

Corps of Engineers, Lieutenant General Cassidy, to appear before the committee. A similar invitation is being extended to the Governor of Florida.

Mr. President, the problem of the Everglades National Park requires a reasonable and an early solution. Resolution is important because of the many scenic, recreational, wildlife, and scientific values found in the park which are found nowhere else. We cannot allow these to be destroyed; they must be preserved.

The Everglades is of importance for still another reason. It is a manifestation of what happens and what is happening in this country under the pressures of population, development, and man's applications of new technology. In pursuit of convenience and material wealth we are too often insensitive to the environment and to the values of the natural world.

#### NOTICE OF HEARINGS

Mr. KENNEDY. Mr. President, I wish to announce that the Subcommittee on Administrative Practice and Procedure of the Senate Judiciary Committee will hold a 1-day hearing on Monday, May 26 at 1:30 a.m. in room 2228, New Senate Office Building. The subject of the hearing will be S. 1144, a bill to remove the statutory ceiling on appropriations for the Administrative Conference of the United States.

#### RECESS

Mr. JAVITS. Mr. President, I ask unanimous consent that the Senate stand in recess, subject to the call of the Chair.

There being no objection, (at 12 o'clock and 31 minutes p.m.) the Senate took a recess subject to the call of the Chair.

On the expiration of the recess (at 1 o'clock and 51 minutes p.m.), the Senate reassembled, and was called to order by the Presiding Officer (Mr. ALLEN in the chair).

#### THE HIGH COST OF DRUGS

Mr. LONG. Mr. President, this morning a great doctor, Dr. John Adriani, of the Charity Hospital of New Orleans made a statement that I believe every doctor in America should read. His statement was about the abuses of the drug industry as it exists in America today. As chairman of the Council on Drugs of the American Medical Association, Dr. Adriani is one of the outstanding experts on this subject.

I believe that Dr. Adriani qualifies for an award for service to humanity for the kind of work he has done in trying to provide for American citizens the best drugs at the lowest cost. Dr. Adriani, in the beginning of his remarks, made the following statement:

I preface my remarks to the committee with the statement that I am strongly biased in my views on matters pertaining to drugs and that my bias in this regard is 100 percent pro-patient and only pro-patient.

Dr. Adriani is a man who has spent his life working with drugs. He has done

this not for money, but for the service that he could render to humanity. He understands the subject as well as anyone. Any doctor or any drugstore owner who would like to know why the public is complaining about the drug prices and practices and why people like the Senator from Louisiana and the Senator from Wisconsin complain and keep making speeches about the fact that the public is being victimized, oppressed, and outraged by the high prices charged for drugs produced at a low cost, ought to read Dr. Adriani's statement.

It takes great courage for a man such as Dr. Adriani to stand up and speak the honest truth when the drug companies are spending hundreds of millions of dollars trying to spread misinformation calculated to mislead and confuse the American people.

Dr. Adriani is perhaps second only to Dr. Alton Ochsner as a private citizen of Louisiana seeking to serve humanity as best he can.

Dr. Ochsner made the courageous fight in America to prove the connection between smoking and cancer, heart disease, and emphysema. He has insisted that the American Cancer Society and the American Heart Society should do something about it. He insisted that the Federal agencies should do something about the health hazard, meaning no ill will toward the tobacco industry, but thinking in terms of suffering humanity.

I have mentioned Dr. Ochsner's name in connection with Dr. Adriani because they are both presently citizens of the New Orleans area. In terms of men in medicine who have done great work for suffering humanity, these two great Americans are persons of whom Louisiana can justly be proud.

Mr. President, I ask unanimous consent that the prepared text of Dr. Adriani's remarks be printed in the RECORD. I challenge any drug manufacturer to prove Dr. Adriani wrong on a single major point.

There being no objection, the remarks were ordered to be printed in the RECORD, as follows:

STATEMENT OF JOHN ADRIANI, M.D., CHARITY HOSPITAL, NEW ORLEANS, LA., TO SENATOR GAYLORD NELSON'S SUBCOMMITTEE ON MONOPOLY, OFFICE OF THE SMALL BUSINESS COMMITTEE, U.S. SENATE

Mr. Chairman and Members of the Committee: It certainly is a compliment to me, who is familiar with so little of the vast fund of available information on drugs, to be invited to appear before this committee. You do me honor by indicating that I may be of assistance to you. The accumulation of knowledge pertaining to drugs over the past several decades has been so phenomenal that no single individual, be he a practitioner of medicine, pharmacologist, pharmacist or other person whose primary interest is drugs, can be expected to know all of the important details concerning all drugs available for use in the treatment of disease.

I preface my remarks to the committee with the statement that I am strongly biased in my views on matters pertaining to drugs and that my bias in this regard is one hundred percent pro-patient and only pro-patient.

#### BACKGROUND AND QUALIFICATIONS

I am John Adriani of New Orleans, Louisiana. I am a Doctor of Medicine who graduated from the College of Physicians and Sur-

geons of Columbia University in 1934. My specialty has been surgery, but my interests have been diversified since I began medical practice. I majored in chemistry before entering medical school and gave strong consideration to becoming a chemist and concentrating my interests in drug chemistry before I finally decided to study medicine. I also had training in physiology under the renowned Doctor Homer Smith at New York University. My contact with surgery made me aware of the woeful lack of knowledge of the action of anesthetics and the primitive methods of administering these drugs which existed in the early 1930's. The methods were nearly as primitive as they were in 1842 when ether was first introduced as an anesthetic.

Anesthetics are drugs which are used to carry a patient halfway to eternity and back. Obviously, these drugs are lethal and the responsibility of administering them is great. The science and specialty of anesthesiology has developed as a result of the recognition by a few physicians three decades ago of the importance of the actions of these drugs and of the knowledge of their proper administration.

An anesthesiologist is one who uses and studies pain relieving drugs in patients. An anesthesiologist must also possess broad knowledge in matters pertaining to other types of drugs because the specialty encompasses the use of drugs which are either antagonists and overcome the effects of anesthetics or are used as adjuncts to augment the effects of anesthetics. In addition, some drugs are used prophylactically to prevent unanticipated and unwanted side effects. Another point of importance is that patients who require anesthesia often are taking drugs prescribed by personal physicians, internists, and other specialists to treat diseases not directly related to the surgical disease for which they are hospitalized. An example would be the use of digitals in a patient to treat existing heart disease, reserpine for the treatment of the high blood pressure which caused the heart to decompensate, a diuretic, which facilitates the elimination of salt and prevents accumulation of water in the tissues, quinidine to make the pulse regular, a tranquilizer to prevent excitement and apprehension, a vasodilator to prevent anginal pain, an anticoagulant to prevent clotting in the vessels of the heart and brain, and insulin to control diabetes. It is not uncommon to find a patient who needs an operation having all these conditions and receiving all these drugs. How these drugs interact with those prescribed by the anesthesiologist and surgeon is a matter of great importance. Little is known about many drug interactions and the subject is now becoming one of intensive study.

The anesthesiologist is, in essence, a clinical pharmacologist who is knowledgeable in the behavior of many drugs. He is familiar with their use in human being who are ill and who are under treatment. His knowledge of drugs stems from their actual use in patients and not merely from information gathered in studies from normal human volunteers or from animals.

My experience in matters pertaining to drugs has been quite diverse, encompassing research in pharmacology, testing of new drugs, the teaching of pharmacology for over thirty years to undergraduate medical, dental, and postdoctoral students. In addition, I am engaged in the training of nurses to administer anesthetics, gases and mists for treating pulmonary (lung) diseases.

I have been a member of the Council on Drugs of the American Medical Association for six years and Chairman from the latter half of 1967 to date. I have been a member of the Revision Committee of the U.S. Pharmacopoeia for the past nine years and was a member of the panel on anesthetics of the Subcommittee on Scope of the U.S.P. ten years before I was made a member of the

Revision Committee. I have been a consultant to the Food and Drug Administration since 1963 when the Kefauver-Harris Amendment was first implemented. I am now also Chairman of the Advisory Committee to the FDA on Anesthetic and Respiratory Drugs.

For the past nine years I have been Associate Director at Charity Hospital of New Orleans, Louisiana, in which capacity I have gained considerable insight into the budgetary problems concerning the care of the sick and the cost of medical supplies, particularly drugs. I have also been a member of the Pharmacy and Therapeutics Committee of Charity Hospital, serving in the capacity of pharmacologist.

My entire professional life as a physician has been devoted as a salaried employee in tax-supported institutions (Bellevue Hospital, New York, and Charity Hospital, New Orleans) in caring for those unable to finance their own cost of medical care. I have no private practice except occasional consultations, testifying as an expert in medicolegal matters, or the treatment of special cases referred to me for problems pertaining to pain. I submit this resumé of my activities to you and to your Committee, Mr. Chairman, to apprise you of the areas of my interest and experience and background in matters pertaining to drugs.

#### TOPICS REQUESTED TO BE DISCUSSED

I am appearing by invitation as an individual physician, representing no organization or institution. My statements reflect my own thinking and opinions and are not to be construed as reflecting opinions of any organization or institution with which I am associated. I have been asked to express any general views I may have on drugs, but specifically to comment on antibiotic combinations, antibiotic overuse, and particularly the overuse of Chloramphenicol.

#### GENERIC NAMING

The problems of drug utilization and prescription methods are complex and are increasing in complexity as the number of drugs introduced into therapeutics increases. The situation can now be described as nearly chaotic. No semblance of order can be made of the existing chaos until all drugs and combinations thereof are designated by given, common, or generic names and not by proprietary, or brand names. Proprietary or brand names are, in essence, aliases. An alias, no matter how used, tends to confuse or to be deceptive. An alias is intended to conceal the true identity of whatever or whomever is being designated by an alias. The use of brand names for drugs serves no constructive purpose; on the contrary, the practice hampers rational drug utilization, rational prescribing and dissemination of drug information. Brand names should be abolished. The public's best interests shall not be served until this is done.

It is a function of the government to do for the people what the people cannot do for themselves. No private group or scientific organization possesses the capability or is empowered to institute reforms in drug nomenclature which are so sorely needed. Obviously, then, this is something that the people cannot do for themselves. Government, therefore, must intervene and act in the public's behalf. The record of the U.S. Government in assuring the public that food products supplied to a consumer are pure and properly labelled is commendable and is known to all. The citizens of no other nation on earth have the assurance that food products which enter interstate commerce are safe, as does the citizenry of this nation. Foods are dispensed by their given names and not by aliases. The brand and the name of the vendor or producer is inscribed on the dispensing container to permit the consumer to purchase the commodity of his choice and preference. It is difficult to understand why drugs, which are equally as important, if not

more important than food, to the health of a nation and well-being of the public are permitted to masquerade under aliases. In essence, the pharmaceutical industry is being granted preferential treatment by being allowed to distribute drugs using brand names, since no other major industry preparing merchandise for human consumption is granted similar special privileges. The reasons given are that merchandise of one manufacturer varies in quality from that of another and that to do otherwise interferes with the physician's prerogative or prescribing a drug of his choice. It is ludicrous to conceive that items so vital to the public health are distributed by brand names, under the guise that to do otherwise would be interfering with the physician's prerogative of selecting the product of a manufacturer which he deems best for his patient. The arguments which have been advanced for justifying the practice of using brand names are not only illogical and superfluous, but even puerile. If it is the object of the pharmaceutical industry to promote ignorance and to confuse not only the physician, but the public as well, the use of brand names effectively accomplishes this purpose. The prime motive, if one gives the matter thoughtful consideration in using aliases for drugs, is to promote sales, to establish monopolies and to stifle competition of rival manufacturers.

#### GENERIC LABELLING

It is my belief that carefully and thoughtfully prepared legislation should be adopted, advocating that compulsory labelling of prescription drugs dispensed either in bulk to pharmacists and physicians or prescription drugs dispensed in individual packages be done by generic, or common names. "By 'common names' I refer to names that are shorter or better known than the generic name. Aspirin is a more common name than the generic name—acetylsalicylic acid. The generic labelling should appear in large, bold-faced type on the label, wrapper, container, brochure and all other identifying devices or documents. The brand name of the manufacturer, if such a drug has a brand name, should be in parentheses beneath the generic name in type no larger than one-eighth the size of the type used for the generic name of the drug. Interposed between the generic name of the drug, in type no larger than that used for the manufacturer's name and the brand name but large enough to be easily legible, should be interposed the chemical name of the drug.

A pharmacist who dispenses to a patient, on a prescription from a physician, a portion of the contents of a drug packaged in bulk should be required to label the package of the drug so dispensed to the purchaser with the generic, or common name of the drug. If the physician has specified dispensing a drug of a particular manufacturer, the manufacturer's name should be indicated in parentheses below the generic name, in order that the physician, as well as the patient, will know whether or not the specified item has been supplied. The labelling on the container given to the patient should be omitted if the physician indicates "do not label" on the prescription.

#### NAMING OF MIXTURES AND COMBINATIONS

Mixtures of drugs would be designated as Mixtures. For example, the mixture now available as Coricidin would be labelled as Chlorpheniramine, Aspirin and Phenacetin Mixture. The brand name Coricidin would not be included in the labelling. Instead, the name, Chlortrimeton, since it is a proprietary ingredient, would appear in parenthesis in type one-eighth the size of type used to name the ingredients of the mixture beneath the name of the ingredient Chlorpheniramine, together with the manufacturer's name. The labelling of mixtures should also carry the chemical names of each ingredient,

in fine print, with the generic or common name in parentheses and the amount of each ingredient in each tablet, capsule, or unit of liquid measure should be indicated in both milligrams and in grains. The latter stipulation would not be a requirement of the labelling applied to the package dispensed by prescription to a patient. These are of interest primarily for the pharmacist, pharmaceutical chemist, or the toxicologist in the event this information is required in cases of poisoning, homicide, determination of purity or biologic assay. An expiration date should be indicated for drugs which have expiration dates.

#### LABELING OF OVER-THE-COUNTER DRUGS

Producers of "over-the-counter drugs" are likewise enjoying special privileges which are far from being in the public's best interest. As a matter of fact, the surveillance of the firms packaging over-the-counter drugs is not as close as that of firms packaging prescription drugs. The FDA has no surveillance over claims of efficacy of over-the-counter drugs made in advertisements, in newspapers, magazines, telecasts, etc., and Federal agencies empowered to take action seldom do so.

Pharmaceutical firms which package a prescription drug which may also be sold over the counter in certain dosage forms often make claims in advertising in newspapers and nonprofessional magazines that would not pass the scrutiny of the FDA. I am thinking specifically of Neosynephrine, packed by Winthrop, in the form of nose drops, which is available over the counter, which, in lay journals is claimed to be effective for "colds." The labeling of over-the-counter drugs should follow the same pattern as that of prescription drugs and the advertisements should be as informative concerning full disclosure and efficacy as prescription drugs.

#### REPACKAGING OF DRUGS

Drugs dispensed by "repackaging firms" should indicate the source of each ingredient, that is, the name of the manufacturer from whom each chemical was purchased. The same requirement should apply to firms distributing a repackaged drug under a brand name or to mixtures. The large manufacturing firms who buy drugs from other firms should indicate on the package that they did not make the drug, by indicating its source, in the same manner as required of the "repackaging houses."

In addition, the American Medical Association should indicate in its code of ethics that physicians should own no stock or interest in any pharmaceutical firm, repackaging firm or pharmacy, and insist that this be enforced at the county society level. No conscientious, ethical physician who lives up to his oath should object. The patient is at his mercy and purchases what he specifies and there should be no conflict of interest.

#### IMPACT OF GENERIC LABELLING

Should one ask, "Will such a change in labelling as is being proposed be in the public's best interest?", the answer will obviously be, "It will." If one asks, "How?", the answer would be, "Everyone will learn and know the real name of a drug"; the physician, the pharmacist, the nurses who take care of the patient, the pharmacist's attendants and the relatives. Pseudonyms and aliases ultimately will disappear, without one bit of harm to the public.

Will physicians be restricted in their prescribing prerogatives if such a plan were placed into effect? The answer is, "Not at all." The physician will still be able to prescribe the drug he chooses, manufactured by the firm he prefers and in which he has confidence. He still will be able to prescribe in the dosage form he chooses and has always used in prescribing the drug. If, for medical reasons, a physician does not

wish a patient to know the identity of a drug, it will still be his prerogative to request this.

Pharmacists will still be required to supply to a patient a drug a physician requests, made by the manufacturer that the physician indicates and prefers. An ethical pharmacist will not substitute an inferior drug, as has been argued that he might do by those who feel that the brand names protect the patient and protect the physician's right to prescribe as he sees fit. If a physician does not object to labelling, the patient is then told what he is to receive and can insist that the pharmacist supply exactly what is prescribed and what the patient is paying for. Patients may be able to shop and obtain a drug at its lowest cost.

The days of mystery in medicine are over. Medicine is a science as well as an art. Patients are not murons. They read, and they are becoming more knowledgeable, and there is no reason for not disclosing all pertinent information to everyone for the proper and safe use of a drug. By using a standard name for each drug, full disclosure will be provided for all persons involved. The chemically oriented physician will have the chemical name. The pharmacist, the pharmaceutical chemist, the toxicologist and the physician who have become accustomed to using brand names will have them at their disposal should they wish them, but in time they will be de-emphasized and brand names hopefully will disappear. Existing hospital formularies can be abbreviated and new ones prepared in hospitals where none now exist. Pharmacists will find that in due time physicians' prescribing habits will change and they will need fewer items on the shelves.

#### GENERIC EQUIVALENCY

The arguments for retaining brand names prescribing have been shrouded and wrapped in that nebulous cloud referred to as "generic equivalency." The paucity of convincing and well-documented data of clinical significance causes one to suspect that this situation has been grossly exaggerated. Should a product of one pharmaceutical firm be chemically equivalent and more effective biologically, then this would be a selling point which a pharmaceutical firm could use in its advertising. The firm could, with justification, capitalize upon this point in its advertising and utilize it as a reason for selecting the drug of that particular firm. The firm thus could boast that its product is superior and has this advantage over that of competing firms. Considerable stretch of the imagination is required for one to see the justification for the use of an alias for designation of a product merely on the basis of generic equivalency. For example, should Ether prepared by SQUIBB be found to be biologically and clinically more effective than that of competitive manufacturers, and I doubt that it would, a physician who is aware of this would request Ether-Squibb. In the event Lidocaine U.S.P. prepared by Astra were demonstrated to be biologically and clinically superior to products distributed by a competing firm, this would not necessarily interfere with a physician's choice to prescribe Lidocaine-Astra instead of the alias, Xyllocaine. Neither would have interference of the physician's prerogative to prescribe the product he deems most effective clinically, if indeed he can make such a distinction, and the best interest of the patient will still be served. The question of generic equivalency has been "ballyhooed" with both scientific and pseudo-scientific data, so that it is virtually impossible to determine what is fact and what is fancy. The situation is almost laughable. Much is said about crystal size, the effect of binders and mordants, coating, etc. This all sounds impressive and has some basis of fact, no doubt, Mr. Chairman, but no one has said what happens to one of these elite, "non-

generic brand name drugs" when it is introduced into the stomach of a patient, the contents of which are not known, the acidity of the juices in the stomach are not known and other variable factors which are bound to exist are not known. What happens to one of these pills or capsules after they are introduced into the stomach and are followed by a martini, potato chips, shrimp remoulade, turtle soup, a steak, potatoes, some wine, salad and desert. If a drug is readily soluble, the chances are excellent that chemical equivalency equals biological and clinical equivalency.

One cannot deny that in some cases biologic potency may vary from one product of one manufacturer to another or even from batch to batch of a given drug by a given manufacturer, but how much is known about all of this which is factual and clinically significant? It appears to me that no one has given this matter much thought over the years and now the matter is being called to the attention of the scientific community and we are becoming aware of something that only time will prove whether or not is important. The effectiveness of a drug taken before breakfast may differ from that of taking the same drug before lunch or before supper or at bedtime, or from one day to the next. Such variable factors as fever, the presence of other drugs, hydration and liver and kidney function may influence the efficacy of a drug. Generic naming must not be confused with generic equivalency. The two terms are distinct, separate entities and not synonymous.

#### ACCEPTABLE STANDARDS

Standards formulated by the U.S. Pharmacopeia, the National Formulary and other agencies are acceptable, reliable standards and should be adhered to at this time until additional well documented information is available, at which time these agencies and scientific groups can revise their standards. As time passes we will no doubt learn more about the so-called "biologic equivalency" and its clinical importance. The standards will then be modified in accordance with our added knowledge, but until such a time the present-day standards are adequate.

There must be a beginning to make order out of chaos, and now is the time to effect changes. The vociferous displeasure which will be voiced will be intense but it can be readily parried by asking, "Is what is being done in the public's best interest?" How can full disclosure of all details pertaining to a drug be anything other than in the patient's best interest?

#### COMPLEXITY OF GENERIC NAMES

The greatest objection and difficulty that one will encounter in attempting to establish uniform nomenclature of drugs will be the complexity of some of the generic names which have been assigned to drugs. This is a matter that will have to be resolved with time. Some names undoubtedly will have to be simplified. Chlorpheniramine, mentioned in the description of Coricidin, is a name that borders on the complex side. There is a tendency among physicians to abbreviate names or use "nicknames." For instance, cyclopropane is usually referred to as "cyclo" by anesthetists. Muscle relaxants are facetiously referred to as "arrow poisons." In the case of the muscle relaxants, for example, Decamethonium is the generic name for Scurine and succinylcholine is the generic name for Anectine or Succostrin. Tubocurarine is a non-patented generic name for Curare and should be retained. These generic names are not difficult to pronounce or spell.

The purpose, Mr. Chairman, in my recommending that the chemical names be included on the package and in the other types of labelling is that one wishing to know the chemistry would have it available. The United States Adopted Names, a committee com-

posed of members of the U.S.P., N.F., Council on Drugs of the AMA, and the FDA, now attempts to incorporate in the name an indication of the chemical nature of the drug. If it were known that the chemical names are required on the labelling, perhaps the USAN would be more inclined to adopt the simpler names and not attempt to follow a chemical type of nomenclature.

#### LICENSING SYSTEMS

A code of good manufacturing practices and other criteria with a licensing system and registration for all individual pharmaceutical products is essential. All drugs would then meet the same standards. This, of course, would be imposing the same requirements on all firms manufacturing drugs equally and would do much to solve the problem and obviate the objection which allegedly exists that some drugs are chemically equivalent but not biologically equivalent. This is not an impossible problem to resolve.

#### FIXED RATIO COMBINATIONS

Physicians have, for years and years, used drug combinations. They will continue to use drug combinations in the future. I see no end to this practice. It is reasonable and logical in some cases. There is a difference, Mr. Chairman, between combinations and fixed ratio combinations. Combinations are essential and not necessarily objectionable. However, there are objections to the use of fixed ratio combinations because no two individuals respond to the same manner to a given drug. The argument advanced in the use of fixed ratio combinations is that a patient then would receive all the medication in one tablet, capsule or teaspoonful of solution or injection. The use of fixed ratio combinations is as logical as selling combinations of salt and pepper in fixed proportions. I am sure that if pepper were combined with salt in a fixed ratio and sold on the premise that one would require only one shaker on the table instead of two the product would have limited sale. Individual tastes vary; some people would like more salt and less pepper and vice versa.

The same principle applies to drugs in combinations of fixed ratio, particularly when they are dissimilar chemically or therapeutically. I have in mind a particular fixed ratio combination which has been recently introduced on the market under the brand name of Innovar. This is a mixture of a new narcotic of great potency, Fentanyl, and a new "tranquillizer," Droperidol. The narcotic causes rigidity of the muscles and interferes with respiration. The tranquillizer has the capability of paralyzing the nerves supplying the blood vessels and causing a fall in blood pressure. The combination is packaged in a ratio of fifty parts of the tranquillizer to one part of the narcotic. When this combination is used, certain individuals overreact to the narcotic while others overreact to the tranquillizer. Such a mixture of fixed proportions is illogical. It has been promoted and, because of its newness, detailed information of its pharmacologic properties is lacking or it has not as yet drifted down to the practicing physician through the normal and unbiased drug information channels; that is, from physicians who actually are familiar with the drug and recognize its side effects. When an N.D.A. of a new product of this sort is approved by the FDA, the "detail men" are the first to acquaint the physician with the product. The package insert, in these cases, provides all of the required available information but this is not sufficient because in many cases the drug has been tested by individuals whom we facetiously refer to as "testimonial writers." Seasoned researchers are not interested in testing drugs in the manner proposed by a sponsoring manufacturer. The data on the N.D.A. applications is not always obtained from research of the highest quality. Side actions and other adverse effects often

remain virtually unknown until a drug is subjected to widespread general use or is studied carefully by seasoned researchers. When a drug is first introduced, we are not fully aware of its actual usefulness and limitations. It is only with time and sad experiences that a drug finds its proper niche in therapeutics.

#### ANTIBIOTIC FIXED RATIO COMBINATIONS

Some fixed ratio combinations of antibiotics and chemotherapeutic agents available on the market are deemed ineffective in certain cases, from data studied by the Review Committee of the NAS-NRC. Inasmuch as the physicians and other scientists on these committees are knowledgeable in their fields and not biased, I would accept their recommendations. In instances where they say that a fixed ratio combination is not effective, this combination should be withdrawn from the market unless supplementary data of proof of efficacy is supplied by a manufacturer. Withdrawal of mixed ratio combinations of these types does not hamper the physician from using combinations. A physician will still be able to prescribe two of three drugs in quantities to suit an individual patient. Antibiotics and chemotherapeutic drugs are far from innocuous drugs. Each type is capable of producing sensitization, kidney, liver, and in some cases nerve damage. Where fixed ratio combinations are used, only one ingredient may be effective but the amount in the mixture is insufficient. The physician may increase the dose if the response is good but not as great as anticipated. It is thus possible for the amount of the ineffective agent to be increased above the toxic level and cause harm to a patient.

#### CHLORAMPHENICOL

I have been asked to comment on the use of Chloramphenicol (Chloromycetin). Chloramphenicol is a valuable drug and certainly nothing should be done to curtail the intelligent use of the drug by knowledgeable physicians in instances in which it is indicated. It not only would be difficult to legislate when a physician should or should not use Chloramphenicol, but such a step would be ill advised. There is no doubt that there has been and probably still is some abuse of the drug. This appears to be decreasing. There are, however, other drugs in other categories that are equally as hazardous as Chloramphenicol but in other ways. They, too, are used thoughtlessly and indiscriminately in certain cases.

#### PHARMACY AND THERAPEUTICS COMMITTEES

The hospital pharmacy and therapeutics committees required by the Joint Commission on Accreditation of Hospitals in accredited hospitals could manage the problem of proper drug usage quite effectively. These committees, however, should be strengthened and be more active than they now are. Their scope should be broadened to include the reporting, not only of adverse reactions, but a review of a drug utilization and promotion of drug education to the hospital visiting staff. The premise upon which the Joint Commission for the Accreditation of Hospitals bases its requirements of accreditation, as far as the medical and surgical visiting staff is concerned, is that the visiting staff governs itself. The philosophy that the staff governs itself can be workable. It is effective in certain, but not all, hospitals. Tissue committees are quite effective in most hospitals in preventing unnecessary surgery. Utilization review committees which review duration of patient stay and hospitalization likewise have been effective; therefore, the same principle could be applied to drug utilization. The pharmacy and therapeutics committee could challenge a physician for using a drug such as Chloramphenicol in situations where it was not indicated or for administering the drug without performing the proper bacteriologic and sensitivity stud-

ies. Legislation is not the answer to this problem. The solution must be by education and self-regulation by the medical profession. The use of drugs presenting hazards similar to Chloramphenicol could be "policed" in a similar manner.

#### ROLE OF THE AMERICAN MEDICAL ASSOCIATION

I realize that the American Medical Association has, over the years, differed with Congressional leaders and governmental agencies in its views concerning the dispensing of health care to the public. I prefer not to say that I agree or disagree with the pronouncements that have been made by the Association because I must admit that I am not familiar with both sides of the story in some cases. I have either heard or read biased sides presented by physicians or read biased sides presented by the government in the news media. Therefore, it is difficult for me to have strong feelings one way or the other in this matter. Again, when in doubt, I apply the rule which serves as my guide—"Is what is being proposed in the best interests of the public?". I would like to emphasize, Mr. Chairman, that medicine, as it is practiced today, is the best in the history of the world. It would not be in the state of development that it is today had it not been for the American Medical Association. Many years ago Abraham Flexner submitted a report on the deplorable status of the various medical schools in the United States. Following the presentation of this report the American Medical Association took the initiative and established uniform standards of medical education in this country. We then surpassed the rest of the world as far as medical standards of medical education and medical practice are concerned. The American Medical Association is a scientific body which can, if it wishes, assemble scientific and medical talent of the highest calibre. The association has and must have a political superstructure. The part of the medical association that the public knows is the "political portion," which is a small portion. After all, the American Medical Association is a democratic organization. It is organized and operates in many ways as does the Congress or the various State legislatures. It is governed by an elected House of Delegates. The actions of the Congress, as depicted in the press, sometimes appear absurd. Likewise, the actions and resolutions of the American Medical Association may appear to be ridiculous and ill conceived to one on the outside looking in who does not know all the ramifications involved in a decision. The portion of the American Medical Association that one does not see is the conglomerate of scientific councils and other divisions not involved in medico-political affairs. The Association may be likened to an iceberg, one-eighth of which protrudes above the water. This portion is the political portion which the public sees.

The functions of the American Medical Association of which the public is not aware are the scientific functions. This is the portion likened to the iceberg which is beneath the water. The Council on Medical Education, which inspects and approves medical schools, internships, residencies and postgraduate programs, a costly and important undertaking, is a little-known body of the Association which serves the best interests of the public. The Council on Drugs, of which I am a member, is promoting the formulation of drug utilization policies, adverse drug reaction reporting and dissemination of medical knowledge to physicians. The activities of the Association are financed to a large extent by physicians' dues and voluntary contributions and to a lesser extent from income from advertising in periodicals published by the Association.

I may appear to be idealistic and naive in making this statement, but I believe the governmental agencies should take into their

confidence and work closely with the various scientific bodies of a national stature, including the AMA, and attempt to cooperate and work jointly for the benefit of all. Any legislation which is hastily passed, ill conceived, is restrictive and appears to encroach upon the physician's prerogative to make decisions and to practice medicine as he deems best for the patient will be construed as punitive and will arouse resentment and resistance. A frustrating situation will be created and the main goal, namely, providing the best health care possible for the public which both the government and the American Medical Association are obligated to provide, will not be attained.

#### THE PHARMACEUTICAL INDUSTRY

In advocating uniform nomenclature I am not castigating or opposing the pharmaceutical industry. One must remember that the pharmaceutical industry operates in a manner similar to any other industry and its primary goal is profits. It has, however, a greater responsibility to the public than any other industry. The patient does not make the decision as to which and whose drug is to be brought. The physician does. The industry should remember this fact but does not always do so. If the profit incentive is removed, then expansion and progressive development of the industry will be stunted and this would not be in the best interests of the public. I am sure that you have information from your hearings which indicates that some pharmaceutical firms have been ruthless, have fixed prices, and have committed acts which have not been in the public's best interests. Nonetheless, the pharmaceutical industry has also contributed its share to the progress of medicine in this country. We need an active and vigorous pharmaceutical industry. There should be regulation of the industry but such regulation should be nonrestrictive in nature. It should create a more competitive environment than now exists and permit a firm to expand and progress and to develop significant and better products and not duplicate products. Any restrictions which are placed upon a firm that remove incentive will not be in the best interests of the public or the medical profession. Restricting monopolistic practices will, of course, encourage competition which is healthy and which is in the best interests of the public.

The question, Mr. Chairman, then is not should we abolish brand names and use generic names, but when? The sooner the better. It can be done, and it will be a step forward in medicine.

I think I have said enough, Mr. Chairman; thank you.