for the patient checks it before applying the results but is relieved of routine, repetitive procedures.

Senator NELSON. Is the receiving physician a cardiologist?

Dr. CACERES. The receiving physician need not be a cardiologist. For physicians who are not cardiologists, we are preparing a short program. At the end of the report you see, the computer will give him a statement to the effect that "this electrocardiogram is abnormal, further consultation is suggested," or that the tracing is normal. These statements would indicate to the physician whether he should get a cardiologist.

In other words, we are developing programs that will be suitable for different types of practitioners. We are aware that certain types of practitioners, because of their practices, should not be expert cardiologists but should be expert in their own field. So we will have phraseology for them to let them take advantage of this system.

Senator NELSON. So if the sending physician is a cardiologist and he has this patient there, he gets this mechanical interpretation back.

Dr. CACERES. Yes.

Senator NELSON. Then he reads this mechanical analysis and makes his interpretation; is that correct?

Dr. CACERES. That is correct.

Senator NELSON. What is the benefit to the cardiologist of following this system rather than simply looking at the electrocardiogram tape as it comes off the machine?

Dr. CACERES. At the present time, there are insufficient cardiologists to read the growing number of necessary electrocardiograms. Several hospitals in large centers find it impossible to obtain the services of cardiologists for routine reading of electrocardiograms. In the Hartford Hospital, for example, physicians have studied their speed in reading electrocardiograms with and without computer help. They found that the computer multiplies the quantity of work they do five times, which means that in reading electrocardiograms one cardiologist can do the work of five. Access to the computer system effectively multiplies the professional manpower resources available. What we envision would be the cardiologist in his heart center reading a great number of tracings, say five times more than he ordinarily would, and with greater precision.

In many other areas we are concerned with the problem of periodic examinations of people who must have electrocardiograms for such things as insurance examinations. These come to the cardiologist. It would be useful in these centers to have this type of work prescreened by a machine system.

One of the problems in the delivery of health systems to heart patients throughout the country is that there are an insufficient number of qualified readers of electrocardiograms. We need to train many more or to provide machine assistance. The latter is the easiest solution.

Senator NELSON. I understand you to say that a cardiologist using this computer system could, in fact, do the work of five other cardiologists daily?

Dr. CACERES. That is true. Those were the results of a study done in Hartford Hospital.

Senator NELSON. Thank you, Doctor.

Did you have any questions, Senator Hatfield?

Senator HATFIELD. No.

Mr. CALLAHAN. Thank you, Dr. Caceres. We appreciate your assistance today very much.

Dr. CACERES. Thank you.

Senator NELSON. Thank you, Dr. Caceres. The committee appreciates very much the contribution of your time.

Mr. CALLAHAN. A somewhat different use will be made of telephonic transmission of EKG's at Salem Memorial Hospital, in Salem, Oreg. Used in conjunction with physiological monitoring in the intensive-care section of the hospital, it will enable the hospital to present cardiographic data to a heart specialist at any time of the day or night. The time saved when an emergency strikes during periods when a cardiologist is not on duty can make the difference between life and death. The Salem Memorial Hospital system of EKG transmission is not for diagnostic use, as we have been discussing so far today, but rather

for determining the lifesaving steps that should be taken in an emergency that occurs, let us say, in the middle of the night.

Immediate indication of a patient's condition is highly important. If the doctor is at his home or office, precious time may be lost while he is driving to the hospital to prescribe the proper treatment. With the system as Salem Memorial is going to use it, when a patient's heart function either exceeds or falls below predetermined limits, an alarm system notifies the nurse. The nurse will call the doctor whose cardiac patient is experiencing difficulty, give oral details of the patient's condition, and then transmit the patient's EKG via a Data-Phone arrangement.

With this information, the doctor is able to determine what steps need to be taken immediately in treating the patient before he leaves for the hospital.

We do not have anyone from Salem Memorial Hospital to participate here today, but Dr. Meyer has indicated that if you have any questions about the application of this kind of a system, he would be glad to discuss them with you.

Senator HATFIELD. I would like to comment that this has created a great deal of excitement out in my hometown. This hospital to which you refer has not only been pioneering in this field, but I think is the first in our State, at least, to offer full helicopter ambulance service, with a heliport on top of the hospital.

When I was talking to Mr. Sukalak at Salem Memorial Hospital last time I was home, he indicated to me there was work well along on the heartline system about the development of a fully portable system, usable wherever telephone service would be available. Could you tell me a little bit about how far along this particular development is?

Mr. CALLAHAN. Yes, sir. What he was referring to, of course, was a portable data-receiving set. The set which we have been demonstrating here is one which is used for the transmission and sending. Work is being undertaken now to look at adapting the EKG Data-Phone receiving set for portable use. I cannot give you any indication at this time as to just exactly how far along that work has proceeded or what the possible availability might be.

Senator HATFIELD. He also mentoned about the possibility of using the Data-Phone service to eliminate inventory or vastly reduce inventory problems as a service to hospitals. Would you care to comment on that, please?

Mr. CALLAHAN. I am not sure, Senator, I understand what he has in mind.

Senator HATFIELD. Well, areas of labor saving that would be involved would be as it relates to the operation of hospital delays and back-order delays due to mistakes, eliminates the need for extensive warehouse services, and things of this type.

Mr. CALLAHAN. Oh, yes. He was referring to administrative applications of data transmission. For instance, in the ordering of supplies, there are a number of systems in operation around the United States now wherein the hospital supply company has installed Data-Phone service so that the hospitals which they service can send their orders directly and be received on a business machine for prompt processing. By doing it in this way, they eliminate the always-present danger of error being inserted by human beings copying and recopying ma-

terial. But not only that, they find that in many cases it enables them to provide same-day service or service the following morning on orders received which, of course, makes it possible for the hospitals to vastly reduce the amount of drugs, the amount of equipment that they have to have on hand, because they have the assurance that they can order it today and have it tomorrow.

Senator HATFIELD. As you know, one of the basic problems we face in the whole health field is the problem of rising costs, particularly as it involves hospital care. I think it is very significant in this potential that you describe here for hospital administration, could represent a significant reduction in costs of operation for hospitals. Is this not true?

Mr. CALLAHAN. Yes, sir; and with the introduction of Touch-Tone telephone service which we will be describing later on, that cost reduction will be even further developed, because—well, a typical price of a Touch-Tone telephone card dialer such as I have here is around $4.50 a month. It has the capability of transmitting ordering information directly to the computer in the way that the Salem people are planning, and replaces an arrangement that presently costs nearly $40 a month in total. Of course, at the same time, it serves the purpose of a regular telephone also.

So there is real potential here for reducing hospital administrative costs.

Senator HATFIELD. Thank you, Mr. Chairman.

Senator NELSON. Go ahead.

Mr. CALLAHAN. In pursuing the cardiac emergency one more step, I would like to raise the question of what happens when a cardiac arrest occurs, when a heart stops. Today thousands are being restored to life through cardiopulmonary resuscitation, an emergency measure in which a stopped heart is brought back to life by rhythmic pressure on the chest. These hearts have been temporarily stilled by strokes, heart attacks, drug reactions, or accidents.

According to the American Heart Association Committee on External Cardiopulmonary Resuscitation, the tragedy is that for every life saved by this technique, probably a dozen are lost because it is not used. Resuscitation is possible in many of the over 500,000 heart disease deaths, the many thousand heart arrests in surgery, and the many thousands of deaths from drowning, suffocation, electric shocks, and other accidents. Tests show that salvage from these deaths can perhaps average more than 100,000 lives per year. The key difficulty is the need to reach the heart victim within 2 minutes; that is, before the brain dies or is irreparably damaged for lack of oxygen.

When an attack occurs in a hospital, the staff can only respond if they are aware of the situation. How do you notify everyone who needs to know—doctors, nurses, technicians spread throughout a large complex? Obviously proper communications are vital, for even within a hospital, it is estimated that 30 percent of patients having attacks die. The problem is compounded by the fact that if a patient is not in the intensive-care ward, staff coordination becomes even more critical, since vital equipment is located in other sections of the hospital.

It is therefore necessary to have some form of communications that will alert emergency team members wherever they may be in the medi-

cal complex; also, to advise other personnel involved in the preparation of operating rooms and vital equipment.

What we would like to show you now is a command alert telephone system that was specially designed to meet this need in any hospital with dial switching telephone service. The backbone of this system is dial switching equipment that provides the regular telephone service in a hospital.

Let me briefly describe the actions that ensue in a matter of seconds.

A patient in room 324 has suffered a cardiac arrest. A nurse can initiate an alert from any dial telephone in the hospital—the one right next to the patient's bed, for instance. There is no special telephone needed for this purpose. The nurse simply dials a special number that has been designated for this particular purpose. Let's say 1212 is this emergency number. The telephone is immediately connected to an announcement machine and a tone is returned to the telephone which tells the nurse, we are ready for message.

The nurse now simply says, "Code Blue, Room 324," and hangs up. Now, this is a typical code used to indicate an emergency condition in a hospital, "Code Blue." This has only taken the nurse a few seconds and it is all the action that is required by her to bring the patient the support she needs. She now can devote her full attention to the patient.

While the nurse is recording the message, the switching equipment is ringing preselected hospital telephones with a distinctive ringing signal. These can be any telephones associated with the hospital system and can vary according to the established emergency procedures. Anyone answering these telephones will hear the alert message, "Code Blue, Room 324."

In the event the telephone is busy at the time of the alert, spurts of tone will be heard on the line signaling that an emergency condition exists. As soon as the person hangs up the telephone, it will ring with the distinctive signal. Upon answering, they will get the alarm, "Code Blue, Room 324."

At the same time, the dial switching equipment can also seize control of the paging system, stop all public address announcements, and broadcast the alert message. Also simultaneously, signaling devices such as pocket radios, horns, bells, or lights can be activated. Any members of the resuscitation team seeing or hearing the signal will dial a predetermined number from any telephone in the hospital to receive the alert message. The emergency code would activate emergency vehicles, shutting off the 110-volt power supply that charges the self-contained batteries and activating the electronic apparatus contained in the cart, such as electrocardiographic and electroencephalographic equipment. This places all the equipment in a ready condition for service the instant the cart reaches the patient.

An elevator is a key factor in moving the resuscitation equipment to the patient and can also be activated by the dial equipment. Upon receiving a signal, the elevator will close its doors and move automatically to the floor where the resuscitation cart or equipment is stored. On arrival, the doors will open and the electric power will be cut off to prevent the car's use by anyone else during the emergency. This cuts vital seconds off the time needed to move the equipment to the patient. The elevator will then be waiting to move the patient to the operating room.

All of this has taken place immediately and automatically as a result of the nurse making a simple telephone call of only a few seconds' duration.

During this period, the system can also be monitored by the switchboard attendant, although no action has been required on her part to coordinate any part of the procedure. The system is not limited to cardiopulmonary emergencies. A separate code could be established for an obstetrical emergency—say, 3333 instead of 1212, and a different set of hospital telephones would be activated. Likewise, surgical or civil emergencies could have their own separate codes.

We have invited Dr. Joel J. Nobel, director of the Graduate Pain Research Foundation in Philadelphia, who has done considerable work in conjunction with this system, to describe the impact of the command telephone system on hospital emergency service.

Dr. Nobel is with us today and I would like to present him at this time.

Senator NELSON. Dr. Nobel, the committee appreciates your coming here today. Would you furnish the reporter your full name and identification for the record?

STATEMENT OF DR. JOEL J. NOBEL, DIRECTOR, GRADUATE PAIN RESEARCH FOUNDATION, PHILADELPHIA, PA.

Dr. NOBEL. Thank you, Mr. Chairman. It is my privilege.

I am Joel J. Nobel, director of the Graduate Pain Research Foundation in Philadelphia.

Senator NELSON. Go ahead, Dr. Nobel.

Dr. NOBEL. Thank you.

The limiting factor in the survival of many patients requiring emergency medical care within the hospital or on arrival in the emergency room is the time required to mobilize emergency care resources. The patient with cardiac arrest is irretrievable if resuscitation is not begun within a few seconds or minutes and the accident victim may die if emergency surgery is delayed.

Despite the current tendency to concentrate more critically ill patients in specialized intensive or coronary care units, emergencies are and will remain a hospitalwide phenomena. Our capability for predicting which patient is a likely candidate for emergency care is still rather limited. From the staffing viewpoint, it is impossible to have a three or four person team with no other duties, standing by 24 hours a day awaiting an emergency. Team members normally have routine hospital duties which they interrupt for emergencies. Team members, like emergencies themselves, can therefore be in any location.

The goal of emergency mobilization is, of course, to deliver a competent, well-equipped team to the patient's bedside as quickly as possible. The time required to bring personnel and equipment to the patient is directly related to delays in communications, elevators, and characteristics of equipment and the physical plant of the hospital.

In large or high-rise urban hospitals, it may require from 3 to 10 minutes to get personnel and equipment to the bedside. Rarely is emergency surgery underway in less than 20 or 25 minutes once a patient has reached the emergency room. The two greatest problems are communications and elevator delays.

Over the past 3 years we have conducted time motion studies of emergency car and concluded that any mobilization system which relies on an entirely human-operated communications sequence is unsatisfactory.

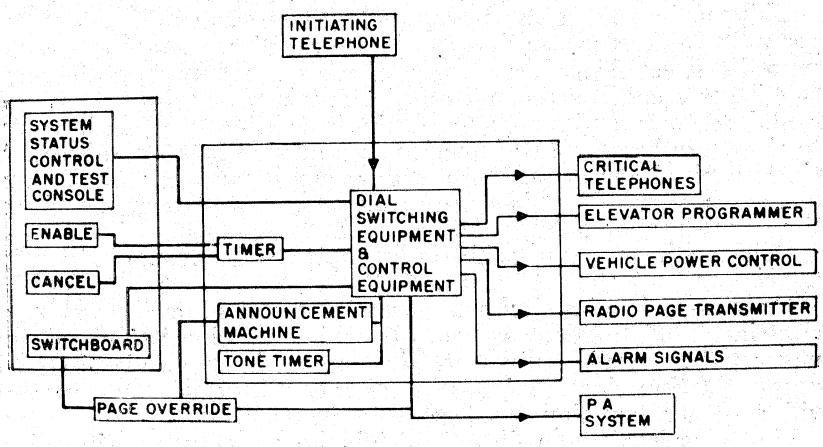
If, for example, a switchboard operator must individually call and awaken four or five people for a night emergency, we can expect unacceptable time delays. Frequently the room number of the emergency location is given in error, either because of the nurse reporting the emergency or, much more frequently, because the operator panics, confuses the message, and mispages the location. This error, due to the operator, actually occurs about 12 percent of the time.

Following a study of many human and technical factors in emergency care mobilization, we identified the problem areas and designed a system which, we feel, will add a new measure of effectiveness to emergency care within the hospital.

We are developing a hospital emergency command system with the support of the Research and Demonstration Grants Branch, Division of Hospital and Medical Facilities of the U.S. Public Health Service. The hospital emergency command system incorporates what was previously described, the command system communications system, with one of its subsystems or components. The total system will permit simultaneous and immediate mobilization of communications, personnel, equipment, and elevators by a single initiating call from any hospital dial telephone.

(The hospital emergency command system illustration referred to follows:)

HOSPITAL EMERGENCY COMMAND SYSTEM
SIMPLIFIED BLOCK DIAGRAM



Dr. NOBEL. Furthermore, it provides a selective mobilization response to the varying requirements of cardiopulmonary arrest, or emergency surgery, or obstetrical emergencies or civil disasters causing a large number of injured persons.

What happens at the present time?

An accident ward nurse must make from five to 10 individual telephone calls to set up emergency surgery at the very time her assistance is most needed at the patient's side. Usually the operating room, admissions, anesthesia, hematology, blood bank, surgical resident, and intern staff physician must all be notified. A nurse at the bedside of a patient requiring resuscitation must wait from 10 to 80 seconds for the switchboard operator to respond to her need for help with a busy daytime switchboard. This is the very time when she must provide physiological support of the patient. She has to breathe for the patient and perform other immediately necessary duties. Communications is critical, but physiological support of the patient is even more desperate.

When the operator does respond, she often mispages the room location. Once knowing where to go, the emergency team members must then wait a lengthy period for an elevator. Elevator delays in hospitals—I am sure you have experienced these delays—can be astronomical in terms of timing for emergency mobilization.

With the hospital emergency command system under development, the nurse at the bedside picks up the telephone, dials a specific number, for example 1212. Keep in mind again, this is the very time the critical support of the patient is required and we do not want the nurse preoccupied with administrative problems in communications.

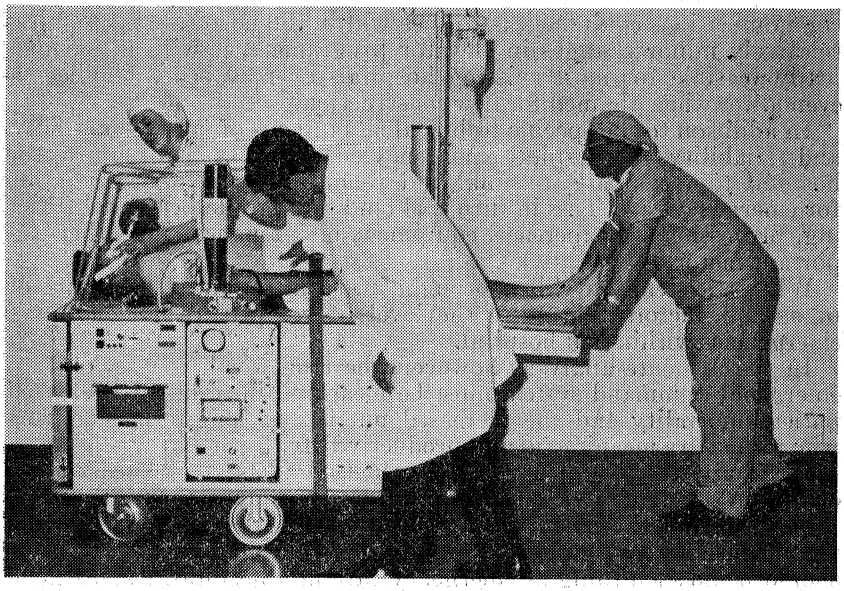
She says "Code Blue, Room 705" and hangs up. There is no switchboard operator lag period. The nurses' voice is recorded. At the same time, a series of vital telephones ring simultaneously with a very distinct ring. Vital phones might include heart station, anesthesia, and night on-call rooms. If the phone is in use, there is a priority interrupt and the message is still transmitted. The system also transmits the message over the public address system and triggers pocket page receivers. The command system also activities a special emergency cart.

This mobile emergency life support system was developed by us 3 years ago to decrease the time required for critical medical emergency procedures, to reduce the number of persons required on the team, to eliminate many common errors in technique, and because of self-contained power and oxygen to sustain the moribund patient in transit to the operating room or intensive care unit. Briefly, it reduces the time required for critical procedures tenfold and reduces the size of the team by half. It is now in general use throughout the United States, in Europe and Vietnam.

(The mobile emergency life support system illustration referred to appears on facing page.)

Dr. NOBEL. The hospital emergency command system transmits an electrical signal to this emergency cart which energizes its elapsed time meter and electronic equipment. The elapsed time meter indicates, of course, the time since the initial alerting telephone call and thus provides a continuous timing reference to the team.

How long has it been since the original event occurred, since there was transmission of the message, what time has gone by, should we



give this drug or another drug which has to be given at specific time intervals?

The electronic equipment preheats in transit to the bedside so no time is wasted with instrument warmup and stabilization. Another electrical impulse is sent to the elevator shaftway, to override the automatic elevator programer which shifts to emergency alert status. Logic circuits select the best elevator in the bank, based on proximity and other factors, send it to the floor and lock it where the emergency cart is located. The elevator unlocks only when the cart is in its cab because of an electronic command interlock between the cart and elevator. Other elevators respond to pocket size command transmitters carried at all times by emergency team members.

For emergency surgical cases brought to the accident ward, a different dialing number is used—for example, automobile accidents, poisoning cases, and so forth. Various vital telephones are used to call different categories of personnel, while the elevator goes to the appropriate floor to receive the patient.

For large multipatient accidents or disasters, the system also links to telephones outside the hospital and can thus summon physicians and supporting personnel from their homes and offices.

The separate events which take place when the hospital emergency command system is triggered by an alerting telephone call have taken some minutes to describe. They are actually simultaneous electrical events which take only several seconds. We have, in effect, substituted simple electrical circuits to provide communications and mobilization in parallel rather than relying on humans to act swiftly and consistently in series.

This is not an esoteric research project. The significance of the hospital emergency command system is simply that it meets a very real need in a very practical manner. Because it utilizes the existing tele-

communications equipment and lines within the hospital and requires relatively minor changes in elevator programers, it will be economically feasible for most existing hospitals over 30 beds. The cost is even lower when planned for new construction.

In addition to the specific technical advantages of speed, simplicity, and reliability, the hospital emergency command system requires the hospital to reevaluate, rethink, and refine its internal organization for emergency care. This in turn will tend to upgrade personnel training, professional competence, equipment maintenance, and other important factors.

When a system like this is brought into a hospital, it has a number of spinoff factors that raise the level of competence for handling emergencies within that hospital.

In the ultimate analysis, however, the true worth of the hospital emergency command system must be measured in terms of decreased patient mortality and the increased number of long-term survivors who return to a meaningful and productive life.

We shall soon begin a 2-year evaluation phase to determine the change in survival rates so that we have specific data.

We feel that the hospital emergency command system will have a significant effect on patient mortality. It is our contention that there should be no such thing as emergency care in a hospital. Emergencies within a hospital are expected and should merely evoke an effective routine response.

Senator NELSON. Thank you, Dr. Nobel.

What is the cost of installing such a system in a hospital?

Mr. CALLAHAN. Mr. Chairman, I think that I can estimate that for you.

In a hospital of 600 to 800 rooms, the cost would be about $150 a month, and for each additional alert arrangement, another $10, so that if you had two different alerting arrangements it would be around $160, and so forth.

Senator NELSON. You mean that in a hospital that has already been built with the elevators operating on their own system, this system can be brought in at a cost of $150 a month?

Dr. NOBEL. We should clarify this a bit. The communications phase can be brought in at that cost. There will be a cost, depending on the number of elevator banks used and installation costs for reprograming, in the range of $10,000.

Now, in the overview for hospital costs, $10,000 is not terribly significant for a refined emergency call system, and a monthly charge of $150 for a large medical center, which may have a telephone bill in the $20,000 range, does not appear to be very significant.

Senator NELSON. Well, so that it is clear for the record, you have certain equipment, emergency equipment, for example, that is electronically activated upon the code call of the nurse in the room in which the emergency occurs. Then when that piece of equipment is brought onto the elevator, the elevator will not move until activated by the electronic relationship between that piece of equipment and the elevator. Can you take the hospital's emergency equipment and add this telecommunications equipment to it?

Dr. NOBEL. That is correct.

Actually, the electronic interlock on the resuscitation or emergency cart is a simple add-on black box. In effect, the cart says to the elevator electronically, I am here, and the elevator responds and says, OK, we will go.

Senator NELSON. Are you saying, then, that if a hospital of 500 or 600 beds wished to install the system that you have described here, they could install the basic system for about $10,000?

Dr. NOBEL. That is correct, sir.

Senator NELSON. And then the cost of servicing or maintaining the system is about $150 a month?

Dr. NOBEL. That is correct.

Senator NELSON. How many hospitals in the country have installed this kind of a system?

Dr. NOBEL. We should tell you that the system is in development and that we are currently installing three prototype test systems for long-term evaluations. We do not feel that we will go ahead with general availability until we have specific patient mortality data that shows how justifiable the system is.

Now, looking forward, it will be a relatively short time before we have this data and we hope that the systems will be generally available throughout the country within the next year or two.

Senator NELSON. Has this equipment been tested yet in an operating hospital?

Dr. NOBEL. Not at present. We have operating laboratory models, we have a computer simulation of the system underway, but the first full scale operating system will not be operating for severa months yet.

Senator NELSON. Do I understand you to say that you are installing this system in three hospitals; pilot tests, so to speak?

Dr. NOBEL. That is correct.

Senator NELSON. Are you free to say what three hospitals they are?

Dr. NOBEL. Yes; the hospitals are all located in the Philadelphia area—Jefferson Medical College Hospital, Hahnemann Medical College Hospital, and Pennsylvania Hospital. These three hospitals were chosen because they represent a very broad spectrum of different problems in architecture, elevators, communications, and so on.

The system is quite adaptable. For example, if you have only manually operated elevators, we go right into their telephone and speak to the elevator operator who makes an appropriate response. In the older hospitals with manually operated elevators, there is no requirement for a $10,000 change in elevator programers. The cost is actually lower.

Senator NELSON. But I did understand you to say that to institute the whole system, not just the elevator part, you are talking about an investment of $10,000?

Dr. NOBEL. Assuming that we are going to use automatic elevators. If we are not going to use automatic elevators, then there is no $10,000 additional cost.

Senator NELSON. Just the $150 monthly maintenance; is that it?

Dr. NOBEL. Just the monthly cost; yes, sir.

Senator NELSON. Then how long do you expect to test this system to find out whether or not you are prepared to make it available to any hospital that wants it?

Dr. NOBEL. We will complete a preliminary evaluation within 1 year and the actual study is a 3-year one, involving installation of systems and total evaluation. But within the first year of operation, we will have a very clear idea as to how justified we are in proceeding ahead on a broad basis.

Senator NELSON. Well, what is the main factor in consideration? If you cut the time in half, that is factor enough; is it not?

Dr. NOBEL. We will do considerably better than cutting the time in half. We estimate, for example, at one of the hospitals that we can reduce mobilization time from about 9 to 1½ minutes. Now, this is certainly significant.

However, even though the hospital emergency command system is desirable in terms of its fixed organization and its routinization of response, we have to show decreased mortality rates—increased survival rates. In the ultimate analysis, this is what is important to us. These statistics take a little more time to gather.

Senator NELSON. Well, I guess the doctors would have to decide that. I would assume that if you cut the time by 7 or 8 or 9 minutes in any emergency, you are going to find that sometime you save a life. I guess I could assert that.

Dr. NOBEL. We are convinced of this, but we want to see it in numbers.

Senator NELSON. Thank you very much for your very interesting presentation. We appreciate it.

Dr. NOBEL. Thank you, Mr. Chairman.

Mr. CALLAHAN. Thank you, Dr. Nobel.

Mr. Chairman, the systems we have described so far illustrate some of the ways that modern communications can help the medical profession fight heart disease more effectively.

In New York, at the Memorial Hospital for Cancer and Allied Diseases, a relatively simple communication system permits computer planning of radiation treatment for other hospitals.

Furthering the concept of regional medical programs, Memorial Hospital, serving as one of the regional cancer centers, has already extended the benefits of its unique, highly sensitive, and accurate treatment planning facilities to two other institutions, one located in the Greater New York metropolitan area and the other in San Francisco. The hospital plans to make this program available to other hospitals nationwide.

Communication between the collaborating hospital and Memorial Hospital, which is a clinical unit of Memorial Sloan-Kettering Cancer Center, is via teletypewriter using the telephone network and a Data-Phone data set. Patient medical data will be sent to Memorial Hospital via the teletypewriter from the participating hospital, describing certain data about the patient contour, the treatment parameters such as the size of the field to be irradiated, the number of portals through which the radiation will be given, the angles at which X-rays will be

delivered, and the kind of radiation equipment for which the computation is to be made.

The data is received at Sloan-Kettering, both in printed form and recorded on punched paper tape.

Since the teletypewriter is also equipped with the Data-Phone, the verbal communications can also be used when needed. The tape is fed into the computer, which is programed to prepare a complete treatment plan. The plan is then transmitted back to the hospital via teletypewriter. Total computer time for the complete treatment plan runs between 5 and 10 minutes, according to the complexities of the computations involved.

Representatives of Memorial Hospital state that before the advent of computers, radiation treatment planning was performed to the best of the ability of the professional making the computations. However, the plans had to be much more grossly calculated, because the time required for highly refined figures would have delayed the treatment of the patient. But even with computer computation, it previously took approximately 4 days for hospitals outside of the New York area to avail themselves of this service by mailing or bringing pertinent patient data to Memorial Hospital.

The two hospitals who have already availed themselves of the program are St. Luke's Hospital in New York, and Mount Zion Hospital in San Francisco.

This program will make Memorial Hospital's advanced computerized system and technical staff available to other hospitals, avoiding costly duplication of staff and equipment. Thus Memorial Hospital, functioning as a regional cancer center, will service institutions across the country. It is planned that this service will include guiding and advising collaborating hospitals via education and staff exchange programs.

As more and more of such regional cancer centers are developed, technical information will be transmitted from one center to another, thus assuring every patient accurate quality radiation treatment whenever and wherever indicated.

The radiation center service will make possible the practical and rapid diagnosis and determination of treatment planning that is so vital to the treatment of cancer patients by radiation.

I have asked Dr. John Laughlin, Attending Physicist at Memorial Hospital for Cancer and Allied Diseases, to describe for us the kind of treatment the computer prescribed. Dr. Laughlin has been associated with Memorial Hospital for Cancer and Allied Diseases for many years. To augment his Telelecture communication, Dr. Laughlin will also use some telewriting. Telewriting with Data-Phone data communication service makes it possible for a speaker to supplement his telephone presentation with handwritten notes or drawings projected on to a screen.

(The telewriting illustration performed in New York follows:)

Mr. CALLAHAN. The notes or diagrams he makes at his study or laboratory are enlarged on the screen here as he writes. Thus, a new capability will be added to graduate study or training programs through the application of a visual dimension to basic telelecture service.

(The telewriting illustration received in the caucus room in Washington appears on facing page.)

Mr. CALLAHAN. We would like now to use both these communications media to bring you Dr. Laughlin's presentation directly from New York City.

Senator NELSON. Go ahead.

Mr. CALLAHAN. Dr. Laughlin?

STATEMENT OF DR. JOHN H. LAUGHLIN, ATTENDING PHYSICIST, MEMORIAL HOSPITAL FOR CANCER & ALLIED DISEASES, NEW YORK, N.Y.

Dr. LAUGHLIN. Yes.

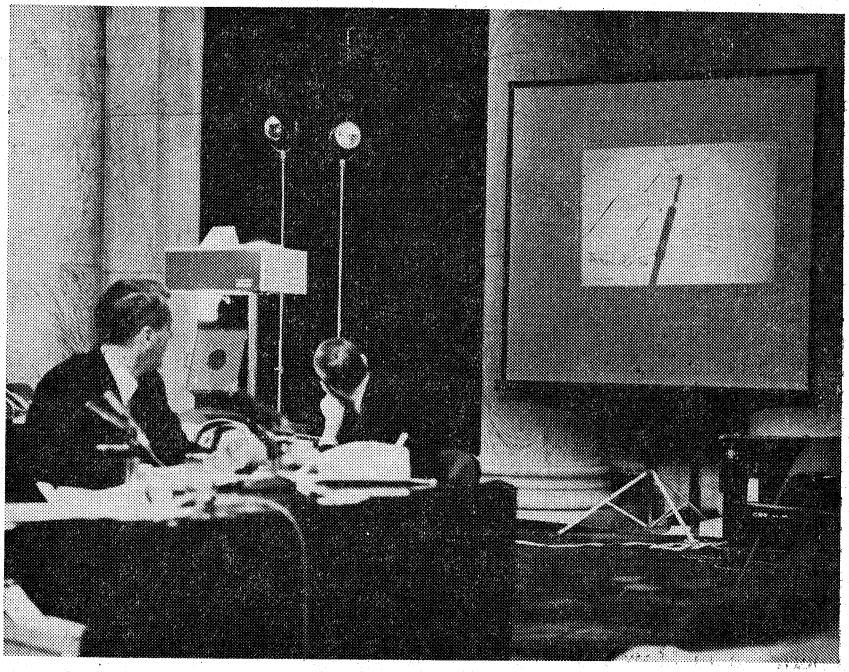
Mr. CALLAHAN. We are ready for your presentation.

Dr. LAUGHLIN. Very well.

This particular example pertains to the application of both computers as well as teletype transmission in the field of radiation therapy. One of the major problems in radiation therapy is the use of radiation sources to treat cancer lesions inside the body.

A typical external radiation source, in this particular case one of our linear accelerator X-ray machines, is used to irradiate the patient externally from outside.

Now, one of the major problems facing the radiation therapist is how to localize the radiation dose inside the lesion and decrease the



radiation damage to the surrounding healthy tissues on the way to the lesion.

In order to approach this problem comprehensively, taking into full consideration the structure of the body, it has been necessary to go to automatic computers.

The treatment planning procedure includes taking the patient's contour in relation to the size and position of the cancer and constructing dose curves which describe the extent to which the X-ray beams is attenuated as it passes through various tissues. If it is planned to direct the radiation beam from several different angles, the amount of radiation delivered to any given tissue must be calculated accordingly.

Now, another approach to the same situation, again assuming that we have a lesion in the lung, would be the actual physical implantation of radioactive sources within the patient. This would involve a surgical procedure by the radiation therapist in which radioactive needles are physically implanted in the tumor.

If this were done according to any particular pattern, a specific distribution of dose could be achieved. But just as in the previous case where external radiation was employed, it is particularly important that this patient receive the actual distribution of the radiation of dose as planned by the therapist.

These are the two methods which are generally employed, both of which require accurate computation.

We have indicated the objective of what we call realistic treatment planning. This is essentially with the necessity of taking into consideration the inhomogeneous structure of the body.

Programs have also been designed to determine at which angles to aim the beam to give the optimum treatment to the tumor and the least radiation to normal tissues. The major result of the program is a three-dimensional distribution of dose in the patient, produced by the radiation fields as specified by the therapist.

With the use of computers in the treatment planning, not only can more information be obtained in a short period of time, but the information is highly refined, so that the radiation therapist can know precisely how much radiation he will deliver to any specific area.

A major recent development has been the extension of the computerized treatment planning carried out in individual centers to affiliated hospitals through the use of special interface equipment and telephone lines. The Memorial Computerized Treatment Planning Service is a pioneer effort in this respect and has been developed to make available to other hospitals the advantages of computer facilities and the associated treatment planning staff.

The need to extend the facilities of computerized treatment planning to radiation therapists in other hospitals which have limited treatment planning facilities has long been recognized. In the past, ocassional treatment plans have been hand-carried by messenger from various other hospitals in the metropolitan area for computation at Memorial Hospital. In order to provide a more convenient and practical treatment planning service for collaborating hospitals, the present teletype-linked treatment planning service was developed and put into operation in March of 1967. The initial two collaborating hospitals were Mount Zion Tumor Institute, San Francisco, Calif., and St. Luke's Hospital, New York City, N.Y. The teletype treatment planning system was demonstrated at the American College of Radiology Computer Conference at the University of Missouri in April 1967. The input and output for treatment plans are transmitted via teletype over regular communication channels. On the average about 30 treatment plans per month are being computed by Memorial Hospital for each collaborating institution.

New programs are being continually developed, according to need. The latest programs will compute dose distributions for any number of nonconverging fields, for any number of nonconverging arc rotations, for any number of wedged fields, as well as for any combination of weighted fields of different field size. Provisions are also made to incorporate corrections for any number of inhomogeneities as well as irregularities in the patient's surface. The computer programs for internal sources are capable of producing dose distributions in any plane at any desired orientation with as many as 100 implanted sources.

Mr. CALLAHAN. Thank you, Dr. Laughlin.

Mr. Chairman, do you have a question of Dr. Laughlin?

Senator NELSON. Yes. I will have a question for you in just a moment, Doctor.

Are you still on, Doctor?

Dr. LAUGHLIN. Yes; right here.

Senator NELSON. Do I understand, then, that the radiologist can send to the computer the various computations, say, as to the size

and weight and age of the patient and the location of the carcinoma and that, then, the computer actually determines the quality of the X-radiation that will be used? That is, it decides how much, how much kilovoltage and how much milliamperage, for example, in this treatment process?

Dr. LAUGHLIN. Yes; the computer is capable of providing the optimum treatment. The way in which it is normally used, however, is that the radiologist would suggest a proposed treatment utilizing a specific radiation energy. The computer would compute this out and then the radiologist conducting the examination would say this is quite an acceptable treatment, or can you not do even better to avoid the radiation dose to a particular area. This would require a repetition of the computer analysis and would be a process of successive approximation to the optimum dose distribution.

Senator NELSON. Does the computer determine what the safety factor is and how many roentgens a patient can take over a certain period, or is that left up to the radiologist?

Dr. LAUGHLIN. That is definitely left to the radiologist. It is his business to have to determine how many roentgens of dose should be administered. But the computer can show him how that dose is going to be distributed throughout the patient's body and warn him of excessive dose level that is going to a healthy tissue region.

Senator NELSON. Then the computer does have to have among its statistics all the factors about the size of that patient, obviously?

Dr. LAUGHLIN. Yes. All the data on the anatomy of the patient, both externally and internally, in the regions which will be exposed to radiation will be vital.

Senator NELSON. In summary, what is the main value of using this computer system rather than just having the roentgenologist make all these calculations himself?

Is it a matter of time or is it a matter of time and accuracy?

Dr. LAUGHLIN. It is a matter of both. As a matter of actual practice, if the roentgenologist had to do all these calculations, he ordinarily simply would not have time to do them and the treatment of the patient in that case would have to rely somewhat on judgment. With the use of these kinds of facilities, he is able to give to all patients a very comprehensive type of analysis which would be prohibitive timewise.

Senator NELSON. Thank you very much, Doctor. It was a very informative presentation. The committee appreciates very much your giving so generously of your time.

Dr. LAUGHLIN. Thank you.

Senator NELSON. Did you have any other questions?

Mr. CALLAHAN. No, thank you, Mr. Chairman, and thank you very much, Dr. Laughlin.

Dr. LAUGHLIN. Thank you.

Mr. CALLAHAN. Mr. Chairman, we will now move to discussion of medical information collection systems, which I have listed as item No. 9 on the agenda.

The communication system I will now report on is another unique and dramatic approach to collecting patient medical data. The tradi-

tional method of taking and recording medical histories and the calculation of test reports involves considerable time for the physician.

As an example, a physician investigating the symptoms of allergy may have to ask the patient several hundred questions and devote several hours of his time. A computer technique now under development at the University of Wisconsin Medical School collects medical history information directly from the patient. It is so simple in operation that it can be used by the patients themselves.

A teletypewriter keyboard provides direct input to the computer. As used at Wisconsin in the investigation of symptoms of allergy, the computer questionnaire has been designed to imitate the normal physician-patient relationship as closely as possible. Simple questions are presented to the patient either on a cathode ray tube similar to a TV screen or a teletypewriter.

A typical question would be, "Have you ever had an allergic reaction to penicillin?" to which the patient replies "Yes," "No," "I do not know," or "I do not understand the question," by simply pressing one of four appropriate keys. The choice of questions presented and the order of their presentation is controlled by the patient's response.

A "Yes" response to a general question is followed by a series of specific qualifying questions. A "No" response results in the skipping of such qualifying questions and the presentation of another general question.

When the answers to questions are not known or not understood, these questions are clarified and explained with varying and simplified technology. The minimum number of questions to be answered by a patient who has no allergy and has taken none of the potentially allergenic drugs included in the program is 29. The maximum number of questions that can be answered by any patient is 320, but there are more than 500 questions in the program.

A printed summary is generated by the computer in each case and the response to every question is recorded on tape and stored in the computer.

At this point, with the assistance of my associate, Mr. Murray, we will call the computer and set it up for a demonstration which will take 2 or 3 minutes.

Senator NELSON. I understand, then, that the computer bank, for example, contains a series of questions on allergies. A patient can sit down in front of this machine and the computer can ask the questions without the necessity of the doctor's presence. The computer will, in a very comprehensive fashion, explore this particular patient relationship to any allergy problem that has been programed and the doctor can then use this information in place of an extensive consultation interview with the patient. Is that correct?

Mr. CALLAHAN. Yes, sir, and after the demonstration Dr. Meyer, who is here with us from the University of Wisconsin, will also discuss in some detail more about the medical aspects of this.

Actually, the best way to get an appreciation of the relationship that is established between patient and computer is for someone with no previous experience to play the role of the patient.

Mr. Chairman, I wonder if you would care to be interviewed for allergy symptons?

Senator NELSON. We tried it for 5 minutes yesterday to be sure I was smart enough to operate it.

Mr. CALLAHAN. OK.

Mr. Murray, is the computer ready to talk with our patient?

Mr. MURRAY. In just a few seconds.

Mr. CALLAHAN. Just to remind you again, Mr. Chairman, in order to respond with a yes to the computer, you simply strike the No. 1 key. To respond no, strike No. 2. If you do not know the answer to the question presented, strike No. 3. If you do not understand the question, strike No. 4.

I will turn it over to you, Mr. Murray.

Senator NELSON. The teletypewriter has given me some instructions. It has just typed out, "The demonstration you are about to see will show how a physician can use a computer to assist him in the gathering of medical data. You will be shown how a computer many miles away can remotely take the medical history of the patient. This is typical of the on-line computer medicine research at the University of Wisconsin Department of Medicine and Clinical Laboratories at Madison, Wis.

"For complete program, push button 1 and return. For medical questions only, push No. 2 and return. For instructions, push No. 3 and return."

I pushed No. 2 and return for the next question.

The question asked by the computer is:

"Are you a physician specializing primarily in the treatment of patients with allergies?"

I will fib to it a little and say "Yes."

So here are the questions that are being submitted now to the patient of a physician who primarily treats allergies. The question to the patient is, "Have you ever had asthma as defined by intermittent episodes of wheezing and dyspnea?"

I will answer that "Yes."

The next question is, "Have you ever had allergic rhinitis as defined by intermittent episodes of runny or stuffy nose and sneezing?"

I can push "Yes" or "No" or I can push button "I do not understand," or "I do not know."

I will continue with the yes and say "Yes" to it.

Next question is, "Have you ever been married?"

I had better say "Yes" to that.

Next question is, "Have you ever been married to a spouse with asthma, allergic rhinitis, or exzema?"

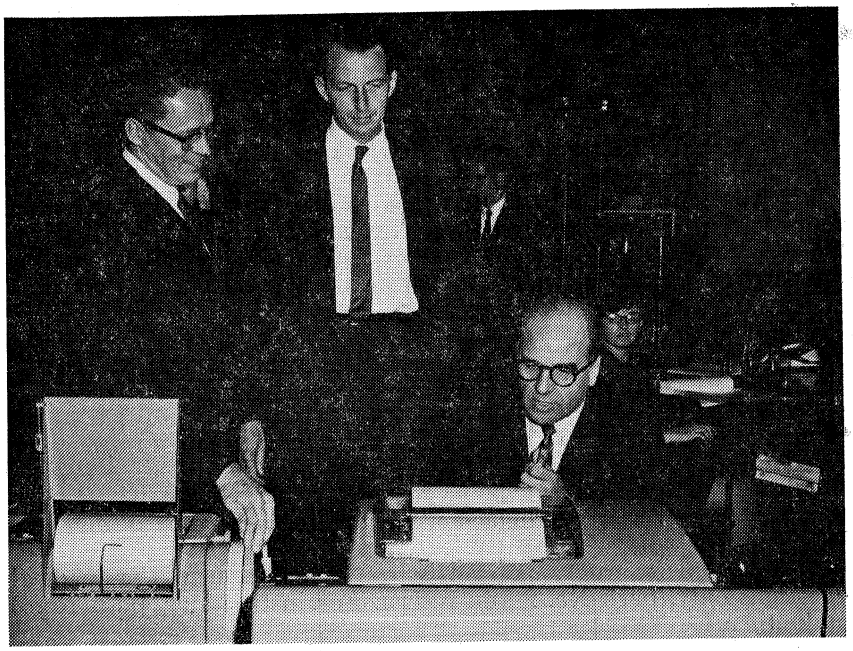
I will answer "No."

What I assume is that this will go through a series of logical questions based upon my answers until it has exhausted all of the information put into the bank.

Is that right, Doctor?

Dr. MEYER. Yes.

(The illustration and printout referred to follow:)



NOW IS THE TIME NO NJCJCJCJ
WTCO ON-LINE

WTCO ON-LINE
ON AT 14:17 CH-E MN 10/30/7 TTY 13

USER NUMBER—E24400
SYSTEM—BASIC
NEW OR OLD—OLD
OLD PROBLEM NAME—PATINS
WAIT.

READY.

RUN
WAIT

PATINS 14:18 CH-E MI 10/30/7

THE DEMONSTRATION YOU ARE ABOUT TO SEE WILL SHOW
HOW A PHYSICIAN CAN USE A COMPUTER TO ASSIST HIM
IN THE GATHERING OF MEDICAL DATA.

YOU WILL BE SHOWN HOW A COMPUTER MANY MILES AWAY CAN
REMOTELY TAKE THE MEDICAL HISTORY OF A PATIENT.
THIS IS TYPICAL OF THE ON LINE COMPUTER MEDICINE
RESEARCH AT
THE UNIVERSITY OF WISCONSIN DEPARTMENT OF MEDICINE
AND CLINICAL
LABORATORIES AT MADISON, WISCONSIN.

FOR COMPLETE PROGRAM—[PUSH 1 AND RETURN]
FOR MEDICAL QUESTIONS ONLY—[PUSH NUMBER 2 AND RETURN]
FOR INSTRUCTIONS—[PUSH NUMBER 3 AND RETURN]
? 3

NUMBER 1=YES.
NUMBER 2=NO.
NUMBER 3=DON'T KNOW.
NUMBER 4=DON'T UNDERSTAND THE QUESTION.
PUSH NUMBER 1 THEN RETURN BUTTON TO SAY YES. TRY IT.
? 1
GOOD—HAVE YOU UNDERSTOOD THUS FAR IF SO SAY
YES BY PUSHING 1 THEN RETURN. IF NOT PUSH 2 THEN RETURN.
? 1
1
GOOD YOU ARE DOING WELL, ANSWERS ARE MADE BY PUSHING
NUMBERED KEYS 1, 2, 3 OR 4. ARE YOU HAVING ANY TROUBLE
? 2
I'M GLAD. IF YOU DON'T UNDERSTAND A QUESTION YOU CAN
PUSH NUMBER 4 AND RETURN BUTTON. TRY IT.
? 4
WHEN YOU ARE READY TO BEGIN THE MEDICAL QUESTIONS,
PUSH THE NUMBER 1 AND THE RETURN BUTTON.
? 1
ARE YOU A PHYSICIAN SPECIALIZING PRIMARILY IN THE
TREATMENT OF PATIENTS WITH ALLERGIES
? 1
HAVE YOU EVER HAD ASTHMA AS DEFINED BY INTERMITTENT
EPISODES OF WHEEZING AND DYSPNEA
? 1
HAVE YOU EVER HAD ALLERGIC RHINITIS AS DEFINED BY
INTERMITTENT EPISODES OF RUNNING OR STUFFY NOSE
AND SNEEZING
? 1
HAVE YOU EVER BEEN MARRIED
? 1
HAVE YOU EVER BEEN MARRIED TO A SPOUSE WITH ASTHMA,
ALLERGIC RHINITIS OR EXZEMA
? 1
WAS THIS ASTHMA
? 2
WAS THIS ALLERGIC RHINITIS
? 1
DID ANYONE LIVING IN YOUR HOME WHILE YOU WERE GROWING
UP HAVE ASTHMA, ALLERGIC RHINITIS, OR EXZEMA
? 1
WAS IT ASTHMA
? 2
WAS IT ALLERGIC RHINITIS
? 5
WAS IT EXZEMA
? 8
HAVE EITHER OF YOUR PARENTS HAD ASTHMA, ALLERGIC
RHINITIS OR EXZEMA
?

Senator NELSON. Is Dr. Meyer now going to explain how this operation works?

Mr. CALLAHAN. Yes, sir. Dr. Meyer, would you please discuss some of the medical aspects of this system of Dr. Slack's and any evaluatory comments about it you want to make?

Senator NELSON. I want to say that I appreciate very much Dr. Meyer's willingness to come here today and present this testimony for the committee.

STATEMENT OF DR. THOMAS C. MEYER, ASSOCIATE DEAN, UNIVERSITY OF WISCONSIN MEDICAL CENTER, MADISON, WIS.

Dr. MEYER. Thank you, Mr. Chairman.

You have heard of some of the uses to which computers are being put in medicine, and in fact, there are so many that this could be a subject of a hearing in itself.

In Wisconsin, we have been interested in the use of computers in what we believe to be two critical areas of the health care process. We believe that significant practical improvement in the process of health care delivery will result.

You have seen something of the use of the computer in taking a history and I will not go further into it. There are many benefits from this. Taking of a history is critical in the evaluation of a patient, but it is time consuming. While it is time consuming, it may be incomplete; therefore, something may be missed which is vital in the history and therefore to the diagnosis and management of the patient. There is lack of standardization by which histories are taken from interviewer to interviewer. Depending upon who is taking a history it may come out in a different way, although the same information may be there. Therefore, it is very difficult to abstract that history from the patient's chart.

You know well of the traditional illegibility of physicians' handwriting. The computer, once it has taken the history, prints it out in very legible form.

There are other advantages that I do not think really one needs to go into at the moment.

Dr. Warner Slack initiated this project of testing whether or not a reasonable history could be obtained from a patient by a computer and plans to do this routinely over the next several years.

The history is taken from the patient. It is printed out in a recognized form to the physician who can then utilize what is in the history. He knows what questions have been negatively answered. He knows what have been positively answered. His time in taking that history has been significantly cut down.

Dr. Slack has developed history programs for gynecological histories, for neurology histories, endocrinology histories, psychiatric history, gastroenterology, and currently pediatric histories are being developed.

The teletypewriter extends the programs which are currently in Madison available only to patients at the University Hospital in Madison. This process can be taken to wherever one plans to take it, utilizing the teletypewriter. This can then go from a doctor's hospital office or a remote hospital to the computer and can be done relatively simply.

Senator NELSON. May I ask a question at this stage?

The doctor receives the typewritten result of the interview between the patient and the computer?

Dr. MEYER. Yes.

Senator NELSON. On a sheet just like the one there, I assume?

Dr. MEYER. Yes, he gets it in a digested form. The computer will ask all the questions and then it will print out the history in a digested form so that the physician does not have to go through all this.

Senator NELSON. So the doctor will not read it in the form of 320 questions and answers; is that right?

Dr. MEYER. No, sir; he will get the major portions of the history, the significant portions where that here been a positive response. He will get that; he will get the positively negative, if I could put it that way, points in the history. If he requests from the computer whether or not it has asked other questions, he can find out. The computer will also give the response to the particular question that the physician happens to be interested in, and that is not printed out in his printout.

Senator NELSON. Then how much reliance does he put on it? By that I mean does he read the history and then decide from reading of it whether or not he would like personally to explore some aspects of the various questions or answers in more detail? Or can you make this sufficiently sophisticated so that there would not be much point in the doctor going any further?

Dr. MEYER. I think that physicians will always ask some questions relating to the history. I think that the interview, and we teach in medical school that the history contributes significantly, probably 75 percent toward the diagnosis of the condition.

From the information obtained from the history, the physician is directed to what type of examination he should do, what type of tests he should do in establishing the diagnosis for the patient.

I think that physicians will be reluctant to not do anything in the way of questioning. I think that their questions will be very much more directed, having obtained this backlog of history which they must have before they can proceed with their diagnostic process.

Senator NELSON. I notice that on the machine the minimum number of questions that could be answered is 29, assuming, I suppose, that every answer was negative as to any allergic or complication at all.

Dr. MEYER. Yes.

Senator NELSON. The number of questions in the machine is 500 and the maximum that can be answered is 320—is that what Mr. Callahan said?

Dr. MEYER. Yes.

Senator NELSON. If a patient answered 320, what is your rough estimate of how much time it would have taken if a physician had followed that same procedure himself?

Dr. MEYER. I would think it would be maybe an hour or an hour and a half, 2 hours. I really do not know. It depends a great deal on the ability of immediate recall of the patient. You know perfectly well that if somebody says to you, is there any diabetes in your family, you have to then think whether Great Aunt Maude had diabetes or whatever. It is dependent on the intelligence of the patient, and on his ability to recall immediately the facts which you require.

Senator NELSON. May I ask this—have you, in experimenting with this, taken some real situations in which you had an intern or doctor

interview or take a history of a patient, and then have a patient do the same on the computer to see what kind of time-savings you would be making for the physician?

Dr. MEYER. This has been done and I wish I could give you the answer. I cannot give it to you with any assurance. There is a considerable time saving to the doctor, but I cannot give it to you in minutes or seconds or hours.

What I can tell you is that Dr. Slack is always very delighted when his computer picks up facts that the physicians, and usually he is testing them against the medical student, the intern, and the resident and the staff man. He will take everything they have obtained in interviewing the patient and he will match it up against what his computer gets from the patient, and he is always very delighted when the computer picks up things that the physicians do not pick up.

To my knowledge, he has not yet got to the stage, or he has not found a significant number of questions that the physicians have managed to pick up that the computer has not picked up.

Now, this is in a development phase and when a question comes up, he can obviously have quickly put it into his computer program.

Senator NELSON. May I suggest at this point, that if you wish to extemporize on anything to shorten the presentation, I would be pleased. We will print in the record the complete presentation of your prepared text. So if you can summarize it so it will be available for me and for the committee at the appropriate time, it will shorten the time of presentation.[2]

I do not know how soon the Senate may be taking some action, but I would suggest we recess for 35 minutes, until 1 o'clock, unless somebody has some time deadline or an airplane schedule they have to meet.

We will resume at 1 o'clock.

(Whereupon, at 12:25 p.m., the subcommittee recessed, to reconvene at 1 p.m. the same day.)

AFTERNOON SESSION

Senator NELSON. The committee will resume its hearings.

I have been told that in the rear of the room they have not been able to hear very well this morning. I think it is because we have not been speaking directly into the microphone. You have to be 5 or 6 inches away speaking straight into it.

I understand that you are going to have a demonstration that involves Dr. Hugo Pribor, chief pathologist at the Institute of Laboratory Medicine at Perth Amboy General Hospital, New Jersey. Is that correct?

Mr. CALLAHAN. Yes, Mr. Chairman.

Senator NELSON. Congressman Edward Patten is here. Would you like to sit up here, Congressman?

Representative PATTEN. Thank you, but I will be leaving soon.

Senator NELSON. Nice to have you come over. You are from Perth Amboy?

Representative PATTEN. Yes.

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[2] See complete prepared statement of Dr. Meyer, p. 1204, infra.

Senator NELSON. I knew that was a good city.
Representative PATTEN. We have a lot of Nelsons there.
Senator NELSON. All right Mr. Callahan, go ahead.
Mr. CALLAHAN. Thank you.

Hospital laboratory tests are becoming increasingly complex and difficult to perform. In many hospitals there is an insufficient number of trained or experienced personnel to perform the various lab analyses. Also, smaller medical facilities do not have the automated analytical instruments to perform these tasks. The combination of communications and computers is helping to solve this problem at Perth Amboy General Hospital in New Jersey. A group of pathologists and other laboratory specialists there developed a clinical laboratory automation system which employs a computer to handle the large volumes of data associated with a hospital laboratory. The computer can, as with the other systems we have demonstrated, transmit information by telephone lines. By placing a call to any location equipped with Data-Phone service and a teletypewriter, the computer can print out a variety of medical data reports.

As Dr. Hugo C. Pribor, director of the Institute of Laboratory Medicine of Perth Amboy General Hospital, will explain in a moment, this communications arrangement makes it possible to deliver data from the analysis of multiphasic screening tests and accumulated patient records direct to other hospitals, nursing homes, or even medical departments of corporations. Dr. Pribor's presentation will show that any medical organization able to deliver patient specimens for analysis in a reasonable time could avail themselves of this service and enjoy the advantages of the most up-to-date laboratory facilities and almost instant access to patient medical records.

Dr. Pribor is on Telelecture now speaking from Perth Amboy and at the conclusion of his remarks we will have an actual demonstration of this system with the data being sent to the teletypewriter here in the caucus room.

Dr. Pribor.

STATEMENT OF HUGO C. PRIBOR, M.D., PH. D., DIRECTOR, INSTITUTE OF LABORATORY MEDICINE, PERTH AMBOY GENERAL HOSPITAL, PERTH AMBOY, N.J.

Dr. PRIBOR. Gentlemen, it is a pleasure to brief a Senate committee on our work in applying data processing to the improvement of health care. Last year, we described to the Subcommittee on Health of the Elderly our plans for setting up a multiphasic screening program for disease detection at this hospital. I have taken the liberty of providing each of you with a copy of our testimony.

The activities I will outline represent a team effort. The team consists of our medical staff, Dr. Samuel Breslow, president, the hospital director Mr. Robert Hoyt, our governing board, and the laboratory specialists outlined in this slide. We have had good consultative support from Professors Welkowitz and Maloney in biomedical engineering at Rutgers, the State University of New Jersey. Through joint

activities we have made considerable progress in developing a small computer system to be used in the hospital laboratories.

We certainly agree that "research is good, but results are better." Those of us who minister to the ill have always looked for ways to apply the products of basic research to patient care. Some of the greatest recent advances have been made in the area of chemistry and biology of disease processes. Through testing procedures, the clinical laboratory can give physicians information which help them apply these newer medical developments to the care of their patients.

For the most part our activities have centered on providing physicians with more and higher quality data. One simple and inexpensive way is to perform a battery of "screening" tests on every patient as soon after admission as possible. Admitted patients come to an admission lounge where a chart is generated, physical measurements are taken, and blood specimens are drawn by a technologist. Then the patient proceeds through X-ray and EKG to the ward. Through the use of automated data processing, results of tests on specimens collected in early afternoon or evening are reported on the patient's chart by 11 p.m. the same day. This could just as easily be reported to any neighboring hospital by Data-Phone.

There are 12 chemical tests that comprise our basic "screening" program. In addition to this, a complete blood count, a test for syphilis, and a urinalysis are done on all adult patients. If patients are scheduled for surgery, a bleeding time, a partial thromboplastin time, and a tourniquet test are performed to rule out any bleeding tendency.

This encompasses our multiphasic screening program on inpatients. Often data is available to the physican by the time he sees his patient for the first time in the hospital. This eliminates a great deal of the piecemeal collection of data that usually goes on in hospitals and often gives only a piecemeal picture of the patient's condition. One recent report, in fact, shows that one out of 14 patients who undergo a battery of screening tests such as ours revealed a condition which would not otherwise have been diagnosed. So you see, biochemical screeening can establish a diagnosis more rapidly in order to help the physician evaluate his patient more accurately. We hope that, as a result, this effort will shorten the patient's stay in the hospital. It is quite possible that application of this principle on a nationwide basis could lead to more efficient utilization of already overcrowded hospital facilities.

In order to gather this laboratory data in our hospital, we have introduced a number of automated analytical instruments. The instrument you see in this slide simultaneously performs 12 chemical tests on a patient's serum. Other pieces of automated apparatus do the hematology testing. Many laboratories throughout the country are using automated equipment of this type right now and there is really nothing unique about it. What is unique about our system, however, is the fact that we have linked these instruments directly to a computer.

(The illustration referred to follows:)

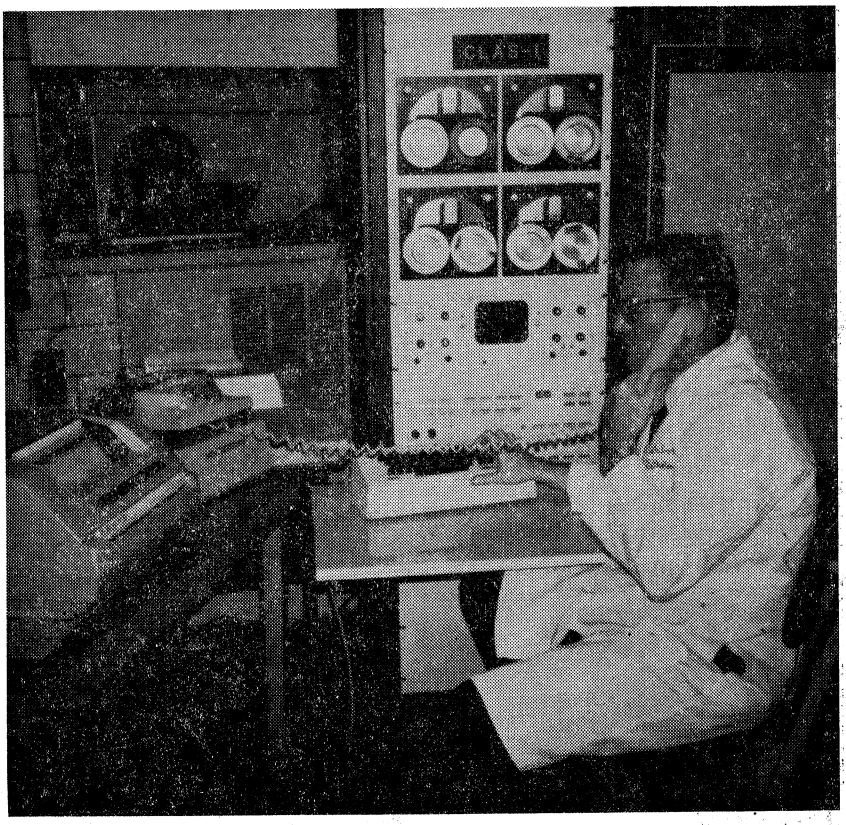
Dr. PRIBOR. Why a computer? The data gathered by newer analytical instruments is quite voluminous. Operating manually, medical technologists would have to spend increasing amounts of their time just handling data, and if we generate more and more data we would simply overload them.

Here is the computer we are discussing. Actually it has many of the desirable features that are found in the laboratory instrument computer.

(The illustration referred to appears on next page.)

Dr. PRIBOR. Dr. George Williams, Chief of the Clinical Pathology Department of the National Institutes of Health, in a recent talk said, and I quote:

> Development and field evaluation of modular automated laboratory data processing systems is essential to permit adaptation to both small hospitals and large centralized laboratories. Two types of systems are minimal, one for the special purpose of hospital patient care, and the other for multiphasic diagnostic or screening use.



We believe that our system precisely fulfills the first type of system Dr. Williams calls for and will be widely applicable in hospital laboratories throughout the country.

The memory unit in our computer is small, but the four tapes can store tremendous amounts of information and retrieve it rapidly. For example, one small tape handles all the laboratory information on all the patients in the hospital.

Another feature of our system is that any of our laboratory personnel can operate this computer. They converse with it through a standard keyboard entry device and a small television display screen. With only a few minutes' training the average person can learn to operate this computer. Much like a teaching machine, the computer guides the operator through the data processing sequence.

Our computer contains four small tapes, a cathode ray tube, the core memory, and the printers. This allows us to perform all routine data processing that was formerly done manually in the laboratory. For instance, the computer tells technologists what patients must have blood work. At the same time, it generates labels for technologists to place on specimen tubes. The computer also generates laboratory work lists and reports for the patient's chart. This is the type of clerical function that is normally expected of a computer, but of a large com-

puter. To achieve this with a computer this small and inexpensive is highly significant in the economics of hospital operation and disease detection.

In addition to clerical work, there are 12 analog input lines that reach from the computer directly to the automated analytical equipment. While it processes other data as previously described, the computer actually takes readings directly from the various pieces of analytical equipment, interprets these readings, calculates the values and records these values as tests results in patient files stored on magnetic tape. This portion of the computer activity we call "on line" operation.

A display on the video screen allows us to select which test the computer should perform. By depressing the E key, for instance, an electrophoresis program is called into the computer. Briefly to explain, Senators, the electrophoresis test represents the separation of some proteins in the serum. This test can detect disease such as cirrhosis, some cancers and other diseases. A variation of this test can be helpful in early detection of heart damage. A display on the screen shows the actual electrophoretic pattern as it would show on the computer screen. As the next step, I instruct the computer to analyze the pattern, give certain qualitative information and print out a complete report. To give you a firsthand look at this test report, later I will generate a report in the caucus room on the teletypewriter via the Data-Phone.

A routine physician's report formerly took at least 14 different slide rule calculations by a medical technologist, the time of the secretary to type it, and a considerable amount of time for the pathologist to review the pattern and arrive at some sort of diagnostic statement. We have programed our computer to do all of this including differential diagnosis. This computer will "diagnose" by matching the pattern for the present specimen against standard patterns programed into the memory. Reports are reviewed by the pathologist for validity and sent to the wards for placement on the patients' charts. Of course, you recognize that one could generate these reports on the hospital wards by the telephone lines as well as anywhere else in the world.

If we have requests for laboratory tests on a given day, we do these tests, and the computer puts information in the patient's file. When it is time to generate reports we add this data to all previous data on the patient, and prepare a new cumulative report. Patient information is provided on the heading and the test groups. We print out the normal values for each of the test procedures. We obtained these normal values in our own laboratory. Values are arranged in 12 different categories of sex and age. By doing this, every patient's test values can be compared against normal values for his sex and age. Senators, a 55-year-old male doesn't look like a 20-year-old student nurse. Why should we expect his blood chemistry values to be the same?

A program written exclusively by our team is for retrieval of data from our surgical pathology files. Several similar reports have been printed there previously and are available for examination. The output you will see is real data although we have deleted every other character to obscure the patient's name for this demonstration.

We are beginning to offer this type of data retrieval to various pathology and hospital laboratories. Soon we will handle the surgical

pathology data from the Albert Einstein Medical School in New York City in a demonstrating project with Dr. Maeir. He will send us his data. We will enter it in the computer. If he desires a particular type of retrieval, he calls us and we print out on a teletypewriter in his department.

We have also programed a large computer at Rutgers University for retrieval of microbiology data. One result of this is a periodic report to our staff physicians correlating bacteria type, body site, and sensitivity of these bacteria to various antibiotic drugs. Such a report can help a physician select the most effective antibiotic to use in treating his patient even before the laboratory has positively identified the specific bacteria. Also underway under contract with the U.S. Public Health Service is a project to automate and computerize the screening and diagnosis of cervical Papanicolau preparations for the detection of cancer in women.

The community hospital and its medical staff will remain the principal agents for delivering health services for the care of the ill and for the preservation of the health of the well. Multiphasic health screening will become an important adjunct to community health services. Under our direction this hospital is establishing a multiphasic screening clinic in this vacant supermarket near the hospital. This will require the development of a considerable amount of automation and data processing capability coupled with the careful study of the logistics of handling large numbers of people. It is possible that such a clinic could become an important center for servicing not only this hospital but also several neighboring hospitals. We can readily see how remote data input and output directly becomes an important function of this type of operation.

Now for those of you who are interested we will begin to print out various report forms on your teletypewriter in the Senate caucus room. While these reports are being generated, I would be glad to answer any questions you might have.

Mr. CALLAHAN. Thank you, Dr. Pribor. We will pass out the copies of the reports that you sent yesterday.

Mr. Chairman, that concludes Dr. Pribor's remarks.

Senator NELSON. I want to thank Dr. Pribor for a very fine contribution and for taking the time to make this presentation to the committee.

Mr. CALLAHAN. Thank you, Dr. Pribor, and goodby.

Dr. PRIBOR. Goodby, and thank you very much.

Mr. CALLAHAN. As has been demonstrated here this morning, Telelecture enables a group or groups to discuss important subjects with specialists in their particular fields, using telephone loudspeaker equipment. The lecturer may speak to one audience or several, even thousands of miles apart. Communication is two way, so listeners may question the speaker, while he in turn directs his presentation to the interests and responses of his audiences. The discussion need not be confined to one specialist only since panel participation can readily be arranged for several speakers, who may be in different parts of the country—or the world.

The Upstate Medical Center, Syracuse, N.Y., is typical of a number of institutions using the medium of Telelecture in continuing

medical education. Richard H. Lyons, M.D., director of the central New York regional medical program states:

> One of the biggest problems in conducting a regional medical program is in the communications between hospitals in the region. * * * Most doctors are unaware of what other community hospitals have to offer in the way of facilities and talent. Ideally, if all hospitals could be interconnected, gaps would be greatly reduced so that consultations between doctors could be expedited as well as the continuing education of physicians, laboratory personnel, nurses and others.

With this objective and to make the best medical resources available to other hospitals in the region, Dr. Lyons established a multipoint telephone conference service interconnecting the Upstate Medical Center with 13 other hospitals within the region. This arrangement permits doctors in Syracuse to give lectures to groups assembled at the participating hospitals. The system is used between 6 and 13 hours per day and telephone conferences are conducted 6 days a week.

The University of Wisconsin Medical Center is also making wide use of Telelecture to some 60 hospital locations across the State. The university is also pioneering in another program of continuing medical education which deserves comment. A Wisconsin physician, confronted late at night with a problem in treating acute meningitis, needs only to reach for a telephone to obtain expert advice. The same is true for the Wisconsin physician who would like to review basic information on the diagnosis and treatment of moles and melanoma. Information on these and 86 other medical subjects are available 24 hours a day through a unique service provided by the university medical center.

By dialing a special telephone number, the physician may listen to tape-recorded lectures prepared by members of the medical school's faculty or the hospital's staff. The lectures average 5 minutes in length, and if the recorded lecture does not provide the specific information sought by the physician, he may contact the lecturer directly, because each tape is concluded with the lecturer's telephone number.

Any new developments in the medical field can be directly taped and immediately made available through this program.

We would like to make a demonstration call to the tape library at the university now and after we hear how it sounds to the local physician, we will ask Dr. Meyer who has been closely associated with both the Telelecture and the tape library to comment on the effectiveness of these programs.

Senator NELSON. Is that call going to be made now?

Mr. CALLAHAN. Yes.

(Whereupon the demonstration described by Mr. Callahan was made for the subcommittee.)

Mr. CALLAHAN. In the interest of time, if it pleases you, we will cut off the tape and ask Dr. Meyer to continue.

Senator NELSON. As I understand, there are some 88 lectures on specific subjects which are available if a physician in Wisconsin makes the telephone call to the university hospital; is that correct?

Dr. MEYER. Any physician throughout the country can call in to this and exhibit 2 in the exhibits I have given you, gives an idea of the scope of the tapes that we now have available. There are now some 170-odd tapes that will become available actually in the middle of November.

Senator NELSON. 170?

Dr. MEYER. Yes, sir.

Senator NELSON. I notice on the brochure—exhibit 2—that is issued by the university, it says "Toll-free medical lectures." Does that mean the cost of the call is free?

Dr. MEYER. It is free in Wisconsin. This was funded under the regional medical program. This is identified there and a physician calling in from anywhere in Wisconsin will get these lectures without cost of the telephone call to himself.

Senator NELSON. On the program, the cost of phoning of this program to make these lectures available, who paid for that?

Dr. MEYER. This was under agreement from the regional medical program in Wisconsin under Public Law 89–239.

Senator NELSON. What is the frequency of the calls that you are now getting?

Dr. MEYER. Currently over the first year of use of this library, there are on an average five calls a day. I would like to add to this that the funds that we had, when we initially started this, precluded us doing any more publicity than one brochure which was sent to each physician in Wisconsin in August 1966. The American Telephone & Telegraph exhibit has been carrying it around the country as part of the Bell seminars in Chicago and New York, and in actual fact, they have been doing more publicity for it than we have been able to do for lack of funds.

Senator NELSON. Are the county medical societies in Wisconsin——

Dr. MEYER. They are aware of it. The initial announcement of it went out throughout the State and county medical societies.

Senator NELSON. How long has this program been in effect?

Dr. MEYER. Since April 1966. This brochure, the doctors in Wisconsin do not have it at the moment. They have the old one which was the one that we issued in August 1966.

Senator NELSON. Is the frequency of use increasing?

Dr. MEYER. No; at the moment it is really fairly static. It has remained at about five. For 4 or 6 weeks after they had printed this initial brochure, the calls went up to 10 or 12 a day, then they gradually dropped off and one's feeling is that this was just our lack of publicity of the service.

Senator NELSON. Do you anticipate that once you have broadened your list of lectures to cover a much larger number of medical problems, the frequency of use will increase?

Dr. MEYER. Yes; we do. We do feel that once people have gotten to know about it and have an opportunity to utilize it, they would utilize it more and more as a storage mechanism for information that they can get instantaneously; that they do not have to memorize or that they can get up-to-date or authoritative information instantaneously. We see a number of applications for this which we have not utilized as yet, but I think it is merely a matter of time before this is done.

Senator NELSON. Since this subcommittee is particularly interested in the question of drugs, will you at some time comment at least briefly on the question of whether or not you feel that there is readily available quickly reliable, authoritative information for physicians on drugs and reactions to drugs and whether or not such a system of

disseminating information to physicians would be a valuable one in the drug field?

Dr. MEYER. We do feel that this has a great deal of flexibility and we could put into it a tremendous amount of information which would be potentially of a great deal of use to physicians in the State. It is a matter of finding the right people to make the correct recordings of the subjects in which they are particularly interested. We do have problems trying to persuade people to try to condense down the information that they are used to giving in 30 minutes to 5 minutes, but this has been, and is being, overcome. I can see no good reason that we couldn't start a drug information service by which a physician encountering a new drug for the first time can call into the library and request information about that drug, whether it be 2 a.m. or during working hours. The drawback of the library is that it is the physician who has got to initiate the calls. We can bombard him with information about it, that it is available, that it is a free service, but unless he puts in the telephone call we are unable to get to him with whatever message he happens to want. Essentially it was designed to make available information to people as they required it—educationally this is sound, that you teach a child what it wants when it asks. You teach anybody, when they ask and in their most receptive phase, to absorb that information. This was the idea in the background with this library.

Senator NELSON. Could you give an example of how this system might be used to inform a doctor about a drug?

Dr. MEYER. What I would like to do is to obtain from the recognized—probably university-based clinical pharmacologist their evaluation of drugs as they come on the market. When a doctor is approached by possibly a pharmaceutical representative concerning a particular drug, either at the time or immediately after the pharmaceutical representative has discussed it with him, he can then call in and ascertain the academic and practical view of that drug which has been detailed to him. Again, it is a matter of how we organize it—that it is merely a matter of getting it organized, that this could very well be put into effect within—we can put a tape into a library within a week of the person saying he will make the tape. If he says "I will make the tape tonight," we can put the tape in the library tomorrow.

Senator NELSON. Supposing the physician is going to prescribe a drug for a patient and he wanted to be certain that a patient who had, say, diabetes or some other disease, would not get a bad reaction to that drug, could he pick up the phone and find out whether this patient should or should not take the drug?

Dr. MEYER. This is what the clinical pharmacologist would put into the tape when he was asked to evaluate the drug. The clinical pharmacologist will say, "This is the action of the drug, this is what it will do, this is what it will not do, and these are the side effects; these are the toxic effects and these are the potentially extremely dangerous effects of the drug," and, therefore, he would say that your patient—or if you are going to give this drug to this patient it should not be given in the presence of diabetes because it will aggravate the diabetes and this would be the type of information that the physician wants.

If I could give you a parallel. One of the physicians who called into the library had a young woman who had cancer of the breast with multiple secondary cancers all around throughout her body. This physician wanted to know what the current status of the taking out of the adrenal glands was in the treatment of widely diffused cancer of the breast. This was his only question. One of the tapes that is in the library discusses the management of what is called secondary carcinomatosis, which is widespread cancer.

The man who made the tape made the specific comment that adrenalectomy, or the taking out of the adrenals was no longer acceptable treatment. This is all that doctor wanted to know from that tape. He got it within 5 minutes of his asking the question. He was really very enthusiastic about this.

In the same way with drugs, the doctor may well have only one problem in his mind about the drug—Will this drug affect the diabetic patient? It is our hope that the clinical pharmacologist would have included that in the tapes. If he doesn't, at least the physician knows who the recognized expert on that drug is and he can call him directly and say, "My patient has diabetes, you didn't say anything about diabetes. Can you give him this drug?"

Senator NELSON Thank you.

Dr. MEYER. I would like to describe perhaps in more detail——

Senator NELSON. Is there any source now availabe to the physician where he can get the kind of information authoritatively and quickly that you have spoken about?

Dr. MEYER. I think we are talking in relative terms. If we are talking in terms of hours or minutes, the answer is "No." If you are talking in terms of days or weeks the answer is "Yes." But there are publications which are well authenticated by which things are sent around to physicians. These are done by independent clinical pharmacologists and these are sent to subscribing physicians and they can find out about the particular drug.

Mr. GORDON. Which publications do you have in mind?

Dr. MEYER. The one that comes to mind is the Medical Letter that is authoritative and well-founded, and a lot of us rely on it to a great degree.

Senator NELSON. Does the Medical Letter have available all the information on the most frequently prescribed drugs?

Dr. MEYER. No, sir. They put out every month the Medical Letter, and they select drugs as they are evaluated by their experts that the physician, if he gets the letter—the Medical Letter—will presumably read it and file it for future reference. But there is always a timelag between the time that the evaluators had evaluated the drug and it arrives on the physician's desk.

Senator NELSON. Even so, that wouldn't meet the problem, would it, of the physician who had read the Medical Letter on a drug 4 months ago, and in the meantime clinicians had discovered that there were additional side effects from the drug? Can the pharmacologist revise his tape to say that "we found another side effect"? There is a lag there, too, is there not?

Dr. MEYER. There is a certain lag, except the pharmacologist can revise it relatively quickly; it becomes updated and again authoritative fairly quickly. It my be a matter of more months before the Medical Letter can get the revision published in the Journal.

Senator NELSON. Does the Medical Letter purport to cover all the drugs?

Dr. MEYER. No.

Senator NELSON. So then the information the doctor may want about a certain drug may not have been covered by that publication.

Dr. MEYER. That is true. Equally, we may not have the particular information that physician may want.

Senator NELSON. All right, go ahead.

Dr. MEYER. I would just ilke to preface what I say about the Telelecture by a few thoughts that we do have about the need for continuing medical education and why we have taken the two communications to deliver that need.

There is a great volume of comparatively static core information which every doctor has. But there is a great deal of information which is constantly changing and which has a relatively short, what is called half-life.

The physician is in the situation then that having got his M.D. he must get to the stage where he can unlearn what has been disproved, what he believed at the time that he was taught it. He must be able to revise and update the things that he did learn that are, in fact, still extant, and he must have a mechanism for acquiring new information which was never taught when he was in medical school.

We feel, as a university, as a State university, that we have the responsibility to the physicians in the State to provide this information for them and thereby to the citizens of the State to provide the latest information to the physicians.

The sources of information for the health professions—for the health professional—are many and varied. The quality and veracity of this information is equally variable. For example, the pharmaceutical representatives serve a distinct purpose in bringing information concerning new drugs to busy physicians and pharmacists. But at the university we have some concern about the appropriateness of the time at which this information is delivered and the context in which it is delivered. The man has a job to do and he does that job.

Much information in textbooks and journals, textbooks certainly, and in some journals, is outdated almost by the time it is published and certainly by the time it has set on somebody's reference shelf for some time. A busy physician delivering health care finds it difficult to leave these responsibilities to go to a medical center for his continuing education.

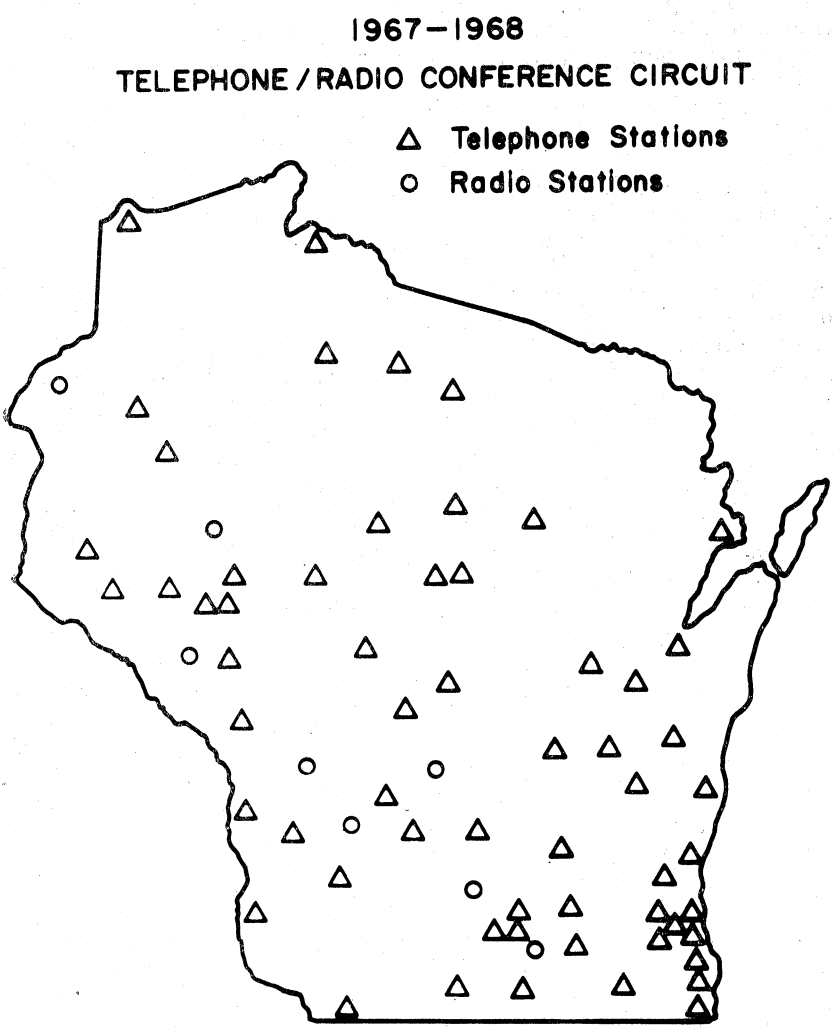
Our problem as medical educators is that our primary responsibility is to medical students. Continuing education or postgraduate education has to compete with the other responsibilities that medical educators have.

Now, medical practice today is very varied and really no two physicians practice exactly the same pattern of practice. Health care today is really a team effort. The nurse, medical technologist, pharmacist, X-ray technologist, hospital administrator, physiotherapist, social worker, and dietitian all have critical roles to play in the total medical care of the patient. They all contribute to the health care effort, therefore as far as we are concerned, our educational efforts have really been across the whole health care field. We decided that our major impact should try to be to make all this information available to these health professions at the time and in the form in which they most require it.

When it comes to implementing these we soon recognized that communications technology was the way in which this could most simply be done. Truly continuing educational programs presented on a regular basis in the health care professional's community is optimal. We must also give them some means of immediate access to authoritative information.

If I may have slide 1, the telephone-radio conference circuit was started in 1965. It has grown very rapidly and as you see in the slide, we have some 58 hospitals which are marked by the triangles linked in the telephone conference circuit.

(The telephone-radio conference circuit illustration referred to follows:)



Dr. MEYER. The circles which you see are hospitals that are linked by radio link. Most of the stations are in the conference rooms of the hospital and each consists of a loudspeaker similar to the one in front of you, a telephone handset and a slide projector similar to the one we are using.

Parenthetically the sound on these telephone conferences is vastly superior to the sound to which you have been exposed today.

We hold the conferences, and exhibits 1 and 4 that I handed out to you are the brochures about these conferences; if you care to look through them you can see the range of material that is being presented over these. We send the slides and visual materials to each station in advance and you can see what happens in an outlying station at the commencement of the lecture.

The pattern of each conference is similar to that developed by Dr. Frank Woolsey at Albany Medical College. He did it on radio. There was a 30-minute presentation followed by 30 minutes of questions, comments and discussion. All the conference participant has to do is merely pick up the telephone handset at his station and talk. What he says is heard over the whole circuit as is the response of the lecturer who is sitting in Madison.

Senator NELSON. How frequently do you have these conferences?

Dr. MEYER. For physicians, we are now having them 3 hours a week. We have if I may just go on about this in 1 week various faculty members of the University may meet 1 hour each with perhaps 300 physicians, 450 nurses, 300 medical technologists, 250 X-ray technologists, 125 hospital administrators, and 100 veterinarians. None of these people have to have more than—20 miles from their community—in fact, most of them stay right in their own community hospital.

Senator NELSON. Is that how many people do listen or have listened?

Dr. MEYER. Yes, sir; this is how many—we take a head count at each station during the conference. There are people taking a head count and this is reported back in to us.

Senator NELSON. Was this an average figure?

Dr. MEYER. This is an average figure.

Senator NELSON. How many physicians in a week?

Dr. MEYER. We have 300 physicians. We have a general medical conference which is up on this corner on the brochure and then we have the specialized conferences. Some of the physicians that go on these general medical conferences may be taking some of the specialized courses as well. But, on the whole, we meet with 300 to 350 physicians every week in one form or another.

Mr. GORDON. How many doctors are there in Wisconsin?

Dr. MEYER. 4,000.

Mr. GORDON. You say you meet with about 300 doctors a week?

Dr. MEYER. Yes.

Mr. GORDON. Are they generally the same doctors from week to week?

Dr. MEYER. On the whole, yes. There is a little variation in that people tend to go to what interests them. But, on the whole, people sign up for either the general medical seminars or for the workshops

or the specialized conferences and the same doctors will come back each time.

Mr. GORDON. We have had estimates from doctors who testified here previously that no more than 10 percent of doctors generally attend medical conferences or participate in such types of continuing education. That seems to fit in fairly well with the figure you just gave us, about 10 percent or a little less.

Dr. MEYER. Yes, sir. We hope that making this more available we have managed to get to some of the physicians who feel that they just cannot leave their health care responsibilities to go to other courses. The figures that you have been given are figures of people who go away to courses rather than the people who take courses in their own communities.

I think it will be interesting to us to see how many get in to take these courses within their own community.

If you will look at the bottom line on this slide you can see how the hours of instruction have increased in the past 3 years of our functions. We started out with 13,000 individual hours of instruction and we are now up to close to 80,000. Again, I would stress the fact that nobody has to move—neither the lecturer or the participants.

(The telephone-radio conferences enrollment, 1965–68, illustration follows:)

Telephone/Radio Conferences

Enrollment - 1965-1968

	1965-66	1966-67	1967-68
Physicians			
General Seminars	286	326	363
Short Courses	64	241	469*
Nurses			
General Seminars	684	400	969
Short Courses			148
Medical Technologists	220	255	466
X-ray Technologists	217	176	262
Hospital Administrators	-	75	130
Veterinary Science	119	57	30
Pharmacists	150	326	350*
Social Workers	236	200	-
Nurse Anesthetists	-	-	75
	1,976	2,056	3,262
Individual Hours of Instruction	13,018	25,068	79,814

* Estimated - enrollment incomplete

Dr. MEYER. I would like to just play a short piece of the recording that we took from the conference last week in that you can recognize the names of the places as I call them in and you can see how widely dispersed these conference stations are and how simple it is for them to get in to talk to the lecturer.

If you look at your program the lecture was on common dermatological conditions and they are questioning the lecturer about their problems that they have with skin diseases.

(Whereupon the demonstration described by Dr. Meyer was performed for the subcommittee.)

Dr. MEYER. I think you can see how you can develop a really close relationship. They have listened to Dr. Johnson talk for some 40 minutes on this and they were now questioning him. As a result of that lecture he had at one session, he presented this lecture twice. If you look at your program, this is on these hours on Tuesday and then he had 17 questions asked him about his presentation in the morning. And he had 27 questions asked him at the afternoon period. We feel that this is achieving a great deal of interchange of information.

I would like to insert some thoughts about our concern of other forms of communications in medical practice and education. You have seen and heard of some of the practical uses of television in service in education. This is as a vehicle for continuing education for physicians throughout the State and we do have some reservations. This medium has been met with a mixed reception. There are enthusiastic reports and you will be hearing from Dr. Wittson about this. Some of these reports are tempered by backroom conversations where difficulties, expense, and time-consuming demands of the medium are discussed. We have doubts as to whether we can transform our busiest, yet most effective didactic and bedside teachers, into television performers. We do not think that much teaching can be accomplished without the teacher and the student being able to interchange ideas. The more sophisticated the student, the more he requires discussion with the teacher.

We have greater interest in the potential of slow-scan television as the vehicle of our major continuing education effort. There are many reasons for this, but essentially slow-scan television will enable us to transmit live conferences at the medical center to as many hospitals as have the receiving equipment with no more than 2 hours of preparation time and at a cost significantly lower than regular television. The drawbacks of slow-scan do not appear to us to be critical in the teaching function.

There is an area of international medical research seminars which would seem to us to be a logical use of satellites for the exchange of information between widely scattered groups of researchers working intensively on common problems. Again, this holds promise for great reduction in travel to international meetings where exchange of ideas takes place in the rather artificial surroundings of a large convention center. Slow-scan television is adaptable to the simplest satellites which have radio receiving and transmitting ability.

The university has a proposal in to the National Aeronautics and Space Agency to utilize one of their weather satellites to link our med-

ical center researchers with research scientists at four medical schools in Japan, four in Australia, one each in Canada, Hawaii, New Zealand, and Mexico. We would conduct these pilot conferences in the same manner as we do the telephone-radio conferences in Wisconsin.

In conclusion I would like to say that in my view we are on the threshold of many new and exciting methods of making available to physicians and allied health personnel the means by which they can review and upgrade their current knowledge, acquire new knowledge, and yet maintain the health care responsibilities they hold in their own communities. These methods will make it possible to meet the specific needs and programs to the varied learning habits of these health practitioners.

It is possible to transmit conferences being regularly held at the medical center with two-way communication to any or many parts of the State or country, so that the Wisconsin idea of the university without walls can come to pass. The key to this venture, as it is to so many other ventures in our world today, is communications. The Wisconsin Telephone Co. has given to us every encouragement and cooperation as we questioned, complained, cajoled, demanded, and decided upon ventures that were as new and as radical to the company as they were to us.

It seems to us that we are providing some services in the education of the physicians in Wisconsin.

Thank you.

Senator NELSON. Thank you very much, Doctor, for your most interesting presentation. We appreciate very much your taking the time to come here today and make this presentation to the committee.

(The prepared statement of Dr. Meyer follows:)

STATEMENT OF DR. THOMAS C. MEYER, ASSOCIATE DEAN, UNIVERSITY OF WISCONSIN MEDICAL CENTER

SECTION I

Mr. Chairman, computers have been put to many uses in medicine and could well be the subject of a hearing in itself. In Wisconsin we are investigating the use of computers in two critical areas of the health care process in the belief that significant practical improvement in that process will result.

A. *Taking of Medical Histories.*—The medical history consists of information of potential clinical significance collected during the course of interview between doctor and patient. There has been relatively little research done on the medical history in spite of the fact that many clinicians consider this to be the most important aspect of the patient's examination. And there are certain practical reasons why research on the medical history is urgently needed. History-taking is very time-consuming and incompleteness often results from time limitations and other factors beyond the physician's control. Further, the lack of standardization from interviewer to interviewer, together with the traditional illegibility of hand-recorded patient records, makes information retrieval for patient care and clinical research difficult and often impossible. Improved methods of collecting and recorded detailed medical histories are needed.

The use of a digital computer to interview patients regarding their medical histories was first tried in 1965 at the University of Wisconsin. The project, under the direction of Dr. Warner Slack, is still in the research stages, but it is hoped that computer-based patient interviewing will be done routinely within the next several years.

The computer has been used in this project to collect the infomation of clinical histories directly from patients, print out summaries in a form immediately useful to physicians and for storage and future use in patient care and clinical research. The patient sits in front of the computer and questions are displayed on a cathode-ray screen. The presentation of questions is a function of patient

responses—questions answered "YES" are followed up in detail and questions not understood are explained further. Responses are made by keyboard entries.

Thus far, results with the program has been encouraging. Over 300 patients have been interviewed by computer. A general medical history and specialty histories dealing with symptoms of allergy and gynecology have been developed and tried clinically. Endocrinology, neurology, psychiatry, gastroenterology and pediatric histories are currently under development.

Teletype machines have also been used as interviwing terminals connected to the computer by telephone line. With this technique, the computer is dialed from the phone on the teletype and when telephone connection is established, questions are printed by the teletype under computer control. Patient responses are made by the teletype keyboard to the computer, which in turn responds with the presentation of another question. Thus far, 60 allergy histories have been taken by teletype. Remote interviewing (teletypes on long distance phone lines to the computer in Madison) have been conducted on a demonstration basis from the Mayo Clinic in Rochester, Minnesota, New York City, Chicago, and Los Angeles. It is hoped that, with such techniques, computer-based patient interviewing can be made available to physicians and their patients in areas removed from computer facilities.

B. *The Computer in the Laboratory.*—The demands for laboratory services have been increasing rapidly over the past decade. Automated instrumentation which can perform certain laboratory tests have helped meet the increased demands, but there still remain the problems of calculating, processing, and communicating the mass of information produced by the laboratory. In order to continue to meet the increasing work load and still maintain the high quality of laboratory information, the use of high speed digital computers is being investigated in many laboratories.

The use of LINC computers in clinical laboratories was pioneered by Dr. G. Phillip Hicks at the University of Wisconsin in late 1964. This has been operating in the University of Wisconsin Clinical Laboratory for over 2 years.

At Wisconsin, programs have been developed to permit the laboratory computer to be used directly by all laboratory staff without special training in computer technology. Laboratory information is collected from the staff by the computer, which provides a real service by performing calculations of test results and statistically analyzing the results. Where automated instruments perform analysis in the laboratory, the computer collects the results directly from 16 instruments simultaneously while checking the quality of each result as it is processed.

In the Wisconsin laboratories, three remote teletype stations are connected to the computer for the distribution of information within the laboratory.

The programs developed at Wisconsin have been placed in the public domain and are available to any other laboratory upon request. To assist other laboratories in evaluating computers, a two-week postgraduate medicine course was presented at Wisconsin in May, 1967. At present, the Wisconsin programs are being used in the Biochemistry Laboratory at Duke University Medical Center under the direction of Dr. Ralph E. Thiers. Upon request, specific programs have been made available. For example, the Wisconsin statistical programs for analyzing laboratory data have been used at Perth Amboy.

As more laboratories throughout the nation install such computer systems, telephone communication lines for the rapid communication and exchange of medical laboratory information will be of great value.

SECTION II

The University of Wisconsin Medical Center and the University Extension have long been pre-occupied with problems of health care personnel which may best be summarized by a series of statements that are pertinent though they may not appear to be related.

(1) While there is a great volume of comparatively static core information which is structural, functional and behavioral in pattern, there is a proportion of what we believe and teach in medicine today which will have been disproved in ten years. There will be a great new body of knowledge which the physician and all those delivering health care will have to acquire if they are to deliver optimal care.

The physician is now and will continue to be in the constant state of having to unlearn certain segments of his fund of informaton, revise and update other

portions of his knowledge and skills in addition to acquiring information which is completely new to him.

(2) The University of Wisconsin has a responsibility to provide health practitioners in Wisconsin with the opportunity to constantly review and update their knowledge in order that they may improve the delivery of health care in their communities.

(3) Optimal learning occurs when an individual has an immediate and urgent need for information. A great deal of information need not be learned provided it is instantaneously available when the physician requires it.

(4) The sources of information for a health professional are many and varied; the quality and veracity of this information is equally variable, e.g., the pharmaceutical representatives serve a distinct purpose in bringing information concerning new drugs to busy physicians and pharmacists. At the University of Wisconsin we have some concern about the appropriateness of the time at which this information is delivered and the context in which it is delivered.

(5) Much information in textbooks and journals is outdated or disproved by the time it is published, and even more unreliable after the publication has been on the individual's reference shelf for a number of years.

(6) The demands on those delivering health care are such that time and distance are barriers to continuing education. It is difficult to leave patient care responsibilities and travel to a medical center for a course which may or may not be relevant to the individual's needs.

(7) The primary responsibility of the medical educator is to train medical students. Continuing education must compete with other responsibilities such as research and service in its demands on his time.

(8) Medical practice today is so varied, it is our belief that no two physicians have the same pattern of demands placed upon them by their patients. Continuing education must be structured to enable the physician to identify and meet his specific needs.

(9) Health care is becoming more and more a team effort. The nurse, medical technologist, pharmacist, x-ray technologist, hospital administrator, physiotherapist, social worker and dietician all have critical roles to play in the total medical care of the patient. Without any one of these ancillary personnel the physician loses a great deal of his effectiveness. Any continuing education program for physicians must encompass opportunities for all health personnel.

To meet these problems the Continuing Education Committee of the University of Wisconsin has developed long-range aims which state:

1. The volume and opportunity for continuing education available is so great that the problems for the busy practitioner are "which, when, how good, and how am I to get it?"

2. The provision for the continuing education of the physicians in the state of Wisconsin is an appropriate function and the duty fo the state university. This education should be—

   a. Of the highest caliber and pertinent to current medical practice;
   b. Presented in a readily available form; and
   c. Available—
      1. To physicians of varying interests and all areas of the state;
      2. At convenient times of the day or night;
      3. At lowest possible cost;
      4. In various and diverse forms in which physicians may require it; and
      5. Without the physician having to absent himself from the responsibilities of his practice for any prolonged period.

3. Discussion of patients and prepared material is the most effective method of continuing education and can best be done on patients well known to the physician.

Implementation of these objectives has been the concern of the Department of Postgraduate Medical Education which soon recognized that communications offered the possibility of providing:

(1) Truly continuing educational programs for all health care personnel, presented on a regular basis in the communities where health care is being delivered.

(2) Greatly increased diffusion of the knowledge and skill of medical educators and at the same time reducing travel time of the faculty and course registrants.

(3) Immediate access to current and authoritative information of emergency nature and the means for the physician to update his knowledge in summary form at the time he requires it—whether this be during office hours or during the night.

I would like, if I may, to give you some examples of the means we have utilized in Wisconsin in an attempt to carry out these objectives:

1. The Telephone/Radio Conference is in essence a party line with some 58 hospital stations linked by a private telephone line with another 9 hospitals listening on radio. Most of the stations are in the conference rooms of the hospitals and each consists of a loudspeaker, telephone handset, and slide projector. Conferences are held at a pre-determined time. Any station with its loudspeaker turned on can hear everything that is said from every other station on the line. Slides and visual materials for each lecture are sent in advance to each station.

The pattern of each conference is essentially similar to the two-way radio conferences developed by Frank Woolsey, M.D. at Albany Medical College in Albany, New York. There is a thirty-minute presentation followed by thirty minutes of questions, comments and discussion. A conference participant having a question or comment has merely to pick up the telephone handset at his station and talk. This is heard over the entire circuit as is the response from the conference moderator or lecturer.

This system has proved to be a very intimate form of instruction and yet one in which the participants can maintain anonymity if they wish. We have experimented with several forms of instruction/discussion programs, most of which have been successful. We have pretested, posttested, and late posttested physicians and demonstrated to our satisfaction that transfer of information is taking place.

One final word about the Telephone/Radio Conferences: In one week various faculty members from the university may meet for an hour each with perhaps 300 physicians, 450 nurses, 300 medical technologists, 250 x-ray technologists, 125 hospital administrators and 100 veterinarians. None of these people have to move more than 20 miles from the community in which they are delivering health care, and the vast majority attend in their home communities. Programs for pharmacists, nurse anesthetists and possibly medical secretaries will be presented in the winter and spring.

(2) The Dial Access Medical Library was instituted in April of 1966 with 88 cartridge tapes of approximately five minutes playing time each. The idea of it was to have available to physicians in Wisconsin new information or information of emergency nature when they needed it. The subject matter range is from the treatment of diabetic coma to the management of bee stings. Physicians wishing informaion have merely to call the library at any time of the day or night and within 20 seconds the tape they have requested will be played for them over the telephone line. The library is located in the University Hospital which has a 24-hour-a-day staff on duty. Evaluation of this service is difficult at the moment, but we do have scattered evidence that the library has contributed to improved patient care. Due to lack of funds to promote it, we have been able to have only one mailing of the brochure to Wisconsin physicians. This was in August, 1966. Demonstrations have been given nationally through an AT&T exhibit at various conventions and during Bell Telephone seminars in Chicago and New York. We have recently been funded under the Wisconsin Regional Medical Program and the United Health Foundations to enlarge the library and set up a duplicate service in Milwaukee. Funds are now available to publicize extensively and, more important, to evaluate the role the dial access library may play in patient care. One great theoretical advantage it has is that the faculty of the University of Wisconsin reviews the tapes regularly (at least once a year) so that the calling physician knows that the information he is obtaining is not more than 12 months old. In many instances we have inserted the date the recording was made. A second dividend from the library is that it gives those of us who have the responsibility of programming future courses an objective account of what physicians in practice want to know. In addition, the calling physician finds out from the tape who the local expert on the subject is and may call him directly for further information.

I would like, if I may, to insert some thoughts which we have concerning other forms of communications in medical practice and medical education. You have seen and heard of some of the practical uses of television in service and education.

(1) Television as a vehicle for continuing education of the health professions is being extensively utilized throughout the nation with mixed reception. Enthusiastic reports are tempered by back-room conversations where the difficulties, expenses and time-consuming demands of the medium are discussed. We have doubts as to whether we can transform our busiest, yet most effective didactic and bedside teachers into television performers. We do not believe that effective teaching can be accomplished without students being able to question the teacher. The more sophisticated the student, the more he requires discussion with the teacher. We applaud the prodigious effort which is necessary to develop educational television to meet the standards of the sophisticated medical audience of this decade.

(2) We have greater interest in the potential of slow-scan television as the vehicle of our major continuing education effort. There are many reasons for this but essentially slow-scan television will enable us to transmit live conferences at the medical center to as many hospitals as have the receiving equipment with no more than two hours of preparation time and at a cost significantly lower than regular television. The drawbacks of slow-scan do not appear to us to be critical in the teaching function.

(3) International medical research seminars would seem to be a logical use of satellites for the exchange of information between widely scattered groups of researchers working intensively on common problems. Again this holds promise for great reduction in travel to international meetings where exchange of ideas takes place in the rather artificial surroundings of a large convention center. Slow-scan television is adaptable to the simplest satellites which have radio receiving and transmitting ability.

The University of Wisconsin has a proposal in to the National Aeronautics and Space Agency to utilize one of their weather satellites to link our Medical Center researchers with research scientists at 4 medical schools in Japan, 4 in Australia, one each in Canada, Hawaii, New Zealand and Mexico. We would conduct these pilot conferences in the same manner as we do the telephone/radio conferences in Wisconsin.

In conclusion, I would like to say that in my view we are on the threshold of many new and exciting methods of making available to physicians and allied health personnel the means by which they can review and update their current knowledge, acquire new knowledge, and yet maintain the health care responsibilities they hold in their own communities. These methods will make it possible to meet the specific needs and program to the varied learning habits of these health practitioners.

It is possible to transmit conferences being regularly held at the medical center with two-way communication to any or many parts of the state or country, so that the Wisconsin Idea of the university without walls can come to pass. The key to this venture, as it is to so many other ventures in our world today, is communications. The Wisconsin telephone company has given us every encouragement and cooperation as we questioned, complained, cajoled, demanded, and decided upon ventures that were as new and as radical to the company as they were to us.

We worked, almost failed, and it seems now have succeeded in providing a service to health professionals which is filling a significant need in Wisconsin.

SECTION III

Single Concept Films.—There have been many techniques devised in the past 10 years which are aimed at better care for the seriously ill patient. Many of these techniques are new and complex, but others are comparatively simple and should be mastered by most practicing physicians. When described in texts, techniques sound more complex than they actually are and there is reluctance to undertake a procedure the physican has never seen. At the present time many of these procedures are being performed only in university medical centers or large community hospitals with regularly conducted in-service training programs. Nevertheless, these procedures are as life-saving in the smaller community hospitals and may contribute to patient comfort wherever the patient may be hospitalized.

There seemed to be virtue in making films available to physicans in all areas of Wisconsin demonstrating the simpler techniques. For convenience, the films are provided in self-rewinding cartridges and shown in automatic projectors.

All the physican has to do is insert the cartridge and press a lever and the 5–10 minute film is shown for his personal study. He may repeat it as many times as he wishes. The films which we are currently circulating is Wisconsin have thus far been met with great interest and enthusiasm by the viewers. Once again we are in the tedious process of evaluating this form of educational venture.

The Picture-Phone would be a logical use for these types of demonstrations so that the physican could review these techniques at his leisure and, when required to utilize a technique, he could view it in much the same way as the dial-access library is utilizing sound tapes only.

Further, it is conceivable that utilizing the Picture-Phone and Touch-Tone the computer would be able to take a patient's history for the physician before the patient sets foot in the physician's office. This would, in my view, conserve a large portion of the physician's time for the more important judgment and decision making process which is the physicians primary role.

Mr. CALLAHAN. With your permission we will move ahead to item 14, discussing closed circuit television.

I would like to describe two examples of how closed circuit television is being used to meet the urgent needs of continuing medical education. One is the Louisiana Hospital Television Network. The second is the Nebraska Psychiatric Institute television system.

Louisiana hospital officials seeking a new way to provide improved training procedures for medical students, doctors, and hospital personnel throughout the State, have established a closed circuit television network that will link all of the State's major hospitals and medical schools.

The first leg of the medical educational television network is in service between Baton Rouge and New Orleans. The second and third phases will be in service by January. Fourteen locations will then be participating in the medical TV educational system.

The Louisiana Hospital Television Network will be the first closed circuit TV system providing medical training statewide and has drawn the interest of State hospital departments from all over the country. The network was conceived in May of 1964 by the Louisiana State Hospital Board. It will provide for doctors and specialists at State hospitals in scattered areas of the State a practically unlimited source of medical information from Louisiana State University, Tulane University Schools of Medicine, Charity Hospital in New Orleans, and Ochsner Foundation Hospital in suburban New Orleans.

In addition to material for interns and residents on matters such as surgical procedures, programing will include psychiatric conferences and continuing education for nurses and attendants.

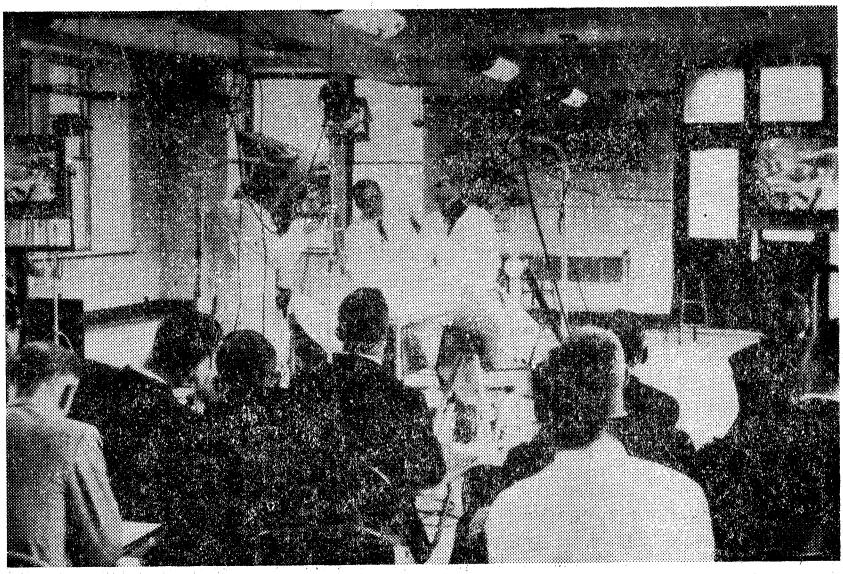
Training nurses and aids in the proper use of new equipment and procedures can be carried out effectively with closed circuit television. Not only do "live" demonstrations increase the speed and retention of education, but taping the programs permits all the shifts of the hospital staff to benefit.

Lectures on highly specialized topics in which the availability of specialists is limited, infrequently occurring surgical procedures and demonstrations of techniques so complex and expensive as to prohibit their repeated performance can be recorded and viewed again and again.

This slide shows a surgical anatomical demonstration performed by a professor of physiology at LSU. The observers are doctors from various parts of the State enrolled in a continuous education program.

In delicate operations, only a few persons can view the operation. TV will allow students statewide to view the procedure live or later on video tape. A full production studio is planned for the Earl K. Long Memorial Hospital in Baton Rouge which will be completed in early 1968 and a mobile unit will enable lectures and operations at any point in the State to be videotaped for later use. In the inauguration ceremonies, the director of the State department of hospitals noted that the system will "make the really great men of medicine universally available." Certainly as other State medical systems are established and interconnected that prediction should be realized.

(The illustration referred to follows:)



Mr. CALLAHAN. One of the real pioneers in the application of closed circuit television to medical training was the Nebraska Psychiatric Institute centered at the College of Medicine at the University of Nebraska in Omaha. The affiliated State hospital is at Norfolk, 112 miles away. Because of the distance, the accessibility of resources between locations was limited. Two-way closed circuit television links the two institutions on a 24-hour basis. This makes it possible for personnel at the University to view patients or other subject material at the hospital while, simultaneously, personnel at the hospital can view psychiatric specialists or presentations at the University.

This television system has been in operation since December 1964. Dr. Cecil L. Wittson, dean of the College of Medicine at the University of Nebraska, will describe the interesting applications of this system. Dr. Wittson is in New York and will address the committee by Telelecture.

Dr. WITTSON.

STATEMENT OF DR. CECIL L. WITTSON, DEAN, UNIVERSITY OF NEBRASKA COLLEGE OF MEDICINE, OMAHA, NEBR.

Dr. WITTSON. Two-way closed circuit television makes possible electronic face-to-face communication between individuals and/or groups, though they may be separated by any number of miles.

In Nebraska we have used this communications tool for 3 years to link Nebraska Psychiatric Institute at the University Medical Center in Omaha and Norfolk State Mental Hospital, 112 miles away.

Though this State hospital is a progressive institution, it still shares common problems with many such facilities throughout the country, problems such as recruiting and holding staff, providing adequate staff education programs, and last, but far from least, the problem of utilizing much-needed specialist services, available only at a large but remotely located medical center.

In 1964 we proposed to use two-way television to fill some of these needs and we received a 7-year grant from the National Institute of Mental Health for a pilot project.

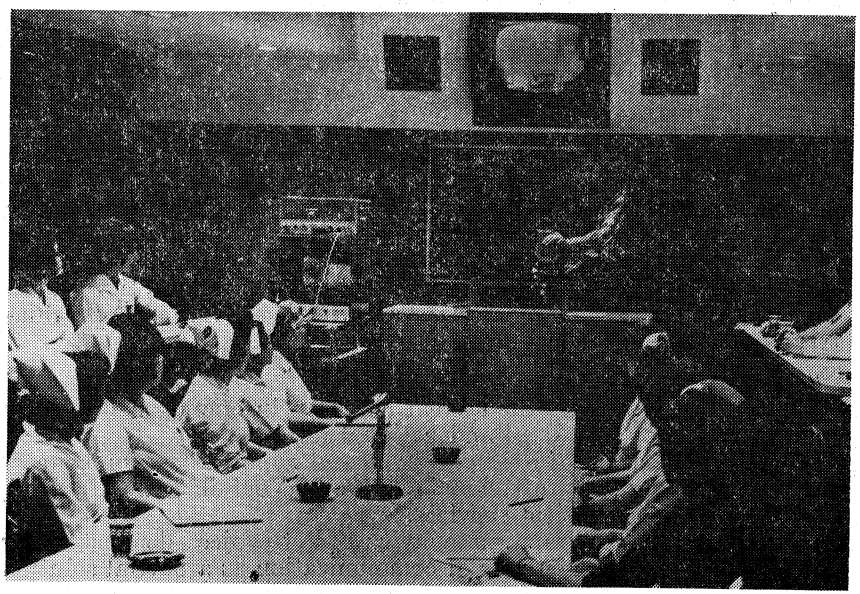
Northwestern Bell Telephone installed and now maintains our two-way transmission system which is in actual use an average of 50 hours each week.

Educational uses

Now, to give you some idea of the potential of the system, let me describe to you just a few of the uses:

Various disciplines in the two institutions—the nurses, social workers, and vocational rehabilitation counselors, each meet regularly for joint seminars, lectures, and videotape presentations.

(The illustration referred to follows:)



Dr. WITTSON. Two-way television makes it possible for the professional staffs of the two institutions to join in weekly grand rounds, with patient presentations and staff discussion.

Distinguished visitors who come to lecture at the University of Nebraska College of Medicine in Omaha are also shared with the State hospital via television.

Various medical college personnel frequently use the system to present programs to specific hospital or community groups.

For example, the Six-County Medical Society in the Norfolk area devotes two of its monthly meetings to continuing medical education. These programs are presented by the faculty of the medical college in Omaha, using two-way TV.

Uses for patient service

New and improved patient services are now available at the State hospital, too.

The medical college neurologist spends 1 hour each week observing neurologic examinations, or reading electroencephalograms, thus supplying a much-needed service.

Consultation is also provided in such areas as child psychiatry, speech diagnosis and therapy, statistical methods, and psychosomatic medicine.

Ward administration is considered one of the most effective uses of the system.

There are 27 wards at the State hospital and not enough staff psychiatrists to go around.

To help relieve this shortage a Nebraska Psychiatric Institute psychiatrist began administering wards on television in January of 1964.

The change in patient care and staff attitudes was rapid. Success of the project was beyond expectations.

Today, three medical college psychiatrists administer 10 wards at the State hospital, spending television time each day with both staff and patients.

Forty-three percent of the patients at Norfolk State Hospital are from the Omaha area. Each week about 20 families use television to visit these patients, making it possible to keep the absent member in the family.

Unfortunately, time does not allow description of the many other uses, such as vocational counseling, placement and followup of the patient returned to the Omaha area, coordination of efforts of the welfare agencies working with the patient and his family, the evaluation of new admissions by Nebraska Psychiatric Institute psychiatrists, and the list goes on and on.

Summary

During the few years the system has been in operation its effects have been felt at both local and national levels.

Locally, utilization of the two-way closed circuit television connection is improving the professional climate of Norfolk State Hospital, and improving its patient services.

Nationally, the program is serving as a pilot project, demonstrating the worth of modern methods of communication as a partial solution

to the problems which confront many mental institutions in this country today.

Mr. CALLAHAN. Thank you, Dr. Wittson.

Mr. Chairman, do you care to ask any questions of Dr. Wittson?

Senator NELSON. I thank Dr. Wittson very much for taking the time to make this valuable presentation to the committee. I do not have any questions.

Mr. CALLAHAN. Thank you very much, Dr. Wittson. Your participation is very much appreciated.

Dr. WITTSON. Thank you.

Mr. CALLAHAN. Goodby.

Dr. WITTSON. Goodby.

Mr. CALLAHAN. Mr. Chairman, this is an appropriate time, I believe, to demonstrate two new communication services which we believe promise to open up new opportunities for the medical profession.

One is Touch-Tone service and the other is Picture-Phone service.

I will discuss Touch-Tone telephone service because really in the traditional use, for people to talk to people, Touch-Tone service is different only in that it employs electronically generated tones instead of electrical pulses in the dialing function.

I will demonstrate.

(Whereupon Mr. Callahan demonstrated the Touch-Tone feature described.)

Mr. CALLAHAN. This feature becomes very important, however, after the call is dialed, and the called station answers. Whereas, the electrical pulses of the dial phone do not pass through the telephone network after the call is connected, the Touch-Tone signals do. Therefore, Touch-Tone makes it possible to communicate not only verbally but with anything which can interpret the Touch-Tone signals—a business machine or computer, for instance.

I will demonstrate how this capability makes it possible to retrieve information from a tape library with no attendant assistance.

It will be apparent how this capability will serve medical tape libraries such as the University of Wisconsin's as the number of tapes in the library and the volume of calls becomes sizable.

Touch-Tone phones can also carry on a dialog with computers equipped with voice answer back capability. I will demonstrate this by calling a computer at the Bell System Data Training Center in Cooperstown, N.Y., and performing some mathematical problems.

The added capability of man-to-machine communication provided by the Touch-Tone phone, coupled with its very low cost, and the nearly universal nature of telephone service, I believe, offers exciting new opportunities to the medical profession.

(Whereupon, Mr. Callahan demonstrated as described.)

Senator NELSON. How does this system differ from what Dr. Meyer presented?

Mr. CALLAHAN. Only that it makes it possible for a physician or anyone who has Touch-Tone telephone service to dial into a tape facility any time of the day or night and select programs at random from the storage location. There is no need to have an attendant.

Senator NELSON. All it eliminates is the conversation with the librarian; is that correct?

Mr. CALLAHAN. Yes; the need to maintain someone on duty at all times. In the beginning of such a system, it doesn't make much difference economically. But as traffic grows and the number of tapes to which access is available continues to increase and runs into hundreds and ultimately into thousands, possibly, then this ability to select any one of those tapes at random becomes very valuable.

The second application of Touch-Tone phone service I would like to demonstrate relates to the computer demonstration we had earlier. As you are aware, Mr. Chairman, computers today have the ability not only to generate signals to a teletypewriter to type out information, they also have voice-answer-back capability or can be equipped with voice-answer-back capabilities so they can in effect converse by telephone with a human being.

In order to demonstrate this feature and the ability of the Touch-Tone telephone to communicate with a computer, I would like to demonstrate how you can do some simple mathematics with the computer and the Touch-Tone telephone.

I will call the computer at the Bell System Data Training Center in Cooperstown, N.Y.

(Whereupon, Mr. Callahan demonstrated to the subcommittee the computer technique described.)

Senator NELSON. What is the purpose of this? I mean what particular aspect of it, the mathematics aspect?

Mr. CALLAHAN. As an actual fact last year, under the auspices of the IBM Corp. and New York Telephone, some high school students in New York City used the Touch-Tone telephone and a computer to do their mathematics homework.

Senator NELSON. Very practical.

Mr. CALLAHAN. The student sets up the problem, and instead of having to go through all the trouble of working it out, he sets up the problem and puts it into the computer. If he did it right, the answer will be right. So what it does, with the computation capability of the computer, it will relieve from professional people the necessity of doing the burdensome labor of mathematical calculations.

Senator NELSON. How would you use that in medicine?

Mr. CALLAHAN. May I defer that question to Dr. Meyer?

Dr. MEYER. We spend a fair amount of time doing physiological calculations. The one that drives me mad is the calculations that we were following of cardiac catheterizations where we calculate the flows and the resistances across valves or in holes in the heart and various physiological data like this. We get a certain amount of data and then it has to be processed in several different ways. Now, there are many, many types of uses where things are reduced to numerical figures, where physiological data is reduced to numbers and must be manipulated in the form of numbers to come out with some understanding, some understandable type of result. This is the type of thing that we would use it for in medicine.

Senator NELSON. All right.

Mr. CALLAHAN. Thank you, Dr. Meyer.

The impact of Touch-Tone telephone, Mr. Chairman, in medicine or in any other profession we believe is not very clear. It is a new service and like all other communications services it is going to have

to stand the test of time and have an opportunity for people like Dr. Meyer and university people to begin to use it and to experiment with it. So that is why I say it has great potential, promise, but not such that we can document it.

As I said, another new service is Picture-Phone and that really isn't a new service because although it is in operation commercially between Chicago, New York, and Washington, D.C., it is in such limited availability, and will be certainly until the seventies, that it would be more appropriate to describe it as a forthcoming service rather than a new service.

But looking to the future it seems that Picture-Phone service even has greater—far greater—implications than Touch-Tone because besically it is a Touch-Tone telephone, with the added dimension of vision. It will be able to do all the things Touch-Tone telephone can do. Not only will we be able to talk to other people, but we will be able to see each other while we talk. And as Touch-Tone telephone has the capability of talking to business machines or computers, so will the Picture-Phone have the capability of talking to a computer. The computer will be able to answer either in the voice mode or with a picture presented to the viewer.

I think the best way to appreciate Picture-Phone is to use it. I will call you on the Picture-Phone set, Mr. Chairman.

(Whereupon, Mr. Callahan demonstrated Picture-Phone for the subcommittee.)

Senator NELSON. What is the value of this as a medical matter?

Mr. CALLAHAN. That's another question that I would like to defer to Dr. Meyer if you don't mind. May I demonstrate, before Dr. Meyer comments on that, on a second application of Picture-Phone. In addition to its ability to show each other's face, I would like to simulate a call to a computer and show the computer answer back. We are not equipped to do the demonstration from the caucus room to the Bell Telephone Laboratory computer in New Jersey. I will use slides to simulate the responses. So if you don't mind, Senator, I will say goodby on our Picture-Phone now and hang up.

(Whereupon, the demonstration with Picture-Phone was concluded.)

Mr. CALLAHAN. By using the Touch-Tone buttons of the Picture-Phone set, we could call a computer. It would answer us with a message presented visually on the Picture-Phone.

(Whereupon, Mr. Callahan demonstrated the system described.)

Mr. CALLAHAN. That concludes the demonstration of the capability that Picture-Phone will offer when it is available beginning in the seventies. If you now, Mr. Chairman, want to hear anything further about the medical implications of this from Dr. Meyer, perhaps he may comment.

Senator NELSON. I do not have any more questions.

Mr. CALLAHAN. Thank you.

Finally, then, Mr. Chairman, we would like to discuss briefly a concept for a drug information system about which you have evidenced considerable interest and a subject with which this subcommittee is particularly familiar.

A subject with which this subcommittee is particularly familiar is the need for an effective communications system for drug informa-

tion, including continuing education for physicians and pharmacists, as well as for alerts on adverse reaction and recalls. The need to quickly reach the large number of people who need to know and still restrict the information from the general public presents a real challenge in planning and developing a system at reasonable cost. A drug recall, for example, should alert 286,000 physicians, 55,000 pharmacists, 22,000 nursing homes, and over 9,000 hospitals, or a minimum of 375,000 locations. Furthermore, we understand that recalls occur on an average of two to 10 times a week. The Food and Drug Administration is considering a plan which would capitalize on the universal, yet discrete nature, of the telephone network. Initially, the national news services also would play a key role in the plan.

The plan would combine two well-tested communications arrangements now in use. From the viewpoint of the doctors and others authorized to receive the drug information, the plan would be similar to the University of Wisconsin tape library. They would dial into a recorded announcement using unpublished telephone numbers which would be released only to authorized professional people. To disseminate the information quickly to the local points where the announcement machines are located, teletypewriter messages would be sent to a point in each State which would in turn send it to the local announcement points. This is very much like the national law enforcement teletypewriter system which links 48 States for fast, secure dissemination of law enforcement messages.

But an important question remains. How do we notify the physicians, pharmacists, and others that there is a drug-alert message for them to receive? An approach being considered is to use the national news services and the local newspapers. When a drug alert was sent out, the newspapers could carry an inobvious signal such as an asterisk or other special mark in a specific place which would be an indication to authorized people.

If and when the system reached the point where urgent or important information was carried daily the need for a notification scheme might be obviated. For instance, it might be used for the introduction of new drugs supplementing the present detailing system or for the continuing medical education of doctors in connection with beneficial or detrimental effects of certain drugs.

The plan could be put into effect on a trial basis in selected regions without need for any capital investment and a relatively small monthly charge in each announcement location. After the plan was working for a reasonable period of time, the effectiveness of this form of communications could be determined. Further studies could then be made to decide on the value of developing a more sophisticated communications system, if needed.

Senator NELSON. Does yours relate only to the question of notification of physicians about a drug that has been recalled? Or, does your proposal also relate to the question of drug information centers in the way Dr. Meyer discussed them?

Mr. CALLAHAN. Our proposal at this time is not that specific, Mr. Chairman. The Food and Drug Administration, I believe, is concerned primarily with the dissemination of emergency information. The system, as I described it, doesn't really even require new equipment to be installed in each State.

For instance, if in Wisconsin the University of Wisconsin were determined to be the dissemination point, then a teletypewriter presently installed at the university could be used to receive this message and the university in turn would disseminate it to points throughout the State, possibly in each county, depending on what the traffic requirement would be, so that the information could be put on a tape and each doctor would only have to make what amounts to a local telephone call to gather the information.

Senator NELSON. Does that cover everything?

Mr. CALLAHAN. Yes, sir. I would like to briefly conclude this presentation on an observation about the regional medical center program now under development.

I hope this presentation has demonstrated that communications can produce new efficiencies in many ways. Transporting a patient to a distant hospital or clinic for an on-the-spot examination and diagnosis will seldom be necessary. Pressure on the supply of beds in the large institutions will be relieved. Waiting for admission to those institutions will be greatly reduced, if not eliminated.

The problem that results from a patient's returning home from a distant medical facility to a practitioner who has not participated in the medical discussions and who may not be entirely confident of being able to provide the special treatment prescribed, which is common in psychiatric cases, will occur less frequently. The hospital of the future will rely more heavily on physiological monitoring, computer-assisted diagnosis, television viewing of patients with concurrent consultation by doctors; and distance need not be a deterrent. Much more use will surely be made of data processing and information retrieval over the communications network. These capabilities are available right now.

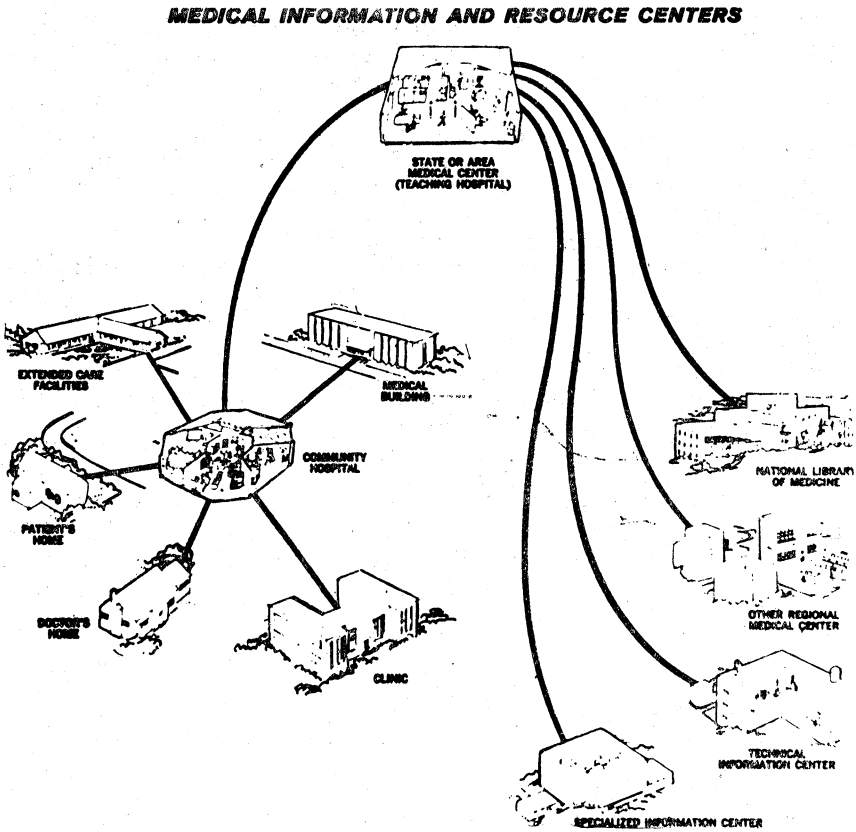
The communications developments discussed today show the trend toward community and regional centers linked by communications to serve hospitals and the medical profession. In turn these local centers will have access to State, area, and specialized information centers, technical information centers, and other national resources or medical libraries. Such complexes will require coordinated voice, video, and data communications, of whatever kind is needed, for administration, patient care, research, and education.

This is the overall communications concept that will be an indispensable part of the regional medical programs initiated by the Surgeon General.

(The overall communications concept illustration referred to appears on next page.)

Mr. CALLAHAN. Through the use of the nationwide communications network, any of the facilities available in State, regional, or national information and resource centers and medical libraries can literally be put at the fingertips of the doctor.

Whether in his home or his office, at the clinic, the hospital, or at an extended-care facility, the doctor will be able to get the information he needs, when he needs it, in the form he wants it, by telephone, by telewriting, by television, or slow-scan television to retrieve X-rays or other photos, by facsimile to duplicate printed material, by teletypewriter for printouts or displayed on a cathode ray tube.



Any of these can also be available on a larger scale for group participation in continuing medical education.

Most of the communications of tomorrow are in fact here today. The widespread application of today's capability will be tomorrow's communications. It is the pioneering efforts of the medical profession, such as the examples reported on today, which will point the way to the realization of what communications can accomplish.

I hope this presentation has been informative and will be helpful to this committee. And I appreciate the opportunity to make this report. Thank you.

Senator NELSON. Well, I thank you, Mr. Callahan, and you, Dr. Meyer, as well as the American Telephone & Telegraph Co., and the doctors who participated by telephone from other locations.

This has been a very informative and useful presentation. We appreciate very much your taking the time and I appreciate how much time you did put into setting up this rather elaborate display.

We thank you all very much.

This will be most valuable for our record.

The subcommittee stands adjourned.

(Whereupon, at 2:55 p.m. the subcommittee adjourned.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

THURSDAY, NOVEMBER 9, 1967

U.S. SENATE,
MONOPOLY SUBCOMMITTEE OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 9:45 a.m., in room 1318, Old Senate Office Building, Senator Gaylord P. Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson and Javits.

Also present: Benjamin Gordon, staff economist; James H. Grossman, minority counsel; Susan H. Hewman, research assistant; and William B. Cherkasky, legislative director, staff of Senator Nelson.

Senator NELSON. We will resume the hearings of the Monopoly Subcommittee of the Select Committee on Small Business.

Dr. Goddard, we welcome you back to the subcommittee to continue our dialog about a number of problems as we discussed previously when you appeared.

Your statement will be printed in full in the record. You may proceed to present it as you see fit. And I assume you have no objections to our interrupting with questions as you go along.[1]

Dr. GODDARD. None at all.

Senator NELSON. Fine. Go ahead, Doctor.

STATEMENT OF DR. JAMES L. GODDARD, COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, ARLINGTON, VA.; ACCOMPANIED BY PAUL A. PUMPIAN, DIRECTOR, OFFICE OF LEGISLATIVE AND GOVERNMENTAL SERVICES; AND WILLIAM W. GOODRICH, GENERAL COUNSEL

Dr. GODDARD. Mr. Chairman, it is a pleasure for me to appear again before this distinguished subcommittee. As you have requested, I will amplify my previous recommendation to this subcommittee that a compendium of prescription drugs should be published by the United States. I will also direct my testimony to an issue which has engendered considerable controversy since my last appearance before this subcommittee. Thus, as you have also requested, I will attempt to clarify my position on marihuana.

As you know, vital information concerning all prescription drugs is presently disseminated via the package insert. A condensation and compilation of package inserts into a readily readable compendium

[1] See complete prepared statement of Dr. Goddard, p. 1261, infra.

distributed without cost to the physicians, pharmacies, hospitals, et cetera, would be a significant step forward in educating the health professions to the safe and effective use of therapeutic agents. It could also relieve the drug industry from the burden of printing the voluminous package inserts as such a compendium could appropriately replace this type of labeling.

The content of package-insert type of labeling is initially approved by FDA during the new-drug clearance procedure and is constantly reviewed by our medical staff to insure that the labeling is consistent with current knowledge. Often the package insert is the only source of such necessary data on medicines which are prescribed daily.

Unfortunately, this information seldom reaches the physician; it remains on the local pharmacist's shelves. Proper utilization of this information is further hampered by the present format of the package inserts.

Senator NELSON. May I interrupt a moment?

Dr. GODDARD. Certainly.

Senator NELSON. Do you have an estimate on the cost of printing, preparing, and supplying these inserts along with the drugs?

Dr. GODDARD. I was advised by the Pharmaceutical Manufacturers Association—this subject was first raised by them, I might add—when they asked would I consider a drug compendium to replace the package insert, that the program presently costs industry about $6 million a year.

Senator NELSON. $6 million?

Dr. GODDARD. Yes, sir.

Senator NELSON. Do I understand you to say that the Pharmaceutical Manufacturers Association raised the question of the preparation of a compendium in place of this?

Dr. GODDARD. Yes. This was in April of 1966. And they pointed out that the matter had been discussed with my predecessor, Commissioner Larrick, and his position was that they could publish a compendium but would have to also continue the use of package inserts for 1 year in order to evaluate the effectiveness of the compendium.

Now, they were anxious to move ahead with this program but didn't see the necessity for running two programs in tandem for a year.

I agreed at that time that we would not require the package insert for the year after the compendium was published.

This was the beginning of our discussions on the drug compendium.

Now, we have had nothing but discussions since that time, and I am hard put to understand the recent statement of the president of the PMA where he was critical of my testimony before a committee of Congress where I expressed my displeasure with the foot dragging—I think I characterized it as that. He said, "Why, we are discussing that matter right now."

Well, they are going to discuss it to death. And I think we stand at a unique point in time. With the National Academy of Sciences efficacy review reports beginning to come back to us, these can form the basis for much of what will be needed in the compendium on the drugs that were marketed between 1938 and 1962. So we truly have an opportunity that is well perceived by the members of the Drug

Research Board of the Academy of Sciences and by others in this field. And that is why I am anxious to get on with the job.

Senator NELSON. Are you carrying on continuous discussions with the Pharmaceutical Manufacturers Association respecting this matter?

Dr. GODDARD. We have been, through the good offices of the National Academy of Sciences meeting on this, and, as I say, for many, many months now.

Senator NELSON. Has the Pharmaceutical Manufacturers Association made any specific proposal as to what kind of a compendium they would like to see?

Dr. GODDARD. Yes, sir.

Senator NELSON. Have you discussed with them who would publish it; would pay for it?

Dr. GODDARD. Yes.

Senator NELSON. What is——

Dr. GODDARD. Let me just state our position for the record. We feel that the Pharmaceutical Manufacturers Association should pay for it.

I have pointed out that this is an opportunity for them to exercise leadership. They state that they sell—that they manufacture, rather—95 percent of the drugs that are sold as prescription drugs. And I say, therefore, they should assume the burden of the additional 5 percent, pay for the publication of a compendium that will be useful to every physician in the country and provide him with comprehensive information on all of the drugs available.

The format we have discussed in some detail. There does seem to be a problem, I am told, from their point of view with a requirement that I wish to impose; namely, that the drugs be discussed under the generic heading, including a brief discussion of the important uses, the dosage, side effects, contraindications for the drug, followed then by a listing of the trade names of the drugs, the dosage forms, and the manufacturers.

Such a book would be cross indexed by both trade and generic name. But this does seem to be a stumbling block—at least I am told that it is.

Now, on the other hand, the people who have been advising me from the Drug Research Board and from the American Medical Association's Council on Drugs feel that this is the only way in which a comprehensive, intelligent job could be done. From just the standpoint of format, it seems necessary to do it this way, otherwise there is great duplication, you see. There may be many manufacturers—there are indeed, I think, some 42 firms or more which produce rauwolfia serpentina as a prescription drug, and I think that Serpasil under the generic name reserpine has 70 firms manufacturing it.

Well, it does not seem sensible to produce a volume that would have in 70 different places the description of a drug; that is, the active ingredient is identical.

Senator NELSON. I guess you address yourself to this question a little later in your statement, but if you produced a compendium, would you contemplate listing every single manufacturer of every drug?

Dr. GODDARD. I hestitate to say every single manufacturer, because, as the Senator knows, there are a number of manufacturers who do a very small intrastate business only, and I do think just as a practical limitation on size, you have to have a cutoff point somewhere. These in-

dividual firms would probably not be listed in such a compendium. But we are interested in having those firms that produce and distribute nationally and even regionally included.

Senator NELSON. How many drugs would be involved?

Dr. GODDARD. Well, there are 21,000, approximately——

Senator NELSON. Different or——

Dr. GODDARD. Different dosage forms of the some 7,000 drugs in the marketplace today. These would all be included.

Senator NELSON. And would a compendium and the drugs included have the approval of FDA?

Dr. GODDARD. It would have to be approved by the Food and Drug Administration since it does serve as a form of labeling. The best possible outcome as far as I am concerned, would be for PMA to exercise leadership in this area, assume the burden and use, if such could be arranged, the format of the PDR, if the owners of PDR were willing to engage in that. I say this because PDR has a great level of acceptance in the country, and this would become competitive, you see.

If such a marriage, if you will, could take place, I think it would find instant acceptance on the part of the practicing physicians. They would receive this volume each year, as they always have, and it would provide them with comprehensive information in terms of coverage of the drugs, as opposed to today's PDR which is on the basis of paid advertising. Even the major firms do not include all of their drugs in today's PDR. So I think it would be a marked improvement and everyone would benefit.

Senator NELSON. All the drug products listed there would have the approval of FDA?

Dr. GODDARD. Of course, the drugs have to have our approval to be in the marketplace.

Now, if you are saying that we would be offering an implicit warning or guarantee that they are efficacious, until the academy review is completed, we could not offer such a guarantee. Until we are in a better position to apply therapeutic equivalency than we are today, we could not offer the physicians such a guarantee.

But that is our goal. It is an achievable goal, and I think it is one that we can accomplish by 1971, as I have indicated in other testimony.

Senator NELSON. Am I correct in saying that to get approval to be introduced into the marketplace at all, a prescription drug has to meet USP standards?

Dr. GODDARD. If it exists in the USP or NF, yes. Combinations are not in USP, of course, so there are many combination drugs in the marketplace today, too.

Mr. GORDON. Well, there are FDA standards, too, aren't there; for example, on antibiotics?

Dr. GODDARD. Yes, there have to be standards, and we do certify them on a batch-by-batch basis.

Mr. GORDON. Perhaps you cover this later, but how useful and effective are the package inserts—do the doctors really read them?

Dr. GODDARD. Most of the time the physician does not receive them, so he does not really have an opportunity to read them.

I have some here, for example. Here is a package insert. I do not think many physicians are going to read this, if he even gets it.

It has selected laboratory data for patients on this drug in tabular form, for example. It is in very small print.

The answer is "No," but the physician does get one particular form, or package insert on biological products, and I think that this should be continued. It is important. These other package inserts, in all sorts of sizes, are printed on what is commonly called in the trade, "bible paper."

Mr. GORDON. What do you mean by "bible paper"?

Dr. GODDARD. Well, it is very thin.

Mr. GORDON. You need a magnifying glass to read the print?

Dr. GODDARD. That is true.

Mr. GORDON. Dr. Goddard, doesn't this present situation really make the doctors more dependent on drug advertising and promotional activity?

Dr. GODDARD. Yes. Of course, that is not their only source of information. But, as I have pointed out on numerous occasions, the industry does spend a significant amount of its income to educate the physicians through advertising.

Mr. GORDON. Are you using that word with quotation marks?

Dr. GODDARD. Well, I say advertising in this field is a form of education, and I am serious when I make that point. And the AMA also now recognizes this point, apparently in response to a recent position the Internal Revenue Service took with respect to their income on general advertising. They pointed out this was different from routine advertising and that it did serve an educational purpose.

And I must agree with that.

Mr. GORDON. Who took that position?

Dr. GODDARD. The AMA.

Mr. GORDON. How about the IRS?

Dr. GODDARD. They haven't responded to this, to my knowledge. But advertising apparently does influence the physicians' choice of the drug. Therefore, I think it is educational. And we are anxious to have a comprehensive, more impartial source of drug information readily available to every physician, every pharmacist and every hospital kept up to date with accurate prescribing information.

Senator NELSON. I don't understand the mechanics of the delivery of the package insert. The doctor himself in his office just writes a prescription. The drugs, with some rare exceptions, come into the pharmacy. Does each package of prescription drugs, no matter how small, have to have an insert?

Dr. GODDARD. That is correct.

Senator NELSON. So then the doctor does not come in contact with that package insert——

Dr. GODDARD. Except for biological products, which tend to go directly to his office.

Senator NELSON. What do you mean by "biological"?

Dr. GODDARD. Well, vaccines and things of this nature, you see.

Senator NELSON. That he administers himself?

Dr. GODDARD. That is correct.

Senator NELSON. I see.

Dr. GODDARD. And intravenous therapy in wards in the hospital are accompanied by the package insert. But by and large these are re-

ceived by the pharmacist and thrown away after he has a file of them, you see. The physician can call the pharmacy and get information on a drug. And some of them do this. But by and large they do not see them. So the system does not accomplish what it set out to accomplish at all.

Senator NELSON. And do I understand that it is your position that if an acceptable compendium were adopted and published, you would be willing to remove the requirement that an insert be used except for biologicals?

Dr. GODDARD. That is correct.

Senator NELSON. Is the insert required by law or is it the result of an administrative ruling?

Dr. GODDARD. Those are the conditions for the approval of a new drug. Yes, sir; statutory.

Senator NELSON. By statute or by a ruling of the FDA?

Dr. GODDARD. Statute.

Senator NELSON. So you would have to change the law respecting the insert——

Dr. GODDARD. Mr. Goodrich, do you want to comment on that?

Mr. GOODRICH. We have authority to exempt a prescription drug from the requirement of that detailed label where it is not necessary for the protection of the public health. We could do so if we had an alternative compendium available to the physician. Then it would not be necessary to carry that information in the packages.

Senator NELSON. Go ahead, Doctor. I have some more questions, but I think you cover some of them in the statement.

Dr. GODDARD. Let me just skip to the third page of the statement.

These label requirements are obviously most essential for proper usage and in order to monitor recalls. The concept of a compendium should in no way abrogate such label information.

Additionally, the regulations require that—

> Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and
>
> If the article is subject to—the new drug, antibotic and insulin provisions—of the Act, the labeling bearing such information in the labeling authorized by the approved new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of insulin or antibiotic drugs: Provided, however, That the information required by (the above paragraph) may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law to administer the drug.

The information required by this regulation is appropriate and useful. I wouldn't believe that anyone would say that the physician relies on promotional literature in medical journals and publications such as the PDR. As you know, we have instituted several regulatory actions against drugs because of their advertisements, and we are presently requesting four drug firms to issue "Dear Doctor" remedial letters in order to correct PDR monographs.

Mr. GORDON. Doctor, can you give us the names of those companies, and also the drugs involved?

Dr. GODDARD. Yes. I can give you those now or for the record.

Mr. GORDON. Could you read them, and then we will put them in the record, also.

Dr. GODDARD. S. E. Massengill, three products: Predsem, Salcort, Salcort-Delta; Organon: Cortrophin Gel, Cortrophin-zinc, Hexadrol phosphate injection, Hexadrol phosphate tabs and elixir; Lakeside Labs, Norparmin. Armour has not been issued, and I would prefer not to mention the drug yet.

(The information referred to follows:)

STATEMENT OF THE FDA CONCERNING COMPANIES REQUESTED TO CORRECT PDR MONOGRAPHS

The three pharmaceutical companies requested to issue "Dear Doctor" letters to correct misinformation occurring in the *Physicians' Desk Reference*, and the specific drugs involved are:

S. E. Massengill Company: Predsem; Salcort; Salcort-Delta.

Lakeside Laboratories: Norparmin.

Organon, Inc.: Cortrophin Gel; Cortrophin Zinc; Hexadrol Phosphate Injection; Hexadrol Tablets and Elixer.

Senator NELSON. Is there approval required by FDA of advertising put in the Physicians' Desk Reference?

Dr. GODDARD. No. That is, of course, a form of labeling, and we review it. And if we find flaws there, we then direct the firms to take remedial action.

Senator NELSON. But you do not review it prior to publication?

Dr. GODDARD. I do not think we should. I think the burden is on the firms. We have explained what the 1962 amendments meant. We are now prepared to explain in even further detail the regulations that we have issued as proposed regulations. And so I do not believe we should have to assume the burden of reviewing prepublication copy. It is quite clear what is required. It should be in fair balance. Physicians should be warned of the bad effects of the drugs as well as told of the good effects.

This type of surveillance of advertising coupled with our administrative action will, I believe, substantially increase the quality of such promotions. Nevertheless, advertising will remain advertising.

The information contained in package inserts is essential to counterbalance the claims made in many drug promotions. As I have pointed out, these inserts are not accomplishing this function, primarily because it does not reach the physician; secondarily, because it is not in readable form.

Now, the compilation of a drug compendium will be a difficult task. The central issue, from FDA's standpoint, is how to abbreviate the package insert material without compromising the public health protection that full information can provide. If we are to condense such labeling, it will still have to adequately reflect current knowledge about the drug. However, we believe that an objective summary, approved by FDA, would be preferable to a package insert which is never read. Also, we believe it will be possible to group several drugs into one category with a general summary covering all the drugs included in the group.

Senator NELSON. Are you satisfied that you have sufficient knowledge, have sufficiently analyzed the problems so that you could, in fact, undertake to develop a compendium in a reasonable amount of time?

Dr. GODDARD. I believe it can be done. As I say, the best way to do it is outside of the Government, in my opinion. It is important enough to me that if it is absolutely necessary, then we can do it as a Federal agency.

Senator NELSON. You would have to be a cooperating agent, anyway, wouldn't you?

Dr. GODDARD. Yes. And I would still prefer, if we had to assume the direct burden, to have much of the work done by contract.

Senator NELSON. And supposing the industry decided they would go ahead, they would, of course, work with you?

Dr. GODDARD. Yes.

Senator NELSON. Do you have any notion, as a practical matter, as to how long it would take to develop and publish an acceptable compendium?

Dr. GODDARD. I think about 18 months would be realistic. It is a large undertaking. Of course, I am optimistic. I think we can do it in that period of time. There are some techniques now available that would lend themselves readily to the production of a volume of this type—the computerized storage of information. Of course, as Mr. Goodrich reminds me, and I bring up once again, the NAS summary is now coming to us, and this will be an integral and important part of that task.

Senator NELSON. What are those summaries?

Dr. GODDARD. These are summaries of their judgments as to efficacy of the drugs marketed between 1938 and 1962. And these represent the opinions of some of the top scientists in the United States who met and discussed drugs that were grouped in 27 categories; 3,000 drugs were involved.

Mr. GORDON. Dr. Goddard, when you talk about efficacy, this is not relative efficacy, is that correct?

Dr. GODDARD. No, sir.

Mr. GORDON. This is merely efficacy as compared to a placebo—better than nothing, is that it?

Dr. GODDARD. Well, they are making judgments, sort of putting these drugs in pigeon holes, if you will, of efficacy. There are no doubts about digitalis you see, for example. We have good direct measuring capabilities that say digitalis changes the heart rate, slows up the heart, increases the force of it.

So we have good information. And with those that are probably efficacious like digitalis, where there is a body of experience in literature, the firms were given the opportunity to pick the best references that supported their claims for review. And, of course, this is primarily a review of the claims that are made for the drugs, too.

So the next category would be probably "nonefficacious" and then "not efficacious." "Efficacious but" is another category. That would refer to trimming back some of the claims that are made, you see.

So the judgments are made against the promotional claims the firms have advocated for this particular drug, not relative evidence.

Mr. GORDON. But the compendium that we are discussing today is not going to include anything on relative efficacy either, is it?

Dr. GODDARD. No.

Mr. GORDON. Well, how is a doctor going to know which is the best drug to prescribe for a particular illness from a relative point of view?

Dr. GODDARD. Well, the physician has to make those judgments all the time. And the information contained in the compendium would be a useful guide to him. But there would not be a direct comparison of this product to that product, is the point I am trying to make.

Mr. GORDON. And yet the doctors who have come before our committee, who are from the academic field and who are connected with large and important hospitals have stated that the problem of relative efficacy is of extreme importance and should be covered by somebody some place.

Dr. GODDARD. Look, efficacy is a function of looking at the drug with respect to the claims that can be supported for it in one sense.

Now, this National Academy report and the material that is embodied in the compendium will be restricted as far as claims are concerned—I mean, the claims have to be substantiated. So in that sense, yes, relative efficacy does get into it. But we have to be careful that we do not get in the business of this antibiotic versus that antibiotic, and permit the same claims for both.

What we are saying is that the claims have to be substantiated, and thus the physician can draw conclusions about relative efficacy.

Senator NELSON. Go ahead.

Dr. GODDARD. Another pressing consideration is whether or not the package insert should be completely done away with in view of the compendium, or merely the requirement of distributing it with each package. As complete labeling is the basis of new drug approval, we recommend that such labeling be retained, and additionally, the package insert type of information should remain available for persons, such as clinical researchers, who are in need of more exhaustive data. In a few instances, it probably will not be possible or even desirable to provide for an exemption from distributing the package insert. For example, I mention the biologicals. That information needs to get to the physician for his views at the time of administration.

Another factor which prompts our endorsement of the compendium is that it will list all drugs, thereby increasing the physician's prescribing range and, of course, pricing information could be included in a supplement thereby fostering more economic prescribing.

However, listing in the compendium should not be construed as governmental approval. As I mentioned before, we are not in a position to guarantee the therapeutic equivalence of all drugs or hence their quality. We are striving toward this goal.

And I mentioned, also, the important role the efficacy review being carried out by the Academy will play.

Now, with sufficient funds—and we estimate about $5 million a year—we could publish such a compendium. We could also provide that listing in the compendium would satisfy the requirements of full disclosure. Although the project could be achieved without increased authority, it would not be the most advantageous manner, in my opin-

ion, in which to proceed. As the drug industry would be relieved of the cost of package inserts by this proposal, I believe it would be appropriate to shift the cost of the compendium to the industry. This, of course, would require legislation.

And additionally, legislation would be desirable to clarify the scope and purpose of the compendium and to realine some present provisions of the act in greater conformity with the compendium concept.

Now, a final comment on this subject—we believe that increasing access to the complete labeling of prescription drugs is in itself enough to justify publication and distribution of a drug-labeling compendium. Additionally, the compendium would list generic products together with their well-known trade name counterparts, thereby facilitating the economic prescribing of generic drugs and increasing the physician's familiarity with the presently complex drug nomenclature.

Senator NELSON. As to the type of information you recommend be included in the compendium, would you consider including the price?

Dr. GODDARD. I mentioned the possibility of a supplement as being a more appropriate way of doing this because price changes do occur rather frequently. And it would tend to minimize the value of that information in a hardbound volume that would stay on the physician's desk for a year at a time, whereas supplemental information will undoubtedly be provided to keep him current on changes on drug labeling, and so forth, perhaps as often as four times a year. So those supplements could also contain pricing information which might be useful to him.

Senator NELSON. Would you continue to update the compendium by including in it additional scientific knowledge such as a Medical Letter report on, say, prednisone?

Dr. GODDARD. No; not unless there was something derived from that letter that indicated a need for a change in labeling.

Senator NELSON. So in the compendium you would simply list the drug by generic name, the companies that manufacture this drug generically or under a trade name, the best known scientific knowledge there is about this drug, its purpose and use and side effects, and so forth?

Dr. GODDARD. Yes; that is correct. And cross index it by both trade name and generic name.

Senator NELSON. And you would think it would take about 18 months to prepare and publish such a compendium?

Dr. GODDARD. Yes, sir.

Senator NELSON. And you think it would be best if the initiative, at least, came from the industry itself?

Dr. GODDARD. I would hope that the private sector of our economy would do this. You know, we have been talking about the need for good information for the physician to prescribe drugs. This would represent good information, unbiased, a source book that he could turn to daily as he needed it. I think this really would be not only in the interest of better medicine and the patients who receive the drug, but also in the long run be in the interest of the pharmaceutical firms. And I would much prefer to see them take the initiative and do the job, than have to have the Government step in and assume another function.

Senator NELSON. A number of Members of the Congress have been interested in a compendium. How do we decide whether we are going to have to provide for it by legislation or whether the industry will do it on its own? What is the status of your dialog with the industry, so we might have some indication?

Dr. GODDARD. Well, you know, Mr. Chairman, if I could answer that question, I think we would have a compendium now in terms of what is to be done. The status is this: There is an additional meeting scheduled at the Academy where we will come together again and discuss this in the very near future.

As I said, 18 months have now elapsed since the industry brought the matter to my attention and requested, in effect, exemption from my predecessor's provision that the package inserts be published concurrently with the compendium for a 1-year period.

Now, I do not know how much longer one should allow before saying, "Well, we just have not been able to get this," and go ahead and have the Government do the job.

Senator NELSON. Are you referring to the National Academy of Sciences?

Dr. GODDARD. I am referring to the 18 months that have elapsed since the president of the PMA raised the question with me.

Senator NELSON. But you said the National Academy.

Dr. GODDARD. Well, the National Academy then became involved about a year ago, and we have had a number of meetings under their aegis since then. We have one more meeting, at least, scheduled in the very near future to discuss this again in detail. But, you see, we keep discussing it and we never get a yes or no from the PMA on it.

Senator NELSON. Is the American Medical Association participating directly?

Dr. GODDARD. They have participated. Their representatives have attended such meetings. The council on drugs of the AMA has advocated for 10 years the publication of such a volume. I do not think there is any disagreement among the scientific community that this represents an unfulfilled need, an important objective could be accomplished. But we just do not seem to be able to get off dead center.

Senator NELSON. Well, is there any dissent in the scientific community as to the question of its feasibility?

Dr. GODDARD. No, sir.

Senator NELSON. When is your next meeting?

Dr. GODDARD. Within 2 weeks. It was to have been tomorrow, but that meeting had to be canceled because not all the participants could attend.

Senator JAVITS. Would the Chair yield for one question?

Senator NELSON. Yes, Senator. Go ahead.

Senator JAVITS. Do you have statutory authority to compile this compendium but no money; or do you lack both?

Dr. GODDARD. We could publish such a compendium, Senator Javits, under present authority.

Senator JAVITS. And is there any inhibition on the part of the executive department, the President, or anybody else stopping you from doing it? You just have no money?

Dr. GODDARD. We have no money. And I made the point prior to your coming in that I would prefer to see it done by private industry.

Now, if we are to do it, then I also feel that the cost of it should be borne by industry, which would be in effect, excused from a present $6-million-a-year program of package inserts.

Senator JAVITS. The way you make them do it would be by imposing a duty and charging a fee or a tax?

Dr. GODDARD. Yes; some sort of arrangement—let's say a registration fee which could be related to the number of drugs that they produce and the unit number, so that it would be a sliding scale.

Senator JAVITS. But that would take legislation.

Dr. GODDARD. That would require legislation. I would also like to see, if that is done, a revolving fund created so that those fees could be used specifically for the purpose of the publication of the compendium.

Senator JAVITS. Your agency comes under the Labor and Public Welfare Committee, does it not? That is where you were confirmed, was it not?

Dr. GODDARD. Under Senator Hill.

Senator JAVITS. Labor and Public Welfare?

Dr. GODDARD. Yes; Labor and Public Welfare.

Senator JAVITS. I am the ranking minority member of that committee, and I was just going to suggest to the Chair—he is a member of the same committee—that we might consider information which would deal with the question. And if it did come before our committee, as it probably would, I think we could bring about fairly expeditious hearings and then you would come to grips with the industry, and they would have to fish or cut bait.

Thank you.

Senator NELSON. Well, I might say to the Senator I have already introduced a bill proposing a compendium, but after discussions with knowledgeable people who do not consider the bill to be adequate, we are preparing another one. I would certainly be pleased to join with the distinguished Senator from New York in making such a proposal.

As Dr. Goddard said, for 10 years the Council on Drugs of the American Medical Association has been saying we need a compendium. There is no dissent in the scientific community about the feasibility of it. All the testimony we have had time after time from distinguished pharmacologists and physicians before this committee is that we need one. Dr. Goddard's position has been that he would like to see the industry do it.

But, Dr. Goddard, if you find out from your next meeting with the academy that they just are not going to do it, I certainly think that Senator Javits and I and whoever else is interested ought to put in legislation to develop the compendium. I do not see why we should wait another 10 years for that.

Do you agree with that?

Dr. GODDARD. I will be happy to keep you advised of the outcome of the meeting.

Senator NELSON. I think it would be worth while for you to mention Senator Javits' comments and mine at the next meeting with the industry.

Dr. GODDARD. Senator, I am sure they will know about it even before the next meeting.

Senator NELSON. I don't know. Some of the representatives are forgetful. I thought you might call it to their attention directly.

Dr. GODDARD. I will be happy to do that, Senator.

Senator NELSON. Did you have any other questions, Senator, on the compendium?

Senator JAVITS. No. Thank you, Mr. Chairman.

Senator NELSON. Thank you, Senator.

If you would just hold up a moment, I had some notes, and I wanted to see if I covered everything I wanted to cover.

Doctor, about 2 weeks ago, I think, the American Telephone & Telegraph Co. appeared, as well as some distinguished physicians, and part of their presentation was a discussion of the idea of making available by telephone communications and otherwise, electronically, information on drugs to doctors so that a doctor could just pick up his phone and dial a number and make an inquiry about a drug and get a 5-minute lecture from a very distinguished authority on the drug, plus the doctor's name so that if he wished to call that doctor directly for a broader exploration of the question, he could do that.

Do you have any views upon the value or feasibility of the use of this kind of development?

Dr. GODDARD. Well, I was acquainted once with an operation that was known as Mediphone, which was intended to serve some of the same purposes that you have talked about. It was a service offered to physicians. And as I recall, the subscription fee was $25 a year. And the physician could call in and get information on any drug in the marketplace. It went bankrupt——

Senator NELSON. That was on drugs?

Dr. GODDARD. Yes; this was on drugs.

Senator NELSON. Where was this system used?

Dr. GODDARD. Well, it was introduced nationally. It was preceded by advertising, offering of subscriptions, and so forth, but it went bankrupt within about 3 months.

I would have to know more of the details as to how the physician would become involved: Would it be on a paid subscription basis? Would it be a free service? Would it be regionalized?

We are looking at the use of the telephone from the standpoint of trying to improve the reporting of adverse reactions of drugs.

We are working with the local medical societies to try to set up a trial to see whether physicians would be more willing to share their drug experiences by reporting them by just using the phone rather than by writing a report. And if this works locally, we may tend to try it regionally from, say, the New England region where the physician could make a call free of charge to a number here in Washington and report adverse experiences. And if that were to work, then we could make it a national system.

Now, ultimately you could have an exchange system built up where the physician could not only call and report an experience, but call and get information.

It is a difficult task. There have been a number of instances of attempts to provide information to physicians.

RCA had a very unsuccessful one, a lecture series on the radio.

I would have to know more about A.T. & T.'s proposal in depth before I comment on the merits of the points you have raised.

Senator NELSON. Did you have the opportunity to read their testimony?

Dr. GODDARD. No; I have not read it yet. I will obtain it and do so.

Senator NELSON. There was a representative present from the University of Wisconsin where, I think, with some Federal funding they have developed an information bank which the doctor can call directly. He has before him a listing of the problems that they are prepared to respond to, and he can call without cost and receive this information.

The point was made that a doctor in an emergency situation or quasi-emergency situation may be dealing with a reaction to a bee sting, for example. He has not had a serious one in the last 4 or 5 years. He wants the latest information and needs to get it quickly. He can pick up the phone and call and immediately would be told what drug to use under what circumstances and what reaction to expect.

What I am asking you is, Does the concept strike you as a valuable one?

Dr. GODDARD. It certainly deserves a trial, Senator. We need to use modern communications techniques to a greater degree than we now do for dissemination that would assist the physician in the practice of medicine.

Senator NELSON. The other aspect that was raised in connection with this kind of communication is its use in the question of drug recalls.

What is your present method of notifying physicians of a recall, especially if it is a very serious recall which requires immediate results?

Dr. GODDARD. Well, for the recall where we deem it necessary to contact all physicians, the company is required to contact all prescribing physicians by direct mail.

That is our present practice.

Now, you will recall that on one or two instances it was deemed necessary to go right into the homes to advise housewives to look in the medicine chest. And that is accomplished by use of the public media.

Normally—rather, usually the recalls are carried out either to the retail level or to the wholesale level, occasionally to the physician and rarely to the consumer level.

Senator JAVITS. Mr. Chairman, may I ask the special permission of the Chair to ask just one question of the witness——

Senator NELSON. Certainly.

Senator JAVITS (continuing). On this marihuana issue.

I just wanted to ask you one question. I read your statement—and Senator Nelson will deal with all the matters in it, I am sure, very effectively—but what I would like to know from you is this:

I do not see anywhere in your statement what you did say that was misquoted. What did you say about marihuana? What was your actual statement?

Dr. GODDARD. All right. May I do two things? One, submit for the record the actual words, but, two, just give you here and now in my own words what I said in response to the question.

(The information referred to follows:)

TRANSCRIPTION OF WCCO TAPE OF GODDARD PRESS CONFERENCE, OCTOBER 17, 1967, UNIVERSITY OF MINNESOTA, MINNEAPOLIS, MINN.

Dr. GODDARD. First of all, marijuana is under the jurisdiction of the Bureau of Narcotics, U.S. Treasury Department. I've been asked to comment on the subject a number of times and I've tried to make my position clear, that first we need more long term research to detect any possible serious side effects from chronic usage. But, secondly, I feel that the present penalty for personal possession is too severe, and I've simply said that the penalties for sale and distribution should remain but, I favor a penalty more comparable to that, that we have for the other hallucinogens. LSD, which is far more a serious and toxic drug than marijuana is, after all, a mild hallucinogen. It just isn't a rational kind of set of penalties for these two classes of drugs.

Question. Would you describe it as being more dangerous than alcohol? Marijuana is more serious than alcohol?

GODDARD. Well, trying to compare two different drugs is a very risky business itself. They have quite different mechanisms of action; alcohol's a depressant, where marijuana is a mild hallucinogen, at best, or maybe a euphoric.

Now, they both share some properties in common, however, they both distort our sense of reality, and therefore it's dangerous to operate heavy equipment or drive a vehicle when we're under the influence of either one of these.

Alcohol, probably lends itself more readily to control on the part of the least to the inexperienced.

So, there are some similarities, but there are also some differences. And as I've mentioned many times, we don't know what the long term effects of smoking marijuana or using marijuana in other forms might be, and we have to carry out this kind of research before, I for one, would be satisfied to say that the drug is safe under any conditions.

Question. Dr. Goddard, what major safeguards do we need in the commercial drug testing?

GODDARD. Well, we seem to have good laws at the present time. It's a matter of having the laws that exist in the form of the Kefauver-Harris Amendment of 1962, followed by those who produce and distribute drugs for the marketplace. I'm satisfied we're making progress in this field. We're trying to get truth in drug advertising. I think we're beginning to see some signs of progress.

Question. Do doctors know about the adverse effect of drugs? Are they well informed on that?

GODDARD. Well, this is one of the areas that the Kefauver-Harris Amendments was designed to correct, the failure on the part of firms who sell these drugs to sort of obscure or tend not to tell the doctor about the bad effects. We are seeing improvements in this, but I'm still not satisfied, that all of the scientific data is properly being provided to the prescribing physician.

Question. Can you specify some drugs that you think might have adverse effects?

GODDARD. Well, we have recently in the past year, in fact, caused a number of "dear doctor" letters to be sent out, and I think the doctors know what these are well enough without my going into details now.

Question. How serious is the shortages of flu serum going to be?

GODDARD. Well, I haven't kept up with the flu vaccine problems this year. I used to, when I was chief of the Communicable Disease Center, because we were the group that predicted how serious the flu season would be. The Division of Biologic Standards, part of the National Institutes of Health in the Public Health Service, determines what the nature of the flu vaccine will be, that the manufacturers turn out. So, it's not under my purview, and I'm not all caught up on the subject right now.

Question. How about drug pricing? Are you investigating companies that maybe sell drugs at inflated prices?

GODDARD. No, we have no responsibility for pricing policies of the drug industry. I'd like to make that clear.

Question. You were speaking of ante facto action by business, getting into the area of your talk this afternoon. Could you communicate to us some of the idea in—in a minute or so?

GODDARD. Well, I was simply trying to say that the business community, be more perceptive as to the writing that's on the wall and begin to take actions

long before the Government pushes them into certain activities, become involved in the community activities, in our national affairs in a different way than they have in the past. This is a risk type of thing, I admit, but it's essential in my thinking, if the business community is going to withstand increasing government regulation.

I am simply trying to say that the automotive industry could have avoided the creation of a National Safety Agency had they built more safety into their vehicles, something they've always been capable of, they have the scientific—the engineering know-how; the only thing they lacked was the desire and the social perceptiveness to realize that if they failed to do it, it would be done for them.

This is what I'm also trying to tell the drug industry, avoid the heavy hand of regulation by acting in a responsible way. Make the decisions yourselves. The food industry has done quite well.

That kills it fellows.

Dr. GODDARD. The question was raised: "Dr. Goddard, is marihuana dangerous, or more dangerous than alcohol? Would you prefer that your daughter smoked pot than drank a cocktail?"

I said, "No, I would not, nor would I want anybody's daughter to smoke marihuana as long as we know so little about the long-term effects. And, secondly, it is dangerous to use when you are operating a vehicle. And third, under the context of today's laws it would be very inappropriate."

Now, I have paraphrased it some, but that was my answer.

Senator JAVITS. That is what you said?

Dr. GODDARD. Yes, sir.

Senator JAVITS. And what they quoted, therefore, was something different?

Dr. GODDARD. Yes, sir.

Senator JAVITS. Are you going to put in the record what they quoted?

Dr. GODDARD. I will do so. And I also have a letter from the wire service that apologized. They investigated the matter thoroughly, and they found I did qualify my statement and that they were wrong. They offered to do everything they could to correct the story that their wire service had carried.

Senator JAVITS. Well, now, the Chair will deal with all of that.

Dr. GODDARD. Yes.

Senator JAVITS. I was only wondering because your statement did not say what you did say.

Now, what did they quote you as saying?

Dr. GODDARD. That I would rather my daughter smoke pot than drink a cocktail.

Senator JAVITS. And was that in quotes?

Dr. GODDARD. No, sir.

Senator JAVITS. It was just their generally stating——

Dr. GODDARD. That is right.

Senator JAVITS. And you have now testified what you did say?

Dr. GODDARD. Yes, sir.

Senator JAVITS. And this represents your statement as a very high Government official?

Dr. GODDARD. Yes, sir.

Senator JAVITS. Thank you very much, Mr. Chairman.

Senator NELSON. Thank you, Senator.

Dr. Goddard does address himself to that question in a little more detail——

Senator JAVITS. Later on, yes. Thank you, Mr. Chairman.

Senator NELSON. You might as well proceed with your statement on that question.

Dr. GODDARD. Mr. Chairman, we appreciate this opportunity to clarify our position with respect to marihuana.

As evidenced by the attention given by representatives of Government, the press, and the professions, it is plain that the increasing use of marihuana is a matter of national concern. I am aware, Mr. Chairman, that statements attributed to me, but which I did not make, have caused additional concern. Let me clarify the record in this regard at the very outset.

I did not say that I would not object to my daughter smoking marihuana.

I did not, and I do not, condone the use of marihuana.

I did not, and I do not, advocate the abolition of controls over marihuana.

I did not, and I do not, propose "legalizing" the drug.

With your permission, Mr. Chairman, I would like to call your attention to one point which arose as a result of an erroneous news dispatch from Minneapolis on October 17. I was reported to have stated that I would not object any more to my daughter smoking marihuana than if she drank a cocktail.

The news dispatch was not correct and Mr. Julius Frandsen, vice president and Washington manager of United Press International, has written me a letter acknowledging error by the United Press International. With your permission, I would like to insert a copy for the record.

Senator NELSON. A copy of the letter?

Dr. GODDARD. Yes, sir.

Senator NELSON. Would you read the letter?

Dr. GODDARD. I can read two paragraphs or the entire letter.

Senator NELSON. Read whatever you think is pertinent.

Dr. GODDARD. Well, I think two paragraphs are most appropriate, and the entire letter I would like to submit for the record.

Senator NELSON. We will print the letter in full in the record.

(The information referred to follows:)

UNITED PRESS INTERNATIONAL,
November 2, 1967.

Dr. JAMES L. GODDARD,
Commissioner, Food and Drug Administration,
Washington, D.C.

DEAR DR. GODDARD: Following my return from a trip, I have been belatedly looking into the circumstances of our dispatches from Minneapolis on October 17 and 18. I find we owe you an apology.

I refer to the UPI dispatch which began, without qualification:

"Food and Drug Administration Commissioner Dr. James Goddard says he would not object to his daughter smoking marijuana any more than if she drank a cocktail."

Unfortunately, no complete tape exists of your exchanges with reporters. The questioning began in an informal session in the front of the auditorium after your speech and no recording equipment was there. Equipment was set up in another room and only the ensuing proceedings at that place were taped.

UPI was represented by Miss Judy Vick of the University of Minnesota News Service. She says her notes show that in the Q. & A. with reporters in the auditorium Victor Cohn of the Minneapolis Tribune asked whether marijuana is more dangerous than alcohol. And that you replied "Whether or not marijuana is more dangerous than alcohol is debatable. I don't happen to think it is."

Miss Vick says that Mr. Cohn then asked whether you would mind if your daughter smoked marijuana any more than if she drank a cocktail, and that you replied "No, except in the context of the present law." I take that to be a reference to the fact that marijuana is illegal and alcohol is legal.

Mr. Cohn's recollection is that his question was to the effect "Would you mind if your daughter took marijuana?" His notes have you responding: "We have talked about it at home. I would (that is, would object) in terms of the law today" and "we really don't know what the long-term effects (of marijuana) are." Followed by some comments about distortion of perception following use of marijuana.

So it has become clear to me that UPI erred in attributing to you unqualified statements which in fact were considerably qualified.

I am sorry if UPI has compounded your problems. We are prepared to carry a dispatch acknowledging our error.

In view of the public uncertainty that now exists as to what you do and do not believe, I hope you will sit down with our Louis Cassels so that he can prepare a definitive dispatch. I believe you know Mr. Cassels and his outstanding record for accuracy and fairness. Please let me know.

Several members of Congress have inquired about our original story, and I am taking the liberty of sending them copies of this letter.

Sincerely,

JULIUS FRANDSEN,
Vice President and Washington Manager.

Dr. GODDARD. In his letter Mr. Frandsen says, "So it has become clear to me that UPI erred in attributing to you unqualified statements which in fact were considerably qualified. I am sorry if UPI has compounded your problems. We are prepared to carry a dispatch acknowledging our error."

Senator NELSON. Did they release a dispatch acknowledging their error?

Dr. GODDARD. I didn't request them to do so, Senator, because of the hearings scheduled for yesterday. And I understand they did carry a very comprehensive story on their wire service last night, although I have not seen it as yet.

Senator NELSON. Thank you. Go ahead.

Dr. GODDARD. A very good story, too, I am told.

Mr. Chairman, I think the press recognizes the importance of the problem marihuana presents to society and makes every effort to provide the Nation with the best information available.

My remarks concerning marihuana—in Minneapolis and elsewhere—have always been in response to questions from the press. In every instance, I have made it abundantly clear that marihuana has been and still remains under the jurisdiction of the U.S. Department of the Treasury. It is often erroneously assumed that the Food and Drug Administration, which administers the drug abuse control amendments, has jurisdiction over not only the controlled drugs—the amphetamines, barbiturates, and hallucinogens—but marihuana as well. Our agency has made every effort to clarify the differences wherever possible.

Senator NELSON. You do not have any jurisdiction over marihuana?

Dr. GODDARD. No. I should point out, however, that the Department of Health, Education, and Welfare has a very broad interest in marihuana in that they have responsibility for the dissemination of information and educational materials on narcotics including—and drugs that are abused, including marihuana. The National Institutes of Mental Health specifically have responsibility for the conduct of research. The National Institutes of Mental Health have a responsibility to provide services under the Narcotics Addicts Rehabilitation Act. The Food and Drug Administration has a responsibility to control the distribution of synthetic marihuana, and to the investigation of the new-drug exemption provisions of the Food and Drug Act. And so the Department is broadly concerned in not only those ways but in its concern with respect to juvenile delinquency where marihuana is often involved in the acts committed by juveniles in our society.

So although we have no responsibility for the control of marihuana—I am trying to say that the Department of Health, Education, and Welfare is very much concerned about the whole subject.

Now, let me make several points about marihuana. First, the shocking growth and use of marihuana has been so rapid that none of us in government, in medicine, or the legal profession has been able to counter it effectively.

The use of marihuana in this country and the rest of the world has a long history, of course.

Senator NELSON. You refer to the shocking increase in its use. Do we have any good statistics on what the increased use is?

Dr. GODDARD. I can give you—to answer you, good statistics in the sense they were seen by a practicing physician, no—some good data on arrests related to marihuana from the State of California. This one source shows, as I recall, juvenile arrests last year increased over the previous year 134 percent. It went up to about 3,800 arrests last year.

Senator NELSON. In California?

Dr. GODDARD. Yes—juveniles, now.

Senator NELSON. When you say juveniles, do you mean under 18?

Dr. GODDARD. That is my understanding of their definition; yes, Mr. Chairman.

Now, in addition——

Senator NELSON. Well, let me get this straight. In coming to your conclusion that there has been a shocking increase in the use of marihuana, you have relied upon various estimates?

Dr. GODDARD (continuing). And statistics that are available. For example, it is estimated that between 400,000 and 3 million persons currently use marihuana or try during the year.

Senator NELSON. Between 400,000 and what?

Dr. GODDARD. Between 400,000 and 3 million people in a year try or use marihuana, and as many as perhaps 20 million people in our society have used marihuana.

Now, some of the statistics I have referred to—the Department of Justice of the State of California reported a total of 28,319 adult drug arrests in 1966.

Senator NELSON. How many?

Dr. GODDARD. 28,319.

Senator NELSON. Where?

Dr. GODDARD. In the State of California.

Senator NELSON. Just California alone?

Dr. GODDARD. Just California.

Senator NELSON. And what was the juvenile use, did you say?

Dr. GODDARD. Well, if I may——

Senator NELSON. Go ahead.

Dr. GODDARD (continuing). Proceed to that. That was the highest figure to date. Fully 32 percent above the preceding year for adult arrests. Some of the increases came from the enforcement for the first time of the drug abuse control amendments, which became effective on February 1, 1966.

"However," to quote from their report, "marihuana offenses amounted for approximately one-half of the 1966 arrests and showed a 71 percent increase over those reported in 1965. Arrests for marihuana and other narcotics increased by 11 percent."

Senator NELSON. These statistics are not in your statement, are they?

Dr. GODDARD. No.

Senator NELSON All right.

Dr. GODDARD. "Dangerous drug arrests showed a 4 percent gain," the report adds. "California adult marihuana arrests in 1966 were three times what they were in 1960. Among juveniles the rise was even more dramatic. Drug arrests in general increased 87 percent between 1965 and 1966, and 140 percent for juvenile marihuana arrests." And the numbers were from 1,623 to 3,869, the lower figure being——

Senator NELSON. From what?

Dr. GODDARD. 1,623 in 1965 and 3,869 in 1966.

Now, the marihuana arrests plus the 898 arrests for dangerous drugs that they made accounted for 93 percent of the juvenile drug arrests in California during 1966.

Now, 60 percent of the juveniles arrested in that year were either age 17 or age 18. So it gives you an idea that the bulk of these people are——

Senator NELSON. Seventeen and 18?

Dr. GODDARD. Yes, sir.

Senator NELSON. Do you have extra copies of that report?

Dr. GODDARD. I can obtain them for you; yes, sir.

Senator NELSON. I would like to print your statistics at this stage in the record, so do you have extra copies with you?

Dr. GODDARD. We can give you this copy, yes.

Senator NELSON. Fine.

(The information referred to follows:)

1966 Drug Arrests in California

A PRELIMINARY SURVEY

Data shown in this report are subject to modification by additional arrest information received prior to formal publication in the annual report *Drug Arrests and Dispositions in California.*

ADULT ARRESTS

The 1966 total of 28,319 adult drug arrests is the highest annual arrest figure recorded by the Bureau of Criminal Statistics to date; this figure exceeds the year-earlier total by 32.1 percent. Marijuana offenses accounted for approximately one-half of the 1966 arrests and showed a 71 percent increase over those reported during 1965. Arrests for "heroin and other narcotics" increased by about 11 percent while arrests for "narcotic addict or user" increased by 6 percent. Dangerous drug arrests showed a 4 percent gain.

Neither Los Angeles County nor the remainder of the state conformed too closely to the statewide averages. Arrests for "narcotic addict or user" increased by 18 percent in Los Angeles County but decreased by 23 percent in the rest of the state. The converse was true for dangerous drug offenses which decreased by 14 percent in Los Angeles County while exhibiting an increase of 33 percent in the other counties.

In 1966 about 59 percent of the adult arrests occurred in Los Angeles County, as compared with 62 percent recorded in 1965, and 68 percent in 1960.

There were 16,820 adult arrests reported by Los Angeles County in 1966; San Diego County reported 2,708; San Francisco County 2,187; and Alameda County 1,469. These four counties alone accounted for 82 percent of the total arrests.

The total of 28,319 adult arrests involved 24,244 individuals. Of the arrests, 16,051 (57 percent) represented persons who were new to the drug file. Relatively few of the new offenders were involved with heroin—about 10 percent. This was in sharp contrast to marijuana, which accounted for over 60 percent of the new subjects. Of the 14,293 adult marijuana arrests during the year, 9,819 involved persons new to the study.

About 38 percent of the subjects arrested were under some form of probation or parole supervision at the time of arrest. Six percent (1,716) were on parole from the Department of Corrections and 1,751, roughly the same proportion, from the California Youth Authority. Less than 3 percent were on parole from the California Rehabilitation Center. Approximately 20 percent were under adult probation supervision.

Because these percentages are based on arrests, some of them multiple, they should be regarded as indications rather than as exact determinations.

JUVENILE ARRESTS

Juvenile arrests rose from 2,691 in 1965 to 5,034, an increase of 87 percent. Los Angeles County reported 3,189, or 63.3 percent of the total. In the other leading counties, Alameda County registered 295 such arrests; San Diego County 253; Orange County 251; and San Francisco 167. San Mateo and Santa Clara counties reported 144 and 126, respectively.

The youth drug problem revolved around marijuana (3,869 arrests) and dangerous drugs (898 arrests). Together, these two offense groups account for 95 percent of juvenile arrests on drug charges. One hundred and nine arrests in 1966 compared with 60 in 1965 involved the possession, sale or use of heroin and other narcotics.

Age 17 appears to be the critical year for youths arrested for drug usage. Those born in 1949 (age 17) made up 40 percent of the total; combined with those born in 1950, the two groups accounted for 63.8 percent of all juvenile arrestees.

SUMMARY

Total adult drug arrests were 32 percent higher in 1966 than in 1965. Adult marijuana arrests increased by 71 percent over 1965 and were more than three times greater than the number reported in 1960.

Juvenile drug arrests increased in number from 2,691 in 1965 to 5,034 in 1966—an increase of about 87 percent. Juvenile marijuana arrests increased from 1,623 to 3,869, or 140 percent.

TABLE 1.—ADULT DRUG ARRESTS REPORTED BY CALIFORNIA LAW ENFORCEMENT AGENCIES, JANUARY 1960 THROUGH DECEMBER 1966 (PROVISIONAL)

[By offense, area of State, and year of arrest]

Area and offense	Year of arrest							Percent change, 1966 over 1965	Percent change, 1966 over 1960
	1960	1961	1962	1963	1964	1965	1966		
Statewide	17,619	16,925	16,250	16,728	19,244	21,444	28,319	32.1	60.7
Marihuana	4,098	3,305	3,291	4,677	6,055	8,349	14,293	71.2	248.8
Heroin and other narcotics	2,244	1,971	1,971	2,206	2,601	2,362	2,610	10.5	16.3
Narcotic addict or user [1]	6,401	5,801	3,532	3,226	4,073	3,473	3,695	6.4	−42.3
Dangerous drugs [1]	3,305	4,322	5,578	4,415	4,595	5,916	6,093	3.0	84.4
Other offenses [2]	1,571	1,526	1,878	2,204	1,920	1,344	1,628	21.1	−3.6
Los Angeles County	11,959	11,604	10,200	10,042	11,671	13,394	16,820	25.6	40.6
Marihuana	2,653	2,316	2,256	3,161	3,964	5,327	8,600	61.4	224.1
Heroin and other narcotics	1,544	1,302	1,187	1,355	1,470	1,254	1,416	12.9	−8.3
Narcotic addict or user [1]	4,771	4,193	2,204	2,014	2,830	2,501	2,942	17.6	−38.1
Dangerous drugs [1]	2,238	3,013	3,742	2,645	2,864	3,779	3,253	−13.9	45.4
Other offenses [2]	753	780	811	867	543	533	609	14.3	−19.1
State less Los Angeles County	5,660	5,321	6,050	6,686	7,573	8,050	11,499	42.8	103.2
Marihuana	1,445	989	1,035	1,516	2,091	3,022	5,693	88.4	294.0
Heroin and other narcotics	700	669	784	851	1,131	1,108	1,194	7.8	70.6
Narcotic addict or user [1]	1,630	1,608	1,328	1,212	1,243	972	753	−22.5	53.8
Dangerous drugs [1]	1,067	1,309	1,836	1,770	1,731	2,137	2,840	32.9	166.2
Other offenses [2]	818	746	1,067	1,337	1,377	811	1,019	25.6	24.6

[1] Includes driving under the influence of narcotics or dangerous drugs.

[2] Includes prescription violations, possession of narcotic paraphernalia, etc. Prior to 1965 driving offenses and all Federal violations were included. Beginning with 1965, Federal violations are shown under the more descriptive offense groups wherever appropriate.

Note: Data are subject to change as additional arrest information is received.

TABLE 2.—ADULT DRUG ARRESTS REPORTED BY CALIFORNIA LAW ENFORCEMENT AGENCIES, 1966 (PROVISIONAL)

[Area of State and county by offense]

County	Total	Marihuana	Heroin and other narcotics	Narcotic addict-user [1]	Dangerous drugs [1]	Other offenses [2]
Statewide	28,319	14,293	2,610	3,695	6,093	1,628
Los Angeles	16,820	8,600	1,416	2,942	3,253	609
San Francisco	2,187	828	375	110	580	294
Alameda	1,469	860	130	126	249	104
Imperial	174	63	45	12	28	26
Kern	91	34	6		41	10
Orange	1,305	771	57	123	294	60
Riverside	309	162	22	14	88	23
San Bernardino	347	155	38	35	94	25
San Diego	2,708	1,202	232	74	981	219
San Luis Obispo	39	28	1		4	6
Santa Barbara	173	115	10	12	14	22
Ventura	295	133	42	66	42	12
Contra Costa	338	208	27	13	53	37
Marin	78	59	5	2	5	7
San Mateo	258	142	13	21	56	26
Santa Clara	420	252	34	32	67	35
Solano	31	26	2		2	1
Napa	17	12	1	4		
Sonoma	100	80	3	1	10	6
Butte	17	8			8	1
Glenn	4	1			3	
Placer	14	6	2	1	5	
Sacramento	258	138	59	17	27	17
Shasta	7	3		2	1	1
Sutter	1	1				
Tehama	1			1		
Yolo	21	8	5		3	5
Yuba	4	2			2	
Fresno	221	86	45	23	30	37
Kings	13	7	1			5
Madera	20	14	4	1		1
Merced	30	24			4	2
San Joaquin	211	58	15	36	98	4
Stanislaus	47	23	3	6	8	7
Tulare	35	20		1	8	6
Del Norte	11	11				
Humboldt	11	4			6	1
Mendocino	11	7	1		2	1
Amador	2		1		1	
El Dorado	19	12	1		2	4
Lassen	2	2				
Nevada	2	1		1		
Plumas	2	2				
Siskiyou	6	2		1	3	
Inyo	3	2	1			
Lake	1				1	
Mariposa						
Mono	19	15	1		1	2
Monterey	101	66	9	11	6	9
San Benito	4	4				
Santa Cruz	60	34	3	7	13	3
Tuolumne	2	2				

[1] Includes driving under the influence of narcotics or dangerous drugs.

[2] Includes prescription violations, possession of narcotic paraphernalia, etc. Prior to 1965 driving offenses and all Federal violations were included. Beginning with 1965, Federal violations are shown under the more descriptive offense groups wherever appropriate.

Note: Data are subject to change as additional arrest information is received.

TABLE 3.—ADULT DRUG ARRESTS REPORTED BY CALIFORNIA LAW ENFORCEMENT AGENCIES, 1966 (PROVISIONAL) SHOWING INITIAL ARRESTS AND REARRESTS BY OFFENSE

Area and offense	Total	Initial [1]	1966 rearrests	
			First [2]	Subsequent [3]
Statewide	28,319	16,051	8,193	4,075
Marihuana	14,293	9,819	2,891	1,583
Heroin and other narcotics	2,610	1,009	1,095	506
Narcotic addict or user [4]	3,695	645	2,176	874
Dangerous drugs [4]	6,093	3,901	1,375	817
Other offenses [5]	1,628	677	656	295
Los Angeles County	16,820	8,627	5,588	2,605
Marihuana	8,600	5,554	2,019	1,027
Heroin and other narcotics	1,416	465	666	285
Narcotic addict or user [4]	2,942	448	1,794	700
Dangerous drugs [4]	3,253	1,926	857	470
Other offenses [5]	609	234	252	123
State less Los Angeles County	11,499	7,424	2,605	1,470
Marihuana	5,693	4,265	872	556
Heroin and other narcotics	1,194	544	429	221
Narcotic addict or user [4]	753	197	382	174
Dangerous drugs [4]	2,840	1,975	518	347
Other offenses [5]	1,019	443	404	172

[1] Individuals appearing for the first time since July 1, 1959.
[2] First 1966 arrests of persons who had previously been arrested between July 1, 1959, and Dec. 31, 1965.
[3] Further arrests of persons who had been arrested at least once before in 1966.
[4] Includes driving under the influence of narcotics or dangerous drugs.
[5] Includes prescription violations, possession of narcotic paraphernalia, etc. Prior to 1965 driving offenses and all Federal violations were included. Beginning with 1965, Federal violations are shown under the more descriptive offense groups wherever appropriate.

Note: Data are subject to change as additional arrest information is received.

TABLE 4.—ADULT DRUG ARRESTS REPORTED BY CALIFORNIA LAW ENFORCEMENT AGENCIES, 1966 (PROVISIONAL)

[Area and offense by parole status]

Area and offense	Total	Parole status						
		None	Department of corrections	CYA	Adult probation	CRC	Other [1]	Unknown
Statewide	28,319	17,590	1,716	1,751	5,753	720	294	495
Marihuana	14,293	9,883	343	1,039	2,599	117	91	221
Heroin and other narcotics	2,610	1,464	297	94	562	108	52	33
Narcotic addict or user [2]	3,695	1,428	728	194	849	403	73	20
Dangerous drugs [2]	6,093	3,953	199	345	1,326	38	48	184
Other offenses [3]	1,628	862	149	79	417	54	30	37
Los Angeles County	16,820	10,223	1,183	1,146	3,316	546	186	220
Marihuana	8,600	5,916	190	694	1,581	64	61	94
Heroin and other narcotics	1,416	793	189	56	260	73	30	15
Narcotic addict or user [2]	2,942	1,113	626	158	616	357	57	15
Dangerous drugs [2]	3,253	2,062	123	206	744	21	25	72
Other offenses [3]	609	339	55	32	115	31	13	24
State less Los Angeles County	11,499	7,367	533	605	2,437	174	108	275
Marihuana	5,693	3,967	153	345	1,018	53	30	127
Heroin and other narcotics	1,194	671	108	38	302	35	22	18
Narcotic addict or user [2]	753	315	102	36	233	46	16	5
Dangerous drugs [2]	2,840	1,891	76	139	582	17	23	112
Other offenses [3]	1,019	523	94	47	302	23	17	13

[1] Includes Federal parole or probation, out of State parole or probation.
[2] Includes driving under the influence of narcotics or dangerous drugs.
[3] Includes prescription violations, possession of narcotic paraphernalia, etc. Prior to 1965, driving offenses and all Federal violations were included. Beginning with 1965, Federal violations are shown under the more descriptive offense groups wherever appropriate.

Note: Data are subject to change as additional arrest information is received.

TABLE 5.—DRUG ARRESTS OF JUVENILES (UNDER 18 YEARS) REPORTED BY CALIFORNIA LAW ENFORCEMENT AGENCIES, 1966 (PROVISIONAL)

[By county and offense]

County	Total	Marihuana [1]	Heroin and other narcotics	Narcotic addict-user	Dangerous drugs	Other offenses [2]
Statewide	5,034	3,869	56	53	898	158
Los Angeles	3,189	2,501	33	29	573	53
San Francisco	167	97	5	3	49	13
Alameda	295	253	1	3	28	10
Imperial	14	8	3	2	1	
Kern	16	6			10	
Orange	251	171	2	1	45	32
Riverside	30	22	1	1	5	1
San Bernardino	35	26		1	7	1
San Diego	253	182	2	2	61	6
San Luis Obispo	6	3			3	
Santa Barbara	67	51		1	9	6
Ventura	66	47	3	5	8	3
Contra Costa	72	62			9	1
Marin	67	50		1	9	7
San Mateo	144	122			16	6
Santa Clara	126	96	1		22	7
Solano	2				2	
Napa	1				1	
Sonoma	32	29			2	1
Sacramento	37	30	4	1	2	
Fresno	17	7		2	7	1
Kings	3				1	2
Merced	7	7				
San Joaquin	25	8	1	1	15	
Stanislaus	24	22			2	
Tulare	8	7			1	
Monterey	21	14			4	3
San Benito						
Butte	1	1				
Glenn	3	3				
Shasta	1				1	
Sutter	2				1	1
Madera	8	7			1	
Humboldt	1	1				
Lake	1	1				
Mendocino	3	3				
Inyo	2	2				
Santa Cruz	34	27			3	4
Placer	2	2				
Yolo	1	1				

[1] Includes use or under influence of marihuana.

[2] Includes prescription violations, possession of narcotic paraphernalia, etc. Prior to 1965 driving offenses and all Federal violations were included. Beginning with 1965, Federal violations are shown under the more descriptive offense groups wherever appropriate.

Note: Data are subject to change as additional arrest information is received.

TABLE 6.—DRUG ARRESTS OF JUVENILES (UNDER 18 YEARS) REPORTED BY CALIFORNIA LAW ENFORCEMENT AGENCIES, 1966 (PROVISIONAL)

[Area and offense by year of birth]

Area and offense	Total	Year of birth				
		1948	1949	1950	1951	1952 and later
Statewide	5,034	1,120	2,023	1,187	516	188
Marihuana [1]	3,869	888	1,595	898	367	121
Heroin and other narcotics	56	13	33	8	2	----
Narcotic addict or user	53	17	28	6	2	----
Dangerous drugs	898	169	311	232	130	56
Other offenses [2]	158	33	56	43	15	11
Los Angeles County	3,189	706	1,221	770	367	125
Marihuana [1]	2,501	565	996	592	265	83
Heroin and other narcotics	33	10	17	6	----	----
Narcotic addict or user	29	9	16	3	1	----
Dangerous drugs	573	111	172	158	92	40
Other offenses [2]	53	11	20	11	9	2
State less Los Angeles County	1,845	414	802	417	149	63
Marihuana [1]	1,368	323	599	306	102	38
Heroin and other narcotics	23	3	16	2	2	----
Narcotic addict or user	24	8	12	3	1	----
Dangerous drugs	325	58	139	74	38	16
Other offenses [2]	105	22	36	32	6	9

[1] Includes use or under influence of marihuana.
[2] Includes prescription violations, possession of narcotic paraphernalia, etc. Prior to 1965 driving offenses and all Federal violations were included. Beginning with 1965, Federal violations are shown under the more descriptive offense groups wherever appropriate.

Note: Data are subject to change as additional arrest information is received.

CHART A

DRUG ARRESTS REPORTED BY CALIFORNIA LAW ENFORCEMENT AGENCIES

1960 THROUGH 1966

BY HALF-YEAR FOR BOTH ADULTS AND JUVENILES

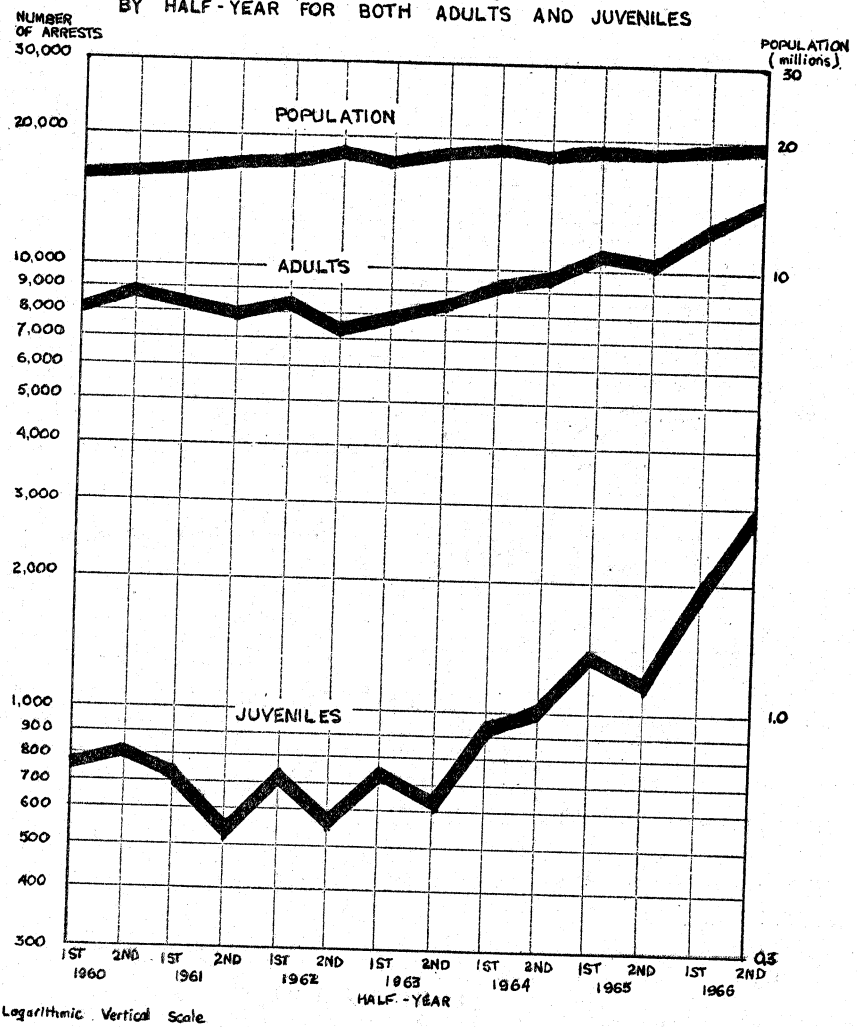
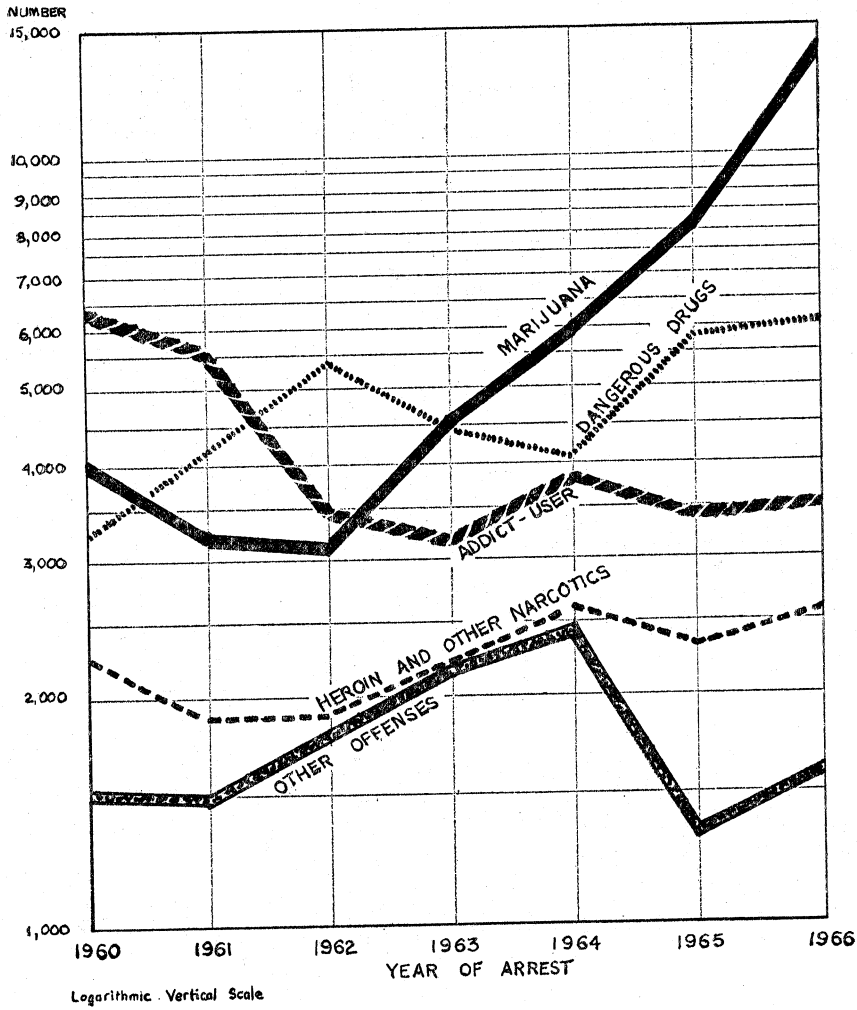


CHART B

ADULT DRUG ARRESTS

1960 THROUGH 1966
BY YEAR OF ARREST AND OFFENSE



Dr. GODDARD. I think there are other sources—the surveys on campuses that have been carried out to try to gain some idea of the misuse of drugs in general have shown on some campuses 20 percent, others 10 percent.

Senator NELSON. When you use this percentage, you mean those who have tried marihuana?

Dr. GODDARD. Yes.

Senator NELSON. Are you just talking about marihuana, or are you talking about——

Dr. GODDARD. I am talking about abuse of drugs, including marihuana. But marihuana is by all odds the most frequent and abused drug.

Senator NELSON. What is the source of the supply?

Dr. GODDARD. Most of the marihuana, I am told, is smuggled into the country from other countries, particularly Mexico and Central America. Some of it is grown domestically. It grows wild, I might point out, in many parts of the United States as a result of our Indian hemp production program during World War II.

Senator NELSON. By what method is it made so easily available on campuses or to young people?

Dr. GODDARD. Well, there is a distribution system that operates. We encounter this drug very often in our drug-abuse control program. In fact, I believe 9 out of 10 arrests that we make we find the individual in possession for sale of not only LSD but also marihuana, or not only amphetamines but also marihuana, or barbiturates and marihuana—any combination. Of course, one of the reasons we have become concerned and I have made the statements I have concerning marihuana is because we do encounter it as a daily occurrence in our drug-abuse control work. It tends to run more to the drugs that we are concerned with than it does with hard narcotics.

Senator NELSON. What was your statistic on use in California by the 17- and 18-year-olds?

Dr. GODDARD. Well, I was pointing out that the increase between 1965 and 1966 was 140 percent in arrests of juveniles. The numbers involved were 1,623 arrested in 1965, and 3,869 in 1966. Now, of those arrested for marihuana possession in California, of the juveniles, 60 percent of them were aged 17 or 18, which indicates the age group where the problem is centered.

Senator NELSON. And this means, does it not, that these are high school juniors and seniors?

Dr. GODDARD. Well, 17 and 18, you know, you are getting into——

Senator NELSON. Seniors in high school.

Dr. GODDARD (continuing). Seniors and graduates, recent graduates.

Senator NELSON. Do you have any notion for the large percentage in this age group as to how they are getting it and why?

Dr. GODDARD. Well, in many instances there is a drug subculture in a given area, let's say that these young people become involved with, or it becomes a thing to do, you see, a way of flaunting society's rules. This is one of the things that people who study this phenomenon say accounts for the involvement of many youths.

I think the Bureau of Narcotics can probably provide you detailed information on sources, you see, how it gets into communities. We see it in our drug-abuse control work, though, where we concentrate our efforts on those who sell, distribute, and manufacture drugs that are under our jurisdiction. We also see them selling marihuana.

Senator NELSON. You recited California statistics. Do you have any evidence to show that this would be representative of the country? Or is it just that California is doing it differently; as they usually do?

Dr. GODDARD. No. I selected those because I am told that California does have more complete statistics perhaps than any other State. It was for this reason. Also, the report happened to be available. It is an intriguing report to read in depth. The increases that have occurred since 1960 through 1966, and their breakdown of figures is perhaps more detailed than other areas provide.

Senator NELSON. In the evaluation of the California statistics, is there any element of more effective enforcement involved?

Dr. GODDARD. Well, of course, this has to be taken into consideration, too, because we are dealing with arrests which may or may not reflect accurately changes in usage. But I think it is generally agreed by all who are involved, college administrators, sociologists who study this kind of societal problem, enforcement officials that we work with at the State and local level, and—well, I cannot speak for the Bureau of Narcotics. You would have to get their opinion. But I believe almost everyone agrees there has been a marked increase in the usage of marihuana in the past 5 to 6 years in this country.

Senator NELSON. And this is a nationwide——

Dr. GODDARD. Yes. It has occurred in many communities. The press has covered, or provided coverage of stories from almost all over the country, you see. And so it is not an isolated thing. It is not something unique in California or New York City or Boston or Washington, but it is occurring all over.

Mr. GORDON. Do you have any hypothesis as to the cause of this increased use?

Dr. GODDARD. It is very difficult to hypothesize. It is also very dangerous. I would be forced to judge that, as in all these things, multiple factors are at work.

First of all, we have seen the development of the so-called hippie generation. And one of the things that they are concerned about, I am told, is the experiences that enlarge one's understanding of one's self, whatever that means.

Mr. GORDON. Well, I was going to ask you what that means.

Dr. GODDARD. I am only quoting. And certain drugs are held by the proponents of this type of subculture, certain drugs will help a person understand himself better. LSD has been pointed to as one, marihuana as another.

Well, both of these are hallucinogens. Of course, much of their attention has centered on hallucinogenic drugs.

As I mentioned earlier, it may be an act of defiance.

A psychiatrist at Harvard last week at a meeting I attended made a statement that he felt strongly this was an expression on the part of the young people of their defiance to our age group, the societal control that they object to. And it was a way of them expressing their hostility.

That is his opinion. It may well be a valid one.

The availability of it certainly has to be taken into account. It is more widely available today perhaps. The epidemiology and thus a better understanding of its availability and usage has to be studied.

The National Institute of Mental Health is developing and supporting projects which will give us a better understanding of why people do turn to drugs of all kinds and abuse them. This, also, is the kind of research we are interested in supporting and are supporting. We work very closely with the National Institute of Mental Health to try to develop this kind of information.

So I do not think we have any real answer to your question today as to why people use marihuana. We can only speculate. But I think there is general agreement on the point that the usage has increased at a large rate.

Senator NELSON. It would seem to me that one of the problems certainly is the educational factor. And everybody, I suppose, has read in the papers of some of the tragic incidents of young people using LSD with no notion about the effects and receiving permanent injury. My question is, what kind of a job are we doing in putting into the high school educational literature, not only on drugs—some of this is pretty tough to deal with—but also on such health hazards as tobacco? We have a pretty good tobacco lobby around the country. But what good information in a readable and interesting fashion is available in the high schools of this country as to what these drugs do, what their effects are, and how dangerous they are? What is available?

Dr. GODDARD. Senator, we think this problem is so important that we have been working with the National Education Association and the Office of Education of Health, Education, and Welfare in the development of curriculum-content material, not only for high school students but elementary school students and junior high school students as well. And the attempt is to introduce into this curriculum at the early stage of development of thought patterns and processes so that the young people can incorporate and acquire attitudes of respect toward drugs, something that seems to be lacking quite often today.

And so we have had the assistance of some of the best science teachers in the United States in developing these materials. And I will be happy to provide you with a description of this program, which is a cooperative venture between FDA, the Office of Education, and NEA. Through this kind of an effort over the long term I believe we can have an impact on the problem. I really think the educational approach is very necessary and important. Until people's attitudes can be successfully changed, we might make, indeed, very little progress in real control.

And so we have viewed this as an extremely difficult undertaking.

Now, there are, of course, other educational materials now available through some of the major drug companies. Smith Kline & French developed a very excellent booklet for the use of high school teachers on drug abuse in general.

Senator NELSON. Did they cover the specific drugs we are talking about?

Dr. GODDARD. Yes, sir, they did; including marihauana. And it is very well done, I must add, and has been widely distributed by that corporation. And this is something that is needed because these source

materials have not been generally available to the teaching profession in a usable form in the past.

Senator NELSON. Could you supply a copy of the Smith Kline & French literature for the committee?

Dr. GODDARD. Yes; I would be happy to do so.[2]

So we are beginning to develop these kinds of materials. We have worked, for example, with the college administrators in an educational program. I think we held seven regional seminars, attended by deans and the administrators of colleges and universities, and have provided them with factual information that can be passed on to their students.

Now, it has to be a very broad approach to the problem, on a very broad understanding developed on the part of our population about the drugs we are abusing. And this is a spectrum of drugs.

And we think this is absolutely essential if we are going to check the marked increase in drug abuse of all types that has occurred in the past two decades.

Senator NELSON. Does the program that you are working on with the National Education Association and the Office of Education have any specific legislative funding for this purpose?

Dr. GODDARD. No. We are doing this out of existing funds. This is part of our general mandate, to provide information to the public. And then, also, under our Bureau of Drug Abuse control program we do have education as one of the major components, you see—enforcement, education, research of the major components of our drug abuse program.

Senator NELSON. I know you believe that education on this subject matter is fundamental to any controlled program.

Dr. GODDARD. Yes, sir.

Senator NELSON. I do not know what you contemplate in that field, but it would seem to me that at a minimum, at a very minimum, there are two things necessary. One is the presence of a teacher in each and every institution—every grade school and high school—who really knows the subject matter, and will develop and teach a course in it. And then, secondly, attractive, readable, interesting literature must be made available to everybody.

Are you tackling these two problems?

Dr. GODDARD. Yes. In fact, the thrust of the program I have already mentioned is to help the teacher have a detailed understanding of the problem and the approaches to be used, give her specific lesson material to use with the youngsters.

Beyond that, we are also working with other professional groups. The retail pharmacies, for example, represent a resource that the schools and the community in general can draw upon to help explain problems of drug abuse and our drug abuse program has effective working relationships with one of the professional organizations to do just this. We think the physicians in communities represent a unique resource that could be called upon. I know there are several community programs of this nature already developed.

We also have produced films—a specific film, for example, called "The Mind Benders," on LSD, hallucinogens. We think this is an outstanding film that helps young people understand the risk involved.

[2] Retained in committee files.

We do not say you should not do this. We try to explain the risk, so that an intelligent person can make the decision without being preached at and see it is very obvious that they should not use the drug.

Now, after having said all those things, we have to say, too, that we recognize the importance of enforcement. I do not wish to minimize this. The State and local officials as well as the Federal officials in the major agencies involved play a very important role. Because one of your major efforts is to decrease the availability, take the stuff out of circulation. If it is out of circulation, it can't be abused. So this is extremely important, that we have, we are provided training programs for State and local officials, police, enforcement officials, and we will do so to an increasing amount so that they understand the whole problem of drug abuse control. We have found them most receptive to the training programs that we have offered to date and we hope to be able to do more of this in the future.

So it is a wide and very broad effort to help bring drugs under control in this country, drugs that are being abused, including marihuana.

Senator NELSON. Specifically, are you developing a body of literature that is going to be available in all the schools in the country?

Dr. GODDARD. Yes; this is the effort that I mentioned to begin with.

Senator NELSON. How far along are you?

Dr. GODDARD. Well, we have some of them already delivered in the pipeline to the school systems. I will be happy to provide those to you so you may put them in the record or examine them as you wish.[3]

Senator NELSON. Are you including in it information about tobacco?

Dr. GODDARD. No, tobacco is not included in this particular program. This is to try to provide an elementary understanding, let us say at the third grade level, of pharmacology. Because man does live in a chemical environment, we want young people to begin to formulate attitudes, attitudes of respect toward these chemicals in their environment at a very early age.

Now, you obviously are not teaching anything very sophisticated to third graders, but you can begin to get the formation of good attitudes toward drugs, which are some of the chemicals that man has to contend with at that early age.

Senator NELSON. But you do not intend to include tobacco.

Dr. GODDARD. No, sir. There is a program within the Public Health Service, an education and information program, on that particular subject. It would be duplicative for us to engage in it.

Senator NELSON. Who is engaged in that?

Dr. GODDARD. Public Health Service.

Senator NELSON. Do you have the money to print, publish, and exhibit to all the schools in the country the literature you are talking about?

Dr. GODDARD. I cannot say we have all the money that will be required this year for the program. The program is phased over two budgets. I think we will have sufficient moneys. It is a high priority item, Senator.

Senator NELSON. And you not only intend to distribute this to schools, but also to pharmacies and doctors?

[3] Retained in committee files.

Dr. GODDARD. No, that is a different program. That is to utilize the professional capability that the pharmacist as a resource person within his community, drawing upon his understanding in depth of drugs, to be a person to lecture to civic groups or to help with a special program in school assembly, in the grade school or junior high or high school.

Senator NELSON. What drugs are you preparing information on?

Dr. GODDARD. These are the drugs that come under the drug abuse control amendments.

Senator NELSON. What are these?

Dr. GODDARD. These are the amphetamines, the stimulants, depressants, the hallucinogens.

Senator NELSON. How many drugs does that involve?

Dr. GODDARD. Several hundred in toto, counting the combinations, but they can be talked about in terms of the stimulants, amphetamines, depressants such as barbiturates, hallucinogens such as LSD, and so forth.

Senator NELSON. How many of these drugs are available legally?

Dr. GODDARD. Legally?

Well, none of the hallucinogens are available legally. But the stimulants and depressants all are available legally.

Senator NELSON. On prescriptions?

Dr. GODDDARD. On prescriptions.

Senator NELSON. Yet they somehow get into the consumer market without prescriptions?

Dr. GODDARD. This is true and it is something which has been growing in terms of the past 20 years, the volume of drugs that have been diverted has apparently grown each year. When we first begin in this area as an agency back after World War II, the thought was that most of the abuse was probably the sort of casual refilling of prescriptions that were out of date or had not been checked as being refillable by the physician. But indeed, this was not the case. There are still, of course, a few drugstores where this goes on and some of our enforcement activities do reflect that.

But by and large, we found that the major problem was diversion from legal channels of supply. I think one of the first awarenesses of this came about as the agency, one of its employees, was able to make a buy of 25,000 barbiturate capsules at a truck stop. This forced the agency to reevaluate how it would use its relatively scarce resources in approaching the whole problem of drug abuse. Instead of trying to concern ourselves with individuals, as I mentioned earlier, we began to go after the point of diversion—where was it being diverted from the legal system? Was it a wholesaler? Did it come from a manufacturer—to identify and ferret out those sources and the impact would be greater. Well, that is the philosophy we still use in our drug abuse control program. We think it is the only rational one for us as a Federal agency to adopt, to go after illegal manufacturers if we are talking about LSD or some of the other hallucinogen; to go after the diverters, perhaps wholesalers, or in some instances, manufacturers, who make stimulants and depressants for the prescription drug trade. Some manufacturers have been found guilty of not keeping the appropriate records and of selling it to persons who obviously were not in the legal supply system. So the drug abuse control amendments

provided the authority for us to audit the books of all firms, not only manufacturers but wholesalers. We are also required to check pharmacies. Now, that is a tremendous undertaking. There are 55,000 pharmacies in the U.S.A. alone and, to audit their recordkeeping practices, we have asked the States to assist us and we have effected contracts with 18 States to date to have the State board of pharmacies audit prescription practices, the recordkeeping practices of local pharmacies. So the program is proceeding and we think the main thrust of it is at those who divert, illegally produce, or legally produce and supply to those who are not in the normal channels of distribution these drugs that can be abused.

Mr. GROSSMAN. Dr. Goddard, getting back to your purported comments, I am particularly concerned about this marihuana question. I wonder if I could read to you from the task force report on drug abuse from the President's Commission on Law Enforcement and Administration of Justice. It says:

> The inadequate data available today—

on marihuana—

> indicate that risk of crime, accidents, and suicide . . . are not likely to be greater than those associated with alcohol and may be less. If the equivalence between alcohol and marijuana is to be accepted as the operating assumption until more facts are at hand—and we think that is a prudent position to take—it follows that a public debate is in order with regard to the best regulation of marijuana.

Would you care to comment on that?

Dr. GODDARD. Well, I have commented a number of times as to the dangers of comparing these two. They are different drugs. One is a depressant, by and large. The other, marihuana, is primarily a hullucinogen, although it does have certain depressing properties depending on the dosage level and the individual availability. Now, I hestitate to draw these comparisons, but I am asked to do so. So I say, well, it's dangerous for people under the influence of alcohol or marihuana to operate heavy equipment or drive a vehicle. The latter distorts your perception of time and the former dulls your ability to handle this heavy equipment, which calls for fine coordination at low speeds. Even beyond that there are certain circumstances under which a drug is used, whether it be alcohol or marihuana, the amount one consumes, the amount one drinks or smokes, the personality of a user is a factor. The user's previous experience with either alcohol or marihuana is important. The inexperienced drinker does not know the signs and can go too far, just as, I am told, the inexperienced user of marihuana can go too far and get into a panic state. Now, these are some of the comparisons that can be made between these two.

If you are talking about comparisons with respect to a health problem, I think there is no question we have more clearly defined the health problem that exists with respect to alcohol: 11,000 deaths a year attributed to cirrhosis; the fatalities that occur as a result of highway accidents caused by people who have ingested too freely, the number of estimated alcoholics in our society—four and a half to five million; the number of heavy drinkers, that many more again, another four and a half or five million. There are approximately 70 million users of alcohol in society. We know the social costs in gross terms of alcohol. We do not have these kinds of data for marihuana.

I can give you a reference if you wish, a more precise pharmacological description of these drugs that are misused in our society. But those are the general comparisons I would draw.

Mr. GROSSMAN. As far as you are concerned, is there any social or medical value for marihuana?

Dr. GODDARD. I certainly know of no medical value at the present time. As I have mentioned before, the recent synthesis of the most active ingredient of marihuana, the tetraphdrocanabenols—THC—is rather interesting. The pharmacologists familiar with this have indicated that it may be helpful to have some of these data available with the mechanism of sleep, possibly the study of euphoria, as a mild euphoriant, the active ingredient may have some merit. So I would not preclude or close the door to the possibility of some useful pharmaceutical agent being developed from one of the synthetic things. But there is no medical purpose in our society for marihuana today and for practical purposes, there has not been since 1937. Now, social, it is hard to comment on, because it apparently does have some social use. People are using it quite widely.

Mr. GROSSMAN. In your testimony you discuss the inconsistencies between the laws relating to LSD and to marihuana. Have you specifically recommended to Congress any changes in the laws relating to marihuana?

Dr. GODDARD. No, sir; I am suggesting that they examine them. I have not, for example, recommended the removal of penalties for personal possession. I am not talking now about possession for sale, but personal possession. I am saying let's look at them. It may be executive seizure is indicated here. There is a whole spectrum of penalties one could consider. I am saying, look, the usage seems to be increasing. The major complaint we hear is about the inconsistency of the penalties and the question keeps coming up, time and time again. I am simply saying, is it not desirable to reexamine it?

Mr. GROSSMAN. Do you feel at all inhibited, perhaps, by law enforcement problems? For example, in this task force report, there is another statement which says:

> In any event, it must be recognized that if the law does outlaw sale, but does not allow arrest for possession, whether this be for LSD, marihuana or any other drug, the work of the police will be long and hard and the public must not expect large numbers of arrests. As a corollary it is quite possible that such a policy would, as many law enforcement persons might fear, result in less suppression of illicit drug traffic and subsequent greater use.

Now, my question is, basically, do you feel that you have one point of view and that the law enforcement people are pushing against your making any changes in these laws?

Dr. GODDARD. Well, reading under the drug abuse control amendments, where we do not have a Federal penalty for personal possession but we do have the privilege of executive seizure, we have not found this to be a handicap. Our position has been that we want to concentrate our efforts on the sellers, the manufacturers, the distributors. Now, we do not condone the possession of LSD and these drugs, nor would I condone the possession of marihuana. It should be seized and taken away. I want to make that clear. Certainly there is room for discussion on this point as to how effective and how needed is the personal possession thing.

No, in our society, if we have these young people who are, for whatever their reason, flaunting the law, this is symptomatic of something deeper. Do we not need to examine what the underlying cause is and get at those problems?

We are also concerned about the turning point in people's lives. Let me explain that by saying, if you have a 17-year-old who has never been arrested, has no record, and is suddenly arrested for possession of drugs, whatever it may be, he then can have a criminal record. He then can be thrown into close association with others who have already committed themselves to a certain way of life. This may be the turning point in this person's life. What I think our department is concerned with is these people. We see the social cost as a very great one. We are trying to say, let us at all points along the line constantly reexamine what it is we are doing to people.

Mr. GROSSMAN. That is my point. Do you feel that, all the way along, you have enough influence with the police and the investigative authorities and that your point of view is put across?

Dr. GODDARD. Well, we are trying in our educational program and seminars directed toward local and State enforcement agencies to find them a broad understanding of the sociological phenomenon. Now, we certainly are not soft on enforcement. I must say I find it anomalous even to be accused in editorials of being a soft enforcer of the Food, Drug, and Cosmetic Act, because most have accused me of being quite the opposite in the past year and a half.

We think our bureau of drug abuse control has been a hard-hitting group. But the emphasis has been somewhat different, primarily on the trafficker. That is where we think we have to place our emphasis.

Mr. GROSSMAN. If I may, just one further question on another area, with regard to LSD.

Following, I think, your testimony in 1966 before the Government Operations Committee, there were some problems with the loopholes, you might say, in the law or in your regulations. I would like to ask you—this is something from one of the committee reports in 1966—"it would appear possible for the amateur chemist and even the qualified inventor or the unqualified to manufacture the drug for personal use without filing any application with FDA. Such a person might argue that he qualifies as a bona fide experimenter in the absence of any standard qualifications for such an experimenter, that he manufactured the drug for personal use only and not for sale, delivery, or other disposition, and is not obligated to file an application with FDA. Moreover, it would appear that this category of person is not required to register with the FDA as a manufacturer under section 510." In other words, can I just go home to my little lab and take care of this without any problem?

Dr. GODDARD. I think you might have a few problems, even if you were a good chemist, because we have placed under control most of the precursors that would be used to manufacture LSD. This does not mean to say that LSD is not being manufactured. We are really still up against it. As fast as we get at one source of manufacture, it seems that another one springs up.

Mr. GROSSMAN. Where have you been finding these sources?

Dr. GODDARD. On the west coast, the east coast.

Mr. GROSSMAN. I mean not where, but by whom, particularly?

Dr. GODDARD. These are individuals who are skilled chemists, let us say, moonlighting.

Mr. GORDON. Commissioner, I notice you referred to the east coast and the west coast. How about the middle?

Dr. GODDARD. We have them in the Middle West, too. They are not devoid of skilled chemists.

Mr. GORDON. I have a couple of questions not related to marihuana but to the FDA.

Next week, some people are going to come to testify before our committee, and in one of the statements I found the following:

> Quality firms are well organized to recall with precision—this deals with precision from all commercial channels—any particular lot of a suspected drug product at any time or to provide emergency advice as to where a particular drug product can be obtained when needed.

Now, we have had, in fact we put into the record, considerable information about recalls and I notice that the recovery, especially from the large companies, has been extremely small. For example, we listed a recall from Ayerst Laboratories of 15 million tablets, of which only 30 percent was recovered. Squibb had a recall of Mycostatin. Only 20 percent of the 18 million tablets was recovered. Here is one recalled with 10 percent recovered, another with only 7.9 percent recovered, yet another with only 4 percent recovered.

Now, would you comment on the statement I read in view of the material on recalls that we got from the FDA?

Dr. GODDARD. Let me point out that you want to be careful. A drug company that only recovered 10 percent, this does not necessarily reflect upon their effectiveness in a given recall, but it may more accurately reflect the time period that elapsed between the production and distribution of the drug and the identification of the problem that required the recall. You see what I am driving at?

Mr. GORDON. No.

Dr. GODDARD. If a drug were subpotent, let us say, and batch No. 2,452 was produced on January 5, 1967, and the subpotency was not discovered until September 10, 1967, most of that batch may have been used by the time the recall is identified as being necessary. So there are several things that operate here. One is the elapsed time. Two is the effectiveness of the firm in getting at the batches at the wholesalers and the retailers level. Now, they have control numbers on product. All companies are required to do this. So they do have a precise way of identifying the drug to those who are in the system.

Now, this does not mean that it is not a lot of effort. It is. The wholesalers in meeting with them have expressed their concern about the cost and the effort that they are put to in helping in these recalls, and the local pharmacist is as well. So effectiveness of recall is again a function of several things. You are hard put at times to know just how effective a recall may have been unless there has been a very short period of time between the date of production and its entrance into the system.

Mr. Goodrich may wish to elaborate on this.

Mr. GOODRICH. Simply to say that our good manufacturing practice regulations require that all companies have the capability of recalling from the market drugs that turn out to be subpotent or otherwise in violation. The mechanisms of action are applicable to all drugs. A

trade-name drug may have to be recalled just as rapidly as a generic name drug and vice versa. We hope that, we think we have the mechanism for getting the drug back off the market on signs of danger.

Mr. GORDON. But the size of the company has nothing to do with the efficiency of recall, then?

Dr. GODDARD. Nothing. They may have a more expensive computer system that will turn out the identification of the invoices, but we require that all companies, large and small, have that capability.

Senator NELSON. From your experience with recalls, do you find any significant difference between the efficiency and the effectiveness of the recall between or among the various companies?

Dr. GODDARD. We find differences; yes.

But we insist that, depending upon the nature of the hazard that calls for the recall, that steps be taken to get the drug back in the most expeditious way. If it happens to be a small firm that cannot do the job, then we have to use our own resources to get it back. But we do have, as I have said, under our requirements for good manufacturing practice, a provision to require this capability.

Senator NELSON. You mean that if a company does not have the capability, FDA will do it for them?

Dr. GODDARD. We had an instance, Senator, in which a company put on the market a—it was not a drug, but a highly flammable, explosive waterproof compound, "X–33". It was necessary that that come off the market and come off the market promptly. The company did not have the money or the ability to get the product back, so we had to make hundreds of seizures throughout the United States in the interest of lifesaving from accidents that could have occurred.

Now, the same could happen with a drug. But we expect to have as a part of our good manufacturing requirements a provision that before a person can deal in drugs, he will have the capability of getting the product back, which does not mean that Food and Drug will never be called on to use its facilities. We frequently are.

Senator NELSON. Do you find differences in either frequency or efficiency on the recalls based upon the size of the company?

In other words, the point I am getting at here is whether small companies are less effective than big ones?

Dr. GODDARD. In general, the larger the company, the more responses they can afford and have available to devote to the problem; yes. So there are differences.

Do not forget, we have a well-defined system in which these take place, namely, the pharmaceutical wholesalers and the retailers, the drug store. These are well identified, whereas if you are dealing with other commercial products such as a solvent or a cleaner, it may be in a host of outlets of different kinds. So you have a much tougher problem.

We had an oven cleaner recently that posed a threat. It was very difficult. The effectiveness of that company's recall—and we worked with them on this—was at a very low level because of the diversity of the kinds of outlets, you see. So the drug business is truly unique in many respects, and this is one of them.

Senator NELSON. A few moments ago, you were discussing LSD and marihuana. I understood you to say that they are used socially; there-

fore, it has a social use. For clarification of the record, I am assuming you do not mean to say they have any constructive social uses.

Dr. GODDARD. I hope my remark would not be interpreted that it did; no. I tried to say that it is a social phenomenon that we have to contend with. It is a bad one.

Senator NELSON. I knew you intended to say that, and I did not want to leave the record open to an incorrect interpretation.

Dr. GODDARD. There are those who disagree.

Mr. GORDON. I have one more question. This is a quote from someone else's statement which we will hear next week:

> Recent figures of FDA inspections, for example, do little to encourage optimism in this regard. The agency made 3,651 inspections of drug plants in 1966. Impressive as that figure may seem, it is 150 inspections less than the 1965 figure and 34 less than the number for 1964. I do not recite these figures to criticize the FDA, Mr. Chairman. Their inspections, of necessity, are becoming more complex and time consuming and FDA personnel shortages are persistent. Nevertheless, fewer inspections are being made, not more. It seems to me, therefore, it would be imprudent to rely heavily or solely on this mechanism as the method of assuring drug quality.

The import of this whole thing is that you cannot rely on the FDA, but rather you have to rely on the reputation and fame of the manufacturer to insure good quality drugs. Since you are here, I think it might be a good idea for you to comment on this.

Dr. GODDARD. We are taking steps to make certain that you can rely on the FDA. We are going to have two different approaches. One is carrying out more selective kinds of inspections. Working with Booz, Allen and Hamilton, we are identifying the critical areas of an inspection, those parts of the inspection that most frequently reveal flaws in the system. So our inspectors will do more partial inspections, but more target kinds of inspections.

Secondly, we are going to select 300 pharmaceutical firms next year for special attention, and add 300 more pharmaceutical firms for special attention the next year. That second year, we will have 600 of the 900 that produce prescriptions under very close surveillance, and the third year, all 900.

Now, let us not misunderstand what I am saying to mean that this will provide complete assurance of quality of drugs. It will not. Most of the responsibility still is and probably belongs on the manufacturer who enters commerce and produces these drugs. Concomitantly, we are operating and will be expanding the National Center for Drug Analysis, where we hope to get up to the analysis of several hundred thousand samples of drugs purchased at the retail level. Thus we will be able to act as a further step in the manufacturer's own quality control program with respect to those features that can be seen in the laboratory.

Now, I would like to make the point that companies, large and small, require surveillance. You look at the recall list and it is not uniquely the property of the small company. Companies constantly make this claim, "Our drugs are better, higher quality, they are guaranteed," these kinds of things. I would like to see the evidence that their drugs are therapeutically more effective than small companies. They point to some isolated episodes that have occurred. We know these, too, and we have taken steps to correct them, such as the sugar-coated tetracycline episode several years ago.

Mr. GORDON. That was a big company, too, was it not?

Dr. GODDARD. That involved a large company, yes. So, yes, they are making the claim, but their making the claim does not make the fact so, is my point.

Mr. GORDON. But it is not so. Is that right?

Dr. GODDARD. Our job literally is to assure the physician: "Doctor, you can prescribe any drugs in the marketplace with the assurance that it will do the job that you had in mind when you selected it." Once that is done, we will have taken a great step.

Mr. GORDON. I have no further questions.

Senator NELSON. We had testimony at an earlier date from a pharmacologist. It was on the question that you have just commented on that I did not intend to raise at this hearing with you. It was on the question of whether, if a drug meets USP standards, the presumption can be made that all drugs which meet that standard are equivalent. The testimony that we have in the record is that there are only about a dozen cases where this did not turn out to be true. The testimony was that for almost all of the thousands of drugs on the market, if they met USP standards, they are equivalent in their therapeutic value and effectiveness.

Do you agree with that position?

Dr. GODDARD. I think that is a fair statement.

Senator NELSON. This was the statement of Dr. Miller of USP.

Dr. GODDARD. I think Dr. Miller's point is well taken. However, I say there is enough concern at the present time about the question of therapeutic equivalency that we are undertaking the testing of about 40 or 50 of the most frequently prescribed drugs that are available as both generic and brand-name drugs to determine biological availability, if you will, blood levels, which indicate that the drug has been absorbed. You can get some direct measurement in humans.

Now, if we find that after 20, 30, 40 of these drugs have been tested that equivalency is present, I think we have reason to feel reassured that this is true across the board.

Now, you see, there are also exceptions, in these systems. A man working on a given piece of equipment in any firm can fail to provide the proper maintenance or can make a slight change; for example, the tab letting pressure could be changed. This could influence the availability of a drug when ingested.

Senator NELSON. Well, it probably would not meet USP standards. It would not dissolve at the proper rate.

Dr. GODDARD. Right. But you see, there would not be any knowledge of that. This means a feedback into the production in terms of the quality program may have to be made. But generally, I agree with Dr. Miller.

Senator NELSON. We are talking about the heart of a persistent argument that goes on in the industry and the medical profession.

Dr. GODDARD. This is why, Senator, I have said, show me your evidence. The large companies that make this claim consistently, and I would like to see their evidence. They have not produced it yet, other than these 12 isolated episodes that you have been talking about.

Senator NELSON. This is the problem about which there is so much confusion. It seems to me that what the industry is really arguing is that the exceptions that we find once in a thousand times prove

the rule that there is not an equivalency among drugs that meet USP standards, when really it is the other way around. The exception just tests the rule. Once in a while the clinical and pharmacological knowledge about a drug is not sufficient at first to set foolproof standards. When more is known, modified standards are developed which incorporate the new knowledge. But this is an exceptional case.

So is it not really true that so far as we know, if drugs meets USP standards those drugs are equivalent therapeutically and you have to prove that they are not? As you know, we had this case recently of prednisone reported on in the Medical Letter. They tested 22 prednisones and accumulated scientific expertise around the country, and on this basis flatly stated that the present differential in price from 59 cents to $17.90 to the pharmacist is not warranted by differences in quality. This has never to this date been refuted by anybody in the industry.

Dr. GODDARD. We are trying to extend that to the drugs most frequently prescribed, those in the 200 most frequently prescribed list that are available by generic as well as by trade name. We are going to conduct that kind of test on human volunteers, you see, through Georgetown, with a contract there, through Public Health Service programs, and perhaps Veterans' Administration programs.

Now, let me point out to support what I have said, every instance that has come up, we and others have moved in on it, have studied it in depth, and it has resulted in a change in the standards. That is necessary. That is a role we must play and the scientific community engages in these kinds of studies to try to understand why the finished product of tetracycline, for example, was not performing at that point in time. When we understand it, then the standard can be changed. But it would seem to me that your point that the exception proves the rule is a valid one. The drugs are therapeutically equivalent until proven otherwise. But we do feel a burden to carry out further testing and get this thing wrapped up. We are going to improve the good manufacturing practices, too, Senator, which will also contribute to the improved quality of drugs.

Senator NELSON. You are going to what?

Dr. GODDARD. Improve what we call the good manufacturing practices, the requirements that manufacturers must meet.

Senator NELSON. You are going to increase the standard; is that what you are saying?

Dr. GODDARD. Yes, in effect.

Senator NELSON. You referred to testing 200 of the most frequently used drugs.

Dr. GODDARD. No, selecting from the 200 most frequently prescribed drugs those that are available in a generic name form. If it is a unique source, there is no point in checking, because of the unique source. Many of these drugs, by the way, came through the NDA procedure originally, so we have the information on clinical effectiveness already in hand.

Mr. GROSSMAN. Dr. Goddard, may I ask you, is then the purpose of the study they are conducting to corroborate the position you now hold as to equivalency?

Dr. GODDARD. Yes; to lay to rest these——

Mr. GROSSMAN. This is really important in these hearings; you realize that?

Dr. GODDARD. Yes.

Mr. GROSSMAN. I just want to understand, what is your position as of right now?

Dr. GODDARD. Our position is drugs generally are equivalent. These cases are the exceptions rather than the rule. I have not seen any evidence that I have asked for from the large companies to show me that this is not the case, other than on an exception basis.

Mr. GROSSMAN. So this study will hopefully——

Dr. GODDARD. Lay this to rest.

Mr. GROSSMAN. When do you assume the study will be completed?

Dr. GODDARD. It will take about 16 months to complete.

Mr. GROSSMAN. This is the same amount of time as the compendium.

Dr. GODDARD. Yes; but for different reasons.

Mr. GROSSMAN. Thank you.

Mr. GORDON. Commissioner, Dr. Solomon Garb, a rather well known pharmacologist at the University of Missouri, testified before our committee that a doctor has to assume, in order to practice medicine, that, when he prescribes any drug, it will be therapeutically effective.

Dr. GODDARD. That is correct.

Mr. GORDON. Otherwise, you cannot prescribe——

Dr. GODDARD. And we think that is our job, to be able to say: "Doctor, you can make that assumption and it is a safe one."

Mr. GORDON. They have been making it, have they not?

Dr. GODDARD. Yes; they have been, or there would not be as many companies in the marketplace as there are.

Senator NELSON. I do not have any further questions at the moment. There are, as per your first appearance, some other matters we will want to explore later and I assume we may bring that up with your staff and set another date for a hearing on some other problems we would like to discuss with you.

Dr. GODDARD. Fine.

Senator NELSON. We appreciate your testifying this morning. You have made a fine contribution.

Dr. GODDARD. Thank you.

(The prepared statement of Dr. Goddard follows:)

STATEMENT OF DR. JAMES L. GODDARD, COMMISSIONER, FOOD AND DRUG ADMINISTRATION

Mr. Chairman: It is a pleasure for me to again appear before this distinguished Subcommittee. As you have requested, I will amplify my previous recommendation to this Subcommittee that a Compendium of prescription drugs should be published by the United States. I will also direct my testimony to an issue which has engendered considerable controversy since my last appearance before this Subcomittee. Thus, as you have also requested, I will attempt to clarify my position on marihuana.

As you know, vital information concerning all prescription drugs is presently disseminated via the "package insert." A condensation and compilation of "package inserts" into a readily readable compendium distributed without cost to the physicians, pharmacies, hospitals, etc., would be a significant step forward in educating the health professions to the safe and effective use of therapeutic agents. It could also relieve the drug industry from the burden of printing the voluminous "package inserts" as such a compendium could appropriately replace this type of labeling.

The content of "package insert" type of labeling is initially approved by FDA during the new drug clearance procedure and is constantly reviewed by our medical staff to insure that the labeling is consistent with current knowledge. Often the "package insert" is the only source of such necessary data on medicines which are prescribed daily.

Unfortunately this information seldom reaches the physician—it remains on the local pharmacist's shelves. Proper utilization of this information is further hampered by the present format of the "package inserts." They are printed in fine type and are extremely lengthy. Adidtionally, it is impossible to determine whether a particular insert is the most up-to-date version, thus the physician may prescribe a drug without full knowledge of recent discoveries that are important to proper use of the product.

Although this full disclosure labeling provides an excellent library of drug information for each pharmacy which might be used to advantage by the prescribing physician, it is essential in our view to develop a mechanism that makes it more available to and more useable by the practicing physician.

The "package insert" only has to accompany the drug package from which the prescription drug is dispensed. The drug labeling would hardly be meaningful to the patient and, indeed, could be detrimental.

The legal basis for an insert is founded in regulations promulgated pursuant to Section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act which requires the labeling of all drugs to bear "adequate directions for use."

These regulations provide that the prescription drug *label* must bear: the statement "Caution: Federal Law prohibits dispensing without prescription"; the recommended or usual dosage; the route of administration if not for oral use; the name of all inactive ingredients (with some exceptions) if not for oral use; and an identifying code number from which it is possible to determine the complete manufacturing history of the drug. These *label* requirements are obviously most essential for proper usage and in order to monitor recalls. The concept of a compendium should in no way abrogate such *label* information.

Additionally, the regulations require:

> "Labeling on or within the package from which the drug is to be dispensed bears adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it is intended, including all purposes for which it is advertised or represented; and
>
> "If the article is subject to (the new drug, antibiotic and insulin provisions) of the act, the labeling bearing such information is the labeling authorized by the approved new-drug application or required as a condition for the certification or the exemption from certification requirements applicable to preparations of insulin or antibiotic drugs: *Provided, however,* That the information required by (the above paragraph) may be omitted from the dispensing package if, but only if, the article is a drug for which directions, hazards, warnings, and use information are commonly known to practitioners licensed by law to administer the drug.

The information required by this regulation is appropriate and useful. I do not believe that anyone would say that the physician is not entitled to such labeling. Instead, the busy physician relies on promotional literature in medical journals and publications such as the Physician's Desk Reference (PDR). As you know, we have instituted several regulatory actions against drugs because of their advertisements, and we are presently requesting four drug firms to issue "Dear Doctor" remedial letters in order to correct PDR monographs. We are also engaged in revising our advertising regulations issued pursuant to the Kefauver-Harris Amendments.

This type of surveillance of advertising coupled with our administrative action will, I believe, substantially increase the quality of such promotions. Nevertheless, advertising will remain advertising.

The information contained in package inserts is essential to counter-balance the claims made in many drug promotions. Unfortunately, the inserts are not accomplishing this function. Primarily, this is because it is not directed to the physician himself. Further, it is not in an easily readable form because of its length, and, of course, there is no index to package inserts or coordination with other drugs. Obviously, the "package stuffer" is just not an available reference

source. It is inconceivable that a practitioner would clutter his office with all this labeling in loose form.

Compilation of a Drug Labeling Compendium will be a difficult task. The central issue, from FDA's standpoint, is how to abbreviate the package insert without compromising public health protection. If we are to condense such labeling, it will still have to adequately reflect current knowledge about the drug. However, we believe that an objective summary, approved by FDA, would be preferable to a package insert which is never read. Also, we believe it will be possible to group several drugs into one category with a general summary covering all the drugs included in the group.

Another pressing consideration is whether or not the package insert should be completely done away with in view of the Compendium, or merely the requirement of distributing it with each package. As this complete labeling is the basis of a new drug approval, we do not recommend that such labeling be completely eliminated. Additionally, the package insert type information should remain available for those persons, such as clinical researchers, in need of such exhaustive data. In a few instances, it will probably not even be possible to provide for an exemption from distributing the "package insert." For example, we believe it is essential to have complete, unabridged information actually accompanying the package when such information may be needed by the physician at the actual time of administration.

Another factor which prompts our endorsement of a Compendium is that it will list all drugs, thereby increasing the physician's prescribing range. And, of course, pricing information could be included as a supplement to the Compendium thereby fostering more economic prescribing. However, listing in the Compendium could be construed as Governmental approval of a product. As we have stated on numerous occasions, FDA is not presently in a position to guarantee the quality of all drugs on the market, although we are constantly striving toward this goal. Nor could we assure the effectiveness of a drug listed in the Compendium. As you know, the NAS/NRC review of effectiveness of drugs marketed between 1938 and 1962 is not yet completed. However, if this review results in the removal of any drug from the market, it would likewise be removed from the Compendium. Thus, the Compendium would if adopted, have to grow with the FDA as we draw closer to our ultimate goal of complete assurance. In this context we would recommend quarterly supplements be published in order to keep the Compendium current.

With sufficient funds (approximately $5 million per annum) the FDA could publish a Compendium. FDA could also provide that listing in the Compendium would satisfy the requirements of full disclosure. Although the project could thus be achieved without increased authority, it would not be the most advantageous manner in which to proceed. As the drug industry will be relieved of the cost of "package inserts" by this proposal, it would be appropriate to shift the cost of the Compendium to that industry. This, of course, would necessitate legislation. Additionally, legislation would be desirable to clarify the scope and purpose of the Compendium and to realign some present provisions of the Act in greater conformity with the Compendium concept.

A final comment on this subject—we believe that increasing access to the complete labeling of prescription drugs is in itself enough to justify publication and distribution of a Drug Labeling Compendium. Additionally, the Compendium would list generic products together with their well-known trade name counterparts, thereby facilitating the economic prescribing of generic drugs and increasing the physician's familiarity with presently complex drug nomenclature.

Mr. Chairman, we appreciate this opportunity to clarify our position with respect to marihuana.

As evidenced by the attention given by representatives of Government, the press, and the professions, it is plain that the increasing use of marihuana is a matter of national concern. I am aware, Mr. Chairman, that statements attributed to me, but which I did not make, have caused additional concern. Let me clarify the record in this regard at the very outset.

I did not say that I would not object to my daughter smoking marihuana.

I did not, and I do not, condone the use of marihuana.

I did not, and I do not, advocate the abolition of controls over marihuana.

I did not, and I do not, propose "legalizing" the drug.

With your permission, Mr. Chairman, I would like to call your attention to one point which arose as the result of an erroneous news dispatch from Minne-

apolis on October 17. I was reported to have stated that I would not object any more to my daughter smoking marihuana than if she drank a cocktail.

The news dispatch was not correct and Mr. Julius Frandsen, Vice President and Washington Manager of United Press International, has written me a letter acknowledging error by UPI. With your permission, I would like to insert a copy for the record.

Mr. Chairman, I think the press recognizes the importance of the problem marihuana presents to society and makes every effort to provide the Nation with the best information available.

My remarks concerning marihuana—in Minneapolis and elsewhere—have always been in response to questions from the press. In every instance, I have made it abundantly clear that marihuana has been and still remains under the jurisdiction of the Bureau of Narcotics of the U.S. Department of the Treasury. It is often erroneously assumed that the Food and Drug Administration, which administers the Drug Abuse Control Amendments, has jurisdiction over not only the controlled drugs—the amphetamines, barbiturates, and hallucinogens—but marihuana as well. Our Agency has made every effort to clarify the differences wherever possible.

Now let me make several points about marihuana. First the shocking growth and use of marihuana has been so rapid that none of us in government, in medicine, or the legal profession has been able to counter it effectively.

The use of marihuana in this country and the rest of the world, has a long history, of course. In the United States, "marihuana" refers to any part of the plant, or an extract such as the resin, which induces changes in physical perception and in psychological reactions. These physical and mental effects will vary in the individual marihuana smoker, depending on four major factors:

The circumstances in which the drug is used;
The amount consumed, usually by smoking;
The personality of the user; and
The user's previous experience with marihuana.

The most common reaction to marihuana is development of a state of mind in which ideas seem disconnected, uncontrolled, and freely flowing. Perception is disturbed, minutes seem to be hours, and seconds seem to be minutes. Space may be broadened, and near objects may appear far away. When large doses are used—doses generally heavier than normally used in this country—extremely vivid hallucinations may occur. With such large doses, panic and a fear of death may make the experience highly unpleasant.

Gentlemen, what I have just told you about marihuana is a resume from one of the most respected textbooks on drugs in this country. It is the third edition of the Pharmacological Basis of Therapeutics by Louis S. Goodman and Alfred Gilman. I refer you to pages 299 and 300 of this volume.

It should be made clear, however, that no one in the scientific or medical communities is satisfied with the level of knowledge we have concerning marihuana and similar drugs. As I have stated on several occasions, there is still much research to be done.

For example, the chemical composition of marihuana has not been fully determined, although what seems to be the plant's most active ingredients have been isolated and synthesized. Scientificaly controlled marihuana studies of varying lengths have not been conducted on animals or humans to determine effects on body tissue and metabolism, or neuromuscular response, and on psychological, and cultural reasons for marihuana use, especially among our young people. The number and characteristics of marihuana users in the United States are virtually unknown, and paths to such use are unexplored.

Mr. Chairman, there are a number of studies that are being conducted under the auspices of the National Institute of Mental Health. I would like to deposit with the Committee at this time a recent listing by the NIMH of their marihuana research and related grant activities. You will notice that underway are several projects on the sociology of marihuana usage, the metabolism of marihuana in man and animals, and patterns of acquisition of the drug. Gradually, we will be able to construct a clearer picture—based upon hard, scientific facts—of this drug, its short and long-term effects, its full identity, and the ways it can and cannot be used by man.

Meanwhile, our enforcement efforts in the Food and Drug Administration as well as in the Bureau of Narcotics must continue. The enforcement strategy of the FDA is to concentrate on those who engage in the illicit manufacture, distri-

bution, and sale of large quantities of those drugs which are abused by some members of our society. This was the position advocated by the Department of Health, Education, and Welfare. This was the position adopted by unanimous vote of the Congress in enacting the Drug Abuse Control Amendments of 1965.

In my opinion, it has worked well.

As you know, Mr. Chairman, the Drug Abuse Control Amendments, which we carry out, include a class of drugs called the hallucinogens. Among these drugs are lysergic acid diethylamide—or LSD—peyote, mescaline, psylocibin, and others, such as DMT and STP, which have recently come upon the scene. Since the establishment of our Bureau of Drug Abuse Control, in February of 1966, we have conducted over 2,000 criminal investigations. A third of these have involved the hallucinogens. Marihuana has been offered for sale or seized in nine out of every ten investigations by our BDAC men following the hallucinogen leads.

Our agents, Mr. Chairman, have moved in on these cases swiftly but with a good sense of who has jurisdiction. BDAC agents in Dallas recently seized 1,000 doses of LSD. At the same time they seized approximately 100 pounds of marihuana, which they turned over to Bureau of Narcotics agents. At New York's Kennedy International Airport, BDAC agents, again working on an LSD case, seized not only a quantity of that drug but about 230 pounds of marihuana as well, which was turned over to local police and agents of the U.S. Customs Service. There are countless instances of marihuana appearing together with the hallucinogens under our jurisdiction. Our agents, working in close cooperation with other Federal agencies and with the excellent cooperation of State and local law enforcement agencies, can account for 931 arrests to date. Sixty percent of these arrests involved the hallucinogens. And, as I have indicated—in both the investigational as well as the arrest stages—marihuana is usually present.

The Food and Drug Administration and the Treasury Department's Bureau of Narcotics have been cooperating in dealing with this problem. There is a formal working agreement between the Bureau of Narcotics and our Bureau of Drug Abuse Control which provides for a close working relationship between our agents in the field as well as our staffs in Washington.

From this brief bit of history let me point out a rather significant anomaly in the penalties with respect to the two hallucinogens, LSD and marihuana. During the past year and a half I have become personally aware of the problem as FDA's Commissioner. For example, our agents may find two individuals in the same room, one possessing LSD—an extremely dangerous drug—and the other possessing marihuana. Our BDAC agents would seize the LSD under the executive seizure provisions of the Drug Abuse Control Amendments, but the person possessing the drug would not be subject to prosecution under the Federal statute. His companion, however, would be taken into custody and be liable to a felony conviction under the laws governing the possession of marihuana, a drug which is less potent than LSD. This is why I consider the penalties to be inconsistent. We find at our Agency, that this inconsistency prevents full and effective protection of the public interest in the matter of abused drugs of any kind. We believe that no useful purpose is served by making a felon of the individual who abuses the dangerous drugs.

Let me emphasize again that I have never advocated the legalization of marihuana. Rather, I have raised the question of the severity of the penalties attached to possession of marihuana and I suggest that the Congress might also wish to review these penalties in the light of enforcement experience throughout local, State, and Federal Governments and as the results of drug research may dictate.

Thank you. I will be happy, Mr. Chairman, to answer any questions you or other Members of the Committee may have.

Senator NELSON. The hearing is adjourned.

(Whereupon, at 11:55 a.m., the hearing was adjourned.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

WEDNESDAY, NOVEMBER 15, 1967

U.S. SENATE,
MONOPOLY SUBCOMMITTEE OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10 a.m., in room 318, Old Senate Office Building, Senator Gaylord P. Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson and Hatfield.

Also present: Benjamin Gordon, staff economist; James H. Grossman, minority counsel; Susan H. Hewman, research assistant; and William B. Cherkasky, legislative director, staff of Senator Nelson.

Senator NELSON. The meeting of the Subcommittee on Monopoly of the Senate Small Business Committee will come to order.

Our witness this morning is Dr. William Apple, executive director of the American Pharmaceutical Association.

Dr. Apple, the committee is very pleased to have you appear this morning. We appreciate your taking the time to come here. The chairman is aware of your distinguished background in the State of Wisconsin and here on the national scene, and we appreciate your contribution to these hearings.

You may proceed to present your testimony in any way you see fit and I trust that you have no objection to the Chair interrupting you from time to time with questions relating to your statements while you are proceeding through your testimony?

STATEMENT OF WILLIAM S. APPLE, PH. D., EXECUTIVE DIRECTOR, AMERICAN PHARMACEUTICAL ASSOCIATION, WASHINGTON, D.C.; ACCOMPANIED BY MARY LOUISE ANDERSEN, SECOND VICE PRESIDENT; MAX W. EGGLESTON, PRESIDENT-ELECT; AND ROBERT F. STEEVES, DIRECTOR, LEGAL DIVISION

Dr. APPLE. Not at all, Mr. Chairman.

Thank you for the opportunity.

Senator NELSON. Would you identify your associates for the record?

Dr. APPLE. Yes.

Mr. Chairman, we have with us Mary Lou Andersen of Wilmington, Del., who is our second vice president. Mrs. Andersen, would you please stand?

Senator NELSON. Welcome to the committee.

Dr. APPLE. And Max W. Eggleston of Waverly, Iowa, who is a member of our board of trustees and president-elect.

Senator NELSON. Welcome to the committee.

Dr. APPLE. To my right is Robert F. Steeves who is director of our legal division.

Senator NELSON. Mr. Steeves.

Would you for the record, Dr. Apple, recite your professional credentials and professional background?

Dr. APPLE. Mr. Chairman, I will be glad to submit a biographical sketch for the record, but very briefly, I have a bachelor of science degree in pharmacy, a masters in business administration with a major in marketing, and a Ph. D. in pharmacy administration from the University of Wisconsin and an honorary doctor of science degree from Long Island University. I am also a registered pharmacist in the State of Wisconsin.

Senator NELSON. And were you associated with the University of Wisconsin School of Pharmacy while you were in Wisconsin?

Dr. APPLE. Yes, for a number of years I was a member of the faculty, and chairman of the department of pharmacy administration at the University of Wisconsin.

Senator NELSON. Then subsequent to that?

Dr. APPLE. I left the University of Wisconsin to come here on July 1, 1958, and became executive director of the association on August 22, 1959.

Senator NELSON. Thank you very much. I have a couple of preliminary questions I would like to ask.

How many members are there in your association?

Dr. APPLE. Mr. Chairman, every time we appear before a congressional committee we are asked what our membership is, so I thought for once I would try to settle it. We have our membership roster on a computer, and I have brought with me the entire membership list of the American Pharmaceutical Association. As of November 6, 1967, we have 46,000 paid members of which approximately 14,000 are student members.

Senator NELSON. And these are, except for the students, all practicing pharmacists?

Dr. APPLE. No, sir; they are not. There are roughly 787 who are not engaged in the practice of pharmacy.

Senator NELSON. And what is the activity of those 700-plus?

Dr. APPLE. Well, some of them are teachers, some of them are researchers, some of them are in the category of people who are interested in pharmacy and are employed in some administrative or executive positions.

Senator NELSON. What percentage of the practicing pharmacists in the United States do you have in your association, do you know?

Dr. APPLE. Roughly a third of those actively engaged in practice.

Senator NELSON. Is there any other national organization of pharmacists?

Dr. APPLE. Yes, Mr. Chairman, there are a number of specialty organizations of pharmacists. Two of them—American Society of Hospital Pharmacists and the American College of Apothecaries—are directly affiliated with us. There is another association made up of owners of drugstores; there is another association of chainstores. There are wholesaler organizations. There are organizations ad infinitum in pharmacy. But the only organization that speaks for the

profession as a whole is the American Pharmaceutical Association which was established in 1852, 5 years after the American Medical and 5 years before the American Dental Association. It is the professional society, sir.

Senator NELSON. Your association is a nonprofit, tax exempt association?

Dr. APPLE. We are a 501(c)(6). We also have a foundation which is a 501(c)(3).

Senator NELSON. But it is a tax exempt organization?

Dr. APPLE. Yes, sir. It is.

Senator NELSON. What is the basis of this exemption?

Mr. STEEVES. It is exempt, a tax exempt organization as a business league under section 501(e)(6), which includes trade associations and professional societies.

Senator NELSON. How many people do you employ in your national office?

Dr. APPLE. We have currently a staff of around 75 full-time professional and clerical employees.

Senator NELSON. Do you have any objection to submitting your financial statement to the committee?

Dr. APPLE. Mr. Chairman, each year we submit a report to our entire membership, active and student, published in our journal which contains the complete proceedings of our annual meeting, its house of delegates, all of its committee reports, the reports of the officers. For example, in this document you will find the report of the treasurer for 1966 on page 300, and you will find our financial statement under exhibit B in schedule 1.

Senator NELSON. Is this the statement that you submit to IRS?

Dr. APPLE. Yes, sir.

Senator NELSON. This is the full statement?

Dr. APPLE. Yes, sir. It isn't the copy of our income tax return. It is the statement prepared by certified public accountants for distribution to our members which shows the source of our entire income as well as the expenditures in detail made by the association. We would be glad to submit a copy of our income tax return if that is what the Senator wishes.

Senator NELSON. If you would submit it to the committee we will decide whether or not we will print it, but we will at least print your financial report to your members in the record.

(The financial report referred to follows:)

AMERICAN PHARMACEUTICAL ASSOCIATION, FINANCIAL STATEMENTS, DECEMBER 31, 1966

OLIVER T. GRAHN,
CERTIFIED PUBLIC ACCOUNTANT,
Severna Park, Md., March 18, 1967.

Dr. HUGO H. SCHAEFER,
Treasurer, American Pharmaceutical Association,
Washington, D.C.

DEAR SIR: I have examined the combined statement of assets, liabilities and fund balances at December 31, 1966, of the American Pharmaceutical Association and the related statements of income and expenses for the year then ended. My examination was made in accordance with generally accepted auditing standards, and accordingly included such tests of the accounting records and such other auditing procedures as I considered necessary in the circumstances.

In my opinion, the accompanying combined statements of assets, liabilities and fund balances, and of income and expenses present fairly the financial position of the American Pharmaceutical Association at December 31, 1966, and the results of its operations for the year then ended, in conformity with generally accepted accounting principles applied on a basis consistent with that of the preceding year.

OLIVER T. GRAHN,
Certified Public Accountant.

EXHIBIT A

AMERICAN PHARMACEUTICAL ASSOCIATION—COMBINED STATEMENT OF ASSETS, LIABILITIES, AND FUND BALANCES, DEC. 31, 1966

	Total	General fund	Fixed assets	Permanent funds	Building and trust funds	Special funds and grants
ASSETS						
Cash	$312,857.77	$228,984.04		$50,700.17	$471.66	$32,701.90
Accounts receivable	81,808.25	81,499.53		308.72		
Securities, schedule 1	522,105.13	267,031.79		253,661.89	1,411.45	
Dues from other funds	3,471.26	3,471.26				
Land and buildings	1,345,232.97		$1,345,232.97			
Furniture and equipment	1.00		1.00			
Prepaid expenses	31,195.93	31,195.93				
Deposit, airline	425.00	425.00				
Deferred NFXII costs	52,688.72	52,688.72				
Total	2,349,786.03	665,296.27	1,345,233.97	304,670.78	1,883.11	32,701.90
LIABILITIES						
Accounts payable:						
Trade	143,577.55	143,512.55				65.00
To funds	3,471.26			3,471.26		
Deferred income:						
Dues and subscriptions	216,343.80	203,696.80				12,647.00
National Formulary XII	200,916.39	200,916.39				
Other	47,702.35	47,702.35				
Total	612,011.35	595,828.09		3,471.26		12,712.00
FUND BALANCES						
Balance, Jan. 1, 1966	1,629,622.94	407,573.58	1,345,233.97	317,893.55	(462,172.03)	21,093.87
Excess of income over expenses, general fund, exhibit B	25,662.24	25,662.24				
Excess of income over expenses, other funds	446,257.14			(16,694.03)	464,055.14	(1,103.97)
Reserve for survey of the profession	100,000.00	100,000.00				
Transfer of building fund deficit	(463,767.64)	(463,767.64)				
Total	1,737,774.68	69,468.18	1,345,233.97	301,199.52	1,883.11	19,989.90

EXHIBIT B

AMERICAN PHARMACEUTICAL ASSOCIATION GENERAL FUND—STATEMENT OF INCOME AND EXPENSES FOR THE YEARS ENDED DEC. 31, 1966, AND DEC. 31, 1965

	Year ended Dec. 31, 1966	Ratio to total income	Year ended Dec. 31, 1965	Ratio to total income
Income:				
Dues	$586,100.67	50.30	$533,375.25	49.81
Journal of American Pharmaceutical Association [1]	117,882.51	10.12	108,541.52	10.13
Journal of Pharmaceutical Sciences [2]	196,770.76	16.89	192,773.11	18.00
National Formulary [2]	115,491.41	9.91	113,989.00	10.65
Public relations service	4,302.70	.37	2,103.95	.20
Health education center service [1]	29,271.00	2.51	22,163.00	2.07
Annual meeting [1]	93,020.15	7.98	84,166.02	7.86
Other income	22,409.14	1.92	13,685.37	1.28
Total	1,165,248.34	100.00	1,070,797.22	100.00
Expenses:				
Officers and council	10,926.84	.94	13,413.24	1.25
Office of the executive director	101,118.04	8.68	74,642.53	6.97
American Pharmaceutical Association Newsletter	39,856.42	3.42	36,523.46	3.41
Reclassification project	4,872.70	.42	6,438.85	.60
Commission on ambulent patients	1,843.12	.16	6,235.06	.58
NDTC prepayment study	2,500.00	.21		
Committee meetings	12,764.73	1.10	4,883.42	.46
Administrative division:				
General	33,641.89	2.89	93,944.32	8.77
Membership records	67,177.70	5.77	37,496.86	3.50
Business Division:				
General	42,984.95	3.69		
Occupancy costs	35,506.23	3.05	19,615.06	1.83
Communication division	282,418.46	24.24	249,868.42	23.35
Legal division	39,136.17	3.36	30,585.18	2.86
Membership division	51,252.11	4.40	68,361.90	6.38
Pharmaceutical services division	32,512.87	2.79	32,697.21	3.05
Scientific division	188,675.00	16.19	209,023.44	19.52
Academy of General Practice	22,756.27	1.95	7,351.55	.69
Academy of Pharmaceutical Sciences	13,091.96	1.12	5,969.19	.56
Contribution to American Pharmaceutical Association Foundation	47,128.35	4.04	49,238.08	4.60
American Pharmaceutical Association Service Corp. grant			50,000.00	4.67
Dues	8,429.09	.72	7,143.34	.66
Provision for survey of the profession	100,000.00	8.58		
Travel: Foreign pharmacy meetings	993.20	.08	3,425.09	.32
Interest			923.62	.08
Total	1,139,586.10	97.80	1,007,779.82	94.11
Excess to exhibit A	25,662.24	2.20	63,017.82	5.89

[1] Direct expenses in connection with this activity are included under "Expenses: Communication division."
[2] Direct expenses in connection with this activity are included under "Expenses: Scientific division."

SCHEDULE 1.—AMERICAN PHARMACEUTICAL ASSOCIATION SECURITIES, DEC. 31, 1966

Name of security	Number of shares	Cost		Market (Dec. 31, 1966)	
		Unit	Total	Unit	Total
Corporate stocks:					
Ford Motor	40	52⅜	$2,095.00	38½	$1,540.00
Diamond Alkali	100	23½	2,350.00	31¾	3,175.00
Union Carbide	50	52¼	2,612.50	47¼	2,362.50
International Business Machine	50	281⅛	14,054.01	371½	18,575.00
Lone Star Gas	100	23½	2,350.00	19¼	1,925.00
United Gas Corp	70	38⅞	2,721.25	48¾	3,412.50
International Paper	81	30	2,430.00	25⅝	2,055.38
General Public Utilities	284	31¾	9,014.00	30¾	8,733.00
Puget Sound Power & Light	70	36¾	2,572.50	32⅝	2,287.25
Firestone Tire	72	33⅜	2,402.88	46	3,312.00
Standard Oil of New Jersey	30	68¼	2,047.50	63¼	1,897.50
General Telephone & Electronics Corp	300	36½	10,925.00	45¼	13,575.00
Trans World Airlines, Inc	200	80½	16,137.50	73⅝	14,735.00
Seaboard Airlines & Railroads	200	37⅝	7,525.00	40⅛	8,025.00
Polaroid Corp	50	137⅛	6,856.25	158¾	7,937.50
Texas Instruments	100	106⅜	10,637.50	99⅞	9,987.50
Corning Glass	50	281⅜	14,068.75	309	15,450.00
Columbia Broadcasting System	200	55⅛	11,175.00	61½	12,300.00
Peoples Gas, Light & Coke	300	35¾	10,725.00	34¾	10,425.00
Sinclair Oil	200	64¼	12,912.50	62¼	12,450.00
Union Electric	400	26¾	10,700.00	25¾	10,300.00
Universal Oil Products	200	62⅛	12,412.50	65⅝	13,135.00
American Smelting & Refining	300	57⅜	17,212.50	54	16,200.00
Heublin, Inc	500	36½	18,100.00	37½	18,562.50
Public Service of New Mexico	500	23⅛	11,877.26	25½	12,750.00
United Airlines	200	62¼	12,450.00	61	12,200.00
Northern Natural Gas, 5.6 percent preferred	50	------	5,500.00	97½	4,875.00
Total	----------	------	233,864.40	------	242,182.63
	Maturity value				
Corporate bonds:					
Columbia Gas, 4⅜ percent, 1988	5,000	101	5,050.00	82½	4,125.00
Arkansas Power & Light, 4⅝ percent, 1992	5,000	100⅞	5,043.75	82	4,100.00
Southern Californian Edison, 6⅛ percent, 1991	50,000	100¼	50,125.00	104½	52,250.00
Trunkline Corp., 6½ percent, 1986	50,000	101½	50,750.00	104	52,000.00
Southwestern Bell, 5⅝ percent, 2006	50,000	92⅝	46,312.50	97½	48,750.00
Natural Gas Pipe, 6¼ percent, 1986	50,000	100¾	50,375.00	103½	51,750.00
Total	----------	------	207,656.25	------	212,975.00
U.S. Treasury obligations:					
U.S. Treasury bonds, 2½ percent, Sept. 15, 1972/67	1,500	------	1,411.45	------	1,411.45
U.S. Treasury bills, Mar. 22, 1967	68,000	------	67,303.64	------	67,303.64
U.S. Treasury bills, Mar. 2, 1967	12,000	------	11,869.39	------	11,869.39
Total	----------	------	80,584.48	------	80,584.48
Grand total	----------	------	522,105.13	------	535,742.11

Dr. APPLE. As the Senator will note, the total dollars and percentage of our income derived from membership dues exceed any other single source. Last year it went over the 50-percent mark and this year it will be even larger in terms of percentage and actual number of dollars received from pharmacists in the United States as membership dues in support of the activities of the association.

Senator NELSON. Does your association publish a regular publication that is distributed to the membership?

Dr. APPLE. We have a number of publications, sir. We have the Journal of the American Pharmaceutical Association.

Senator NELSON. How often is that published?

Dr. APPLE. That goes to each member monthly. We have a newsletter that goes to each member every other week. We have a Journal of Pharmaceutical Sciences which goes to those members who wish to have that journal sent to them. We also publish the National Formulary.

Senator NELSON. You mean your organization publishes it, the National Formulary?

Dr. APPLE. That is right, sir.

Mr. GORDON. That is one of the official compendia of the United States; is it not?

Dr. APPLE. The National Formulary is one of the official compendia recognized under the Food, Drug, and Cosmetic Act.

Senator NELSON. How long have you published the National Formulary?

Dr. APPLE. Since its inception.

Senator NELSON. And was the National Formulary authorized by the act of Congress?

Dr. APPLE. Yes.

The United States Pharmacopeia and National Formulary are two of the official compendia that are recognized under the Food, Drug, and Cosmetic act.

Senator NELSON. Do you in any of your publications regularly publish scientific material respecting drugs for distribution to the pharmacists?

Dr. APPLE. Yes, sir.

In both of the Journal of the American Pharmaceutical Association, material which will be of interest to the practicing pharmacist and in the Journal of Pharmaceutical Sciences material which will be of particular interest to researchers, educators, scientists as a whole, not only in pharmacy, but in many other disciplines.

Senator NELSON. Go ahead, Doctor, and present your statement as you see fit.

We welcome Senator Hatfield here this morning.

Dr. APPLE. Mr. Chairman, we are pleased to have this opportunity to present the views of our profession on some of the issues involved in these hearings. The subcommittee's invitation to us listed specific topics you wished us to cover and we are happy to respond.

We can assure you that the Nation's pharmacists have been following closely the hearings of this subcommittee. Many of the questions that have been asked of witnesses here publicly have been asked from pharmaceutical association platforms and in other forums for years. Fortunately, the subcommittee has access to information and resources to generate a more informative dialog on many of the issues.

The records of these hearings contain a wealth of information about the pharmaceutical industry, its marketing structure, its economics, and its contributions to our society. And, the record for the industry is being made by those most capable of presenting an accurate and detailed explanation for individual firms involved in the hearings. Our profession, as well as the public, is learning a great deal from the testimony and resultant discussion of these hearings.

Senator NELSON. Dr. Apple, may I interrupt for just a moment? Have you read all of the published hearings thus far?

Dr. APPLE. I have read most of the statements, Senator.

Senator NELSON. We are interested as a committee in the best scientific presentation of the varying viewpoints about the problems we are considering. Are you familiar with the professional reputation of the professional witnesses who have appeared here?

Dr. APPLE. Mr. Chairman, as I read the statements and the biographical sketches of the individual witnesses, I certainly was impressed with the individual qualifications of the scientists who appeared before you as well as the executives of the pharmaceutical industry.

Senator NELSON. If you have any suggestions, from your wide professional contacts, as to additional witnesses with special expertise in any aspect of the hearings that we are conducting, the chairman and the committee would appreciate your suggestions and would be willing to consider hearing them. We welcome suggestions from anybody in the related professions, whether it be pharmacy, pharmacology, medicine, or the manufacturing side of drugs. So if you can suggest witnesses who have some special knowledge in fields that have been covered or should be covered, the committee would be glad to consider calling any of the witnesses you may suggest. We do wish to have the best possible record and where viewpoints are in conflict we want to be sure that we have both sides or more, if there are more than two sides, so that the committee and the public will be better prepared to evaluate the testimony that has been presented.

I might say that some people have been critical of my conduct of these hearings on the grounds that the hearings haven't been objective or haven't been fair. It has been my attempt to make them so, and I repeat what I have said on previous occasions: We want to hear from the best witnesses representing all viewpoints of the problems that we are considering.

We can't hear everybody, of course. We have had requests from all over the United States, and we would have to run for several years to meet all the requests. But in order to have balance, we will hear testimony from those who have conflicting viewpoints about various problems that we are presenting, whether they represent industry or whether they are critical of industry, or whether they are out of the professions, practicing physicians or professors, or what have you. So if you have some suggestions we would like to put them together with the other requests that we have had and then attempt, in a balanced way, to invite the best experts that we can find so that all viewpoints will be heard.

Dr. APPLE. Mr. Chairman, we will be glad to review the list of witnesses who have already appeared and those scheduled to appear and send you any recommendations we have on that subject.

Senator NELSON. I guess, as of this date, you represent the only major profession in the health field which we have not, in fact, invited to appear before the committee. So if anybody has a complaint it is your organization, not the others. They have all at least had one witness here, but I don't want you to think that I have been intentionally discriminating against your organization.

I realize you have been called to appear here very late, just as the Pharmaceutical Manufacturers Association has, although representatives of individual firms have been here previously.

Dr. APPLE. Frankly, Mr. Chairman, we were appearing before other Senate and House committees rather frequently the last few months and we appreciate the reprieve.

Senator NELSON. Proceed, Dr. Apple.

I know Senator Hatfield, as you have questions, you will interrupt. Dr. Apple is perfectly agreeable to having his testimony interrupted at any time.

Dr. APPLE. Quite honestly we regret that some individual firms in the pharmaceutical industry as a whole are again being exposed to public scrutiny, lay press headlines and uncomplimentary discussions. We would far prefer to see such changes as are needed accomplished voluntarily, out of the public spotlight. Unfortunately for all of us, the industry generally has refused to take appropriate action. Prodding and protests from our association over the past decade, from individual pharmacists and from the profession as a whole have been to little avail.

Senator NELSON. What kind of prodding and protests are you referring to, or do you get specific about that at a later place in your statement?

Dr. APPLE. Well, we do generally throughout our testimony, Mr. Chairman, but basically here I have reference to the meetings that we have had with individual firms, with industry spokesmen, with the committee reports presented at our annual meetings over the years, where specific issues were discussed and our recommendations and pleas to industry were outlined in detail; resolutions adopted by our Association on price discrimination, on nomenclature, on samples, and other subjects in which we have a mutual interest.

Senator NELSON. Have you had any success with the major issues that you have raised with the industry?

Dr. APPLE. We have copies of our committee reports here which we will be glad to file with the committee so that they can see the specific comments we have made to industry.

Senator NELSON. The committee would like to have those reports for the files, and if it seems appropriate we will incorporate them into the record of the hearings.[1]

Dr. APPLE. We are surprised and shocked that industry spokesmen would now accuse us of being political opportunists or insincere for saying publicly what we and other pharmacists have been saying in industry-profession meetings for many years. We suppose that the industry's complaint is designed to rally its forces and create doubt in the minds of pharmacists who have not studied the issues.

For years we have heard attempted justifications for the large price differentials and discriminatory pricing practices. None of them rings true, though there is some substance of truth in the many rationalizations that have been offered. We fully understand that research costs must be recovered, that quality-control costs must be included, that premarketing testing and promotion and all other operational and administrative costs must be covered by sales income. This is elementary business economics.

Senator NELSON. You surmise that the industry's complaint is designed to rally its forces and create doubt in the minds of pharmacists. Do you have any specific evidence other than the publicity that appears in various professional journals and publications that there have been specific attempts by the industry to appeal to the pharmacist with respect to the issues that you have been raising for years?

[1] Retained in committee files.

Dr. APPLE. I certainly have personal conversations and correspondence from our members that start out and say "Mr. So and So, the sales representative of the X Co., was in today to tell me this and I didn't know we had this position," and they proceed to outline what to me is apparently gross misinformation. In other words, I would say candidly that I think the industry is detailing the pharmacists very well about our position these days, very well from their standpoint but not from ours.

Senator NELSON. Do I understand you to say that from what you hear and see the industry is using detail men to advance its position with respect to the problems you raise and to be critical of your association as such?

Dr. APPLE. Yes, sir.

Senator NELSON. Do you have evidence that this is a widespread attempt by the industry all over the country through their detail men?

Dr. APPLE. I don't know to what extent very frankly. I have asked my staff not to even bother to tell me about it because we have more important things to do, Senator.

Senator NELSON. Have they sent out any publications or communications or letters directly to your members?

Dr. APPLE. Well, they have taken certain papers and reproduced them and distributed them to members.

Senator NELSON. When you say certain papers, to what do you refer?

Dr. APPLE. Speeches that were presented at certain meetings.

Senator NELSON. Speeches made by whom?

Dr. APPLE. Educators basically; material that is pro their viewpoint. I don't see anything wrong in this, Senator, because we have our method of communicating to our members with our viewpoint.

Senator NELSON. I wouldn't suggest there was anything wrong in it. It is a free country and everybody is entitled to present his viewpoint to the public.

Dr. APPLE. I think the thing we resent is now being accused as being political opportunists for expressing our viewpoint.

Senator NELSON. The committee would simply be interested in how widespread the activity is.

Dr. APPLE. This statement was made in the last few weeks by the president of the Pharmaceutical Manufacturers at two public meetings.

Senator NELSON. What statement?

Dr. APPLE. The fact that we are being political opportunists and insincere for expressing our viewpoints.

Senator NELSON. And these statements were made on what occasion?

Dr. APPLE. On occasion of the public meeting of drugstore owners in Houston and on occasion of the midyear meeting of the Pharmaceutical Manufacturers Association.

Senator NELSON. I know that you say on page 3 that "for years we have heard attempted justifications for the large price differentials and discriminatory pricing practices." And "none of them rings true," to quote you. Are you referring in particular to the discrimination in price to the pharmacists, the drugstore owner, versus the price offered to the Defense Supply Agency or Veterans' Administration or to hospitals or public institutions for the same drug?

Dr. APPLE. In general, yes; but I explain that in detail a little farther on here, Senator.

Senator NELSON. Senator Hatfield has some questions.

Senator HATFIELD. Dr. Apple, I would like to ask you, in terms of your testimony here, what is the basis for the accusation of being "political opportunists," as you use the phrase? What are the words "political opportunists"; what appropriate use of those words in relation to your profession?

Dr. APPLE. Well, Senator, I suppose I should have put that material in quotes because that was exactly the words used in the speech made. That sentence perhaps should have been put in quotes. Those are not my words. Those are Mr. Stetler's words.

Senator HATFIELD. How are we to interpret that as a committee? What is your professional organization and professional group, how does political opportunism get involved here? Is there some reference to this committee, coming before this committee, or what? Why did they use the words "political opportunists?"

Dr. APPLE. Senator, if I can quote from this statement presented by the president of the Pharmaceutical Manufacturers Association on November 1, 1967:

"Our industry has been under attack from various"——

Senator NELSON. Excuse me, whose statement is this?

Dr. APPLE. Mr. Stetler's.

Senator NELSON. Before what group?

Dr. APPLE. Before the National Association of Retail Druggists.

Senator NELSON. Where was this?

Dr. APPLE. Houston, Tex.

Senator NELSON. All right.

Dr. APPLE (reading):

> Our industry has been under attack from various politicians for too many years. We are getting a little tired of the game and in the present instance it is more than a little disconcerting to know, and we certainly do, that the Nelson Subcommittee and Russell Long and his staff have been getting considerable assistance and encouragement from some representatives in pharmacy. This in my opinion is an unexplainable and a most reckless type of activity.

Senator NELSON. Obviously, since Senator Long and I are statesmen, he is referring to you as a politician. [Laughter.]

Senator HATFIELD. I didn't quite catch where the phrase "political opportunists" was referred to.

Dr. APPLE. That came earlier in the speech, sir.

It goes on to say:

> For those who have chosen this latter course based on honest personal calculations or beliefs I have no criticism, but those who, based on cold political calculations, have decided they can improve their personal or professional position by throwing an industry, another profession or a segment of their own profession, to the Congressional wolves in my opinion deserve our collective condemnation.

Senator HATFIELD. Those are very interesting statements but I don't quite follow the use of, in your testimony, the words "political opportunists."

Mr. STEEVES. I think that particular statement, Senator, was our interpretation of those two passages.

Senator HATFIELD. So you are really not then quoting directly, this phrase from any testimony?

Dr. APPLE. It is based on——

Senator HATFIELD. This is an interpretation of your association or your group on what was said?

Down in the next paragraph it tends to be, on the surface at least, a bit contradictory:

For years we have heard attempted justifications for the large rise differentials and discriminatory practices. None of them rings true, though there is some substance of truth.

Well, what ratio of truth to untruth is there in this statement that you make? How is this committee to interpret your comments here; is there a 60–40 differential or ratio, or is there a 50–50 or a 70–30? How much truth and how much untruth?

Dr. APPLE. Senator, I think if I am allowed to proceed with my statement you can make your own evaluation where I have tried to point out the specifics and certainly you can judge on that basis.

Now, when an industry representative says that he can't sit in a room and explain why his price is different than someone else's price, there is an element of truth. Perhaps the antitrust laws won't permit such a gathering. But it doesn't explain away the price differences.

Mr. STEEVES. It is also the case in the area of quantity prices, Senator. Of course, there is some economy in bulk purchases and prices, so when an industry spokesman explains the disparity in prices based on the quantities, there is some substance of truth to that. However, that is not a complete explanation for some of the wide price differentials that we have seen. This is what we mean by saying there is some substance of truth. There is some promotional value, there are some economic savings through quantity purchases but, of course, it is only part of the story. I don't know that we could evaluate it in terms of 60–40 or any percentage.

Senator HATFIELD. Then, actually, the phraseology here should have been perhaps a little differently stated. "None of them rings true" is pretty categorical.

Mr. STEEVES. That is right.

Senator HATFIELD. If you had started the sentence as if there is some substance of truth and then qualify that—but when you start out by saying "none of them rings true" and then try to qualify something as categorical as that, I think it is a little misleading.

On this price point, I gather from your testimony and from others representing your viewpoint, there is a feeling that the pharmacist has a greater understanding of the price problem in the new drugs coming on to the market, and the changing price picture and structure than the physician has. The pharmacist is dealing with this day in and day out and, therefore, he has a better comprehension of the overall price problem, is this not the essence of your thinking——

Dr. APPLE. Yes, sir.

Senator HATFIELD (continuing). Than the practicing physician?

Dr. APPLE. Yes, sir.

Senator HATFIELD. Yes, all right. Then let me ask you this: Do you have any knowledge of pharmacists who seek to keep doctors informed? Let's say, here is a pharmacist who has a continuing relationship with certain physicians through prescriptions that are sent by the physician, and over a period of time this pharmacist realizes that this doctor is prescribing a certain and particular drug, and that there are some new changes in this drug picture or new prices that are involved and perhaps other drugs that are equally good. Does the phar-

macist initiate any kind of an action to inform this doctor or doctors of these changing situations?

Dr. APPLE. Senator, I would say that many pharmacists have done this over the past, and it is going on with increasing frequency, especially because, as we have mentioned in our testimony, the American Medical Association has asked the doctor to be conscious of what the patient is paying for his drugs, which has in itself motivated the physician to ask the pharmacist more questions. On the other side of the fence, we have, of course, the public itself saying to the pharmacist "Why do I have to pay so much?"

Now this particularly happens when, for example, you have a product that a physician can buy at a fraction of the price the pharmacist has to pay, and the physician may give that product to his patient, and subsequently that patient may go somewhere else or may need some and it is not convenient for him to get back to the physician's office, and the physician will say "Well, I will call your pharmacist. Which pharmacy do you want me to call?" And the patient will go there and the pharmacist will say "That prescription is so many dollars." Then, the patient will blow up—he will come right out and say "But Dr. So and So only charges me so much for the drug." Well, even removing the pharmacist's fee for the service he renders, the pharmacist must charge much more than the physician because the drug cost him much more.

Mr. STEEVES. I also have, Senator, from November 13, Drug Topics, a trade publication, which discusses what pharmacists think about generics. One paragraph says:

> Asked if physicians discussed the use of generics with them, 81 percent of the respondents gave a negative reply. However, 38 percent reported having had such discussions with their doctor clients.

So I think that this would be one barometer of the number who may be involved in this type of activity.

Senator NELSON. Did I understand you to say that between the price paid by the doctor supplying the drug to his patients and that paid by the dispensing pharmacist, there is a differential in favor of the doctor? If the doctor decides that he wants to buy directly from a manufacturer, does he buy at a price that is lower as a matter of practice than the price the retail pharmacist has to pay?

Dr. APPLE. Sometimes that occurs. We know there are various promotional efforts that are directed exclusively toward the physician and that the pharmacist doesn't have the opportunity to participate in them.

Senator NELSON. But the individual practicing physician, unless he has his own pharmacy, doesn't as a matter of practice buy drugs directly; does he?

Dr. APPLE. Well, dispensing physicians are still a problem to our profession, sir.

Senator NELSON. But if he is a dispensing physician, does he buy at a lower price as a matter of practice than the pharmacist?

Dr. APPLE. In the case of many drugs, that is true, sir. I wouldn't want to categorically say it happens with every single purchase made by the physician, but in sufficient cases to cause the pharmacists serious relations with his patients.

Senator NELSON. What kind of a case were you referring to in which the patient gets a drug from a doctor and then subsequently the doctor writes a prescription and the patient then objects to the price he pays at the drugstore?

Mr. STEEVES. Frequently, in order to get—there was a case of the diuretic in which the company, as a promotion to hospitals and to dispensing physicians, would give 500 tablets free with the purchase of 500. This would be a 50-percent break.

Senator NELSON. You mean if the physician would buy 500——

Mr. STEEVES. They would get 500 free. The community pharmacist now would have to pay the list price. So the physician would be buying at a 50-percent discount.

Senator NELSON. You are not talking about the physician who has his own pharmacy?

Mr. STEEVES. No.

Senator NELSON. You are just talking about an ordinary practicing physician who buys 500 of this diuretic directly from the manufacturer and then receives 500 free, although he does not have his own pharmacy?

Mr. STEEVES. He dispenses directly from his office those drugs that he uses.

Senator NELSON. And then he charges his patients a fee for the drug?

Mr. STEEVES. It varies. Some of them charge a fee depending on the cost of the drug involved and some of them include drugs in their overall fee. This varies with dispensing physicians.

Senator NELSON. I am not talking about the case where the manufacturer supplies samples of drugs and the physician gives them away to patients without a fee. I am raising an issue that I wasn't aware of, where an individual, practicing physician who doesn't have his own pharmacy, as a matter of general practice, is offered a drug at a certain price and then is given 500 units free. Is the charging of a fee by the doctor for such drugs a common practice?

Mr. STEEVES. I think that the Subcommittee on Antitrust and Monopoly has been holding hearings on the problems of physician ownership of pharmacies and drug companies and some of the information they have developed there shows that there are companies who cater, who specialize in catering, to dispensing physicians with low-cost drugs.

Senator NELSON. I am not talking about dispensing physicians. I am talking about the ordinary physician in his office who doesn't dispense drugs at all except in a special case when a manufacturer wants to promote a drug with the doctor, and sells him 500 units and gives him 500 free. Is that a practice that occurs frequently?

Dr. APPLE. Senator, I think a physician basically is either a prescriber or dispenser, as we use that terminology. As a general rule, he prescribes all drugs and, perhaps, the only ones he actually hands to a patient are samples, in contrast to a physicion who makes it a routine and regular practice of furnishing medication to the patient.

Senator NELSON. So that it is clear in the record, we are talking about a physician who dispenses the drug from his own office. The manufacturer may take this diuretic to which you referred, and sell 500 to the doctor and give him 500 free, and he is then in direct competition with the pharmacist. The doctor is honest, so he charges the same

markup fee that the pharmacist would. But since the drug costs him only half as much the patient pays much less than the normal retail price. Is that the kind of case you are talking about?

Dr. APPLE. That is one example; yes, sir.

Senator NELSON. Why would they give this deal to the dispensing physician and not give the same deal to the pharmacist?

Mr. STEEVES. The physician, of course, has the advantage that he can choose which drug he is going to dispense. So that if he is going to have a thousand of company X's product there, he is going to dispense that particular product. The pharmacist, on the other hand, has to dispense what the doctor prescribes, and, therefore, the way it has been explained to me is that this is the way to get the doctor to use your particular product if he is a dispensing physician, give him a price break so he gets the product in there and he is going to use it.

On the other hand, if he is a prescriber and you detail him, the next detail man may come along and have you prescribe something else. So there would be no promotional advantage of giving the price break to the pharmacist.

Senator NELSON. So if I understand you correctly, you are saying that to give the dispensing physician a price break is a matter of promotion since the doctor is the prescriber and if he gets used to prescribing this drug he may continue to prescribe by the brand name of the firm which sold him the drug.

Mr. STEEVES. No, because ordinarily if it is a dispensing physician, he is going to be dispensing that drug continually. It is generally thought that price here is a major consideration and that perhaps if the next company comes along and gives a little better price the next time he needs a diuretic, he will use the next company if it meets with his medical judgment. I don't think the firms suppose that the physician will change from dispensing to prescribing.

Senator NELSON. I don't mean that. The idea of the promotion was to introduce this particular trade name diuretic to the doctor; is that what you are saying?

Mr. STEEVES. It could be.

Mr. GORDON. You are not referring only to injectables, are you? Aren't you referring also to oral diuretics?

Dr. APPLE. I was referring to all dosage forms basically.

Mr. GORDON. The physician has to dispense the injectable himself, doesn't he?

Mr. STEEVES. He ordinarily administers that.

Dr. APPLE. He administers the drug or has his nurse administer it under his supervision.

Mr. GORDON. Yes.

Mr. STEEVES. But the discussions we were talking about here, Mr. Gordon, relate primarily to drugs that can be self-administered, tablets, capsules.

Mr. GORDON. All right.

Senator HATFIELD. May I ask a question on this: In the field of nonprescription drugs, are there any price benefits or breaks or whatever you call it, given from the industry to the pharmacists directly? You are speaking of a price break being given from a pharmaceutical house to a physician, a dispensing physician, as I understand.

Mr. STEEVES. Of prescription drugs?

Senator HATFIELD. Prescription drugs. All right. If he gets 500 he get 500 or whatever it is. Are there any such price breaks given to the pharmacists running a drugstore, a pharmacy?

Mr. STEEVES. Yes.

Senator HATFIELD. From the pharmaceutical house for nonprescription drugs?

Mr. STEEVES. Yes.

Senator HATFIELD. So in other words, you then can get the same kind of price breaks if you push certain drugs under this same basic arrangement?

Mr. STEEVES. This is correct. If you pick up the pharmaceutical literature you will see an extra 10 percent if you buy a case of this cough syrup or that cough syrup; yes.

Senator HATFIELD. But, it is wrong for the physican, and it is right for you?

Mr. STEEVES. No.

Dr. APPLE. No, Senator, I think the analogy is between pharmaceuticals and nonprescription drugs or any other commodity that might be available in a drugstore. In the latter case, you will find that the manufacturer publicly offers a deal, a quantity discount, a promotion which is available to anybody who wants to buy it. Now——

Senator HATFIELD. To any pharmacies who want to buy it?

Dr. APPLE. It can be to grocery stores. It can be supermarkets. It can be any type of retail outlet.

Mr. STEEVES. Dispensing physicians?

Dr. APPLE. It can be physician himself if he wants to buy it.

Senator HATFIELD. I see.

How do they make this selective list then with physicians? I suppose you are inferring that this broad type of price deal is not given to every physician as it is to every druggist?

Mr. STEEVES. Generally, I think it would be available to any physician.

Dr. APPLE. I think it would be.

Senator HATFIELD. In other words, it is the same broad base proposition, so to speak, professional proposition.

Mr. STEEVES. For those in the medical profession; yes.

Senator NELSON. But not to the pharmacist at that stage.

Mr. STEEVES. There is another factor, Senator. You mention these price breaks and so on. Our journal policy will not accept these ads emphasizing the profit or the deal promotion. This has been our policy for a number of years. We would like to have the drugs promoted and sold to our members and sold to the public on the basis of intrinsic merit, not on the basis of an extra 10 percent, and if—we could go through our journal over the last several years and you will see some of the ads that have been modified at our request. Some of the ads which appear in the general trade press have not run in our journal.

Senator NELSON. Does this philosophy prevail within the profession of pharmacy?

Mr. STEEVES. I think it is growing. I don't know whether I could say it prevails at the present time.

Senator NELSON. Let me ask you another question on this pricing.

Certain physicians have said that they sometimes use symbols in prescriptions that are taken to a drugstore to indicate that the individual who needs the drug is an indigent and, therefore, a different price should be applied than in the case where that symbol is not present. Do you know about this practice?

Mr. STEEVES. Yes.

Dr. APPLE. There was a code word that was fostered by one of the other organizations in pharmacy for a number of years, but about 4 or 5 years ago they dropped the word on advice of the Justice Department—I think—you have reference to a symbol put on the prescription which indicates to the pharmacist what the price is as well as symbols that encourage the pharmacist to give special price consideration to individual patients.

Senator NELSON. Yes.

Dr. APPLE. For example, designation "PP" referring to an indigent person.

Senator NELSON. That is the practice today so there is this pricing differential within the pharmacy outlet.

Dr. APPLE. I would say that the practice is disappearing rather rapidly because in most cases some State program or third party is paying for them rather than the individual.

Mr. STEEVES. If I could add for just a minute, Senator, I have just talked to two of our community practitioners. Mr. Eggleston says it has been a long time since he has seen that abbreviation and Mrs. Andersen says that title 19 has just about eliminated it in her area. I think this is generally true, before we had the title 19 broad program, before we had any of these poverty programs on drugs, this was a more widespread practice but it is on the wane now.

Senator HATFIELD. On this practice of pricing in the pharmacy outlet, do you have any records or any evidence on this constant report we get that in the ghettos the pharmacy outlets are charging higher prices for their drugs than they are in other parts of the same city?

Dr. APPLE. Mr. Chairman, I have no direct information yet. I have read the article that appeared in the New England Journal of Medicine. I understand that the Boston newspapers this week are carrying some survey of their own. We are now starting to look into this situation. We haven't proceeded far enough where I could intelligently and accurately give the committee any information.

I can say that our association certainly does not condone the practice of an individual being charged a different fee for his prescription based on any kind of discrimination whatsoever.

Senator HATFIELD. But you are involved right now, I understand you to say, in investigating this discriminatory pricing within the pharmacy profession that you represent?

Dr. APPLE. Well, we aren't investigating that. We are investigating the reports that we have brought to our attention. Our association per se is not an investigatory body. In other words, when we see something that involves an individual member of our association, for example, we are concerned. We do mention some of this——

Mr. STEEVES. I think on page 15, Senator, to get down to the position of the association, we do say that there are some pharmacists who oppose price discrimination by drug manufacturers, but who support the inequitable markup system of prescription pricing.

Senator NELSON. Does the Senator object if we just get to that in the normal course of the testimony, unless you really want to pursue it at this point?

Senator HATFIELD. I have just one further question on this point. I will be very happy to wait until you develop it in your testimony.

When you were talking about discriminatory practices toward you from a pharmaceutical house or a manufacturer, I want to just get clearly in mind that you are just as concerned about discriminatory price fixing or price practice as it relates within your profession toward the general customer. Is it not true you are just as concerned with that?

Dr. APPPLE. We are certainly concerned with that, Senator.

Senator HATFIELD. And you are utilizing your office and your association to correct that problem toward other people as you feel should be corrected toward you. Is that correct?

Dr. APPLE. That is exactly our position.

Mr. STEEVES. Correct.

Senator NELSON. Go ahead, Doctor.

Dr. APPLE. One of the difficulties we have had, and continue to have, is how these various calculations balance out or fail to balance out. For example, testimony before this subcommittee from the representatives of a particular firm shows that 5-milligram prednisone tablets can be produced for about $0.50 per hundred. The break-even point for this major, research-oriented manufacturer was estimated by it to be $1.36. Add to this 25 percent for profit and 10 percent for research costs and the accumulated total is about $1.84. Yet the price to the pharmacist for the past decade has been nearly $18. Are we to believe that a quality product cannot be produced and marketed below this price by any other manufacturer?

We have not taken the position that there are any "unwarranted profits" in the drug industry. Our profession has not criticized the profit levels of the industry as being excessive. In fact, we have taken no position on this subject to date. We have assumed that the profit level was adequate and proper—though certainly much greater than community pharmacists enjoy.

We want the pharmaceutical industry to be profitable. The material issues are whether the prices are justifiable and whether the marketing policies that produce these profits are in the public interest. It may be that the price of drugs could be reduced and marketing practices could be changed without altering the overall profit level of the industry.

Mr. Chairman, we favor and support the patent system which has contributed so much to the progress of our country and the welfare of its citizens. We do not distinguish here between patents for drugs and other discoveries. We firmly believe that discovery and invention should be rewarded handsomely to encourage continued development and progress. We feel certain that the American contributions to pharmaceutical and medical science would not have been so rapid and important without the patent system.

Senator NELSON. May I interrupt just a minute to go back to page 4? You refer to prednisone priced at $1.84 by a calculation you used which begins with the manufacturer's estimated costs of $1.38. With a 25-percent profit, and 10 percent for research costs, the cumulative total is $1.84. Are you familiar with the Medical Letter that came out some several weeks ago on the drug prednisone?

Dr. APPLE. I am, sir, in general, with its contents; yes.

Senator NELSON. In the Medical Letter, which I have before me, they discussed the results of tests run on 22 prednisone products plus the opinions of their consultants with respect to the drug. They also listed price differentials for this drug that ranged from $0.59 all the way up to $17.90. I think your $16 is probably the latest revised price; is that what you are using?

Dr. APPLE. No; I said, "has been nearly $18."

Senator NELSON. In the Red Book the highest price has been listed at $17.90 for 100 tablets.

Dr. APPLE. That is right.

Senator NELSON. But the price of that drug goes all the way down to $0.59 a hundred, and the price charged by Merck, a research-oriented corporation, is $2.20 a hundred. So the Medical Letter shows that the 22 prednisones they tested vary in price from $0.59 a hundred to $17.90 a hundred, and they assert that all these products are of equivalent therapeutic value.

Do you have any explanation for this astonishing difference in price? If the argument is that those who are charging $0.59, and $0.75, and $0.93, and $0.85, and $0.61 a hundred are not research oriented, the fact of the matter is that Merck, for example, is research oriented and they charge $2.20 a hundred. And Upjohn is research oriented and they charge $2.25 a hundred.

Do you have any explanation of how it is possible for the $17.90 tablets to be sold in the retail market when there is available a brand name, even skipping the much cheaper ones, at one-eighth the cost from Upjohn, for example, and from Merck?

How is it possible in a competitive situation that although all these drugs are of equivalent value therapeutically, the one selling to the pharmacist for $17.90 is obviously being used the most—as a matter of fact that company has a third of market in the world on Meticorten. How do you explain that at the retail level Merck isn't the one that just takes over the whole market, to take a trade-name company, or any other trade-name company selling at much lower prices? This wouldn't happen if we were talking about automobiles; it wouldn't happen if it were clothes or shoes. People look at the price differential in such products, it seems to me. How do you explain the fact that in the retail drug market the $17.90 product keeps selling?

Dr. APPLE. Mr. Chairman, if the physician prescribes the $17.90 drug, obviously, the pharmacist is going to have no choice but to dispense it, so I think you are going to have to look for your answer to the prescribing habits of the physician rather than the dispensing habits of the pharmacist.

But I might add that at our house-of-delegates meeting last April our committee on legislation recommended the following to the house, which was adopted:

The Committee is cognizant of the wide price discrepancies charged by some individual manufacturers for their own products where it can be assumed there is no difference in either quality or efficacy. The Committee recommends that the Association, if invited to testify at these hearings, not presume that it has the facts and information to explain these wide price differences. This is data that the individual manufacturers will have to provide themselves.

I think our house-of-delegates took a very wise position. We don't have the facts that account for this difference. We can explain to the committee that the mechanism is obviously the use of the brand name, which creates a captive situation.

Senator NELSON. But you see this gets right to the very heart of the argument made by the manufacturers, in which they claim that the doctor can only rely upon a distinguished, reputable, established trade-name company. Therefore, the doctor doesn't dare to gamble and shouldn't gamble with his patients' health by prescribing a prednisone made by Wolins Pharmacal that costs $0.59 a hundred, or Zenith at $0.75 a hundred, or Sherry Pharmacal, or U.S. Vitamin Pharmacal at $2, or any of the rest of them.

Here we have a case that goes right to the heart of their argument. There is available from a distinguished trade-name company, Merck, a prednisone product at $2.20. This is not a generic company and they do conduct search and, like the rest of these companies, they are a reputable firm. You also have Upjohn's product available at $2.25. And yet in the marketplace, Meticorten, at a cost of $17.90 to the pharmacist, is selling very well. Why do the doctors prescribe it? You know, most people would be pretty outraged to have a copy of the Medical Letter, which every doctor in this country says is a very distinguished scientific publication, and which industry representatives who testified here called a very reliable publication and then have their physicians prescribe Meticorten at $17.90 plus the mark-up, when right there in the marketplace—taking the industry's argument on their own grounds that you should stick to the research-oriented trade-name companies—another distinguished company is selling the drug at one-eighth the cost. Now, what is your explanation for how this can happen?

Dr. APPLE. Mr. Chairman, I think we said here, "are we to believe that a quality product cannot be produced and marketed below this price?" We don't believe it, as a matter of fact, and I think there is a trend going on, as Senator Hatfield indicated, where pharmacists are now starting to point to physicians and say, you have one product by Upjohn and one product by Merck, Sharp and Dohme at a fraction of the price and there is no—they don't get into the quality argument, generic brand name argument, because I would say that basically any physician in the United States would accept Upjohn's reputation or Merck, Sharp & Dohme's reputation, as well as they would Schering's reputation. So there are no question marks there. It boils down exactly to price. We don't have the latest market figures but certainly the industry can provide them. It would seem to me that either Upjohn or Merck, Sharp & Dohme could move ahead in this particular market by just telling the medical profession that their product is available at $2.20 or $2.25.

Pharmacists tell me, our president-elect behind here told me just the other day, that he no longer stocks Meticorten because physicians are prescribing the other products after he discussed comparative costs with them.

Senator NELSON. What does he do when the prescription which comes in is for Meticorten, for example?

Mr. EGGLESTON. Of course, I am a community pharmacist in a community of 6,500 people.

Senator NELSON. Would you identify yourself?

Mr. EGGLESTON. My name is Max Eggleston. I am a community pharmacist from Waverly, Iowa, and president-elect of the American Pharmaceutical Association. In a community of 6,500 people it is a little easier to talk to physicians. But in the case of prednisone, when the price differential and the quality from a good manufacturer became available as the result of the expiration of patents, we let our physicians know that prednisone was available from a research-oriented pharmaceutical house and we were going to provide those if so desired. As a result we get no prescriptions for Meticorten and, as a matter of fact, I would say we never get them.

Senator NELSON. I can only say about that that the ordinary, hard-pressed little consumer having trouble meeting the grocery bill and paying the taxes ought to be shocked out of his shoes, and would be, if he knew that he is paying $17.90 plus a markup for a drug when right there in the marketplace there is an equivalent item, with scientific evidence to support its therapeutic value, at one-eighth the price, and one-tenth, and one-twentieth the price, as a matter of fact at $0.59. I don't care what price anybody charges, but what bothers me about this is that the public doesn't have the facts or have the opportunity to pay $0.59 and is reaching down into his piggy bank to come up with $17.90 plus a markup. This is a shocking business.

I don't know of any other area in the marketplace, unless there is a monopoly, where competing items are available, and where this kind of disparity would last 1 day. It wouldn't last a day in this case, either, if the consumer knew the whole story.

Dr. APPLE. Later on here, Mr. Chairman, we have explained some of the actions that we think pharmacists can take to help the public.

Senator HATFIELD. Mr. Chairman, and Dr. Apple, I quite agree with what our chairman said in this matter of the problem of the consumer in not having this information. And I appreciate what you said about the pharmacists informing the doctors about these price differentials, and even in larger communities than 6,500. I hope this can become a more general practice.

Let me ask you, is this not also the case, as it involves a multimillion-dollar business today known as vitamins that are not on the prescription requirement list, on which there are brand-name vitamins in a drugstore, where the average consumer goes, which are selling for a great deal higher price than, say, nonbrand names? And doesn't the pharmacist here have also a role to play in helping counsel in terms of what is equivalent and within the variation of price?

I have read articles, as I am sure you have read articles, about the vitamin industry today and what it does in terms of moneymaking, economic growth, and so forth, but isn't this something your association is also desperately involved in and concerned about as it relates to the consumer?

Mr. STEEVES. What you say is true in terms of, if you will, the private label versus the national brand, I guess, would be the best way to describe it. And I am sure you are also aware of the controversy over the rationale of daily supplementation of vitamins, the scientific controversy that is going on in this country in this area. We have to get the scientific desirability of supplementing and who gets supplemented settled as well. In other words, some people, no matter what the cost of

vitamins would be paying too much for something they don't need. We have to identify where vitamins can be used properly, and then, of course, you come to your question on price.

We would hope that we could resolve the first question as to the need for supplementation and the proper use of supplementation by vitamins, and then I think we would be in a position to deal with the second question of price.

Senator HATFIELD. But at the present time there is a distinct problem here in this price field of a variation, a wide variation, of vitamins available to the consumer at the drugstore.

Mr. STEEVES. That is correct.

Senator HATFIELD. And pharmacists are in a role of prescribing, if you can say it in a broad sense, because they are counseling the customers. The customer says, "Well, Mr. Brown, which one of these is the best vitamin?" Well, now, he can help that customer by selecting an equivalency that is less costly or he can push the brand name and make more in his markup, and so forth.

This is a problem.

Dr. APPLE. Well, Mr. Chairman, and Senator Hatfield, I would have to answer that there may have been a time, a decade or so ago, when the pharmacist could have participated in this kind of educational activity for the consumer, with the consumer, but in the case of vitamins, that day is gone because most vitamins are now being sold in other installations, in grocery stores, supermarkets, vending machines, and you name it. One of the largest sales promotions for vitamins is by the mail-order distributors.

Senator HATFIELD. But there are a goodly number of us who are still going to drugstores to buy our medicines and our vitamins and prescriptions.

Dr. APPLE. We are delighted to hear that, Senator.

Senator HATFIELD. Are you engaged, though, in an educational program within your profession?

Dr. APPLE. Yes. We have a program called a health education service in which we actually work with all voluntary health agencies and the agencies of the Federal Government accumulating literature for consumer education. These racks, containing educational pamphlets on many subjects, are being, and have been, placed in pharmacies for a number of years.

We also have, as I have indicated later in our testimony, prepared educational material for the pharmacist on nonprescription drugs.

Our first "Handbook of Non-Prescription Drugs" does not cover the subject of vitamins. I think I would agree with the Senator that our profession has a public responsibility in this area.

Senator HATFIELD. And we are shocked at prednisone today, as an example you cite here. But I think we could be shocked, also, at some of the price differentials within the vitamin field and the kind of relationship of seller to customer as it relates in that field as, by the analogy we are now drawing, of the relationship of prescriber to patient. I am just as concerned that we move in every way possible to help protect the consumer, and that we raise these questions and these examples which I think are properly raised by you this morning.

But, also, I think we ought to be making certain that your association is doing everything it can to have completely clean hands on this whole problem of the consumer and his well being.

Mr. GROSSMAN. Dr. Apple, may I ask you a question, too, in the same light?

In other words, following Senator Hatfield's line of questioning, why, in other words, are you any better than a doctor who prescribes a brand-name drug, when I can go into your drugstore and the pharmacist puts out in front of me a brand-name vitamin, what is the difference? In other words, the industry——

Dr. APPLE. I think you have to draw a basic distinction between prescription drugs in which the consumer does not have a say—and I have indicated that further on in our testimony—and other consumer goods, such as vitamins, which are legally available without a third party's order and the consumer is free to choose. The same application can be made to tires as well as to vitamins.

The consumer needs more information to be an intelligent purchasing agent for himself. He needs the best advice he can get. But in the case of prescription drugs the consumer is not in this picture.

Mr. GROSSMAN. I just wonder who can better provide him with that information than the pharmacist when he comes in. I frankly don't see the distinction.

Mr. STEEVES. This is true, that the pharmacist can provide him counsel, except it is the patient in this particular case that makes the final decision. Also, you have to recognize that some of the same problems are involved in the vitamin field that are involved in the area of prescription drugs the subcommittee is investigating.

Some pharmacists believe, and I don't think this has been investigated publicly, that the brand-name vitamin, even though it may sell at two or three times the price or at double the price, or whatever the premium may be, is actually the best thing for the patient. That the other vitamin may be subpotent or poorer quality—some of the same issues you are facing with prescription drugs. Perhaps resolution of the issue as to prescription drugs on this therapeutic equivalence will be of some help to the pharmacist in the——

Mr. GROSSMAN. I want to make it clear I am not intending to defend anyone, but I am wondering, you say the industry should take the lead, and I see the same point here so far as you are concerned.

Dr. APPLE. I am happy to answer the question now. One of my staff just told me that a vitamin chapter will be published in the February issue of our journal. The delay was in waiting for clarification of the Food and Drug Administration on proposed regulations.

Mr. GROSSMAN. Thank you.

Senator HATFIELD. Thank you, Mr. Chairman.

Senator NELSON. Just so the record is clear on this: A few moments ago Senator Hatfield referred to the question of the consumer not having enough information.

I am sure he agrees with me that in order to insure that nobody will be misled, it is really the doctor and the pharmacist who need the information.

So far as I am concerned, and I am sure the committee will agree, the discretion to make the decision about prescribing drugs of a brand

company is in the hands of the physician, and unless he is operating under a formulary of some kind or another, which is a very good system, he is frequently working with inadequate information. So it is my position that what we are trying to do mostly is to be sure that the doctor gets adequate information about drugs. I think if he had the kind of information that is found in the Medical Letter he would be prescribing one of the cheaper brands, of prednisone, in this case, as is recommended by the Medical Letter itself.

So what we are trying to do is not interfere with the physician's discretion, but to see to it that he gets enough information so that he can exercise wisely the discretion that he has.

Go ahead.

Dr. APPLE. There has been much discussion about patents for "molecular manipulations." This form of research sometimes leads to new discoveries of considerable value. To the extent that potential patentability for "molecular manipulations" leads to new compounds and therapeutic entities, it serves a useful purpose for society.

We do, however, believe that the patent system and not the trademark statute provides the incentive for research and innovation in the pharmaceutical world. It is the patent system which provides a modicum of protection for risk capital, for investment in product and market development, and for investment in the education of the prescribing and dispensing practitioners. In our view, there is nothing wrong with this system and its rewards.

A patent on a drug product marketed under its generic name provides as much protection, revenue, and benefit as does the same product marketed under a brand name. Briefly stated, the nomenclature under which a drug product is distributed has no effect on its therapeutic value or safety for the patient. The patentee can set a price on his product, however named, to return more than his investment in research, development, production, and distribution. These basic facts have not been sufficiently emphasized in the current discussion.

Also overlooked is the fact that the patentee of a drug is the sole source of that drug unless he, voluntarily, licenses someone else to enter the market. Where a licensee is also marketing the same product, we would expect that the licensee's price would be much less because of the absence of research, development, and other costs which justify the patentee's price. When such a situation exists, we would expect pharmacists to act as the public's purchasing agents and obtain the drugs as economically as possible.

Mr. GORDON. You mean as economically as possible consistent with quality; isn't that correct?

Dr. APPLE. Yes; we certainly do. Quality is certainly a factor. We would have to take into consideration whether the drug was a post-1962 drug, whether it had an NDA, whether safety and efficacy had been approved by FDA, whether it was a certified drug, but we are certainly not talking about the cheapest drug, Mr. Chairman.

In testimony before the Senate Committee on Finance, during September, we reported that the "brand-name era" in pharmaceuticals is coming to an end. We were merely reporting an observation about prescription drugs as we and others have seen it.

Senator NELSON. What do you mean, the brand-name era coming to an end?

Dr. APPLE. I think I explained it, sir. Certainly the public interest in the quality and cost of drugs has been effectively rekindled since your subcommitte initiated its hearings several months ago. In addition to focusing attention on specific issues, these hearings have stimulated examination of policies and positions by most of the parties involved. The unrest of the public, organized labor, the aged and other groups in our society, as well as the Government, reflects their concern about the cost of drugs and the large price differentials to various buyers, between "brands" and "generics" and among various "brands" and "generics." This restiveness originally spared the physician and the pharmacist, but it now has taken hold among all of the health practitioners.

The interest of the American Medical Association in the cost of drugs is evidenced by its own surveys conducted earlier this year in Chicago. Mr. Chairman, you have very timely and cogently exposed these surveys for what they are, but the very fact, for whatever reason, that the National Professional Society of Physicians chose to involve itself directly in drug costs to patients is conclusive evidence of the growing public impatience.

Senator NELSON. As you are aware, some weeks ago, the Peoples Drug chain and the Gray's Drug chain representing over 400 retail outlets announced that they were going to stock a complete line of generic drugs from reliable manufacturers. Is this the kind of thing you are referring to when you say that the brand-name era in pharmaceuticals is coming to an end?

Dr. APPLE. It certainly is, Mr. Chairman.

One of the questions that the pharmacist has had over the past decade is, Where do I get a quality generic? He always has been in doubt about the use of the drug, and we see evidence now where many manufacturers have come forward and offered the pharmacist a line of generics certainly he can feel confident about.

Mr. Chairman, you mentioned one of them just now, and I think you would be interested in seeing what we are talking about.

This is the line of generics offered by Alliance, and I don't mean to imply that there aren't others that are available by equally competent manufacturers.

Senator NELSON. How broad a spectrum of different drugs do they offer?

Dr. APPLE. These are the drugs that they are currently offering. Alliance is a group of wholesalers and, apparently, the wholesalers must feel that the pharmacist needs such drugs or they wouldn't go to the extent of arranging to pool their interests to have one of the pharmaceutical manufacturers in this country who is well known, produce this line for them.

Now, historically speaking, of course, there have been companies that have made generic products to specifications of other manufacturers, or other agencies interested in purchasing large quantities of drugs. Many of them cater directly only to large institutional purchasers. They aren't interested in putting up a batch of 50 bottles or 100 bottles of a hundred tablets. The mechanism, of course, is now available through the change that has taken place in the marketplace and this is one of the reasons why we think the brand-name era is coming to an end. Articles have been printed, and we have a number of them here we would be glad to submit——

Senator NELSON. They are articles on what, Doctor?

Dr. APPLE. The increasing use of generics all over the country.

Senator NELSON. I would like to have you submit them for the committee files and if they seem useful for the record we will have them printed in the record.[2]

It is your view, then, that developments like that initiated by Peoples & Grays and this one here indicate a growing demand for reliable quality generics and the beginnings of an expanded program of stocking generic drugs by the retail pharmacist?

Dr. APPLE. Generic in itself has always had the connotation of being a bad word, an evil term, and I think we finally have come to an educational point where we recognize that what you call a drug is no criterion of its quality. The label, the nomenclature, goes on last. The quality is built in first, and for this reason, I think prescribers and others, pharmacists certainly, are taking a keener interest in the use of generic drugs.

Senator NELSON. Well, it is true, is it not, that a number of the most distinguished brand-name manufacturers also are manufacturing generic drugs, is that not correct?

Dr. APPLE. Yes, it is.

Mr. GORDON. They are really not generic drugs. They are regular drugs under a generic name. We are really talking about names rather than drugs, aren't we?

Dr. APPLE. I would agree with you, Mr. Gordon, that there isn't such a thing as a generic drug.

It is the use of, we prefer to——

Mr. GORDON. Why don't we call it official names rather than generic names?

Dr. APPLE. Official name, scientific name, established name is the nomenclature system we go by.

Senator NELSON. Go ahead.

Dr. APPLE. Because of the interest of this subcommittee and other congressional bodies, the public, the professions and the government at all levels are taking a thorough look at drug costs and expenditures. The day is not far away, as we see it, when the prices for similar dosage forms of drugs with identical therapeutic ingredients and comparable therapeutic effectiveness will be narrowed to insignificance.

Mr. GORDON. How do you expect to get this without legislation?

Dr. APPLE. Well, I have said the unanswered question is whether this result will be achieved without legislation. We see it happening through the mechanism of a hospital pharmacy and therapeutics committee—first, the general deemphasis on the brand name, the increasing emphasis on established nomenclature, the hospital formulary system being adopted in a general community environment as a community formulary system which we comment on later in our testimony, the comparative knowledge about manufacturers' prices, both among physicians and pharmacists. Certainly the commentary of the General Accounting Office, the implementation of title XIX, the legislation offered by Senator Long and Senator Montoya, the hearings by Mr. Dingell and the hearings of this subcommittee are all factors that are going to, as we see it, produce some changes.

[2] Retained in committee files.

Perhaps the hearings of this subcommittee and others of the 90th Congress will appear in historical perspective as the major social pressure of this transitional period. Certainly, the transition would be much slower without this congressional prodding and the support of the profession of pharmacy.

In our statement to the Senate Committee on Finance, we also reported that pharmacists have no regrets over the demise of the "brand-name era" for prescription drugs. We believe that we adequately reflected the attitude of the practitioners of our profession.

The "brand name era" has been characterized by large price differentials for identical products sold to government, hospitals, and other preferred buyers; heavy promotional costs; excessive sampling; special prices to dispensing physicians to gain acceptance for a particular brand; free goods to pharmacists with large volumes; and price premiums for what are essentially identical drugs.

The testimony presented on prednisone and reserpine before the subcommittee forms cases in point. The manufacturers could not affirm, scientifically, that any one of their particular brands was in any therapeutic sense superior to any of the others, yet community pharmacists are forced to purchase some at substantial price premiums.

We cannot believe that any enlightened member of our profession would urge continuance of a system that spawns these practices. We are confident that some of the leaders in the pharmaceutical industry are recognizing the basic inequities which both patients and pharmacists have had to endure. Even if it were in our self-interest, pharmacists couldn't restore the "brand name percentage market" era. We would be at a loss as to how to begin the first step in turning the clock backward.

There are several benefits which will accrue to the public and to our profession if prescribing by scientific nomenclature becomes the rule by choice rather than the exception by necessity.

Mr. GORDON. The former president of the Pharmaceutical Manufacturers Association once stated that, and I quote, "One of the greatest evils of the use of protected names lies in the confusion they create."

Do you agree with him?

Dr. APPLE. I would certainly agree with that statement.

Mr. GORDON. That was, as you know, Dr. Austin Smith.

Dr. APPLE. If I recall correctly, though, I think he said that when he was with the Council on Drugs of the American Medical Association.

Mr. GORDON. That is correct.

Senator NELSON. He would stand by it all right after he became president of the manufacturers association, don't you think?

Dr. APPLE. Leading medical practitioners and educators who have testified before congressional committees have pointed out the manifold benefits to medical care through the emphasis on scientific nomenclature in prescribing medication for patients. From the viewpoint of the pharmacist, all of his professional education would be better utilized for the benefit of patients if nonproprietary nomenclature was employed by manufacturers as well as prescribers.

The pharmacist is the member of the health team who is the specialist in drug therapy. Today, a pharmacist studies drugs a minimum of 5

or 6 years at an accredited college of pharmacy, and spends a year of internship dispensing drugs. This knowledge of drugs is more fully and effectively utilized when the pharmacist has a greater role in the selection of the drug product to be dispensed than when that decision is preempted by the mechanism of a brand name. The pharmacist can also exert a greater influence and effect as the patient's purchasing agent when he is given a choice in selecting the particular product to be dispensed.

Senator NELSON. What role, precisely, do you think a pharmacist should play, and does your concept of this involve the question of the State antisubstitution legislation that has been passed which permits the pharmacist to exercise his discretion if a generic name is prescribed but takes away all of his discretion if a brand name is prescribed?

Dr. APPLE. Mr. Chairman, I will come to the latter part of your question in a moment, but to answer the first part of your question, some years ago I gave a speech and outlined a situation where I envisioned, if you will, the future of pharmacy in relationship to medicine being where the physician would make the diagnosis, would send his chart down to the pharmacist who would then confer with the physician and recommend to him the therapy to be used. I think we will become that sophisticated in the role that we play in medical care in the future.

Now, in the last 5 years, the profession's educational program has shifted in that direction. We already have at the University of Wisconsin, at the University of California, at Ohio State University, where pharmacy students are now being brought to the bedside, as well as practicing pharmacists employed in the hospital, as members of the staff making rounds with physicians, discussing the therapy, the regimen to be used, and utilizing their scientific education, if you will.

Senator NELSON. Isn't it correct that in a good hospital practice or in a group practice where there are pharmacists present they are in continual consultation both as to the establishment of the formulary, changes in the formulary, and the physician's day-to-day prescribing?

Dr. APPLE. In all the accredited hospitals that have a pharmacy and therapeutics committee the pharmacist is generally the secretary of that committee and plays the role of providing the impetus for its actions to be sure, in the kind of situation you describe, Senator.

But, as a matter of fact, I see a more increasing role than that.

The more we attend meetings and conferences on the shortage of medical manpower in this country, and the fact that our population explosion indicates that we can't build medical schools fast enough, we are going to have to find better utilization of these medical skills and here we sit with a profession that is ready to provide an ancillary service to a much greater degree than it is being utilized.

We think in the interest of society we ought to move ahead.

Mr. GORDON. Dr. Apple, you say the pharmacist can act as the patient's purchasing agent in selecting the particular product to be dispensed.

At present, the pharmacist generally adds a certain percentage markup to his cost when dispensing the drug to the patient. That is correct; is it not?

Dr. APPLE. The markup system is still the most prevalent in this country.

Mr. GORDON. Now, it is also correct, I believe, that the higher priced drug gives the pharmacist a larger absolute profit.

Dr. APPLE. That is a matter of sheer mathematics. Certainly it does.

Mr. GORDON. Given the present system, then, isn't there somewhat of a conflict of interest in allowing the pharmacist to select the particular product to be dispensed? In other words, it is to his economic interest to dispense a higher priced product than a lower priced product given the present system; isn't that correct?

Dr. APPLE. That is theoretically true, but I think I go into that later on here, Mr. Gordon, in which I explain the markup system, the professional-fee system, the contrast in these systems, and I would prefer to go through it at that point if you don't mind, and give you an answer to that question after we have covered that.

Mr. GORDON. All right.

Senator NELSON. We will at this time recess until 12:30, if that is allright with everybody here.

(Whereupon, at 11:55 a.m., the subcommittee recessed, to reconvene at 12:30 p.m., the same day.)

AFTERNOON SESSION

Senator NELSON. The hearing will resume.

Dr. Apple, I believe you were on page 11; is that correct?

Dr. APPLE. Yes, sir.

Senator NELSON. You have referred to research in your statement, and this committee has continually had discussions about trade names and generic names and what they mean, and so forth. If trade names were to be eleminated from use, do you have any judgment or guess about how that might affect research in the drug field?

STATEMENT OF DR. WILLIAM S. APPLE ET AL.—Resumed

Dr. APPLE. Well, Mr. Chairman, if you mean by the use of some coined name rather than the established name, a proprietary name, which has no scientific relationship to the drug itself, it would seem to us that, certainly, if a manufacturer is going to invest in research to discover or improve a drug, and receives a process patent which permits him to have a 17-year limited monopoly, he has complete access to reimburse himself for that research investment.

We can't fathom how the use of proprietary names has anything to do with research because we have the cases of many firms which do no research but which use proprietary names. And they really don't mean anything.

Brand names assist the advertising and promotion of a drug; they do not have anything to do with the effect of the drug, the scientific production and discovery, and certainly not with the patent system, which guarantees manufacturers the reward of their investment in research.

Our association stands for the patent system 100 percent. We don't see how anybody can be asked to invest millions of dollars and not have an opportunity to recover his investment.

But we don't see where brand names have anything to do with the system of recovering for research.

Senator NELSON. Then do I understand you to say that it would be preferable if the name used on a prescription was the established name and if the doctor wished to name the company that he should do that on his prescription?

Dr. APPLE. Prednisone Schering would have given Schering as much protection for its research as any other nomenclature system.

Senator NELSON. We have had previous testimony, too, that endorses this position and I am interested to see that you, as a representative of the National Organization of Pharmacists, also endorse this position.

I would like to have you just proceed with your statement. I have to leave shortly. The reason you didn't get farther in your statement is that I occupied most of the time in questioning, but in any event I do have a commitment to keep.

Senator Hatfield hopes that he will be able to get back around 1:30. If he doesn't, Mr. Gordon and the minority counsel will listen to the testimony and ask questions. I assume you have no objection to that.

Dr. APPLE. Certainly not, Senator.

We firmly believe that pharmacists, in community and institutional practice, will contribute an ever-increasing amount of the drug therapy information to physicians. This aspect of the practice of the profession of pharmacy will be enhanced when more prescription orders are written in nonproprietary terms. The whole emphasis in drug education will be shared more equally by the physician and the pharmacist, as we think it should be. The pharmacist will then have the opportunity of serving the medical profession as a therapeutic consultant more frequently and effectively than at present.

This is logical because the pharmacist is more readily available when the decision for a particular patient is being made than is the manufacturer's representative, and the pharmacist has a knowledge of all available drugs on the market, not just those of a particular firm.

There are economic benefits which also will be realized by wider use of established names. In the case of prescription drugs, the one who orders does not pay and may have little knowledge about the cost of his order or the cost of alternatives. We do not criticize company salesmen for not presenting these alternatives to the physician. We do not criticize physicians for not having an independent knowledge of comparative drug costs. After all, this is the pharmacist's area of expertise and we think society will be better off when the physician makes better use of the pharmacist's knowledge.

With any ordinary consumer commodity, the consumer makes the choice on how much a given branded article is worth to him. He can examine the relative merits and costs of alternatives and arrive at his own decision. The Congress has enacted legislation to assist the consumer in making some of these decisions more intelligently.

Presciption drugs are not ordinary consumer commodities. Our laws do not treat prescriptions as ordinary consumer commodities. With prescription drugs, the consumer cannot weigh the alternatives, so others must do it for him. We fail to see how brand names for prescription drugs help either the physician or the pharmacist weigh the alternatives. And, we think this important distinction itself suggests

that the public interest is not best served when prescription-drug products are promoted by brand names.

Brand names for prescription drugs are a very effective marketing tool for the manufacturer. The use of a brand name on prescription drugs permits the manufacturer to establish that name during the protected patent period and then to extend his market share far beyond the life of the patent. After a minimum of 17 years of prescribing a brand name for a given therapeutic agent, the mere expiration of the legal patent period will not overnight result in a change of prescribing patterns.

There is the cost, during the patent period, not only of developing a market for the therapeutic agent itself, but an additional cost for promoting and establishing the brand name of the drug product. This latter cost little benefits medical care. It does, however, provide a substantial benefit for the manufacturer. Through brand-name dominance in the marketplace, it is possible to perpetuate a price differential even when "generic" or other "brand" products appear on the market after the patent expires. This dominance also permits the manufacturer to practice price discrimination selectively among different purchasers—a fairly common practice.

Not only do we have trademarks for various brands of drugs, but we also have trademarks for dosage forms of drugs, such as Pulvules, Spansules, Tabloids, and other designations. One wonders what the result would be under the substitution laws if the established name of the drug were prescribed with a trademarked dosage-form designation and the pharmacist dispended a "generic."

Competition in the pharmaceutical industry is concentrated at the prescribed level for the particular brand names on a prescription order. Brand names for prescription drugs effectively eliminate price competition in a large number of cases, whether or not the drug is patented. While we can accept and support the limited monopoly of the patent system, we cannot support the brand-markup concept for prescription drugs and its attendant consequences.

Mr. Chairman, there are subjects which every profession discusses ad infinitum. In pharmacy, one of these subjects is prescription pricing. The current discussion boils down to this: Should pharmacists use the markup system or the professional fee system?

In addition to APhA, the advocates of the fee system within pharmacy include the American College of Apothecaries and the American Society of Hospital Pharmacists. While not active advocates, members of the National Association of Chain Drug Stores favor the fee system. A recent survey of NACDS members reported in the September 18, 1967, issue of FDC Reports, "The Pink Sheet" revealed that:

> 52 percent of the members replying to an NACDS questionnaire favored pricing pegged to cost plus a fixed fee, and 23 percent favored cost plus a flexible fee.

While we do not think that the Pharmaceutical Manufacturers Association or individual companies should tell pharmacists what to charge for their dispensing services, publicly and privately most of the industry is actively opposing the professional fee for pharmacists.

Spokesmen for the drug firms say they oppose the professional fee because they fear pharmacists will lose interest in brand names if their

remuneration is dissociated from the cost of the drug product dispensed. It is not difficult to understand why pharmacists who use the markup system are complacent about brand name prescribing.

APhA for the past several years has been trying to educate pharmacists on the advantages that the professional fee system holds for both the patient and the prescriber as well as the pharmacist. We think the fee system also serves the best interest of the pharmaceutical industry.

Briefly stated, the cost of the drug to the pharmacist has absolutely no bearing on the professional functions he performs in dispensing a prescription order. If he applies a 40-percent markup on an $18 drug cost, he must add $12; on a $1.80 drug cost he must add $1.20. The professional service rendered in each case is the same.

There are some pharmacists who oppose price discrimination by drug manufacturers but who support the inequitable markup system of prescription pricing. The inherent inequity of the markup system is that patients who require the more expensive drug products must subsidize patients who require the low-cost medications and this results in price discrimination among patients.

One of the most frequently voiced objections to the professional fee is that it does not take into consideration elementary cost accounting factors. Let's look at this myth.

A recently reported cost accounting study revealed the U.S. average cost of dispensing a prescription order is $1.69. If we add $0.31 average net profit per prescription, we would have $2 as the total which would have to be added to the actual cost of the drug product to recover all of the operating costs and yield an 8.5-percent net profit on the 1966 U.S. average prescription charge of $3.60.

According to the 1966 Lilly Digest, the average number of prescriptions dispensed was 19,962 per pharmacy reported in its study. Again using the $2 figure, the total amount of dollars required to pay for operating expenses and yield an 8.5-percent net profit would be $39,924. Under the markup system, some prescriptions would contribute as little as $0.25 or $0.50, while others might contribute as much as $5 or $10 to yield the $39,924 gross margin. Under the professional fee system, each prescription would contribute $2—the average fee required to provide professional service in this hypothetical example.

If one patient requires a drug which costs the pharmacist $12, we see no reason why he should be charged $27, while another patient who requires a drug which costs the pharmacist $1.20 should be charged only $2.70. Under the markup system, one patient is overcharged $13 to recover the $0.50 undercharge to 26 patients. Isn't it more equitable for the patient who needs the $12 drug to pay $14 for his prescription while the 26 patients who need the $1.20 drug each pay $3.20 for their prescriptions?

The opponents of the markup system will quickly point out that the inventory investment in a $12 drug is $10.80 more than in a $1.20 drug while completely ignoring that the $1.50 markup added to the $1.20 cost of the drug fails to even cover the bare operating expenses. The point is that in the end each system will produce the same number of dollars for a specific pharmacy when the professional fee established by that pharmacy is equated to the gross margin of the average prescription charge of that pharmacy.

A new distraction recently has been interjected in the discussion. Opponents of the professional fee claim it could become a political football. They argue that if the Government reimburses pharmacists on the basis of an average fee, Government might initially establish an equitable fee, but as costs for Government-financed programs increase, the Government can be expected to try to force the fee downward. They overlook the simple fact that Government can just as easily reduce a percentage markup or the base cost to which the markup is applied. We feel that there is less danger of this happening under the fee method because the cost of providing the pharmaceutical service in dispensing a prescription can be readily verified and is independent of the drug acquisition cost.

The American Pharmaceutical Association supports and is encouraging the use of the professional fee system because we believe that it serves the public interest as well as provides a sound economic base for the services provided by the practitioners of our profession. We have encouraged its use in public assistance and prepayment programs. We have supported its inclusion in legislative proposals before Congress and State legislatures.

Some have characterized our efforts as unexplainable and almost reckless type of activity. Without apology or hesitation, we have expressed our opinion in unmistakable terms. We are pleased with the progress we are making. The professional fee method is now part of the reimbursement procedure for pharmaceutical services in many State public assistance programs. It was incorporated in the prepayment program for pharmaceutical services recently negotiated by the United Auto Workers. The Government Accounting Office has recommended the professional fee as the preferred method for reimbursement in Government-financed programs. On a nationwide basis, the professional fee has been used in the CHAMPUS program since October 1, 1966.

We would like to complete our comments on this subject by quoting the summary of a recent article by Dr. Robert V. Evanson, professor of pharmacy administration, Purdue University:

> The leaders in pharmacy who say that drugs are not articles of trade in pharmacy at the practitioner's level are correct. * * * In the pharmacy they are dispensed as component parts of a professional service. Therefore, legend drugs should not be classed as consumer goods, nor should they be sold at a markup.
>
> If this concept is ever fully accepted by pharmacy's functionaries, and especially its practitioners, a lot of currently sticky problems will eventually be solved. The Pharmaceutical Manufacturers Association will not have to be evasive on price discussions with practitioners, nor will it have to sit in Senate investigations trying to double-talk its members' pricing practices to the detriment of pharmacy as a whole. The American Medical Association will not be sounding off about pharmacists' high prices and drug shopping to its physicians' patients. Each physician will be stuck with his own treatment costs to justify to his own patients. Pharmacists will define their role as professionals and will charge fees commensurate with the services rendered and the lowest cost possible for those services.
>
> Finally, when the patient asks the pharmacist, "Why does this prescription cost so much?", he can answer very simply and truthfully. He can cite the manufacturer's cost, or he can cite the higher priced drug selected or the total quantity prescribed by the physician. In every instance, he can tell the patient that he is getting exactly what the physician ordered at the manufacturer's cost price to him, and that all he is paying the pharmacist is a small fee for his professional service. Every element involved is openly and directly responsible to the patient for his own part in the cost of drugs, and to me this makes sense in a system now given to buck-passing and laws.

The American Pharmaceutical Association supports the right of any manufacturer to make and market prescription drugs just as enthusiastically as we support the right of any pharmacist to practice where he prefers. We don't expect the economic system of our country to guarantee either the manufacturers' or our practitioners' financial or professional success.

Just a manufacturers claim the right to put as many drugs on the market as they can, so do pharmacists have the right to attempt to eliminate needless duplication in the inventories they carry. For example, there are more than 70 sources for prednisone, but it would be inefficient and costly for every pharmacist to have a product from each on hand.

Mr. GORDON. Would it be correct to say that the widespread prescribing by official names would simplify the inventory problem for the pharmacists?

Dr. APPLE. It certainly would, in my opinion.

Mr. GORDON. Would you explain how.

Dr. APPLE. Well, as I have indicated, there are 70 sources of prednisone, there are endless sources for tetracycline, and many other drugs.

The pharmacist might, in consultation with the practitioners of medicine, he serves in his particular area, decide to stock two or three or four different ones depending on this consultation, but it would not result in the kind of a situation where whatever is called for he would have to produce, and, therefore, there is no limitation at the moment on the inventory he might have to carry.

Here we are just saying that the forces of the marketplace ought to work in terms of the pharmacist having the right to keep his inventory down.

If he can convince a group of physicians that they ought to prescribe a particular drug manufactured by a particular firm, that ought to be his prerogative, just as much as it is the manufacturer's prerogative on the other side of the coin.

Commissioner Goddard recently reported that our drug armamentarium currently includes about 7,000 single chemical entities and compounds sold under 21,000 different labels. This, in no small measure, is a blessing for our society, but at the same time it is a serious problem for both the practitioners who prescribe and dispense drugs.

In some instances we have many firms manufacturing the same therapeutic agent in the same dosage form. We have a number of firms producing slight variations of the basic ingredient and others producing essentially new products for the same therapeutic use.

We fully expect that pharmacists always will carry a representative inventory—an inventory from which prescribers may select an appropriate therapeutic agent of their choice to treat the symptom they diagnose. But, we sincerely hope that physicians and pharmacists, working together, can help bring some of the efficiency and economy in the community environment that they have been successful in implementing in the institutional environment.

Rational drug therapy can be achieved with a relatively small number of drugs. Evidence of this fact is that a mere 200 drug products—many representing different brands of the same therapeutic agent and others combinations of two or more ingredients—accounted

for about 50 percent of the prescription medication dispensed last year.

Under current law, the success or failure of a given drug has been entrusted to the marketplace. If the marketplace is to perform this function for society as intended, we must insure that its various forces operate freely and effectively.

There is unlimited duplication of brand name pharmaceuticals, and this problem was apparent long before attention was focused on the generic brand issue.

In our opinion, it was this proliferation of different brands of the same drug which contributed to the enactment of the antisubstitution laws and our profession helped and, indeed, led the battle for enactment of these statutes in some instances. To our knowledge——

Mr. GROSSMAN. Dr. Apple, I wonder if I might ask just one question with regard to inventories. In all that you have presented here, would you not say then that one of the ramifications of what you recommend is that it would cost the pharmacist less because he would have to stock less, is that true?

Dr. APPLE. Well, it would cost him less in terms of dollar investment. But equally important, he might be able to buy in larger quantities, and that also would help reduce the cost.

Mr. GROSSMAN. I wondered if you would care to comment on something that the industry people have talked about. Basically there are some drugs that are very seldom used, and that they are forced to produce—not forced, but they produce—and that I assume that the pharmacies would carry, and yet the cost of these drugs, of course, is very high because they are very little used.

Mr. GORDON. May I comment on that?

Mr. GROSSMAN. Certainly.

Mr. GORDON. What puzzles me is why shouldn't those who get these rare drugs pay a price for them, that would cover their cost?

For example, I cannot see any justification for a person in a ghetto who needs tetracycline having to pay a higher price for tetracycline because a wealthier person might need a rarer drug. Why should he subsidize that wealthier person?

Mr. GROSSMAN. What I am getting at is, would you continue to stock these items?

Dr. APPLE. Let me say most of the drugs that you have reference to, I believe, are not stocked generally by pharmacists anyway.

Mr. GROSSMAN. I see.

Dr. APPLE. Because they are so rarely used, they are kept in inventory by the manufacturer, and as the manufacturer directly makes them available to the physician at the hospital or at the particular time they are needed.

Mr. GROSSMAN. So you do not normally carry them anywy.

Dr. APPLE. That is right.

Mr. GORDON. How big a deal is this anyhow? Does it involve so much money? Does it involve so many products? How big is it?

Dr. APPLE. Mr. Gordon, we have no knowledge—we know what some of the drugs are, but to the extent they are used and all that we have no statistical information.

To our knowledge, no State which did not have an antisubstitution provision in a prior law has enacted such a separate statute in the last

decade. Also, none of the States which has such a statute or regulation has repealed it, and we count 39 at the present time.

In our opinion, the substitution concept of today is a far cry from that which we knew prior to 1950. Substitution, historically, referred to the substitution of a different therapeutic agent than that prescribed by the physician. However, the brand substitution concept is relatively new and is based on the premise that the substitution of one brand for another brand of the same drug is analogous to supplying a different therapeutic agent. This is largely a thesis that no one can seem to prove.

Mr. GORDON. Since the antisubstitution laws, as you say, are anachronistic, would you support their elimination?

Dr. APPLE. Mr. Gordon, 2 years ago, at our 1965 meeting, there was considerable discussion about this subject, and our house of delegates took the position that a special ad hoc committee should be appointed to study the entire issue, and such a committee was appointed and has met on several occasions and will continue to meet until it is ready to submit a report to our house of delegates.

Offhand I would say repeal does not seem to appear to be practical and may not even be desirable, but perhaps the antisubstitution laws can be made to serve a useful social purpose. I think later on here we indicate that.

Mr. GORDON. You are saying, I guess, that they do not serve a useful social purpose at the present time; is that correct?

Dr. APPLE. Well, this is a subject matter which our committee has been asked to come up with an opinion to pass on to the house of delegates, so that the association will have a definite position, and I am sure you can appreciate that this is a policy matter that the house of delegates is going to have to speak on before I can speak for it or against it.

Mr. GORDON. Let me ask you this: Who or what organizations were responsible for getting these laws on the books?

Dr. APPLE. Well, as I indicated, at times our own profession did through our own associations, but, as I recall the situation, it evolved in this way: I think others could, perhaps, give you a better accounting of it. The pharmaceutical industry created a special task force, a special organization called the National Pharmaceutical Council, which led the effort for the enactment of these antisubstitution laws.

Mr. GORDON. They worked through the State legislatures, I presume, on a State-by-State basis.

Dr. APPLE. Yes, sir.

Mr. GORDON. Please continue.

Dr. APPLE. We recognize that there are isolated examples of seemingly identical drug products which are not therapeutically equal. In some of these cases, the evidence is only the report of a single observation with no indication as to whether the result was due to some idiosyncrasy of the patient or the drug. In others, it is clear that the product involved should not have been on the market at all because it failed to meet the legal standards, due to poor manufacturing practices. And, because our knowledge about drug action in humans is still incomplete, a differential response may be identified but not explained.

Mr. GORDON. Dr. Apple, you quoted Commissioner Goddard on page 21 of your statement as saying that there are about 7,000 single

chemical entities and compounds sold on the market which are sold under 21,000 different labels.

Can you tell us how many drugs you know about which meet standards set by the USP and the National Formulary and are not clinically effective?

Dr. APPLE. We have published in our journal, as I recall, one or two isolated experiences of this kind.

Mr. GORDON. Well, to your knowledge, has the report of these cases been based on high-quality scientific studies?

Dr. APPLE. I do not think that I could characterize the quality of the study. I do know from the reading I have done, and I do not claim to have any expertise in this particular area, that there is a great deal of concern about the quality of some of this type of research and verification process itself.

There was a book recently published by Dr. Barnard Beard, who is a sociologist, but also serves on the National Research Council, that characterized this whole type of research, and pointed out that the most qualified researchers do not seem to have any appetite for this routine type of testing. But I would be glad to ask our scientific division to submit to the committee any information we have on this subject.

Mr. GORDON. I think the subcommittee would appreciate that very much.

I want to pursue this a little further. Do you happen to be acquainted with the material which currently appears in the Reader's Digest as a paid advertisement of the Pharmaceutical Manufacturers Association?

Dr. APPLE. You mean "Medicines and Your Family's Health"?

Mr. GORDON. I believe that is what it is called.

Now, there is a reference to a patient almost losing his life because a pharmacist dispensed tolbutamide under its official name.

What is your reaction to this article?

Dr. APPLE. We were concerned when we first read that article because there was an implication, of course, that the pharmacist—regarding the pharmacist's conduct, No. 1.

No. 2, we were concerned in finding out the facts, so we proceeded to go back to the original report in the literature, and we traced the situation back from there. According to the information we have received from our colleagues in Canada, this particular drug was dispensed as a brand-name drug to a patient a number of times, and then subsequently because of the complaint of the patient about the cost of the drug, the pharmacist was authorized to use a drug under its established name which cost considerably less, and the patient received supplies of this drug in May, June, and July of 1962, and then in September of 1962 he received another prescription for tolbutamide tablets, and it was this last prescription that the tablets were found to pass through the patient and found in the stool unchanged.

At that point, the drug was assayed to determine whether or not it met the standards, and they quickly found out it did not disintegrate after 45 minutes in gastric juice, followed by 63 minutes in intestinal juice. The point was the drug did not meet the established standards of the law of Canada and, therefore, should not have been on the market.

Here is a case of a drug that did not meet the standards that was out on the market.

I want to make it clear I am only saying that particular last batch did not meet the standards, because there is no evidence of the patient having suffered any untoward reaction or having any problem with that same generic drug during the three previous periods in which a prescription was dispensed for him.

But I think the key point here is that the fact that the drug did not meet the standards established by the law in Canada in the first place.

Mr. GORDON. The article does not have that additional essential information, does it?

Dr. APPLE. No, the article does not.

I have received numerous phone calls from pharmacists, feeling that the article reflects on their integrity and their professional acumen and other things, and pharmacists have chosen to write directly to the Pharmaceutical Manufacturers Association about this particular situation.

I would say that this is just starting to come in because this, I believe, appears in the November issue of the Reader's Digest. I have an advance copy which was sent to me by the Pharmaceutical Manufacturers Association. But, as I understand it, it is in the current issue, the November issue, and we are just starting now to get a reaction from pharmacists as to what they think of it.

I might tell you here is a, I just yesterday received a letter, and I think this letter is, perhaps, typical of the few others I have received, as well as the telephone calls I have received. I will be glad to submit this.

Mr. GORDON. Would you read it, please, and submit it for the record also.

Dr. APPLE. Well, the letter is addressed to the Pharmaceutical Manufacturers Association, and it says:

> Your letter to our hospital administrator containing a copy of articles to be published in the November issue of Reader's Digest has been reviewed by myself.
>
> As I am certain that you are interested in the opinions of people concerned with these matters, I do wish to make a few comments. In brief I feel that articles such as "The Anonymous Drug That Hospitalized a Patient" is in poor professional taste. It pictures a dispensing pharmacist as being a part in a medication error. Further it does nothing to instill patient confidence in the physician and pharmacists who care for him since the patient has no idea as to the quality controls of the company manufacturing his drug. To me, the article seems to do little to instill confidence in the patient of American Pharmaceutical Manufacturers.
>
> The increasing frequency of drug recalls from reputable companies is gradually becoming known to the public and may well create doubt in the mind of the patient as to the efficacy of a prescribed drug regardless of its source.

This is from the director of pharmacy service at St. Luke's Hospital in Cleveland, Ohio.

Mr. GORDON. Will you submit that for the record, please?

Dr. APPLE. Yes, sir.

(The information referred to follows:)

SAINT LUKE'S HOSPITAL
OF THE METHODIST CHURCH,
Cleveland, Ohio, November 10, 1967.

Mr. C. JOSEPH STETLER,
President, Pharmaceutical Manufacturers Association,
Washington, D.C.

DEAR MR. STETLER: Your letter to our hospital administrator containing a copy of articles to be published in the November issue of Reader's Digest has been reviewed by myself.

As I am certain that you are interested in the opinions of people concerned with these matters, I do wish to make a few comments. In brief I feel that articles such as "The Anonymous Drug that Hospitalized a Patient" is in poor professional taste. It pictures a dispensing pharmacist as being a part in a medication error. Further it does nothing to instill patient confidence in the physicians and phamacists who care for him since the patient has no idea as to the quality controls of the company manufacturing his drug. To me, the article seems to do little to instill confidence in the patient of American Pharmaceutical Manufacturers.

The increasing frequency of drug recalls from reputable companies is gradually becoming known to the public and may well create doubt in the mind of the patient as to the efficacy of a prescribed drug regardless of its source.

Sincerely yours,

FRANZ W. GEISZ, Pharm. D.,
Director of Pharmacy Service.

Mr. GORDON. Please continue.

Dr. APPLE. We think that the problem of poor quality drugs is diminishing. Legislation in 1962 substantially strengthened regulatory control of the drug supply of this Nation. Added and improved manufacturing standards through regulations and new analytical procedures and equipment are contributing to improved quality. In recent testimony before the Senate Committee on Finance, the president of the Pharmaceutical Manufacturers Association, representing producers of over 95 percent of the brand and generic drug products made and sold in this country, stated:

> We already have, under the Federal Food, Drug and Cosmetic Act, comprehensive mechanisms for assuring that only safe and effective drug products are on the market.

Even if we can prove, with reliable scientific evidence, that a few drugs in final dosage form vary significantly in therapeutic response produced in the patient depending upon which manufacturer made them, this would still not explain why we should not use interchangeably other drug products with insignificant therapeutic differences. The exceptions, if any, should be kept in perspective; they should not govern our entire prescribing and dispensing decisions.

If our drug laws must be strengthened to provide batch certification for clinical effectiveness of every drug product before marketing, then we should be prepared to take this step. We do not believe that this drastic step is either necessary or desirable but will reserve judgment on this point.

This dilemma of duplication of drug products has been solved in hospitals, welfare programs, and elsewhere—such as in some clinic- and physician-owned pharmacies—by establishing formularies. We have not heard evidence that a properly functioning formulary system has had either an adverse effect on patient care, the quality of drug

used or competition or innovation in the pharmaceutical industry. In fact, all reports indicate that price competition is much greater—and prices much lower—in the hospital drug market, patient care is improved and economic benefits are realized.

The formulary system in hospitals has the endorsement of our association, the American Society of Hospital Pharmacists, the American Medical Association, and the American Hospital Association.

Mr. GORDON. Dr. Apple, what brought all this about?

Dr. APPLE. Well, as I have indicated in my next sentence, these four organizations several years ago sat down and drafted a set of guiding principles for hospital formularies, and a copy is appended for reference.

We have also included for the committee's files a copy of the statement by the American Society of Hospital Pharmacists which gives you the hospital formulary system, a formulary service, drug coding, and outlines of this entire subject matter. We would like to submit this for the committee files, too.

Mr. GORDON. Fine.

Dr. APPLE. Your question was, How did it come about?

Mr. GORDON. Yes, what brought this about? When was the necessity or desirability of having these formularies determined?

Dr. APPLE. I did not understand your question, Mr. Gordon. You want to know when the formularies started or when this last situation that resulted in these four organizations establishing a policy statement occurred?

Mr. GORDON. Yes, that latter one.

Dr. APPLE. It is the latter one you want to know?

Mr. GORDON. Yes.

Dr. APPLE. In 1962 we sent a letter to the American Hospital Association, the American Medical Association, and the American Society of Hospital Pharmacists. I could read the letter or insert it for the record.

Mr. GORDON. Why don't you submit it for the record.

(The letter referred to follows:)

AMERICAN PHARMACEUTICAL ASSOCIATION,
Washington, D.C., December 26, 1962.

Dr. EDWIN L. CROSBY,
Director, American Hospital Association.

Dr. F. J. L. BLASINGAME,
Executive Vice-President,
American Medical Association.

Mr. JOSEPH ODDIS,
Executive Secretary,
American Society of Hospital Pharmacists.

GENTLEMEN: During recent months there has been increasing discussion of the subject of "prior consent" in medical, hospital and pharmaceutical circles. A careful review of papers presented on the subject and analysis of off-the-record comments which have been brought to our attention as well as discussions in which our officers and staff have participated have led to our concluding that the professions concerned urgently need to improve their communications on this subject.

Many people consider the subject of "prior consent" as directly and only related to the practice of medicine and pharmacy in hospitals. Others consider it as an appendage of some formulary system. Still others confuse it with the subject of "substitution." The subject has been addressed from both ethical and legal considerations in the narrowest and broadest sense.

The American Pharmaceutical Association has a particular interest in this subject because "prior consent" is involved in the practice of pharmacy as often, and perhaps more frequently, outside of the hospital environment than inside. Prescribers have for years given their "prior consent" to pharmacists outside of the hospital environment. From a legalistic viewpoint we have from time to time cautioned the members of our profession about the personal liability that may be involved and the necessity for their securing such "prior consent" in writing rather than verbally.

The American Pharmaceutical Association recognizes that the professional privilege and legal responsibility for prescribing medication rests with the medical practitioner. The professional privilege and legal responsibility for dispensing medication rests with the pharmacist. Moreover, in good practice and under long established interprofessional relations, a prescriber may authorize a pharmacist to select the particular article to be dispensed pursuant to the prescriber's order for a therapeutic substance.

If a prescriber has the right to give "prior consent" to a pharmacist selecting the particular article to be dispensed, then the pharmacist can dispense the prescription medication in accordance with such "prior consent."

By selecting the particular article we have reference to the maker or source of a drug and not to the particular therapeutic substance.

Pharmacy has never questioned the right of the prescriber in this matter. Moreover, no federal or state statute prohibits the exercise by a physician, of his right in this matter. On the other hand if the medical profession should decide that it is against their principles of ethics for a physician to exercise his right by giving "prior consent" then the profession of pharmacy would be obliged to review its position.

The urgency for all interested parties in arriving at mutual concepts and hopefully an understanding in this matter stems from the fact that many state legislatures will be in session during 1963 and there is more than a possibility that certain interested parties may present their solutions to the problem to the legislatures for consideration. We believe this could be most unfortunate and decidedly not in the public interest.

Because of the confusion which already exists among some of our respective practitioners there can be little doubt that legislative hearings would be clouded with conflicting testimony and leave the public with the impression that the professions are not competent to resolve questions arising within their own practice.

Because of these reasons the American Pharmaceutical Association recommends that a conference be arranged for the explicit purpose of reviewing our respective understandings on the subject of "prior consent" and its application to our respective professional practices. We would like to suggest a date mutually convenient during the last week in January at our headquarters in Washington, D.C.

Sincerely,

WILLIAM S. APPLE,
Executive Director.

Mr. GORDON. I was just wondering what——

Dr. APPLE. In the letter we said that during recent months there had been increasing discussion of the "prior consent" in medical, hospital, and pharmaceutical services, and a controversy was developing. We suggested that we sit down and try to develop a statement which everybody could subscribe to. In other words, the formulary system was being attacked at that particular time.

Mr. GORDON. By whom?

Dr. APPLE. Basically by interests of the pharmaceutical industry, and to some extent by some interests in the medical profession.

Mr. GORDON. At what level was all this discussed?

Dr. APPLE. When I initiated this request for this conference and followed it up with personal telephone calls to the executives of these organizations, I asked that they either personally serve or be represented by at the highest possible level. We had Dr. Crosby, the director of the American Hospital Association, at some of these meetings; we

had his pharmacy staff member and others; Mr. Oddis represented the American Society of Hospital Pharmacists; I represented the American Pharmaceutical Association; we had AMA at the executive vice president level, the general counsel, the director of their law division.

Mr. GORDON. Who was the general counsel at that time?

Dr. APPLE. Mr. Stetler was the person who participated in most of these meetings in 1963.

Mr. GORDON. And he was at that time in favor of the formulary system?

Dr. APPLE. I cannot answer that.

Mr. GORDON. At least he represented the AMA.

Dr. APPLE. He represented the AMA, and the statement that was finally worked out during these conferences was subsequently ratified by the boards of the four organizations, including the AMA Board of Trustees.

We have a copy of that statement appended to the record here of our testimony.

Mr. GORDON. Do I understand correctly that Mr. Stetler now is opposing the formulary system?

Dr. APPLE. I have no knowledge of this.

Mr. GORDON. I was just wondering.

Dr. APPLE. We think the formulary concept can be extended through communities with the cooperation of the medical and pharmaceutical professions and with the same beneficial effects. For lack of a better title, we refer to this as a community formulary. The antisubstitution laws would not pose any serious impediment and, in fact, would assure effective functioning of the community formulary.

The local medical and pharmaceutical societies would establish a pharmacy and therapeutics committee to develop a list of drugs to be utilized. This listing then would be circulated to all physicians and pharmacists in the area. Information included would be the scientific name of the drug and the acceptable suppliers chosen on the basis of the collective experience of the panel, literature reports, comparative product costs, therapy rationale—in much the same manner as is now done in hospitals.

When the prescriber wrote his prescription order, he would merely signify that he wished the pharmacist to use the "formulary equivalent," or he could prescribe by established name with the direction that a formulary-accepted product be utilized. If the pharmacist dispensed a product other than that listed in the formulary, he would, of course, have violated the antisubstitution law, just as if he had used one brand in place of another. Under this system, the physician would know that he was not receiving an "unknown" product of dubious quality.

Several pharmaceutical groups have indicated an interest in "testing" this concept in a number of States, and we plan to lend our every assistance to these efforts. We think that effective development of such a system would be consonant with the hallowed principles of medical and pharmaceutical practice and serve the public interest.

Much has been made of the need for pharmacists to know why two drug products may be different. But, if the pharmacist is going to be able to use this knowledge for the benefit of society, he must have the

factual information on how the drug products do in fact differ. Until now, this information has not been available.

All accredited hospitals must have pharmacy and therapeutics committees. The purpose of these committees is to constantly improve the quality of drug therapy. A byproduct of their activity is to keep the hospital pharmacy's inventory to the minimum by eliminating needless duplications, not by reducing the useful therapeutic agents available to the prescriber. Another byproduct is purchasing an acceptable quality drug product at the lowest possible cost. We believe that physicians and pharmacists can effectively introduce some of these same benefits for patients outside the hospital by developing a community formulary system.

Seven years ago a discussion started on how more complete and reliable information on prescription drug products could be made available and disseminated to the prescribing and dispensing professions. In 1960, we filed statements with the Department of Health, Education, and Welfare outlining our interest and making specific suggestions.

It was our position then that the increase of information on the package or package insert would not effectively provide the prescriber with the desired information. As we pointed out, the prescriber seldom sees the product or its packaged content. Moreover, we also pointed out that the package insert constitutes an inefficient and ineffective means of promptly communicating current information to pharmacists.

As an alternative to the proposals offered by the Food and Drug Administration at that time, we recommended a nine-point program involving the cooperative efforts of FDA, the pharmaceutical industry, and the health professions immediately involved. Copies of our 1960 statements are attached.

Since 1960, we have had discussions with FDA and members of the pharmaceutical industry on this subject. For example, we have pointed out that when there are supplements to, or modifications in, the package insert, there may be a considerable timelag before the information reaches the physician or the pharmacist. These practitioners have no obvious way of knowing if the package insert they have in their possession at a given moment is the most recent one approved by FDA.

In 1964, APhA considered publishing a compilation of the latest approved labeling for the 500 most frequently prescribed drugs. We were forced to abandon the project because at that time FDA was unable to provide us with the information we required.

Currently, we are participating in the discussions of the National Academy of Sciences/National Research Council on the possible alternatives for the current package insert system. Based on our experience the past 7 years, we can underscore the growing importance of a better means of communicating specific drug product information to the medical and pharmaceutical professions.

This need is not limited to prescription legend drugs. It extends to drug products available and utilized in self-medication. We believe that our association is making real progress in meeting this need. Three months ago, we published a "Handbook of Nonprescription Drugs"—the first such comprehensive reference in the world. It has

been well received by physicians and pharmacists, and before the year ends we will be reprinting it for the third time.

APhA is still hopeful that the need for information on prescription legend drugs can be met promptly through the voluntary, cooperative efforts of the professions concerned and the pharmaceutical industry. We can assure the manufacturers and FDA that any soundly conceived effort will have our assistance.

In conclusion, we recognize that the health and life of people today increasingly depend upon drugs. For 115 years, the American Pharmaceutical Association has supported constructive steps—and initiated several—to improve the Nation's drug supply and, Mr. Gordon, as a matter of fact, just late this month our Academy of Pharmaceutical Sciences is sponsoring a program here in Washington, and the entire symposium is devoted to the subject of development of safer and more effective drugs. I would be glad to supply the committee copies of the program and abstracts for its files.

Mr. GORDON. Thank you very much. We do appreciate that.

Dr. APPLE. As I have indicated, we have supported constructive steps and initiated several, to improve the Nation's drug supply and the professional services involved in making drugs available to patients. This will continue to be one of our major objectives. Thank you.

(The attachments to Dr. Apple's statement follow:)

AMERICAN PHARMACEUTICAL ASSOCIATION,
Washington, D.C., September 20, 1960.

Re notice of proposal to amend labeling requirements (21 CFR 1, 130) dated July 18, 1960; appearing in Federal Register July 22, 1960 (25 F.R. 6985).

HEARING CLERK,
Department of Health, Education, and Welfare,
Washington, D.C.

DEAR SIR: The following statement is submitted in response to the opportunity afforded by the Commissioner of Food & Drugs for interested persons to express their views on the proposed labeling regulations.

Realizing that others will comment upon those phases of the proposed regulations of immediate interest to them, our remarks will be confined to matters directly affecting the American Pharmaceutical Association, the profession of pharmacy, and the efforts of pharmacists to discharge their professional responsibilities as drug and therapeutic device consultants to prescribers and as community custodians of drugs and such devices.

We are in complete agreement with the intent of the proposed amendments which are advanced in the interest of providing more complete information relevant to the professional use of any article bearing a prescription legend or otherwise limited to order of particular practitioners. Our Association has repeatedly advocated increased disclosure of product information in order that pharmacists may serve more proficiently in their capacity as consultants to prescribers of all prescription legend articles. To meet the demand for reliable information, individual pharmacists have, among other things, attempted to maintain product reference libraries and to develop extensive product reference brochure files within pharmacies. At their own expense, in order to be of service to prescribers, some pharmacists have even attempted to publish and distribute product information gleaned from a variety of reference sources.

For the guidance of every practitioner licensed by law to administer prescription legend articles, complete product information concerning use, dosage, cautions, and contraindications should be readily available. For these reasons, we believe in the principle, embodied in the proposed regulations; that is, of disseminating additional product information. However, we seriously question the practicality of certain aspects of the mechanism proposed for achieving our mutual purpose—the availability of complete product information for prescribers.

SECTION 1.106(b)(3)

The information required by this subsection is designed for communication to, and use by, practitioners licensed by law to administer prescription legend drugs. However, in the usual course of employing such a drug, the prescriber creates a prescription which in turn is communicated to the pharmacist. Therefore, the prescriber does not see either the product or its packaged contents. It is the pharmacist who has physical possession of the product, its container or wrapper, and any written, printed, or graphic material accompanying such an article. Consequently, there is no basis for believing that by increasing the volume of literature included in every prescription drug container, communication of information to prescribers will thereby be facilitated.

A pharmacist with numerous packages of a particular drug in stock will have numerous copies of the same literature, which will seldom or never be seen by the prescriber. Moreover, as supplementary information develops, each existing product container and enclosures would be incomplete, inaccurate, or otherwise deficient under the proposed regulations.

A realistic appraisal of product expense for initial packaging, shipping, and storage in relation to the degree of product information communicated to prescribers which might be achieved by the proposed procedures will reveal the impracticality of this particular mechanism. This significant expense ultimately would have to be passed on to the patient, thereby increasing the cost of his medication, with little hope of achieving the desired purpose of the proposed regulations.

Furthermore, the existence of extensive professional information within each product package increases the risk of this information passing into hands of the laity. Obviously, this might easily result in untoward consequences. It must be remembered that the purpose of exempting drugs, subject to the requirements of Section 503(b)(1) of the Act, from Section 502(f)(1) is to preclude the use of dangerous prescription legend drugs except under the direct supervision of a practitioner licensed by law to administer such drugs.

As an alternative to the proposals contained in this subsection, we recommend a cooperative arrangement, involving the Food and Drug Administration, the pharmaceutical industry, and the health professions immediately involved, through which the following procedures would be effected:

1. Every manufacturer would be charged with the responsibility of preparing, for each product subject to the regulations, a complete "official brochure" containing full professional information.

2. The "official brochure" would be in accordance with the new regulations proposed by the Food and Drug Administration.

3. A non-governmental, non-profit agency approved for that purpose by the Food and Drug Administration, the United States Pharmacopeia Revision Committee, and the Committee on National Formulary would serve as the coordinator and distributor of each "official brochure."

4. The "official brochure" design would be uniform in format and conform to specifications developed by the agency referred to in paragraph 3 with the advice of the United States Pharmacopeia Revision Committee and the Committee on National Formulary.

5. All production, publication, and distribution costs for each "official brochure" would be borne by the respective manufacturer.

6. The agency referred to in paragraph 3 would promptly distribute each "official brochure" to every pharmacy in the United States.

7. Pharmacists would be advised that the availability of these brochures is as essential for the proper information of the medical and pharmacal professions with regard to the drugs involved as is the case with the latest editions of the United States Pharmacopeia and the National Formulary. By state board ruling or by state law the availability of the resulting compilation of "official brochures" could be made a part of the standard prescription equipment of every pharmacy.

8. Additional copies of each "official brochure" would be made available for distribution to pharmacies so that any practitioner licensed to administer the drug described in an "official brochure" could obtain the desired information or a copy of the "official brochure" from a pharmacy as well as from the agency referred to in paragraph 3, or from the manufacturer of the drug.

9. It would be expected that accredited institutions engaged in preparing persons to practice any of the professions in the health science group would also be supplied with copies of the "official brochure."

A unique feature of this proposal is the added benefit of having the "official brochure" information locally available to the practitioner through every pharmacy although supplies of the drug may not be at hand. Furthermore, the "official brochure" information could thereby be available to the practitioner even before the manufacturer begins the initial marketing and distribution of his product.

If, as we trust, our suggestion meets with favor, we will be pleased to cooperate with the Food and Drug Administration, the United States Pharmacopeia, the National Formulary and the pharmaceutical industry in order to make this essential distribution of information on each product subject to the regulations effective.

SECTION 1.106(b)(4)

This proposed regulation would require that *full* information accompany all labeling "that furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage" for use. Some modification is needed. It is our belief that journal advertisements and promotional literature sent directly to professional personnel should be clearly differentiated from "labeling." Because of inclusiveness usually associated with the term "labeling," we fear that without modification unreasonably long, involved, and extensive advertising copy could be required for otherwise simple advertisements.

Under the proposed regulation, serious questions arise about possible significant curtailment in the degree of advertising in professional and scientific journals. We believe such advertising curtailment will adversely affect the continued publication of professional journals, the principle purpose of which is the dissemination of scientific, technical, and research information irrespective of products advertised. The sale of advertising space in professional journals helps in large measure to defray the costs of these essential publications.

It is our opinion that the purposes intended by the proposed regulations would be achieved through an arrangement by which all advertisements would contain a precautionary statement referring the reader to the "official brochure" for additional necessary information and indicating its availability from (a) any pharmacy, (b) the non-governmental, non-profit agency approved for that purpose by the Food and Drug Administration, the United States Pharmacopeia Revision Committee, and the Committee on National Formulary, or (c) the manufacturer of the drug. By employing the mechanism we have just suggested, the purposes of the proposed regulations would be achieved without placing unreasonable burdens upon advertising copy and interfering with the publication of essential professional journals and the dissemination of scientific information.

SECTION 1.106 (c)(3) AND (d)(3)

Because our comments, opinions, and suggestions pertaining to these sections parallel those stated in relation to Section 1.106(b)(3), in the interest of conserving your time, we will not repeat them.

SECTION 1.106 (c)(4) AND (d)(4)

Because our comments, opinions, and suggestions pertaining to these sections parallel those stated in relation to Section 1.106(b)(4), in the interest of conserving your time, we will not repeat them.

The American Pharmaceutical Association, its facilities, and its entire personnel, are ready to assist the Food and Drug Administration in effecting the objectives we have outlined. We also respectfully request that our Association be given the opportunity to participate in any future hearings which may be held to resolve differences of opinion over the proposed regulations which have been expressed by interested persons.

Sincerely,

WILLIAM S. APPLE, *Secretary.*

AMERICAN PHARMACEUTICAL ASSOCIATION,
Washington, D.C., September 23, 1960.

Re notice of proposal to amend labeling requirements (21 CFR 1, 130) dated July 18, 1960; appearing in Federal Register, July 22, 1960 (25 F.R. 6895).

HEARING CLERK,
Department of Health, Education and Welfare,
Washington, D.C.

DEAR SIR: The American Pharmaceutical Association desires to file the following supplemental statement. Our original statement was filed on September 20, 1960.

We have noted that statements filed by other interested parties contain divergent recommendations worthy of consideration and suggestions for discussions on their viewpoints. In the interest of bringing to the Department of Health, Education and Welfare the most constructive consensus possible on the major problem of placing adequate information in the hands of the health professions, the American Phamaceutical Association recommends that an early conference be arranged by the Food and Drug Administration with representatives of the pharmaceutical industry, medicine, and pharmacy.

We feel that such a conference under the leadership of the Food and Drug Administration would be most productive, and the American Pharmaceutical Association is prepared to participate.

Sincerely yours,

WILLIAM S. APPLE, *Secretary.*

Mr. GORDON. Mr. Grossman, do you have any questions?

Mr. GROSSMAN. Dr. Apple, I have several questions here.

Getting back to your community formulary, I think this is a very progressive, constructive idea, and I wondered—you say on page 27 of your testimony that several pharmaceutical groups have indicated an interest in testing this concept in a number of States. I wonder if you could be more specific.

Dr. APPLE. Well, not at this time. These are all preliminary meetings that we have had, and until the State and local organizations concerned have come to a firm decision and have had their conferences with the counterpart medical societies at the respective levels, I think it would be premature to comment on our discussions.

Mr. GROSSMAN. For example, could not these be used in certain disadvantaged areas in large cities to cut the prices of drugs to these people that Senator Hatfield was talking about earlier?

Mr. STEEVES. We have suggested, Mr. Grossman, that the pharmacists in the area of OEO clinics, for example, get together in just this type of a proposition, develop a formulary so that they can meet the economics that are involved in these OEO clinics, and we have been doing this for some time. This is already in progress and being considered in a number of areas.

Dr. APPLE. You see the immediate reaction of a Federal agency is to go in there and start its own pharmacy program, and we do have this problem right now with OEO. As we have indicated in testimony before other committees of the Senate and the House, there are ways which the community pharmacist can continue to serve without this disruptive situation if we are given an opportunity, and the opportunity hinges basically on two things: One, the opportunity for pharmacists to buy as cheaply as the Government buys and other favored

customers; and two, on the utilization of a formulary system to avoid a lot of duplication.

Mr. GROSSMAN. Have you been in touch with the industry on this one point you raise about whether you would be able to buy at the same rates that the hospital formularies would be able to buy or are now able to buy?

Mr. STEEVES. No; but the problem is, Mr. Grossman, that you might not be able to purchase the identical product from the same company, but you can get a comparable price under the formulary system. If the Government can buy, let us say, prednisone at $1 a hundred, you can find other products on the market that are a dollar a hundred.

Mr. GROSSMAN. This is just the kind of thing that I think you are talking about that the industry could do, it is the kind of thing that the insurance industry is moving into, and I see no reason why the pharmacists would not want to expedite this kind of thing and try to show you are going to make a contribution in these areas.

Mr. STEEVES. We have said that we would.

Dr. APPLE. We would welcome any pronouncement by any pharmaceutical manufacturers of such decisions or a pronouncement by the Pharmaceutical Manufacturers Association that this is its new policy.

Mr. GROSSMAN. One of the questions that I have is, What is going to happen to the little pharmacist who has a little store down in his area? Is he going to fight you through the local organization to set up these kinds of things? Have you had any problems with him yet or is this still in a thinking stage?

Dr. APPLE. Well, you are talking about the little man——

Mr. GROSSMAN. The small businessman.

Dr. APPLE. The little man as you refer to him, the pharmacist in practice in the community, is the gut of our membership, and he is the one who is turning to us for assistance and help. He is the one who wants to know, "What can I do that will help me compete with the Government, help me compete with other people, to help me to be able to provide my service more economically so that physicians are not directing prescriptions to discounters and everybody else?"

Mr. GROSSMAN. I take it that these same small pharmacists are having difficulty with the hospital formulary competition; is that true?

Dr. APPLE. Well, the hospital formulary when it works for inpatients in the hospital obviously does not affect the pharmacist who is serving noninstitutionalized patients.

Mr. GROSSMAN. I am talking about outpatient services.

Dr. APPLE. You are starting to get a meld of services between the institution and the home environment. We used to look at the hospitals as a distinct separate world of their own, and the community pharmacy in another world. But that has all disappeared. They are all serving patients, one day the patient is in the hospital, the next day he is an outpatient, and he needs the same pharmaceutical service.

Mr. GROSSMAN. Just one final note then: What would you say then, what are the major impediments to setting this kind of thing up in the Woodlawn area of Chicago or in New York, in Bedford-Stuyvesant, and similar places like that, soon?

Dr. APPLE. I do not think there is a major impediment. I just think it is matter of an educational program. I would say that when phar-

macists understand this and can sit down and help explain it to physicians—this is basically what has happened in the hospital environment—you take the physician who is in the hospital 3 hours a day, accustomed to practicing this way, if he stops and thinks about it, why shouldn't he practice the other 8 hours a day using the same type of system. I have had a number of physicians, when I have put it to them this way, say, "Come to think of it, why shouldn't we? If it is good enough for us in the hospital it ought to be good enough for our patients outside of the hospital."

Mr. GROSSMAN. Thank you.

Mr. GORDON. Dr. Apple, on behalf of the subcommittee I want to thank you very much for coming here and giving us the benefit of your views. Thank you very much.

Dr. APPLE. Thank you, Mr. Gordon.

Mr. GORDON. The hearings will resume tomorrow morning at 10 a.m. in this room.

(Whereupon, at 1:45 p.m., the subcommittee adjourned until 10 a.m., Thursday, November 16, 1967.)

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

THURSDAY, NOVEMBER 16, 1967

U.S. SENATE,
MONOPOLY SUBCOMMITTEE OF THE
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C.

The subcommittee met, pursuant to recess, at 10 a.m. in room 318, Old Senate Office Building, Senator Gaylord P. Nelson (chairman of the subcommittee) presiding.

Present: Senators Nelson, Javits, and Hatfield.

Also present: Benjamin Gordon, staff economist; James H. Grossman, minority counsel; Susan H. Hewman, research assistant; and William B. Cherkasky, legislative director, staff of Senator Nelson.

Senator NELSON. The Monopoly Subcommittee of the Small Business Committee will come to order.

The subcommittee welcomes the Pharmaceutical Manufacturers Association this morning and its president, Mr. C. Joseph Stetler, and his associates. We appreciate having you here today to present the industry viewpoint on the important issues that are being considered by the committee. You represent a distinguished industry that has made a great contribution to the health and welfare of our country and the rest of the world. Your member companies employ a number of the finest scientists, doctors, pharmacologists, and researchers in the medical health field. Since your industry does work in the field of health directly affecting all of our citizens, the Congress, as a representative of the public, has an important responsibility to protect the public interest. The PMA and many others, including doctors, pharmacists, pharmacologists, editorial writers, and interested specialists in the health field have been critical of some aspects of the conduct of these hearings. Some have said they are unnecessary or that the subject is not a proper concern of Congress, or that the hearings are unfair or loaded against the industry.

Since I am conducting these hearings, the major responsibility is mine, subject, of course, to direction by the members of the committee itself. And, I accept that responsibility quite happily.

I have attempted to conduct these hearings as fairly and honestly as I know how. I have been conducting hearings for 20 years as a State legislature and Governor and U.S. Senator, and this is the first time I have been criticized as being unfair in the conduct of hearings.

I have repeatedly assured the Pharmaceutical Manufacturers Association and its member firms that all valid interested groups would be heard and in proper balance. I think we are doing just that.

But since the PMA does not believe that to be the case, we will explore at some period during these hearings in detail all complaints

and criticisms that PMA has, or any member of the PMA has, of the conduct of these hearings, and let the record speak for itself.

I am confident that the record will show that we have given every consideration to the industry that it is possible to give, and if there is some consideration I have omitted, I would be glad to hear about it.

I publicly invited every single member of the PMA to appear before the committee months ago. They are all free to come and make any statement that they may wish to make before this committee. Of the 136 PMA members, only two thus far have volunteered to come. Three others have come at invitation.

I would ask the Pharmaceutical Manufacturers Association what more this chairman can do, to give the members of the industry a chance to be heard so that their case can be fairly presented?

I now repeat my invitation to every single member company of your association to appear before this committee. If all 136 want to appear, we will hear them—if I am still here long enough to hear that many.

At the end of today's hearings, or next week, or any other time, I will accept from the president of the PMA a list of your members who want to testify. I will make arrangements for them to testify. And then, if you have any legitimate complaints against the conduct of these hearings, I think you should tell us today exactly what those complaints are, so that the committee may consider them. If not, then I think you should not make criticisms elsewhere around the country that you are not willing to make to the committee itself. I think that is fair.

So at some stage, I would like to hear the complaints you have about the hearings and if there is any way I can rectify them, I will, because I have not offered the medical profession, or the pharmacologists, or the pharmacists, or any other group, the right to send in every single member, as I have in the past to the Pharmaceutical Manufacturers Association, without any results thus far, except for the volunteering of two companies.

The amount of material that you have presented is quite massive. I am not sure what is the best way to handle it, or whether with the amount we have it will be possible to get through all of it today.

But there are a number of matters that I want to take up first. One of them is immediately current, and I would like some discussion of that sometime today. I refer to a PMA advertisement which appeared in the Reader's Digest this month. And I will read—in order to be more precise—my comments on that.

An advertisement by the Pharmaceutical Manufacturers Association in the form of an eight-page pullout pamphlet has appeared in the November 1967 issue of the Reader's Digest. The format of the section is designed to look like part of the ordinary editorial content of the magazine. The only indication that this section is paid advertising is the words "Special Advertising Section" which appear in small print on only the first page of the eight-page section.

On the next page, the first of four articles which comprise the section begin without any further indication that these articles are, in fact, the advertising matter to which reference has been made. To further confuse the reader, ads clearly identifiable as product advertisements have

been interspersed among regular Reader's Digest articles which immediately follow the PMA section. Thus, the reader may be led to believe that it is these latter ads which actually make up the "Special Advertising Section."

At the same time that this ad is being run in the Reader's Digest, reprints of this pamphlet are being circulated to offices of practicing physicians for their waiting rooms and to various government agencies. These reprints, however, differ from the section which appears in the Reader's Digest in one very important respect: The PMA has deleted the words "special advertising section." The result, of course, is that there is absolutely no indication that this pamphlet is an advertisement. Neither the doctor nor the patient who reads this ad while waiting to see his doctor has any way of knowing that he is reading ad copy which glorifies the members of the very group who paid to have this material written.

Further, a note appears opposite the first page of the section which tells the reader that he may order a reprint by writing to "Health," Post Office Box 28111, Washington, D.C. The designation "Health," rather than the actual name of the organization involved, seems to me to give the impression that a nonindustry philanthropic group is sponsoring the reading matter which follows—not a trade association representing drug manufacturers.

I wrote to the U.S. Department of Justice, the Federal Trade Commission, and the Food and Drug Administration to call this matter to their attention and to ask for their comments.

The Department of Justice subsequently took an interest in this question and in a letter which I received on Monday, Edwin M. Zimmerman, Acting Assistant Attorney General, Antitrust Division, stated that:

> The omission of the words "Special Advertising Section" might mislead the recipients into believing that material prepared by the Association or its members for purposes of an advertisement was initiated by disinterested authorities, for the purpose of discouraging the sale of generic drugs.
>
> Accordingly, this circulation of the reprints may raise problems under Section 5 of the Federal Trade Commission Act which proscribes unlawful and deceptive practices in commerce.
>
> We are conferring with representatives of the Federal Trade Commission to determine what further action should be taken.

In a response received by me on Tuesday, Paul Rand Dixon, Chairman of the Federal Trade Commission, informed me that an investigation is being undertaken by his staff "to determine whether the practices in question constitute a violation of section 5 of the Federal Trade Commission Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in commerce."

I have also received an answer from Dr. Herbert L. Ley, Director of the Bureau of Medicine of the Food and Drug Administration. Dr. Ley's review of the section for content accuracy revealed that parts of the four articles which make up the section contain material which is misleading in its implications as to the industry's accomplishments and the relative quality of brand name and generic drugs.

(The letters referred to follow:)

U.S. DEPARTMENT OF JUSTICE,
Washington, D.C., November 13, 1967.

Hon. GAYLORD NELSON,
Chairman, Monopoly Subcommittee,
U.S. Senate,
Washington, D.C.

DEAR SENATOR NELSON: The Attorney General has asked us to reply to your letter dated November 2, 1967, the receipt of which he acknowledged to you by letter dated November 3, 1967.

Your letter requested our views as to a special advertising section placed in the Reader's Digest by the Pharmaceutical Manufacturers Association, reprints of which were thereafter circulated by the Association without disclosing that the reprint was a paid advertisement and not part of the editorial content of that publication.

Such an omission from the reprints might mislead the recipients into believing that material prepared by the Association or its members for purposes of an advertisement was initiated by disinterested authorities for the purpose of discouraging the sale of generic drugs. Accordingly, this circulation of the reprints may raise problems under Section 5 of the Federal Trade Commission Act which proscribes unlawful and deceptive practices in commerce.

We are conferring with representatives of the Federal Trade Commission to determine what further action should be taken.

Sincerely yours,

EDWIN M. ZIMMERMAN,
Acting Assistant Attorney General,
Antitrust Division.

FEDERAL TRADE COMMISSION,
Washington, D.C., November 14, 1967.

Re file No. 682 3194.
Hon. GAYLORD NELSON,
Chairman, Monopoly Subcommittee, Select Committee on Small Business,
U.S. Senate, Washington, D.C.

DEAR MR. CHAIRMAN: In accordance with your request, I have made inquiry as to the status of the consideration being accorded by the Bureau of Deceptive Practices to the matter of the publication of a section in the November, 1967, issue of The Reader's Digest, paid for by the Pharmaceutical Manufacturers Association, and the dissemination of a reprint thereof.

I am advised that the staff is now engaged in an inquiry seeking to develop sufficient evidence to enable the Commission to determine whether the practices in question constitute a violation of section 5 of the Federal Trade Commission Act, which prohibits unfair methods of competition and unfair or deceptive acts or practices in commerce.

You will, I am sure, understand that I cannot at this time offer any comment respecting the legality of the practice, inasmuch as the matter will be before me for decision when the pending investigation has been concluded.

With best wishes, I am,

Sincerely yours,

PAUL RAND DIXON,
Chairman.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C.

Hon. GAYLORD NELSON,
Chairman, Subcommittee on Monopoly, Select Committee on Small Business,
U.S. Senate, Washington, D.C.

DEAR SENATOR NELSON: This responds to your request for our comments on the advertisement by the Pharmaceutical Manufacturers Association, which appeared in the November, 1967 issue of Reader's Digest.

This advertisement is not product oriented in the usual sense. Primarily because the advertisement is not specific as to the name of a drug manufactured, packed or distributed by a named firm, we do not believe that the Federal Food, Drug, and Cosmetic Act provides a clear basis for proceeding against the ad or its subsequent use as a promotional pamphlet under any provisions of the

Act. Our regulations in point are concerned primarily with advertisements and other promotional material directed to prescribers, not to the public.

About a year ago, we discussed with the advertising agencies and the pharmaceutical firms some of the problems that would arise if promotional labeling for prescription products, particularly oral contraceptives in that case, should be directed to the public. We concluded that such promotions would be acceptable provided that they included appropriate warning information and specified the particulars in a policy statement published in the Federal Register on September 13, 1967.

Since that time we have discussed with individual pharmaceutical firms the content of institutional advertisements which offered the possibility of crossing the line to product promotion. Advertisements that are product oriented (which the Reader's Digest article is not) would require a brief summary of indications, side effects, and contraindications and they would have to contain this information in a form that would be understandable to the non-professional audience.

The portion of the Reader's Digest reprint titled "What Ever Became of Those Quarantine Signs" has been reviewed for factual accuracy. No direct claim for pharmaceutical company research involvement is made except for whooping couch (pertussis) "vaccine," and in that case it appears that several pharmaceutical firms supported extramural basic research on pertussis immunization in the 1930's and 40's. The other "vaccines" were developed from basic research not supported to any significant extent by pharmaceutical firms. Although the function of the pharmaceutical industry in production of "vaccines" for marketing is an important credit in their favor, the tone and implications of this article for the general reader go beyond mere credit for manufacturing ability.

The facts stated in the article "The Anonymous Drug That Hospitalized a Patient" are in general agreement with those given in Dr. Arnold Carter's letter to the Canadian Medical Association Journal. Attached is a copy of Dr. Arnold Carter's letter to the Journal. The fact that this "generic" brand did not meet the official monograph specifications makes it improper to compare its effectiveness with a product meeting official compendium specifications. It cannot be determined whether only a batch failed in meeting the disintegration specifications or whether the manufacturer produced most of his tablets in this manner. Failures of this type can be checked in the laboratory and action taken accordingly.

The comparable product sold in the United States was introduced to the market in 1957 and has been subject to United States Pharmacopeia standards, including disintegration time testing, since 1960. To the best of our knowledge no comparable problem has been identified in the American product.

The facts in the section entitled "Medicines for the Troubled Mind" could present better historical perspective. By stating that "Dr. Kline reported to the New York Academy of Sciences in 1954 that reserpine had 'proved an effective sedative in mental hospitals,'" the unnamed authors of the article totally disregard historical fact. Reserpine was supplied by the Swiss from CIBA to the Psychiatric University Clinic Burghoelzli in Zurich, Switzerland, where in 1953 it was first used in the treatment of mental illness in the Western world and reported to the medical profession. Similarly the implication of the paragraphs relating to the use of the phenothiazine related compounds ignores the fact that the earliest useful member of this group, chlorpromazine (Thorazine), was synthesized in France in 1950 and first used clinically in France in 1952.

If we can be of further assistance, please let us know.

Sincerely yours,

HERBERT L. LEY, JR., M.D.,
Director, Bureau of Medicine.

Senator NELSON. There is no question that the entire ad is designed to avoid disclosing that it is, in fact, advertisement paid for by the drug industry. This calculated deception even goes so far as to include a solicitation to the reader to write to an organization called Health for reprints of the section.

Even on the last page, the words, "Published as a Public Service by the Pharmaceutical Manufacturers Association," are misleading since advertising is not generally considered to be a public service.

Clearly, an attempt has been made here to use the wide circulation of the Reader's Digest to convince a large segment of the public that an advertisement written on behalf of the drug industry and paid for by its trade organization is an ordinary unbiased magazine article. The implication, of course, is that the PMA is supporting an objective discussion of health problems as a matter of public service, rather than an advertisement calculated to serve the interests of its member firms.

I am sure that the PMA was aware of the implications of the ad when they inserted it. I think that as a matter of public interest this ad ought to be discussed here at some stage, because I am of the opinion that a vast majority of the public would not recognize the insert in the Reader's Digest and certainly not the reprint as in fact an advertisement. And whereas PMA is entitled to advertise. I think the public is entitled to know whether an article is an independent objective research article written by an independent individual or whether it is an advertisement sponsored by a trade association.

That is why I have brought this out today.

I do not by any means want to preempt all your time—but I shall preempt some of it.

One other matter I want to raise, which I shall not raise immediately, is the question of your obvious strong feeling that there has been a distinct bias against the industry in the witnesses who have appeared here. I would like to take up that question, but I will defer that to a later moment.

How long is the summary that you have there, Mr. Stetler?

Mr. STETLER. My summary will take between 15 and 20 minutes.

Senator NELSON. Well, I have not in the past permitted witnesses to summarize for the very simple reason that I have questions to ask about the full statement as I go along. What happens is that if a summary is given and the statement is merely printed in full, I have to go back to the statement and go through it to ask questions which occurred to me in my reading of the material.

Now, I am willing to try that, if you prefer. I am not sure it will shorten the time. A couple of weeks ago one of the witnesses wanted to summarize, and I declined because what happens is that we print your summary, then we print the whole testimony. Then after it is all printed we start asking questions about the full text, which appears somewhere else in the record. So the reader has to jump back and forth from the questions to the testimony itself, whereas the only way it is really understandable is if as your presented statement appears in the record, the questions are raised and answered at the appropriate place.

Don't you suppose that you could start reading, and at various places where you elaborate, just suggest that you would like to summarize in a sentence or two, and if I do not have any questions, we can skip a page here and there.

Would that be satisfactory?

Mr. STETLER. Senator, I will be delighted to do it any way you want it done. I can do it either way.

Senator NELSON. Let us try it that way. I think it will make a better record.

Mr. STETLER. Before I begin the statement, I would like to ask this question. You have raised two important points. Do you want me to comment on those now, or did you say you would prefer to wait until later?

Senator NELSON. Well, I am happy to have you comment on it right now, if you like.

Mr. STETLER. I think it might be better.

STATEMENT OF C. JOSEPH STETLER, PRESIDENT, PHARMACEUTICAL MANUFACTURERS ASSOCIATION, WASHINGTON, D.C.; ACCOMPANIED BY LLOYD N. CUTLER, SPECIAL LEGAL COUNSEL; DR. A. E. SLESSER, ASSOCIATE DIRECTOR OF QUALITY CONTROL, SMITH, KLEIN & FRENCH LABORATORIES; AND DR. ROBERT QUINNELL, DIRECTOR, MEDICAL RELATIONS, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Mr. STETLER. On my comments with respect to the hearings, I have never felt nor have I ever said that this is not an appropriate activity of Congress or this committee, nor that such hearings may not be necessary.

Senator NELSON. You understand that I did not assert that you did say that. I said that various groups have made several criticisms, and one of them is that this is not an appropriate subject matter for congressional consideration. I am not aware that you have ever said that.

Mr. STETLER. As a matter of fact, I think it is a completely appropriate subject for inquiry. And my comments as to who have or who have not been heard have not related to the members of the pharmaceutical industry primarily, although I did comment that we would prefer that the PMA have an opportunity to testify before individual companies. And as you know, we discussed that before. But five companies were put on in advance.

If other companies should be here, I think they will be glad to appear. But I think the predominant view in the industry is that the subjects that have come up in these hearings, that affect the industry, can be appropriately discussed by me or by the men that I have with me from our companies and our sections.

Now, what I have said—and this is in the area of criticism——

Senator NELSON. Let me go back to that point for a minute.

As you are aware, from the very beginning, 5 days before the hearings ever started, you were in my office with your counsel to ask when you could be heard. I told you to let me know when you wanted to be heard. And I also stated very early in the hearings that I would be happy to hear from the whole industry, all its individual members, as well as the PMA.

I trust you don't think it is a matter of fairness, so far as the committee is concerned, whether we invite and schedule individual member companies to appear before or after the association, do you?

Mr. STETLER. We thought it would be preferable—it would add something to the hearing—if we could give a general presentation. As you know——

Senator NELSON. But that is not a matter of fairness, is it?

Mr. STETLER. Only that three of the five companies that were involved were before the committee because of a particular price situation that was of interest to the company and to the committee. And that seemed to us like rather specific items which might better follow a general presentation by the industry. But I must say that is not my main point.

The main point is this.

The major items that have come up in the hearings have dealt with medical and scientific issues—primarily the subject of generic and therapeutic equivalency—the major issues, it seems to us, have dealt with issues of equivalency—generic and therapeutic—some on the compendium, and some on the detailing of doctors. But certainly doctors and scientists and some of these scientific issues have been in the forefront of the hearings.

Now, we think that to the extent that medicine or pharmacologists has been heard, they have expressed a minority view. We think there is another view, and in our opinion it is the predominant view. And that there are some people that should be called by the committee or if they have asked to testify, that they should be allowed to testify. And there have been quite a number that have done just that.

I think really it is with respect to the scheduling of some of those nonindustry witnesses that there has been, in our opinion, a problem. It is in that area that I have said I think the other side of the scientific case before the committee should be more fully exposed.

I still have that feeling.

Senator NELSON. Well, I am sure that if you were conducting the hearings, you would conduct them differently. But a serious question that seems to me to be raised is that in a number of speeches you have made, you stated directly or implied that the hearings have been loaded against the industry, that you have not had a chance to appear, or that you do not know when you can appear. And this was said very shortly after the hearings started, even though I had gone into that in some detail with you in private.

Here is the sort of thing I am referring to.

In Chicago, on September 23, a little more than a month ago, in a speech to the annual convention of the American Medical Writers Association, you stated, "The fact is the pattern of the hearings was set on the first day by the testimony I have just described, and it has not changed in 4 months as one handpicked witness has followed the other to the stand. I use 'handpicked' in the most liberal, deliberate, and factual way."

That was said with the intent of convincing those people that these hearings have been unfair, biased, and loaded against the industry—isn't it?

Mr. STETLER. Not against the industry. They have not covered the scientific issues in a way to give the other side—and there is another side—an opportunity to present their views.

Now, I mean by the other side groups that have asked to testify, like the American Academy of General Practice, the two national organizations of interns, the American Medical Association, the Association of Abdominal Surgeons—groups of this type that speak for large numbers of doctors and scientists. I think they can give a more representative view than an individual physician who speaks for himself.

Senator NELSON. How do you know all these organizations have asked to appear?

Mr. STETLER. They have told me they have asked to appear.

Senator NELSON. As you are well aware, we cannot hear everybody on the same day. I simply respond to that by saying that there is nobody, no group that is better prepared, it seems to me, to answer any single question about generic equivalency, quality control, or pricing than your individual members.

At the beginning of the hearings, I publicly extended an invitation to every single PMA member to appear before this subcommittee.

I will document this in the record later—I begged them to come during the first week of the hearings.

So you are not satisfied with the fact that I did not invite as witnesses some people that you would like to have. But I do not know how you can prefer any witness in the world over your own members, and I do not know of any witnesses that are better prepared to talk about generic equivalency and all the aspects of the problems that we have discussed than your own members. I have asked them to come, and they have not come. So how can you go to Chicago and say the witnesses who have been picked are loaded against you, when at any time I would have taken any one of your members and put them on, but I could not get them.

Mr. STETLER. Senator, in your remarks on the 15th, which were most appropriate, and frankly is what guided me—when these hearings started—you not only invited industry witnesses, but you very properly invited anybody with an interest in this controversy to come and be heard.

Now, I have not said that industry has been disadvantaged. What I have said is that these other groups should be heard.

Now, as far as the Academy of General Practice is concerned, they have been advised that they will not have an opportunity to be heard, that there is not enough time for them. And I think, frankly, that when they represent 30,000 active general practitioners, they have a right to be heard.

Senator NELSON. Well, the Academy of General Practice will be heard. If the staff members sent out a letter saying they won't, the staff is in error. I have said repeatedly that every valid viewpoint will be heard. I cannot hear everybody.

Yesterday, for the first time, we had testimony from a representative of the American Pharmaceutical Association. I suppose they are entitled to exactly the same complaint as you have made—they got on the same week. The Academy of General Practitioners could have the same complaint. We cannot take them all at once.

But my point is that the one advantage I gave to the industry, that I did not give, because I could not, to any other interested group was to tell you in my office, and tell them here from the chairman's chair several times that I will take any single industry witness that is willing to come because this involves them more directly, more immediately, and in more ways than any other group in America.

So in order to be fair, I said "Come on in any time you want to." They have all the expertise in the world. They manufacture the drugs. They know what generic equivalency is. No representative of the Academy of Physicians has more knowledge about this than the best

experts in the industry. No private practicing physician can match that knowledge. No single pharmacologist could match knowledge that these big distinguished companies have themselves.

So I repeatedly said "Come on in."

Now, you charge that the hearings have heard, as you put it, only "handpicked witnesses." Well, I was trying to handpick yours. I invited them all. And they would not volunteer.

My point is that you should have said to that audience in Chicago in order to be fair yourself, "I don't like the order in which the witnesses have appeared, but my own representatives, my own 136 members, defaulted and did not step forward and volunteer to appear." Then I would not have any criticism.

Bt the fault lies exactly and precisely right on the shoulders of the member companies that manufacture drugs, because I begged them to come in. I cannot think of anybody better prepared to discuss this question. If they do not come, I am not to be blamed for that, am I?

Mr. STETLER. Senator, we are obviously in disagreement on this point.

Senator NELSON. Am I or am I not to be blamed for your members failing to come in and present their case?

Mr. STETLER. You are not to be blamed for that, and you have not been blamed for that. I get back to my other point.

It is the other element that I think should be heard in these hearings.

A good deal of time was spent, for instance, last Thursday, by Dr. Goddard on the subject of a drug compendium. And we came in for some kicking around on that occasion. Now, a drug compendium is allegedly for physicians. I think physicians should have a chance to tell you what they think they want or need with respect to a drug compendium. Let us hear from doctors on that one.

Senator NELSON. Where would you start? I suppose everybody could have different ideas as to where we might start to have testimony on the drug compendium. Do you know of any better place to start than with the head of the Food and Drug Administration?

Mr. STETLER. I would start with the American Medical Association or the Academy of General Practice because——

Senator NELSON. I am glad you raised that question. We invited Dr. Thomas Hayes of the American Medical Association to come before the committee—the AMA refused to let him come.

Mr. STETLER. Senator, the American Medical Association has written three times to the committee to be heard. Now, I think——

Senator NELSON. Just a minute. We invited Dr. Thomas Hayes. He is head of the drug council; is that not correct?

Mr. STETLER. Correct.

Senator NELSON. We invited him to come, and the president of the AMA refused to let him come. Do you know that?

Mr. STETLER. I think the AMA should be permitted to select their witnesses, if they are going to appear before this committee. And they did not want Dr. Hayes to be the witness.

Senator NELSON. He is head of the drug council.

Mr. STETLER. They have a lot of people in higher positions in the AMA than Dr. Hayes.

Senator NELSON. Can you speak for the president? Would the president of the AMA come?

Mr. STETLER. I do not know. I think he probably asked to come.

Senator NELSON. We would like to have the president of the AMA. We would like to have the head of the drug council. And if they have some suggestions we will take those, too. But I don't think the AMA ought to select exclusively who would come. The fact is, as you know, that Dr. Annis, past president of the AMA, wrote to Senator Smathers and said he would like to come. He was not on the board of the AMA at that time.

Mr. STETLER. He is on the board now.

Senator NELSON. I told Senator Smathers that we will put on individual doctors when we can arrange the time. Then, when Dr. Annis became a member of the board, the AMA wrote and said, "We want Dr. Annis to speak for us." Well, I would like to hear the head of the drug council, who was willing to come, as I understand it, but who was not permitted to come by the president. I would like to have the AMA president testify. And we would take Dr. Annis, too. Is there anything unfair about that?

Mr. STETLER. I think they should be heard and I think that is a good idea.

Senator NELSON. Well, we have already invited Dr. Hayes, and they have turned that down.

Mr. STETLER. I think they are waiting now for a reply to their request to be heard.

Senator NELSON. Well, I make an open invitation to the president of the AMA, and again to Dr. Hayes, head of the drug council, to come. If they are willing to come, we will also take Dr. Annis, who was not on the board at the time that he made a personal request to come. Subsequently he went on the board, and then the AMA said, "He will speak for us." Well, that is fine, but I am not prepared to permit him to be the exclusive spokesman for the AMA, and I do not think I have to be.

Mr. STETLER. Well, I cannot comment on that, obviously.

Senator NELSON. Well, just so the public knows I invited Dr. Hayes, director of the drug council for the AMA, and he was willing to appear, but the AMA would not let him come. I think that ought to be a part of the record.

We made a public statement inviting the president of the AMA to come, too. We have not heard from that invitation.

Mr. STETLER. Senator, actually, I think you have a fairly recent letter from the AMA reiterating their desire to have a date set for them to appear.

Senator NELSON. Who is "them"?

Mr. STETLER. Whoever they select as their witness.

Senator NELSON. The letter said they want Dr. Annis.

Mr. STETLER. He is a perfectly legitimate witness. He is a member of their board, a past president of the AMA.

Senator NELSON. Fine. I am glad to have past presidents. I would like the current president.

Mr. STETLER. I am sure he will be available and willing to testify.

Senator NELSON. All right. He has not responded to our public invitation. Dr. Thomas Hayes has not been permitted to come. I want to be fair about this.

I want the AMA to be represented by their top people, their drug council. I will repeat the invitation publicly, as I have in the past, to

the president of the AMA, and to the head of the drug council, Dr. Hayes, and they can bring Dr. Annis along with them. We will hear them all in 1 or 2 days. This has been my posture from the beginning. To leave the impression I have not been offering the change to these people to appear is not correct. For them to say that they want Dr. Annis, otherwise they won't come and that I am unfair is a lot of nonsense. I think the committee ought to have something to say about who they ask to come, too. If the AMA wants to bring Dr. Annis or a dozen other people, we are perfectly willing to hear them. But to say that we have been unfair about this I think is quite preposterous. And you have repeated this kind of statement in Montreal, Canada.

There is loads of this material, Mr. Stetler. I have a TV transcript, "Interview with Joseph Stetler. Interviewed by Steward Finley."

Mr. Finley asked you:

> Has the pharmaceutical industry been asked to testify yet?
> No; we have not been asked as yet. We are assured by Senator Nelson that we will have that opportunity, but we have not had it yet. Some of the issues that have developed in the hearings to date are medical in nature. We understand that some qualified physicians of medical organizations have asked for the opportunity to testify. We are hopeful they will have that chance soon.

What date was that TV script?

Mr. STETLER It has been a couple of months ago. I am not sure of the date.

Senator NELSON. That was after you had been in my office and been assured you would have a chance. It is after I invited the whole industry to come one by one; is it not?

Mr. STETLER. It is also after I wrote about three or four letters trying to pin down specific dates, letters to which I never received a response.

Senator NELSON. We are going to put this all in the record. But the fact of the matter is that you did not write a letter until you made all kinds of speeches saying I did not let you appear.

This was after weeks has passed subsequent to the conference in my office.

Mr. STETLER. Senator, I wrote to you early in June, before that statement was ever made.

Senator NELSON. Do you have the date of that TV script?

Mr. STETLER. I do not have it right here; I could supply it. I think it was probably in August. I would have to check that.

Senator NELSON. And then there was a radio script at the same time.

Would you mind telling the committee where you distributed this TV spot and the radio script?

Mr. STETLER. That was distributed to 100 TV stations around the United States.

Senator NELSON. How many in the State of Wisconsin?

Mr. STETLER. Probably one, but I do not know for sure.

Senator NELSON. Would you give me a list of the stations, radio and TV, that it was distributed to?

Mr. STETLER. It went to 100 TV stations and 200 radio stations. I will be glad to supply that list.

Senator NELSON. I would like to have you supply the list of radio and TV stations to which the statement was sent, as well as the date on which it was made.

Mr. STETLER. Right.

(The information referred to, subsequently received, follows:)

RADIO STATIONS TO WHICH TAPED INTERVIEW FEATURING C. JOSEPH STETLER WERE MAILED, JUNE 5, 1967

WATM, Atmore, Ala.
WAPI, Birmingham, Ala.
WBIB, Centreville, Ala.
WHOS, Decatur, Ala.
WWWF, Fayette, Ala.
WAAX, Gadsden, Ala.
WERH, Hamilton, Ala.
WLCB, Moulton, Ala.
WFEB, Sylacauga, Ala.
KCAM, Glenallen, Alaska
KAPR, Douglas, Ariz.
KFIF, Tucson, Ariz.
KJWH, Camden, Ark.
KCCB, Corning, Ark.
KMAG, Fort Smith, Ark.
KOSY, Texarkana, Ark.
KIBS, Bishop, Calif.
KBMX, Coalinga, Calif.
KRDU, Dinuba, Calif.
KOAD, Lemore, Calif.
KFWB, Los Angeles, Calif.
KGOL, Palm Desert, Calif.
KIBE, Palo Alto, Calif.
KRLA, Pasadena, Calif.
KLOA, Ridgecrest, Calif.
KCBQ, San Diego, Calif.
KWIZ, Santa Ana, Calif.
KSUE, Susanville, Calif.
KOMY, Watsonville, Calif.
KSYC, Yreka, Calif.
KGIW, Alamosa, Colo.
KVFC, Cortez, Colo.
KAVI, Rocky Ford, Colo.
KGEK, Sterling, Colo.
WLAD, Danbury, Conn.
WSUB, Groton, Conn.
WLIS, Old Saybrook, Conn.
WSTC, Stamford, Conn.
WTOR, Torrington, Conn.
WILI, Willimantic, Conn.
WEHW, Windsor, Conn.
WZEP, Defuniak Springs, Fla.
WFBF, Fernandina Beach, Fla.
WYSE, Inverness, Fla.
WFFG, Marathon, Fla.
WPCF, Panama City, Fla.
WSCM, Pamana City, Fla.
WTRR, Sanford, Fla.
WALT, Tampa, Fla.
WQXI, Atlanta, Ga.
WBBK, Blakely, Ga.
WDYX, Buford, Ga.
WGAA, Cedartown, Ga.
WTTI, Dalton, Ga.
WDGL, Douglasville, Ga.
WSGC, Elberton, Ga.
WBHB, Fitzgerald, Ga.
WVOH, Hazelhurst, Ga.
WLOP, Jessup, Ga.
WLFA, Lafayette, Ga.
WSNT, Sandersville, Ga.
WPAX, Thomasville, Ga.
WACL, Waycross, Ga.
KPOI, Honolulu, Hawaii
KUPI, Idaho Falls, Idaho
KAIN, Nampa, Idaho
WCAZ, Carthage, Ill.
WAAF, Chicago, Ill.
WDQN, Du Quoin, Ill.
WRMN, Elgin, Ill.
WMIX, Mount Vernon, Ill.
WCMY, Ottawa, Ill.
WIRL, Peoria, Ill.
WIZZ, Streator, Ill.
WCSI, Columbus, Ind.
WCMR, Elkhart, Ind.
WROZ, Evansville, Ind.
WASK, Lafayette, Ind.
WJCD, Seymour, Ind.
WGVA, South Bend, Ind.
KSO, Des Moines, Iowa
KMAN, Manhattan, Kans.
KULY, Ulysses, Kans.
WHBN, Harrodsburg, Ky.
WKIC, Hazard, Ky.
WMTL, Leitchfield, Ky.
WPHN, Liberty, Ky.
WNVL, Nicholasville, Ky.
KCIL, Houma, La.
KXKW, Lafayette, La.
WBME, Belfast, Maine
WLKN, Lincoln, Maine
WFBR, Baltimore, Md.
WNAC, Boston, Mass.
WHAV, Haverhill, Mass.
WMRC, Milford, Mass.
WBRK, Pittsfield, Mass.
WAAB, Worcester, Mass.
WABX, Detroit, Mich.
WFDF, Flint, Mich.
WCSR, Hillsdale, Mich.
WJBL, Holland, Mich.
WJPD, Ishpeming, Mich.
WKLZ, Kalamazoo, Mich.
WJPW, Rockford, Mich.
KDHL, Faribault, Minn.
KDWA, Hastings, Minn.
KLFD, Litchfield, Minn.
KYSM, Mankato, Minn.
KCUE, Red Wing, Minn.
WHNY, McComb, Miss.
KFVS, Cape Girardeau, Mo.
KDFA, Doniphan, Mo.
KHMO, Hannibal, Mo.
WMBH, Joplin, Mo.
KQYX, Joplin, Mo.
KCMK, Kansas City, Mo.
KFUO, St. Louis, Mo.
KDRO, Sedalia, Mo.
KALM, Tahyer, Mo.
KWRE, Warrenton, Mo.
KGVW, Belgrade, Mont.
KBMN, Bozeman, Mont.
KLTZ, Glasgow, Mont.
KUDI, Great Falls, Mont.
KGEZ, Kalispell, Mont.

RADIO STATIONS TO WHICH TAPED INTERVIEW FEATURING C. JOSEPH STETLER WERE MAILED, JUNE 5. 1967—Continued

WJAG, Norfolk, Nebr.
KNEV, Reno, Nev.
KWNA, Winnemucca, Nev.
WRAN, Dover, N.J.
KRAC, Almagordo, N. Mex.
KSRC, Socorro, N. Mex.
WKSN, Jamestown, N.Y.
WICY, Malone, N.Y.
WHN, New York, N.Y.
WIRY, Plattsburgh, N.Y.
WAPC, Riverhead, N.Y.
WKJK, Granite Falls, N.C.
WDSL, Mocksville, N.C.
WPAQ, Mount Airy, N.C.
WKRK, Murphy, N.C.
WRNB, New Bern, N.C.
WYNA, Raleigh, N.C.
WNCA, Siler City, N.C.
WMFD, Wilmington, N.C.
WGTM, Wilson, N.C.
WKRC, Cincinnati, Ohio
WMNI, Cleveland, Ohio
WWOW, Conneaut, Ohio
WTIG, Massillon, Ohio
KGYN, Guymon, Okla.
KTMC, McAlester, Okla.
KLCO, Poteau, Okla.
KGFF, Shawnee, Okla.
KROW, Dallas, Oreg.
KWVR, Enterprise, Oreg.
KTIX, Pendleton, Oreg.
KPRB, Redmond, Oreg.
WAEB, Allentown, Pa.
WISR, Butler, Pa.
WWGO, Erie, Pa.
WHUN, Huntingdon, Pa.
WDAS, Philadelphia, Pa.
WATS, Sayre, Pa.
WMBT, Shenandoah, Pa.
WANB, Waynesburg, Pa.
WHIM, Providence, R.I.
WERI, Westerly, R.I.
WCOS, Columbia, S.C.
WFIS, Fountain Inn, S.C.
WTND, Orangeburg, S.C.
WBBR, Travelers Rest, S.C.
WGOG, Walhalla, S.C.
KNWC, Sioux Falls, S .Dak.
WOPI, Bristol, Tenn.
WJJM, Lewisburg, Tenn.
KBOX, Dallas, Tex.
KWRD, Henderson, Tex.
KBNO, Houston, Tex.
KGVL, Port Lavaca, Tex.
KTEO, San Angelo, Tex.
KWTX, Waco, Tex.
WFLS, Fredericksburg, Va.
WDDY, Gloucester, Va.
WRGM, Richmond, Va.
WEER, Warrenton, Va.
WHWB, Rutland, Vt.
KAPS, Mount Vernon, Wash.
KONP, Port Angeles, Wash.
KGDN, Seattle, Wash.
KDNC, Spokane, Wash.
WBOY, Clarksburg, W. Va.
WTCS, Fairmont, W .Va.
WTAP, Parkersburg, W. Va.
WHLL, Wheeling, W. Va.
WHBY, Appleton, Wis.
WRJC, Mauston, Wis.
WEMP, Milwaukee, Wis.
WIBU, Poynette, Wis.
KMER, Kemmerer, Wyo.

TV STATIONS TO WHICH FILMED INTERVIEW FEATURING C. JOSEPH STETLER WERE MAILED, JUNE 5, 1967

WBRC–TV, Birmingham, Ala.
WMSL–TV, Decatur, Ala.
WTVY–TV, Dothan, Ala.
WOWL–TV, Florence, Ala.
WAAY–TV, Huntsville, Ala.
WKAB–TV, Montgomery, Ala.
WSLA–TV, Selma, Ala.
KPHO–TV, Phoenix, Ariz.
KOLD–TV, Tucson, Ariz.
KBLU–TV, Yuma, Ariz.
KFSA–TV, Fort Smith, Ark.
KATV, Little Rock, Ark.
KERO–TV, Bakersfield, Calif.
WHSL–TV, Chico, Calif.
WCFT–TV, Concord, Calif.
KIEM–TV, Eureka, Calif.
KJEO–TV, Fresno, Calif.
KCET–TV, Los Angeles, Calif.
KSBW–TV, Salinas, Calif.
KAAR–TV, San Diego, Calif.
KSBY–TV, San Luis Obispo, Calif.
KEYT–TV, Santa Barbara, Calif.
KRDO–TV, Colorado Springs, Colo.
KREZ–TV, Durango, Colo.
KREX–TV, Grand Junction, Colo.
KTVS, Sterling, Colo.
WHNB–TV, W. Hartford, Conn.
WTTG–TV, Washington, D.C.
WINK–TV, Fort Myers, Fla.
WLBW–TV, Miami, Fla.
WFTV, Orlando, Fla.
WJHG, Panama City, Fla.
WCTV, Tallahassee, Fla.
WPTV, West Palm Beach, Fla.
WALB–TV, Albany, Ga.
WMAZ–TV, Macon, Ga.
WTOC–TV, Savannah, Ga.
KTVB–TV, Boise, Idaho
KID–TV, Idaho Falls, Idaho
WCHU–TV, Champaign, Ill.
WCIU–TV, Chicago, Ill.
WTVP–TV, Decatur, Ill.
WIRL–TV, Peoria, Ill.
WREX–TV, Rockford, Ill.

TV STATIONS TO WHICH FILMED INTERVIEW FEATURING C. JOSEPH STETLER WERE MAILED, JUNE 5, 1967—Continued

WSJV–TV, Elkhart, Ind.
WHET–TV, Evansville, Ind.
WPTA–TV, Fort Wayne, Ind.
WLWI–TV, Indianapolis, Ind.
WFAM–TV, Lafayette, Ind.
WLBC–TV, Muncie, Ind.
KVFD–TV, Fort Dodge, Iowa
KTVO–TV, Ottumwa, Iowa
KTIV–TV, Sioux City, Iowa
KWWL–TV, Waterloo, Iowa
KAYS–TV, Hays, Kans.
KSLN–TV, Salina, Kans.
KAKE–TV, Wichita, Kans.
WLTV, Bowling Green, Ky.
WKYT–TV, Lexington, Ky.
KALB–TV, Alexandria, La.
KATC–TV, Lafayette, La.
KPLC–TV, Lake Charles, La.
WVUE–TV, New Orleans, La.
KTBS–TV, Shreveport, La.
WABI–TV, Bangor, Maine.
WAGM–TV, Presque Isle, Maine
WJZ–TV, Baltimore, Md.
WBOC–TV, Salisbury, Md.
WGBH–TV, Boston, Mass.
WHYN–TV, Springfield, Mass.
WTVS–TV, Detroit, Mich.
WJRT–TV, Flint, Mich.
WKZO–TV, Kalamazoo, Mich.
WJIM–TV, Lansing, Mich.
WWTV, Traverse City, Mich.
KMBC–TV, Kansas City, Mo.
KTVI–TV, St. Louis, Mo.
KBIM–TV, Roswell, N. Mex.
WBEN–TV, Buffalo, N.Y.
WROC–TV, Rochester, N.Y.
KOLN–TV, Lincoln, Nebr.
WYNE–TV, Omaha, Nebr.
WRAL–TV, Raleigh, N.C.
WCPO–TV, Cincinnati, Ohio
WEWS–TV, Cleveland, Ohio
WBNS–TV, Columbus, Ohio
KATV, Portland, Oreg.
WIBF–TV, Jenkintown, Pa. (Phila.)
WRCB–TV, Chattanooga, Tenn.
KRLD–TV, Dallas, Tex.
KHOU–TV, Galveston, Tex.
WLVA–TV, Lynchburg, Va.
WTVR, Richmond, Va.
KXLY–TV, Spokane, Wash.
WEAU–TV, Eau Claire, Wis.
WBAY–TV, Green Bay, Wis.
WISC–TV, Madison, Wis.
WISN–TV, Milwaukee, Wis.
WSAU–TV, Wausau, Wis.
WHTN–TV, Huntington, W. Va.

Senator NELSON. Let us look at a statement of yours made at the annual meeting of the National Association of Retail Druggists, November 1, 1967, Houston, Tex., just a few days ago:

I cannot emphasize too strongly the significance of the Nelson hearings as they stand today, not only to drug manufacturers, but to the health professions and the public as well. If, as is now the case, the final record of the Nelson hearings is filled with distorted and biased material, it could eventually become the foundation for ill-conceived legislation such as I have just described. The record should and must be straight in the public interest.

You say "filled with distorted and biased material." I want to go through the witness list with you witness by witness, and find out what parts are distorted and biased.

You refer to people like Dr. Modell?

Mr. STETLER. No; I refer to the first witness, for one, Mr. Haddad.

Senator NELSON. I guess the committee would concede that he was not on your side.

Mr. STETLER. Not only not on our side; I do not think he was on anybody's side with some of the material that went in the record.

Senator NELSON. You could have had an industry witness on the stand at any time afterward to refute him, and you can do it today. I have no defense of anything any witness says here. They have to stand on their own.

Mr. STETLER. Senator, I want to say the comments made were not directed at you, but to the testimony that went in. I happen to think some of the testimony that went in, and we can document—some that went in was not proper, not fair—not because the witnesses were not on our side. But the main issue again I have tried to make is that certain groups that have not been heard should be heard, because only

one side has been heard to date. I just make that point. I think it is a simple point. If you say that the Academy and the AMA and these other people are going to be heard, I think the other side will be heard.

Senator NELSON. Well, why didn't you tell the druggists, at the meeting of the National Association of Retail Druggists that I have repeatedly stated that every single valid viewpoint would be appropriately represented? We cannot hold the hearing in the stadium and have everybody speak at once. What you are arguing about is the order in which they have been heard. The point I want to make clear to the public is that this chairman has said from the first day that we will hear every single member of your association and every drug manufacturer in America. And they did not come. I cannot help that. But to leave the impression that the hearings have been filled with distortion and bias, when your own members refused to come is preposterous. And when I asked a half dozen of their representatives, "When would you like to come?" they said, "Senator, we do not want to come." You know that as well as I do.

Mr. STETLER. Senator, they have said they would like to have the PMA present the case for them. And we are happy to be here today to have that chance.

Senator NELSON. Mr. Stetler, I am happy to have you here today, but on the first page you say, "I am not of course in a position to answer charges or questions addressed to any particular company."

Mr. STETLER. That is right—against any particular company. But the charges and the issues before this committee are much broader than that.

We are prepared with six men here, all highly trained in their field, to tell you in some considerable detail about the major issues that have been raised in the hearings.

Senator NELSON. We are glad to have you. But my point is that we had particular companies first because we had particular issues we wanted to raise. And, furthermore we were willing to hear these companies on all the general issues as well. Every one of your major companies has people who are prepared to discuss all the issues affecting that company, or the industry as a whole.

Mr. STETLER. It would have been a complete waste of your time to bring in 136 companies. We can do it if we have the chance today to present this testimony.

Senator NELSON. You did not even want to bring in any of them really. We have had an open invitation since last May, and yet you are complaining that the viewpoint of the industry has not been heard. You are not the industry. You are a hired representative of the industry. You represent the firms who account for 95 percent of the production in the industry, as I understand it. But the people who manufacture the drugs and their scientists, their chemists, their pharmacologists, their researchers, their business managers, their presidents, are in the companies you represent. Nobody in the world can speak better for the industry than these distinguished people.

You have left the impression all over this country—the implication is perfectly clear in your speeches—that this committee, meaning Senator Nelson, has loaded the record with biased material. You would

have had all the material you wanted, biased or unbiased, by your own companies in this record, but they have declined to come forward. I think that has to be made clear.

I say again—bring in your companies. I will give them dates.

Mr. STETLER. The men I have with me today come from particular companies. They are the qualified experts that you want to hear from.

Senator NELSON. Well, let me give you another example of what I mean.

This is from a speech you made in Montreal, Canada, October 25, 1967:

As you well know, our industry has been under attack from politicians such as Senator Nelson for too many years, and believe me we are getting a little tired of the game. It is also more than a little disconcerting to know, and we certainly do, that the Nelson Subcommittee and Russell Long and his staff have been getting considerable assistance and encouragement from some representatives of pharmacies. This in my opinion is unexplainable, and a most reckless type of activity.

Would you like to comment on that?

Mr. STETLER. Yes.

Senator NELSON. Now, you have been under attack by Senator Nelson. Start there, will you?

Mr. STETLER. I did not say I have. I said the industry has. And the industry has. Any casual reading of the transcript of these hearings to date could not be interpreted as anything but an attack on the drug industry.

Also comments that have been made—the speech that was given for you in Wisconsin, on August 25, stated a lot of conclusions with respect to the issues before this committee—conclusions that I think probably should await the outcome of the hearings when all of these people have had a chance to testify.

Now, as far as pharmacy is concerned, certain elements of pharmacy have been active in helping to draft bills like S. 2299 which we happen to honestly think are not only detrimental to the industry, but to medicine, pharmacy, and the public.

Now, there are different feelings in pharmacy on this particular issue, and I think both sides should be heard.

I made those statements. And until all of the elements and all of the interested parties that were invited on May 15 are heard, I think the hearing is not full and complete.

Senator NELSON. Let me quote a statement of yours given before a meeting of the Texas Medical Association in Austin on January 21, 1967, before the hearings ever began.

It might remind you of a little bit of a slight bias in advance.

We are facing a hydra-headed threat from two directions. Senator Gaylord Nelson of Wisconsin, Chairman of the Senate Monopoly Subcommittee of the Small Business Committee has announced he is going to hold drug hearings during the next couple of months. This will undoubtedly mean side trips into the field of prices, profits—as well as industry marketing and promotion. It sounds like an inquisition in the classic mold, which will test our capacity for taking verbal punishment, our ability to absorb ill-founded accusations and bounce back with reason and truth, and our willingness to stay on our feet fighting for what we believe is right and best for the Nation's health care.

You had us all categorized 3 months before the hearings started.

Or was it 5 months?

I repeat—all sides will be heard as I have said in the beginning. And I cannot hear them all at once.

I suppose Dr. Apple could have complained. I apologized to him yesterday. I said, "You are the first representative of the pharmacists which I have called, and tomorrow Mr. Stetler will appear. If there is a complaint about the order in which you are called or about how long it has taken, you have the same complaint that Mr. Stetler has expressed all over the United States. But at least I have told Mr. Stetler to have every single company who supports his association to appear before the committee, and we have only had two volunteers."

So I repeat my offer for them to come again. All the viewpoints will be heard. I cannot hear them all at once. I suppose if you were chairman, we would have a different order in which you would call them.

But I think we have had a long list of very distinguished witnesses although you may differ with them.

Let us take a look at them.

On the fourth day of the hearings we started with experts in the field. We had Dr. Walter Modell, director, clinical pharmacology, Cornell University. Do you consider him an expert witness?

Mr. STETLER. I consider him to be a well-qualified man in the field. Good man.

Senator NELSON, Dr. Walter Richard Burack, Harvard Medical School; Dr. Melvin D. Small, Georgetown Medical School; Dr. James Haughton, first deputy administrator, Health Services Administration, New York City; Dr. Harry L. Williams, profesor of pharmacology, Emory University; Dr. D. F. McGee, chairman, Department of Pharmacology, Creighton University; Dr. Lloyd C. Miller, director of revision, United States Pharmacopeia—your organization participates in the standards for establishing the standards for the drugs in the Pharmacopeia—Dr. Solomon Garb, Department of Pharmacology, University of Missouri; Dr. J. Fitelson, drug and therapeutic information, New York; Dr. Leighton Cluff, chairman, Department of Medicine, University of Florida; Dr. Margaret McCarron, Los Angeles County Hospital; Harold W. Burrows, president, Parke-Davis Co., Detroit; W. H. Conzen, president, Schering Corp., New Jersey; Dr. Calvin Kunin, Department of Preventive Medicine, University of Virginia; Dr. Martin Cherkasky, director, Montefiore Hospital, Bronx, N.Y.; Dr. James Goddard, Commissioner of FDA; Henry DeBoest, vice president of the Eli Lilly Co.; Richard Furlough, president, E. R. Squibb & Sons; Dr. Frederick Wolff, director of research, Washington Hospital Center, professor of medicine at George Washington School of Medicine; President Silloway of CIBA; George Callahan, sales projects manager, American Telephone & Telegraph Co.; Dr. James Goddard, again, Commissioner, Food and Drug Administration; Dr. Edward G. Feldmann, director of the National Formulary. Aren't these distinguished people with knowledge in this field?

Mr. STETLER. Some are and some are not.

Senator NELSON. Which ones are not?

Mr. STETLER. Well, some of them are relatively unknown. I am sure they have a right to their own view, and they expressed it. But I make the point there are others who speak for greater numbers, who are

better qualified than many of those witnesses, and whose views have not been telegraphed in advance—some of those men were witnesses before the Kefauver committee, 7, 8, 9 years ago.

Senator NELSON. Do you have any suggestions, pharmacists, pharmacologists, doctors, or others who you would like to have appear?

Mr. STETLER. Yes, sir.

Senator NELSON. Who have you?

Mr. STETLER. I could supply you with a list, if you would like.

Senator NELSON. How about Dr. Alfred Gilman; is he distinguished in the field?

Mr. STETLER. Yes, sir.

Senator NELSON. Would you be satisfied that he was scientifically qualified?

Mr. STETLER. I am sure he is well qualified.

Senator NELSON. He had told us he did not want to come, but we will reinvite him.

Mr. STETLER. Of course, that is his personal decision. He is a well-qualified man—I can assure you of that.

Senator, you raised an important issue with respect to the Reader's Digest. Could I comment on that?

Senator NELSON. Sure.

Mr. STETLER. This Reader's Digest program was brought to the PMA's attention something over a year ago. And it was presented to us by the Reader's Digest, and by N. W. Ayer, an advertising agency. It is a new venture for us, and we thought a very fine venture, one which we envisioned as giving us an opportunity to communicate on an institutional basis with the public. And it is something that as an industry and as an association we have not done in the past.

Now, I realize—because I have gotten the results of your letters to these agencies of Government—that there now are questions raised about it. I can say this about it—that the format of the publication in the Reader's Digest was presented to us by this magazine and by this ad agency. Very frankly—I am familiar with the format and agreed with it.

Senator NELSON. Was it your ad agency?

Mr. STETLER. No; they came to us with Reader's Digest. It was a joint presentation by the agency and the Reader's Digest.

Senator NELSON. Did you approve of the ad?

Mr. STETLER. Yes. I saw the format and I didn't disagree with them. It is an eight-page, detachable insert in Reader's Digest.

As you know, the first page indicates that it is a special advertising section, and the last page indicates that it is sponsored by the PMA.

Senator NELSON. As a public service?

Mr. STETLER. That is right. But nobody gets eight pages in the Reader's Digest without paying for it. I think everybody realizes that.

Also, those eight pages are separately numbered from the rest of the book. I believe the paper is the paper they normally use for ad copy. But I can tell you this. And I can say this emphatically, because I had a great deal to do with the decision.

There was definitely no intention of any deception. We have sent this to many, many people. I have yet to receive a letter from any-

body that says they were deceived by the format or the lack of any clear identification in the tear-out—other than the people we heard from at your—in response to your letter.

Senator NELSON. You have not received a letter from anybody who said they were deceived?

Mr. STETLER. That is right.

Senator NELSON. Well, if they were deceived, how would they know it?

Mr. STETLER. They could take affront at the format. They could say, "In my opinion, this format is deceptive," as you have said in your letters to the Department. But nobody has called this to our attention and said they had a problem with it.

Senator HATFIELD. Mr. Chairman, I would like to comment that could happen after the fact. They may have been deceived or brainwashed, either one.

Senator NELSON. You are talking about your side of the political field, not mine.

Go ahead.

Mr. STETLER. I can tell you this.

I assure you that we did this in good faith. We thought, and would still believe, that anybody that has as much experience as the Reader's Digest, and this ad agency, which is a nationally known agency, would know what is the proper form of an ad and what is not. We took their approach, and we accepted it. And we still think it is not misleading. As I say I have heard nothing from anybody other than the agencies of the Government that have been asked to comment, that there has been any trouble with it.

I will say this in addition.

Since this question has been raised, I can assure you that in the next issue, on each inside page, there will be a repetition of this special advertising section—just on the chance that somebody has been misled. But that does not mean that when this thing was started there was any concept that that could be a possibility, and I assure you on my part it was not, or on the part of the PMA who is responsible for this.

Senator NELSON. Well, a couple of questions about that.

I looked at this ad very carefully, and it says "Special Advertising Section." And then you flip the page and it appears to be—the objective is clear—it appears to be just an independent article in the Reader's Digest.

Mr. STETLER. That was not my objective or ours, I can assure you. The table of contents on the front also indicates that there are four articles, and what the titles are for the articles inside this eight-page detachable magazine within a magazine.

Senator NELSON. If you look at every other ad before and after—I have looked at 10 or 15 of them—they are all clearly marked as advertisements. This is the only one that is not. And then opposite the front page it says, "If your copy has been removed, write to Health, Post Office Box 2811." Why not write to the Pharmaceutical Manufacturers Association? Is that your post office number?

Mr. STETLER. Let me comment on that.

First of all, incidentally, this type of a detachable insert did not start with us in the Reader's Digest. There have been many many others and they have handled these in a variety of ways but this was

not—the inception of this kind of an approach with this magazine. This magazine goes to something like 17 million people, and I do not know how many others, whose hands it comes into. But we did not want them writing to the PMA for copies of reprints, not for any deceptive reason, but just because it would be very tough to handle our mail if it came that way. I understand it is not unusual in getting a post office box to use some other word than the name of the corporation or a long name. Once again, I do not think anybody was deceived by that. And certainly nobody that has written in for a reprint has indicated a problem with it.

But if that creates a problem——

Senator NELSON. Do you really mean if an ordinary reader looked at this, and it says "Write to Health," he wouldn't have the impression he is writing to some independent health publication?

Mr. STETLER. I don't know what his impression might be. All I know he is writing for a reprint. When he gets it he will know what this is and what it says. It is clearly indicated.

Senator NELSON. On page 24 it says, "If your copy has been removed," and if it has been removed, there is nothing to tell them anything about an advertisement.

Mr. STETLER. As you would label this as propaganda—there is no propaganda on this page, either. He has to write for the reprint. When he gets the reprint it is clearly identified.

Senator NELSON. No. When he gets the reprint, very carefully the words "Special Advertising Section" have been removed. Why is that done?

Mr. STETLER. It is indicated where it was in the journal—on the back—that it is part of a series from the Pharmaceutical Manufacturers Association.

Senator NELSON. You are saying here that if your copy has been removed write to "Health." On this opening page the words "Special Advertising Section" appear. Then on the reprint that you send them "Special Advertising Section" has been removed, so that you receive a reprint that says "Why have many dread diseases vanished, what is the drug name, what are the drugs that reach troubled minds, where are prescription prices going?" And it says "Medicines and Your Family's Health," reprinted from the November 1967 issue of the Reader's Digest.

Now, Mr. Stetler, you know that every single person in the United States, with the rarest of exceptions, is going to say "Well, this is a very interesting little objective health article." I am not talking about the quality of it. You may defend that or not. But the point is that the reader, the doctor, the pharmacist, the patient, is going to look at that and say "This is a very nice little article about drugs." And he is going to be misled. I think that is clear as a bell.

Mr. STETLER. Well, I hope that is not so. It was not intended. I have had nothing to indicate that that has happened. I think it would have been really in many ways—I suppose it would be difficult for us to tell our story where somebody would not feel that we were trying to be deceptive. But this was a very honest, sincere effort for the first time to get a message across to the public, and we have not communicated with the public before. I am sure somebody would find fault with it, no matter how we prepared it.

Senator NELSON. You can criticize all kinds of advertising. But here is a tax-exempt organization circulating to the public all over the United States a pamphlet which would require a fairly sophisticated person to discern as an ad, when the only indication after he gets through reading, if he bothers to read the fine print, is the phrase "First in a series published as a public service by the Pharmaceutical Manufacturers Association." If this was the only thing I ever saw, my interpretation would be that the Pharmaceutical Manufacturers Association selected an article written by an independent source that they thought was pretty reliable and favorable to their industry, and decided to spread it around the country. It would not occur to me from just glancing at these words that it was prepared by the PMA. I might wonder who the author was, but ordinarily not.

So I do not see how the public is going to know that this piece that is being circulated is in fact a piece of advertising. And if it is advertising, at least you should alert the people of that fact.

Now, it seems to me that as a tax-exempt organization, you have a double responsibility, a higher responsibility to the public than some of those who are not tax exempt.

Mr. STETLER. We have the same responsibility as far as not deceiving, whether we are tax exempt or not. And there is no intention here to deceive. Just two points. I say again that this was prepared in this format at the request of people that have had experience. I can tell you one thing, one final thing on this, as far as we are concerned, and that is, since a question has been raised, on the reprints I am going to make sure that in future quarterly supplements, and there are going to be three more in the Reader's Digest, on the front page it is going to say "Advertising Section, reprinted from the Reader's Digest."

Senator NELSON. Where is it going to say that?

Mr. STETLER. Right there on the reprint, right on the front (indicating).

Senator NELSON. Have you discussed this with the Federal Trade Commission?

Mr. STETLER. Yes; I have. I spent an hour last Friday afternoon in Mr. Sweeney's office, and we have supplied him with all of the background and all the information. I should say one other thing.

The letters that we sent out distributing these reprints clearly indicated that there was a project sponsored by the Pharmaceutical Manufacturers Association. Now, we have given him all the background. We sent out a press release. We have given him that. All this clearly identifies the PMA as a sponsor of this project. We have never tried to hide it. We have been rather proud of it.

Senator NELSON. You mean to the doctors you sent it to?

Mr. STETLER. We sent it to a lot of folks. We sent it to you as a Member of the Congress, to the Members of the Congress, to various State legislators. And frankly we have gotten a great number of good letters in response to it.

Senator NELSON. How many of these reprints have you sent out?

Mr. STETLER. There were a million reprints produced, and I think most of them have been distributed.

Senator NELSON. Has every doctor in the United States received one?

Mr. STETLER. I am sure he has not; no. We have had requests from some. But not a very high percentage; no.

Senator NELSON. But you have printed a million of these copies?

Mr. STETLER. A million of these were prepared by Reader's Digest, and supplied to us as an overrun.

Senator NELSON. What is the nature of the list you are sending it to?

Mr. STETLER. This was sent with a covering letter to Members of Congress, to members of State legislatures.

Senator NELSON. One copy each?

Mr. STETLER. On those, yes. I will read the list here. They went to our members, copies for distribution to employees, stockholders, physicians, they went to Federal and State executives, university officials, went to hospital administrators, to news media, to physicians and hospitals on request, and to pharmacists on request, and to National-State professional organizations. The physician requests have numbered 23,000.

Senator NELSON. Physician requests?

Mr. STETLER. Yes.

Senator NELSON. How many physicians did you send it to directly?

Mr. STETLER. Only to those who requested it—23,000.

Senator NELSON. The patient, of course, would not see the letter. He would see this ad here which does not contain the word "advertising" in it a single time.

Mr. STETLER. He would. And as I have just said, since the question has been raised, the next issue is going to be clearly identified.

But I can assure you that from the source of this suggested format, and on my reading of it, I did not think it was misleading, and I still do not. And apparently the people we have heard from do not think so.

Senator NELSON. What is the total cost of the series of four?

Mr. STETLER. Each of these inserts in the Reader's Digest cost about $250,000. That is close to a million dollars for four.

Senator NELSON. This is part of a series that will be run 4 months in a row?

Mr. STETLER. It is going to be run quarterly; four times; yes.

Senator NELSON. What is the cost of the reprints?

Mr. STETLER. It is a very small amount. I cannot recall. It is a small amount. It is an overrun when they run the magazine, and the reprints are inexpensive. I would say maybe a million reprints cost $5,000. I would have to check on that.

Senator NELSON. Would you send the committee the amount?

Mr. STETLER. Oh, surely.[1]

Senator NELSON. The reprints, or the overrun, as you called it, was printed and supplied to you by the Reader's Digest?

Mr. STETLER. Right.

Senator NELSON. So when you compare the front page of the two, it is clear that a positive action was taken to remove the type which says "Special Advertising Section" in the magazine, and leaves it off in the reprint; correct?

Mr. STETLER. Left off.

Senator NELSON. It would have to be removed?

[1] Mr. Stetler subsequently stated: "We obtained a total of 1,250,000 reprints of the PMA advertising section from the November issue of the Reader's Digest. The cost of these reprints was $6,287.50."

Mr. STETLER. When they did the excess run, they took that off.

Senator NELSON. Well, can you believe there was any intent on the part of whoever did it, other than to mislead the public as to what it was?

Mr. STETLER. I can tell you with assurance there was no intent on my part. And I am responsible for the PMA's part of it. It was their recommended format. I accepted it. And I do not attribute deception to them, and certainly there was none on our part.

Senator, could I begin on this statement?

Senator NELSON. I just have one other item here, and then Senator Hatfield has a question.

I think with regard to this ad I ought to put something in the record at this stage. It is a letter from Wolins Pharmaceutical, and I quote:

As a follow-up to our report to you of October 19, 1967, we enclose the November issue of Reader's Digest.

This issue, as you no doubt know, contains an 8-page advertising section placed by the Pharmaceutical Manufacturers' Association. We offer it as additional and continuing evidence that the PMA is going out of its way to malign generic name drugs and undermine public confidence in them.

We draw your particular attention to page M–4, second column, to the article's reference to tolbutamide. We were not aware that tolbutamide was available under its generic name. The patent is owned by Upjohn, circa 1957, and the drug is produced and sold in the United States only by Upjohn under the name Orinase. It is one of the fifty most prescribed drugs. Wolins has no knowledge of it ever being offered in this country under its generic name; in fact, we believe that we are safe in saying that no other brand name manufacturer in the U.S. produces it either.

We wonder why the PMA has to go all the way to Canada to find an example of an unsatisfactory generic name drug? Canada, of course, does not impose the strict manufacturing controls in operation in the United States. Yet 50 million people were exposed to this distorted presentation.

Mr. STETLER. We are prepared to illustrate in our testimony some very specific examples in the United States.

Senator NELSON. All right.

One more thing about the example of tolbutamide. I want to put in a letter in the record to the Canadian Medical Journal by Arnold K. Carter, M.D., of Windsor, Ontario, in which he comments on the case of tolbutamide used as an example in the Reader's Digest article:

The firm replied at once that the tablets submitted were not of their manufacture, as judged by physical appearance, but that they would analyze them and report. The findings, which I received shortly, were as follows:

These tablets contained 500 mg. of tolbutamide but did not disintegrate after 45 minutes in gastric juice followed by 63 minutes in intestinal juice. They are completely outside the limits set by the food and drug regulations for tablets sold in Canada.

This is the exact example you are using—then the drug being used manufactured in Canada did not meet Canadian standards, and certainly did not meet ours, so it certainly cannot be an indictment of generic drugs as such.

Mr. STETLER. Senator, this drug was sold in Canada. Whether it met standards or not, it was available as a generic product. I am sure it is easy after it passed through the patient for somebody to say it did not meet standards.

(The letter referred to follows:)

[From the Canad. Med. Ass. J., Jan. 12, 1963, vol. 88]

SUBSTITUTION FOR BRAND-NAMED DRUGS

To the EDITOR:

The serious consequences of a request by one of my diabetic patients that his druggist be allowed to supply a cheaper drug to refill my prescription for a brand-name tolbutamide prompts this communication. I believe it has a significant bearing on the present controversy about generic drug prescribing and might well alert some of my fellow physicians to hazards inherent in this practice.

This patient who had been controlled for 11 months on diet and 1 g. daily of tolbutamide (Mobenol) inexplicably went out of control recently, his fasting blood sugar rising rapidly to 287 mg. %. At that time the patient noted tolbutamide tablets intact in his stools and brought one tablet in to me. He was then asked to bring in the remainder of his prescribed tablets, and since his case record still specified that he was taking Mobenol, these were forwarded to the manufacturer, together with the passed tablet. At the same time the patient was hospitalized and his diabetes mellitus was controlled on the former dosage of tolbutamide.

The firm replied at once that the tablets submitted were not of their manufacture, as judged by physical appearance, but that they would analyze them and report. The findings, which I received shortly, were as follows:

"These tablets contained 500 mg. of tolbutamide but did not distintegrate after 45 minutes in gastric juice followed by 63 minutes in intestinal juice. They are completely outside the limits set by the Food and Drug Regulations for tablets sold in Canada."

In other words, although these tablets contained the labelled quantity of drug, they were to all intents and purposes quite useless.

This episode has, therefore, resulted in temporary lapse in control of the patient's diabetes, and also necessitated the expense and inconvenience of a period of hospitalization in order to regain control. It has also resulted in subsequent investigation of the pharmacy concerned by the Ontario College of Pharmacy inspector which revealed a notation on the prescription concerned that permission to substitute a cheaper brand had been obtained from myself by telephone through my nurse.

This case, which has been a traumatic experience for the patient and myself, of course, does not necessarily indict all or even the majority of unbranded drugs as being suspect. However, since diabetes is one of the few areas of therapeutics where failure of response to a drug can be observed clinically and measured objectively, I consider this instance most significant and revealing. It makes one wonder how many product failures occur in other circumstances where results are less obvious or dramatic.

Until existing regulations allowing the import into Canada, distribution and sale at discount prices, of unassayed drugs are altered, I will henceforth not prescribe any drug without specifying a brand or manufacturer.

ARNOLD K. CARTER, M.D.

WINDSOR, ONTARIO.

Senator NELSON. Senator Hatfield.

Senator HATFIELD. Mr. Chairman, I would like to pursue this for just one or two moments, because as I understand, Mr. Stetler, you said earlier that the Reader's Digest approached you on this possible advertisement, and that it was drawn then in conjunction with an advertising company?

Mr. STETLER. Yes, sir.

Senator HATFIELD. Mr. Chairman, I suggest that perhaps you have focused upon something that might involve even the Reader's Digest, that perhaps we might have them before our committee—for the simple reason that if you look a few pages later, you will find another advertisement, a single-page advertisement which is not perforated, but purely a part of the magazine—it is not listed with a page number, because it, like this particular advertisement that we are talking

about, precedes the actual articles that are listed in the index. It uses the same format as a regular article, like on page 111—I just choose this at random. It says this article is "Cool Talk About Drugs." That is a regular article. But on this one it says "Advertisement—Doctors find way to shrink painful hemorrhoids and promptly relieve pain, itching, in most cases, by Dr. James Henry Weston." Then it talks about—and I want the full page in the record, if you will, please—"the effectiveness of this treatment has been convincingly proved by leading doctors in New York City, Washington, D.C., and a Midwest medical center."

(The article referred to follows:)

Advertisement

Doctors Find Way To Shrink Painful Hemorrhoids

and promptly relieve pain, itching in most cases.

BY JAMES HENRY WESTON

The effectiveness of this treatment has been convincingly proved by leading doctors in New York City, Washington, D.C., and at a Midwest Medical Center.

A scientific research institute has discovered a medication which has the ability in most cases—to actually shrink hemorrhoids and to promptly stop the itching, burning, and relieve pain.

In case after case, the sufferer first notices relief from the itching and pain. Then tender swelling of the inflamed hemorrhoids is gently reduced. And all without the use of narcotics or stinging astringents of any kind.

Tests conducted on hundreds of patients by a leading hemorrhoidal specialist in New York City, in Washington, D.C., and at a Midwest Medical Center proved this so.

The answer is Preparation H®. There's no other formula for the treatment of hemorrhoids like it. Preparation H also lubricates, soothes irritated tissues and contains a special bacteriostatic to help prevent further infection. In fact, Preparation H has proved so successful that it outsells all other hemorrhoid remedies combined.

Preparation H is obtainable in ointment or suppository form at drug counters everywhere. No prescription is needed.

Senator HATFIELD. I am not going to read the entire article, but it is in the exact format of a regular printed article in the Reader's Digest. But it says in the last sentence or two—

Preparation H—

And that is what is being advertised—

the answer is Preparation H. There is no other formula for the treatment of hemorrhoids like it. Preparation H also lubricates, soothes irritated tissues, and contains a special bateriostatic to help prevent further infection. In fact, Preparation H has proved so successful that it outsells all other hemorrhoid remedies combined. Preparation H is obtainable in ointment or suppository form at drug counters everywhere. No prescription is needed.

Now, that is pretty sound, I suppose. In advertising that is a pretty hard sell.

But if you note, Mr. Chairman, this is in the same format as an article that would appear as a regularly written article in the Reader's Digest.

Now, if the Reader's Digest is going out to companies and associations and other groups, and selling advertising on this format basis that most represents their own normal format, which was brought up by our chairman so well this morning as a tendency to mislead the public—whether it is the intention of the advertiser or not—that the impression that is given to many casual readers. It seems to me, then, rather than merely focusing upon this gentleman and his association, that perhaps we ought to bring in the Reader's Digest, or ask the Federal Trade Commission to investigate the entire advertising policy of the Reader's Digest—because to me this can be as misleading—even though it is headed "Advertisement"—as the one we are talking about with the PMA, which is also headed up in the Reader's Digest "Special Advertisement," and has perforated pages, which this other one does not. So I think we may have even a bigger subject than what we have been talking about thus far this morning.

Senator NELSON. I think the distinguished Senator from Oregon is correct. The fact of the matter is that the intent of all of these kinds of ads is to mislead the consumer. There cannot be any other intent at all. And this is why everything is played so subtly. In this piece by the PMA, the word "advertisement" does not appear one single time. I think I could pass that out to ordinary people all over, and then give them a test on it, and there would not be one in a thousand who would guess it was an ad.

Now, if the consumer, who has a difficult enough time in these complicated days of sophisticated material and equipment on the market, is going to be professionally and calculatedly misled by clever advertising firms, and the biggest circulation magazine in America, I think Senator Hatfield is correct that this particular question ought to be looked into also.

I do not know any other way to protect the consumer. In the article the Senator just read, if a person did not happen to notice the word "advertisement" he would take it as the gospel truth, and the answer to his problem, and be fooled and confused by the whole business.

I think it is a sad commentary on the integrity and quality of presentation of products and material to the consumer in this country today.