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Food Drug Cosmetic Law JOURNAL

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THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

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Food Laws and Their Influence on International Trade.—This article, which begins on page 453, was presented by *Paul M. Karl* at SOS 70, Third International Congress on Food Science and Technology. Mr. Karl contends that worldwide harmonization of national food laws has become a modern necessity, because the demand for food from other countries has grown, "(b)ut diverging food laws have created trade barriers even higher than any presented by tariffs or quotas." To facilitate harmonization, Mr. Karl suggests an interstate treaty or similar agreement carried out by one international body, so that differing results and overlapping would be avoided. Above all, the author says that harmonization should consist of a food act based exclusively on the principles of health and honesty, with elaboration of interpreting rules entrusted to competent expert groups. Mr. Karl is associated with CPC International Inc.

Trends in Product Safety Protection.—*Sam Hart*, Director of FDA's Office of Product Safety, presented this article at the Federal Bar Association Annual Convention on September 18, 1970. The author says that the voice of the consumer is being heard and heeded, and notes the additional responsibilities that FDA has assumed in response to the growing consumer movement, such as the establishment of the Federal Hazardous Substances Labeling Act, Child Protection and Toy Safety Act, and National Commission on Product Safety. Congressional activity with reference to consumer legislation is also mentioned, and includes a proposed independent consumer council to represent the consumer and appear on his behalf before Federal departments and agencies, improved food standards, the Delaney Amendment, and many proposed safety laws. This article begins on page 460.

Remarks on Medical Devices.—*Larry R. Pilot* is Special Assistant to the Commissioner of Food and Drugs, FDA. He discusses FDA's historical interest in devices in the light of the Administration's present activities and contemplated future changes in order to achieve a better understanding of the problem of legislation for medical devices. Since new legislation is needed, Mr. Pilot urges non-government interests to exercise initiative and imagination in developing essential criteria and concrete proposals. The article, which begins on page 466, was presented before the Food and Drug Section of the Federal Bar Association in Washington, D. C., on September 18, 1970.

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Food·Drug·Cosmetic Law Journal

Legal Considerations for the Pharmacist Undertaking New Drug Consultation Responsibilities

By SIDNEY H. WILLIG

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PHARMACISTS TODAY ARE SEEKING to develop new avenues of service to the public and their co-professionals in the delivery of health care.[1] This is in keeping with the gradual expansion of their undergraduate and postgraduate curricula, and the upgrading of faculty and facilities that have enabled them to undergo substantial preparation in both the chemical and medical sciences.

In recent years, pharmacy graduates, both in community practice and academic pursuits, have found these capabilities a source of personal and collective frustration, in that traditional practice did not bring into useful activity the information and abilities that they had accumulated.

For the pharmacist in academia, this problem was solved in the past decade when industry and government, well aware of his expertise and greatly in need of it, offered careers and consultancies. The pharmacy schools have provided ideal recruitment potential and, as a result, have encouraged even greater sophistication in curricula,

[1] *Action in Pharmacy*, 1, 1, (January, 1969).

whether in the substance of the mandated pharmacy subjects or in elective offerings. There is every sign that this development will continue, and it has been highly salutary for the profession of pharmacy and gained for it long-overdue recognition in the challenge of new accomplishment, as well as in status and compensation.

Frustrations exist for the pharmacist in community practice. While third-party payment systems and the availability of more health-care dollars has, along with the inflationary boom, increased community pharmacy proprietors' income before taxes, and pharmacist employees in community and hospital pharmacy have enjoyed wage increases and small beneficial changes in status, their public and institutional image has not been enhanced. As a matter of fact, in some localities a keen observer may note circumstances that make for pessimistic observations. Pricing practices have been assailed. Attempts to keep drug, device and cosmetic sales collateral to pharmacy practice, and in pharmacies only, have been met by rebuff at the hands of the courts and legislators.

In recognition of this trend, the hospital pharmacist, seeking to distinguish his service potential in an institutional atmosphere where team action is requisite to overcome personnel shortages in physicians and professional nurses, has bid to become the physician's close assistant in institutional drug administration.

The fact remains that he can only move from one position to the other if the hospital has a pharmacist (and many do not), and if he feels confident that he has the current information and ability to assume the new role in augmentation of the traditional one.

In all hospitals, therefore, where pharmacists are available, they patently advise their physician colleagues as to the details of usage and manufacture of classes of drugs or particular brands of drugs. In some instances, this advice is brought out in committee work, in others by internal publications. In most instances, it is given in response to specific questions put by the would-be prescribers. They also help keep interns, nurses and other hospital personnel current by giving talks to groups and visits to wards.

In a few institutions, members of the pharmacy staff are enjoying a clinical experience by accompanying either physicians on hospital rounds, or nurses in administration of drugs. In both instances, reports indicate that their presence and assistance is welcome and has advantages for the patient. It is in this clinical area that the hospital pharmacist, then, is seeking to use his great education and experience

in a manner to enhance his usefulness and prestige within the institutional setting.

The community pharmacist, as he serves the smaller institutions, may not economically afford the luxury of seeking or offering clinical experience in the nursing homes or small hospitals. His clinical experience is a face-to-face relationship with patients who bring him prescriptions for dispensing, buy non-prescription drugs and frequently ask his advice as to purchases of over-the-counter drugs, devices or cosmetics. As to these latter, he sees himself threatened by discount operations that use these sales as "loss leaders" for more lucrative sales in soft goods, furniture, cosmetics or own brand merchandise. Further, these threats come from sources other than the usual drug outlet. He must operate in competition with supermarket and department stores, novelty chains and cosmetic boutiques. None of these, however, can compete with him on the basis of his professional ability and comprehension. Therefore, in some instances, he has turned his establishment into an exclusive prescription pharmacy. To this he sometimes adds surgical goods and sickroom supplies.

Whether this is economically sufficient may be doubtful. A solution has, therefore, been offered that may satisfy both needs more fully. Since the pharmacist is a storehouse of knowledge on the character, the safety, the efficacy of drugs, as well as their availability, should he not bring this ability into service for the benefit of his patrons?

From this, the concept of the pharmacist as a keeper of his patron's drug profile has come into being.

The Contemplated Act

If the pharmacist keeps a record of the drugs prescribed for his patrons, he can question a prescription order that may threaten an undesirable interaction for the patient by calling the prescriber and advising him of the problem as he sees it.

At the same time, from the drug profile, he can guide the patron in safe choice of over-the-counter remedies that might otherwise modify or interact with prescription medication currently in use by the patron.

To keep the profile current and complete, the patient will either have to obtain all drug items from the particular pharmacy, or advise that profile-bearing pharmacy of any drugs or prescription medication obtained elsewhere and identify them for the record.

Questions are raised that center about ethical proprieties when the pharmacist finds from the profile that the prescription order he has just been given to dispense, or the copy he has been given to record, presents some threat of undesirable interaction, or overdosage through synergism, with drugs formerly or currently in use by the patient. In the broad sense, they raise legal questions as well. These range from possibilities of liability in terms of breach of contract, or the torts of negligence, invasion of privacy and the physician-patient privileged communication, and even libel and slander.

Breach of Contract

If the pharmacist offers to provide and maintain a patient's drug profile for his patron and his family, consideration in the form of fairly exclusive patronage is implicit. In short, out of the relationship which starts with the offer of a promise to carry on a beneficial procedure,[2] a discussion as to its purposes and its merits, and ongoing consideration for the promise of performance by the pharmacist in the form of profit,[3] are we not describing the hallmarks of a contractual relationship? We may view it as single or serial. As a matter of fact, each individual sale represents performance of a contract, and that is what the law of sales, the theory of breach of warranty and the uniform commercial code are all about.

Therefore, while pharmacists are thinking in terms of "service" to which the remedy for breach of contract applies,[4] patrons and courts can probably readily perceive sale of "products" to which remedies in breach of warranty,[5] express and implied, apply.

If the pharmacist thus undertakes an additional duty to overlie the service and sale of products normally considered, the contractual remedies for breach will undoubtedly be made available to the pharmacy patron involved. Not only must the additional agreed-upon activity be consistently and well performed, but it is plausible to expect that on such arrangements the pharmacist may be held liable even in the absence of proof of negligence.[6]

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[2] *Noel v. Proud*, 13 Neg. Cases 2nd 871 (Kansas 1961).

[3] *Winterbottom v. Wright*, 10 *M & W* 109, 152 *Eng. Rep.* 402.

[4] *Diblee v. Groves Hospital* (following *Perlmutter v. Beth Israel, N. Y.*), 364 P. 2nd 1085.

[5] *Highland Pharmacy v. White*, 144 Va. 106; *Smith v. Denholm & McKay Co.*, 288 Mass. 234; *Henderson v. National Drug Co.*, 23 A. 2d 743.

[6] *Gottsdanker v. Cutter Labs.*, 182 Cal. App. 2nd 602, 79 ALR 2nd 301.

Negligence

In the personal inter-relationships that occur between professionals and the public they service, responsibility for negligence, unintentional as it is, depends on the presence of a duty in law. Obviously, as a pharmacist, one has a legal duty to the patient to deliver to him the exact drug ordered, in proper unadulterated condition and labeled as directed.[7] The duties of proper storage, handling, buying from reliable sources,[8] measuring and counting accurately and checking labeling with proper directions, all stem from the legal duty in dispensing. Any failure, whether omissive or commissive, in the careful and prudent exercise of that function, in comparison to what the public has a right to expect from the average pharmacist or the pharmacist's peers in the locale, makes him a candidate for liability. So, given a duty and failing in it, if the patient should thereby be harmed as a direct result of the failure, he can make out a *prima facie* case in negligence.[9]

If screening a patient's drug profile is a duty he accepts—or that most pharmacists accept—this undoubtedly will become part of the standard of care which will serve to measure proper exercise of the duty of dispensing drugs.[10]

The pharmacist stands forewarned with respect to his role as it affects prescription drugs. He assumes a traditional and valuable function as a consultant in drug utility, a legally and ethically questionable one as selectant. The latter function has been explored at great length in a previous article by this author[11] and others. The fact is that existing antisubstitution laws and board rules of practice and professional codes are constant reminders that the legislative and administrative authorities see no prerogative for the practicing pharmacist in undertaking unilaterally the replacement of prescribed drug products. This is true in every aspect of pharmaceutical practice, and this author has previously explained that the Federal Food, Drug, and Cosmetic Act's definition and subsequent interpretation of "misbranding" is simply equatable with substitution.

To further substantiate and encourage these views, it has been variously held that a pharmacist will not be found liable for harm

[7] *Thomas v. Winchester*, 6 N. Y. 397.

[8] *Willson v. Faxon, Williams and Faxon*, 208 N. Y. 108.

[9] *Knoefel v. Atkins*, 40 Ind. App. 428; *Dunlap v. Oak Cliff Pharmacy*, 288 S. W. 236; *Faulkner v. Birch*, 120 Ill. App. 281.

[10] *Favolara v. Aetna Insurance Co.*, 144 So. 2nd 544; *Norton v. Argonaut Insurance Co.*, 144 So. 2nd 249.

[11] Willig, Sidney H., "Ethical and Legal Implications of Drug Substitution," FOOD DRUG COSMETIC LAW JOURNAL 23:284 (June 1968).

alleged by the user of the prescription he filled, where he has filled it correctly and in strict accordance with the physician's prescription order and dispensed from the manufacturer's original package. In *McLeod v. W. S. Merrell* (Florida),[12] the court said:

> Obviously the patient-purchaser did not rely upon the judgment of the retail druggist in assuming that the drug would be fit for its intended purpose. This confidence had been placed in the M.D. who prescribed the remedy. Supposedly, he in turn had placed his reliance on the representations of the manufacturer.

At the present time, outside of blatant dosage or directive errors that the average prudent pharmacist is supposed to be able to note and forestall, errors as to choice of drug are the physician's problem.[13] The physician screens out their possibility by his case history discussion with the patient. When a drug that interacts with other medication creates difficulties for the patient, it creates problems for the physician unless it can be shown that he was misled or misinformed by the manufacturer.

If the pharmacist wishes to assume the screening function, he must do it properly and on a full-time basis. Otherwise, since he is the last chance of sparing the patient, his failure to check the drug profile record *this* time or his mistake, having done so, will likely be the proximate cause of the patient's harm from the drug in the eyes of the Court.[14]

This case is not very different from the case of the pharmacist in the hospital who works closely with the physician and nurse in direct care and drug administration to the patient.

An institutional arrangement that utilizes the pharmacist's skills in this fashion interposes another safeguard in prescriptive and administrative procedures involving drugs.[15] It also establishes another area of responsibility for errors. While the pharmacist will interview patients and observe for possible adverse drug reactions or interreactions, the physician and the nurse will also retain these data, which is their usual responsibility.[16] So in a sense, while we have another safeguard, and potentially a highly desirable one, we also add another target defendant in terms of personal and employer liability.

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[12] *McLeod v. W. S. Merrell Co.*, 174 So. 2nd 736 (1965).

[13] *Magee v. Wyeth Labs, Inc.*, 214 Cal. App. 2nd 340. *Sandal v. State*, 13 ALR 1268; *Tombari v. Connors*, 85 Conn. 231. *People's Service Drug Stores Inc. v. Somerville*, 161 Md. 662.

[14] *Brewer v. Knight Drug Co., Inc.*, 55 Ga. App. 352; *Watkins v. Potts*, 65 ALR 1097; *Darling v. Charleston Community Hospital*, 33 Ill. 2nd 326.

[15] "Hospital Medication Errors," *J. A. M. A.*, 195, 31-32, (January 17, 1963).

[16] *Brown v. Hannibal*, 66 Missouri 588.

Further, if this arrangement is held desirable and carried on for a while, its abandonment might embarrass the hospital employer when a patient might infer that drug damage she suffered might have been prevented had the hospital continued its policy of using pharmacists in this manner.[17]

This does not mean that hospital pharmacists and community pharmacists must remain within the parameters of pharmacy practice set in the 1940's and 1950's. It does require, however, that all those who undertake the newer measures and functions be fully qualified to carry them out—that within each hospital and community unit all pharmacists be equally capable—and finally it requires that the profession as a whole be "in step" and qualified to be "in step." If you voluntarily offer and create a higher standard of careful practice, the public has a legal right to assume that pharmacists can and will consistently perform according to that standard. Colleagues in the associated professions of medicine and nursing will be similarly disposed and similarly expectant.

Like the possibility of breach of contract or breach of warranty action, such new procedures necessitate discussion and understanding with those who provide insurance for usual and traditional[18] activities.

As a matter of fact, since the locality rule is fast fading as a defensive mechanism in negligence and malpractice, courts may assume that where higher standards of care are available in other places, the profession in a particular locality cannot cling to lower standards, however uniformly, that endanger their patients.

In summary, there is no reason why pharmacists may not undertake additional responsibilities as to drugs, even though these responsibilities are normally those of the physician, nurse or others. This may lend greater safety to the dispensing and administration of drugs to patients, which is an important objective and motivation for change. Pharmacists must realize, however, that—jointly or severally—they are undertaking additional legal responsibility and the benefits must be weighed against the risks.[19] Further, they may not exceed the prerogatives of their own practice acts, nor independently intrude on those of physicians or nurses beyond the reasonable application of agency principles.

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[17] *Kolesar v. U. S.*, 198 F. Supp. 517; *Ball Memorial Hospital v. Freeman*, 196 N. E. 2nd 274 and *Bing v. Thunig*, 143 N. E. 2nd 3.

[18] *Fiorentino v. Wenger*, 272 N. Y. S. 2nd 557.

[19] *India Towing Co. v. U. S.*, 350 U. S. 61; see Restatement (Second) of Torts, Section 402A.

Privileged Communications

Privileged communications are determined by statute and generally run from patient to physician. Where a state actually provides for such a privilege, (and many do not), it exists for the benefit of the patient, and not the physician. Pharmacists are really not involved in the legal pressures of this privilege.[20] When the physician writes out the prescription order, enters it on his record and hands it to the patient, it is a privileged communication if the state recognizes the doctrine statutorily. However, the patient immediately discloses it to the pharmacist for dispensing. Obviously, the pharmacist has an ethical obligation to maintain secrecy about the prescription order, except insofar as the patient may authorize him to divulge its contents to another. But there is no legal duty that depends on the fact that it is a privileged communication. Certainly, if the pharmacist asks the patient if he may call her present physician to advise him of a previous physician's prescription order, or prescription medication results, the patient can authorize it. The physician in either event, as previous or present prescriber, has no privilege he can legally preserve from disclosure in this ordinary course of events.

Invasion of Privacy

What if the patient leaves the prescription order for delivery of the medication later in the day? In the interim, the pharmacist checks its ingredients against the patient's drug profile and is concerned. He calls the prescriber and divulges the cause of his concern from the patient's record. Is this an invasion of the patient's privacy? It is doubtful that such an action is likely to sustain a lawsuit. There is nothing here to cause the patient harm, embarrassment and expense. It is done with apparent agency from patient to pharmacist, albeit assumed by the latter. It is limited by necessity to the patient's agent, the prescribing physician.

If the pharmacist is concerned about the highly unlikely possibilities of problems arising from privileged communications or claims of invasion of privacy, he need merely have the patient sign the profile chart, and authorize his inquiry and his divulgence as necessary to safeguard his use of drugs. This would be a simple recorded

[20] *Deutschmann v. Third Avenue R. Co.*, 84 N. Y. S. 887.

consent. It might be vulnerable to disproof if it were oral, but it would be legal too.

How about the physician and invasion of privacy? Once we go beyond the privileged communication statute, if one exists, and the ethical aspects of the patient-physician-pharmacist relationship, the prescription content contains no trade secrets, patentable formulae or mystic incantations. In short, the nature and description of the prescription order the physician wrote can only conceivably be foreclosed from disclosure by the patient, not the physician. When the motivation is good and for the patient's benefit, we may find physicians on occasion irate—but not likely with grounds to litigate.

Slander and Libel

Whether we consider libel oral slander, or slander oral libel, we know these as intentional torts of defamation. They hold their victim up to loss of money, reputation and status within the community. It is hard to see that passing on the contents of a patient's prescription order by one physician to the patient's new prescriber would ever be construed as a defamatory publication as regards the patient. In communicating the information to the new physician, however, or describing the situation to the patient, there may be times when a pharmacist's frustration may impugn the ability and the reputation of either physician.[21] When this happens, the pharmacist is in trouble. Of all the legal considerations, this might turn out to be the "trouble-maker" for those who desire to keep patient drug profiles.

Conclusion

In a sense, like the Good Samaritan, the pharmacist can undertake to help create safer, healthier and more technically perfect conditions of drug use. But in doing so, he must be willing to run the risk of criticism from the public as well as from his co-professionals in the event of failure.

We are dealing here with legal hypotheses, with cause and effect. There is little or no case law because these practices are being considered rather than universally performed. As to the principles involved, however, case law does provide us with predictability and understanding. **[The End]**

[21] *Tarleton v. Lagarde*, 16 So. 180.

Food Laws and Their Influence on International Trade

By PAUL M. KARL

Mr. Karl, Who Is Associated with CPC International Inc., Presented His Paper at SOS 70, Third International Congress on Food Science and Technology, Held in Washington, D. C., on August 10, 1970.

THE FIRST COUNTRIES IN OUR MODERN WORLD, predominantly in Europe, began to codify their initial food laws at just about the time that Jules Verne published his famous and thrilling book, "Around the World in 80 Days," in 1873.

For Verne and his contemporaries, a trip around the world in 80 days was an outstanding success which could only be accomplished by a few highly gifted people—and only then with the assistance of the international dateline somewhere down the Pacific Ocean. For us, a trip around the world has become a matter of hours and mainly a question of paying the fare. Technical development since Verne is outstanding and—even more important—is not limited to a "trip around the world." The production of food, its science and technology, have been progressing in similar, or even greater, strides. Admittedly, Verne and his contemporaries already knew processed food; not only products such as bread and sausages, wine and beer, but also "industrial" products, such as sucrose, for example. Compared with today's food technology, food production in Verne's time is like traveling with Christopher Columbus to the Americas instead of using a jet liner.

And yet the majority of food laws now in force are still tied to basic formulations prepared in the days of Jules Verne, and subsequently merely retouched in haphazard fashion here and there.

Antiquation and Diversification

Antiquation is not the only problem we face. A comparison of present food laws and regulations throughout the world—or only in

a given region—is characterized by numerous and often incredible divergencies, not only in its formal system, but also in material content. There probably was not much need for uniform regulations a century ago, because border-crossing trade in food products, except maybe some basic commodities, was minimal.

With increasing traffic facilities, however, consumers met their neighboring consumers across the border, became acquainted with them, and often liked their food and way of eating. As a result, the demand for food from other countries increasingly grew. Modern transport systems made it possible to ship food from more affluent countries into those where there was either a general lack of food or sparsity of certain commodities. But diverging food laws have created trade barriers even higher than any represented by tariffs or quotas.

A former German food law official illustrated the current food law situation with a few, yet striking lines. In his "Credo of World Food Laws"[1] he stated:

> Food laws applicable not only in Europe but also in the whole world are a hodgepodge of archaic patchwork regulations far behind the times, the technology of food and the needs of consumers.

These obstacles in international food trade should belong to the past. We have to realize that the consumer's interest in high-quality food and its ready availability to him has nothing to do with his nationality. If we wish to achieve a uniform legislation, we have to give up some of our national legislative power. However, this is a small price to pay for the closer worldwide integration of food laws.

Causes of Dissimilarity

Trying to trace the reasons for these legal divergencies, we have to base our considerations on the assumption that scientific insight and knowledge should be the same in any country, disregarding its national borders. Furthermore, assuming that food regulations are, to a good extent at least, a scientific knowledge expressed in legal terminology, we must conclude that diverging food laws are either evidence of a lack of legislative logic, or that this legislation is influenced by interests other than the basic food legal principles.

I think we all agree that the principles of health and honesty in food production and trade should be the exclusive basis of each developed food law system. Both are ancient and approved legal

[1] Edmund Forschbach, "Wanted: A Credo for World Food Laws," 18 Food Drug Cosmetic Law Journal 93 (February 1963).

principles. For the first time they can be found in the culture of the Hittites, who had a highly developed social system in the district of today's Anatolia nearly 3,500 years ago. There is a clay plate in a Turkish museum with the following inscription (I put it into Shakespearian English to illustrate its venerable age):

THOU SHALT NOT POISON THY NEIGHBOUR'S FAT!
THOU SHALT NOT BEWITCH THY NEIGHBOUR'S FAT!

This is probably the oldest recorded food law which people have made. "THOU SHALT NOT POISON" means, You shall put on the market only wholesome and safe food. "THOU SHALT NOT BEWITCH" means, in this connection, You shall not mislead the consumer. These two legal principles of health and honesty in the food market can plainly and clearly be realized. Both principles have lasted for thousands of years. And they were realized anew a few years ago on an all-European level in the supreme rule on which the Commission for the Codex Alimentarius Europeaus (CAE), a forerunner to the Joint FAO/WHO Codex Alimentarius Commission, had based its work to create a European Food Codex. It reads as follows:

> Supreme law in honest food trade is the well-being of the consumer, his protection against damage to health and his protection against misguidance and fraud. All economic and technical considerations are subordinated to this supreme law.

Although all modern national food law systems are said to be based on these principles of health and honesty, the divergent legal philosophies of Roman and Anglo-Saxon jurisprudence, diversified cultural and social development, different eating habits, the repercussions of two world wars and the times of distress connected with them, resulted in food laws which, concerning their material content, legal system and formal structure, differ largely in each country. Additionally, a good deal of prejudice, misinformation, political interests and other considerations led the food law development astray. Let me mention just a few basic examples of major divergencies.

1) Food Additives

There are not only very significant differences regarding the acceptability—let alone permitted levels and applications—of single, specific food additives, there are also basic deviations in the definitions of food additives. Some major approaches in a rather simplified form are: A food additive is a substance:

a) which is not normally consumed as such;
b) which does not occur in nature—"foreign substance";
c) which has no nutritive value;

d) which performs a typical function; such as preservatives, antioxidants, stabilizers, colorants, etc.;

e) which is added to a food or otherwise becomes part of it.

If it is "generally recognized as safe" (GRAS) it is not considered an additive.

Each one of these basic approaches will, to some extent, overlap with the others. However, each single definition also will embrace a number of substances which the others do not. This is of practical significance, since the majority of food law systems are governed by the "principle of prohibition," which generally prohibits the use of differently defined food additives unless they are specifically permitted in so-called "positive lists."

2) **Compositional Requirements**

Vertical, product-related standards or ordinances specify primarily the maximum and/or minimum amounts of mandatory or optional ingredients. These, again, vary from one country to another. For instance, these include the maximum amount of nutritive sweeteners in a fruit preserve, the minimum drained weight in canned fruits and vegetables, the minimum fat content in oleomargarine, the maximum of unmalted carbohydrates in beer and, and, and . . . !

3) **Food Grading Aspects**

Food grading aspects also vary greatly from country to country. Again, just a few references: size grading of canned green peas, expressed in diameter or sieve size (either round or square mesh); syrup strength in canned peaches or other fruit in degree Brix; . . . and you name it.

Let us stop right here, even though it would be tempting to continue with aspects such as labeling, hygiene, contaminants, packaging and transportation, processing procedures, equipment, quality control and, last but not least, enforcement, which again differ from one country to another.

The influence of all these divergencies on the border-crossing trade with food products is obvious. The presence of a single, harmless food additive or a slight variance in compositional or grading requirements may cause a complete halt to a given food product at its borders.

It is also clear from these observations that a continuous modification and renewal of food laws on a nationalistic basis does not bring a solution. A further uncoordinated regulatory escalation would only add to the present confusion.

Worldwide Harmonization

A way out of this chaos can be found only in supranational or international harmonization of national food laws. This would offer an excellent opportunity to remodel and update antiquated provisions.

The idea of standardizing or harmonizing food regulations on a supranational or international level is by no means a creation of our days. Since the International Chemical Congress held in Brussels in 1894, European countries have been talking about the necessity of a *Codex Alimentarius Europeaeus*. Only in 1958 did this project gain shape when, through the initiative of Minister Dr. Hans Frenzel of Austria, a European Council for the Codex Alimentarius was formed to draft such a uniform Food Code. At a conference in Geneva in October, 1962, a Joint Commission of Food and Agriculture Organization (FAO) and World Health Organization (WHO) was founded and took over the project on a worldwide basis. During the years, considerable progress has been achieved.

While the Europeans were still talking, the Latin-American countries went to work. Already in the late 1920's, a "Codex Alimentarius Sudamericanus" was drafted. The project, however, faded out, and only 30 years later at the Sixth Latin American Congress held in Caracas in 1955, a Special Commission for the study of a *Latin-American Food Code* was formed under the chairmanship of Professor Dr. Carlos A. Grau of Argentina. Four years later, at the Seventh Latin-American Congress held in Mexico City in 1959, the first edition of a Latin-American Food Code was approved. This first version was followed by a second revised edition, adopted by the Eighth Latin-American Chemical Congress held in Buenos Aires in 1962 and published two years later. There exists a standing "Latin-American Food Council" which has the task to keep the Code up to date.

In 1964 and 1965, the Pan American Health Office, a regional office of WHO, issued a voluminous set of "Sanitary Food Standards" which have been submitted to the Health Ministers of the Central American Common Market Countries and Panama.

Turning to Europe again, I would first mention the body with the broadest geographical coverage. The Council of Europe undertook a European harmonization by means of suggested multilateral conventions, up to now, however, with little or no success.

The food law harmonization within the Common Market differs distinctly from all other projects, since it is based on an international treaty ratified by the national parliaments of the six member nations.

This treaty makes the harmonization of food laws and other technical regulations obligatory and forms a firm basis for the harmonization which all other endeavors regrettably lack.

Overlapping and Differing Results

Food Law Harmonization became a favorite pastime on the part of many of today's organizations. When FAO and WHO started their joint program for international food standardization, a survey on international organizations and their efforts in food law harmonization was compiled. This list, even in condensed form, occupies some 30 pages of the official report of the initial 1962 Session of the FAO/WHO Food Standards Program, and presumably since then became even longer. This is both encouraging and frightening at the same time. It shows the awareness of many groups in different sectors of our society as well as a great interest in an integration of our food regulatory systems. Also, however, it is a danger in itself. The multitude of harmonization efforts will inevitably lead to geographical and substantive overlappings and thus, again, to differing results. We may well risk a harmonization of our food laws into disharmony.

Many of the standardization activities from earlier years are now coordinated in their efforts with the Joint FAO/WHO Food Standards Program and this is good. Still, it is probably not more than a vision today to see one single worldwide body with the exclusive responsibility for food standardization the world over. And yet, I believe, this day will come. The Joint FAO/WHO Food Standards Program, assisted by integrated regional subgroups, would probably be the most successful candidate.

The Latin-American Food Code Council might wish to serve within the Joint FAO/WHO Food Standards Program as Coordinating Committee for Latin-America, just as the former European Codex Alimentarius Commission became the Coordinating Committee for Europe. The Common Market, which is obligated to harmonize its food laws on the basis of the Rome Treaty, should be further urged to cooperate even closer with this program.

Mechanics of Harmonization

Now let me touch briefly upon a final point relating to the mechanics of food law harmonization. As I have already stressed, the principles of health and honesty should be the sole basis of each food law system and constitute exclusively its legislative target.

Such a "Magna Charta" for food laws should always be left intact in its essence and be invariable. As a kind of constitution it should guide the development of specific food regulations. Compositional standards which deal with individual foodstuffs or special food groups must be a mere interpretation referring to products and branches and a specification of the basic principles. Contrary to the established rules framework, the interpreting provisions must be flexibly shaped and have the possibility of amendment so that they may be adapted to the technological and scientific progress in a quick and smooth manner, as well as to all changes in the needs of the consumers.

If you agree with me on this philosophy, any food legal codification—and likewise, any harmonization—has to start with a framework consisting of a basic food act, which sets the fundamental principles, the general definitions and the legal system. Only this basic framework, plus, perhaps, general regulations regarding the use of food additives, are worthy of legislative measures. The elaboration of interpreting rules can and should be entrusted to one or several committees of food experts, as was done in Austria more than a half century ago.

Summary

Permit me to summarize—and please consider this summary as my personal concern regarding world food laws:

1) The national food laws throughout the world differ from each other radically, and are in many cases to varying degrees outdated.

2) Harmonization of these laws on a worldwide basis has become a necessity of our days. It is an instrument essential to mutual understanding and a piece in the mosaic of international integration.

3) A legal basis in the form of an interstate treaty or similar agreement would facilitate harmonization and yield broader results.

4) Harmonization activities carried out by one international body, such as the Joint FAO/WHO Food Standards Program, would help to avoid differing results. This body may have subsidiary regional groups. A closer coordination with EEC Harmonization should be established to avoid harmonization into disharmony.

5) First step of food law harmonization is a framework consisting of a food act based exclusively on the principles of health and honesty. The elaboration of interpreting rules relating to specific commodities does not require legislative activity. It should be entrusted to competent expert groups. **[The End]**

Trends
In Product Safety Protection

By SAM HART

Mr. Hart, Director of FDA's Office of Product Safety, Presented His Article at the Federal Bar Association Annual Convention, September 18, 1970.

AN IDENTIFIABLE CONSUMER MOVEMENT has made itself known to us within the past few years. We have read of it in our newspapers and heard of it via our radio and television media. Many of our political leaders have expressed a particular interest and concern with it, and the food and drug administration (FDA)—whose basic commitment is, and always has been, to protect the American consumer from product hazards—has a vital role in it.

FDA has been enforcing federal laws to insure safe, pure, and wholesome food, safe and effective drugs and therapeutic devices, and safe cosmetics, and to insure that all of these products are honestly and informatively labeled and packaged.

FDA's Increased Responsibilities

In December 1968, FDA took on the additional responsibility of safety of products used in and around the home with the establishment of the Office of Product Safety. FDA has taken a special interest in protecting children with its activities under the Federal Hazardous Substances Labeling Act of 1960—which requires that certain substances intended for home use be labeled conspicuously to warn of potential danger because of their hazardous properties—chemical or toxicological. The Child Protection Act of 1966 amended the preceding 1960 labeling law to include, among other things, the authority to ban the sale of toys and other articles for children containing hazardous substances, regardless of their packaging. And in 1969, the Child Protection and Toy Safety Act was passed, autho-

rizing FDA to remove and keep from the market toys and other children's products with electrical, mechanical, or thermal hazards. This act is all-inclusive. Any hazard not specifically defined elsewhere is defined as a mechanical hazard by Section 2(d)(S)(9) of the Act. This law did not go into effect until the early part of this year. Since it became effective, our office has worked with manufacturers to correct reported hazards in these products. Some products already have been redesigned and others have been discontinued through cooperative efforts. We are drafting regulations for the implementation of this Act, and will check factories and retail outlets where toys and other children's products are sold.

Several years ago, FDA was responsible for banning X-33, a dangerously flammable waterproofing treatment for masonry, "cracker balls"—imported fireworks which looked like candy and certain cereal products and were mistaken for these by children, and certain imported dolls with highly flammable faces. More recently, FDA has banned carbon tetrachloride and certain dangerous fireworks, has removed flammable toy tunnels from the market, has warned consumers of a danger of injuries with certain older models of kitchen mixers, has warned consumers of the danger of carbon monoxide poisoning from charcoal briquets and proposed that a warning be placed on the packages, has alerted the public to the dangers of flammable clothing, and is presently involved in keeping miniature Christmas tree lights with faulty wiring from the market.

These are a few examples that illustrate the vital role in consumer protection that FDA has shared with other government agencies. The National Commission on Product Safety—authorized by law and appointed by President Johnson in May 1968—was established to "conduct a comprehensive study and investigation of the scope and adequacy of measures now employed to protect consumers against unreasonable risks of injuries which may be caused by hazardous household products." This commission issued its final report at the end of June, 1970, in which it recommended, among other things, that an independent consumer product safety commission be established as a regulatory federal agency concerned exclusively with the safety of consumer products. The Commission recommended also that this new agency be empowered to develop and set mandatory consumer product safety standards when necessary. Bills have been introduced in both the House and Senate incorporating the recommendations of the Commission.

Congressional Activity

There is a great deal of congressional activity presently on consumer legislation. A cabinet-level department of consumer affairs has been the subject of proposals for a number of years. One of the chief advocates of the Department recently has been Representative Benjamin S. Rosenthal of New York. In the 91st Congress, his Consumer Department bill (HR 6037) had almost 100 co-sponsors.

Representative Florence P. Dwyer of New Jersey, with about 60 co-sponsors, introduced a bill (HR 13793) in 1969 proposing a White House consumer affairs office to promote consumer interests and provide representation before other Federal agencies.

President Nixon, in his October 30, 1969 message on consumer affairs, requested legislation to make the White House consumer affairs office statutory, and to establish a consumer fraud division in the Justice Department. Representative Dwyer introduced the Administration bill (HR 14758) two weeks later.

In addition to the consumer department bill and the Administration proposal, hearings were held in 1969 on a Senate bill (S. 2959) to establish an independent Consumer Council, a non-government organization representing the consumer and appearing on his behalf before Federal departments and agencies.

After hearings before the House Executive and Legislative Reorganization Subcommittee, Representative Rosenthal revised his bill to substitute an independent agency for a Cabinet-level agency. The new agency would retain the advocacy functions envisioned for the proposed department, but responsibilities for enforcing laws would remain in the agencies where they are.

Subsequently, a compromise was worked out between the Rosenthal and Dwyer bills to establish an independent Consumer Protection Agency (CPA) and to strengthen and make statutory the existing White House consumer affairs office.

The Consumer Protection Act of 1970 (HR 18214), as it is known, would empower the agency to intervene on behalf of consumers in proceedings before Federal agencies and in certain lawsuits. Enforcement of consumer protection laws already on the books would be left with the agencies and departments already administering them.

This Act also would make permanent the Office of Consumer Affairs which now exists by Presidential order. It would strengthen this office's authority to set Federal policy among the 39 Federal departments and agencies charged with some aspect of consumer protection.

Among the more controversial powers of the agency would be the authority to arrange for testing of products and to publicize the results of such tests, including brand names. Both the Consumer Protection Agency and the Office of Consumer Affairs could act on citizen complaints or develop their own complaints. This bill is now in the House Rules Committee awaiting a rule outlining conditions under which it may be brought to the floor for a vote.

A Senate committee has endorsed, in principle, a bill similar to the House bill, although there are numerous differences in detail This bill awaits final Committee action.

Numerous bills have been proposed to improve food standards. One would establish a Federal Inspection Program for egg products, and then would set up a similar inspection program for fish. Both would require stronger state and local programs.

The Delaney Amendment of the Food and Drug Act requires that HEW remove from the market any food additive shown to cause cancer in animals or man—no matter what the dosage.

The Federal Trade Commission and FDA are investigating the effect on health of enzyme-active household detergents to determine whether they cause dermatitis and pulmonary symptoms.

Numerous safety laws have been proposed—for example, one would improve railway safety by increasing federal controls; another would give the Secretary of Transportation wide power to establish safety standards for boating and would require all users of boating equipment to display evidence of compliance. Senator Nelson has a proposal to provide an improved and enforceable procedure for notifying customers of tire defects.

Ralph Nader is seeking legislation to remedy neglect of safety measures by manufacturers of light airplanes, which he charges to be one of "the Most Lethal of the Major Forms of Transportation in the United States."

This activity indicates, without a doubt, that the voice of the consumer is being heard—and what he has to say is being heeded.

Now I will recap the activities of FDA as carried out by the Office of Product Safety.

Office of Product Safety

The Office is presently composed of four divisions—Product Safety Studies, Poison Control, Hazardous Substances, and Product Research. In addition, on the immediate staff of the Director we have a limited number of personnel who prepare programs and guidelines for the field, consider regulatory recommendations made by the field, maintain contact and liaison with industry, and develop the overall plans for this program.

The Division of Product Safety Studies receives reports from approximately 135 hospitals across the United States giving information on the injuries being treated through their emergency rooms. The data received includes the type, severity, and extent of the injury, the product involved, the conditions at the time of injury, etcetera. This data will be analyzed to determine the types of products most frequently associated with accidents, as well as those products producing the more severe type injuries.

In addition, the field staff will investigate in depth certain of the injuries to determine whether or not a particular hazardous condition exists due to product design which could be changed, and thus eliminate or reduce the actual or potential hazard.

Using the analysis of the data from the National Injury Surveillance System—the hospital reporting system—and the in-depth investigation reports, we can set priorities, establish programs and guidelines, and effect corrective action. We do not at this time have any statutory authority to insist that the manufacturer take positive action to eliminate the hazard from those consumer products presenting an electrical, mechanical, or thermal hazard—other than toys or other articles intended for use by children. In these cases, we will discuss the problem with the firm concerned and solicit their voluntary action to correct or eliminate the problem. If such action on the part of the firm is not adequate or if the hazard is great, we will use a press release to alert and inform the consumers of the hazard.

The Division of Poison Control works as the national clearinghouse for approximately 550 poison control centers throughout the United States. They receive reports of accidental ingestion of products; maintain and distribute data on the ingredients, toxicity, symp-

toms, and treatment should a product be ingested; and conduct educational programs. This Division is now in the process of computerizing the data on about 3,000 products. A pilot study is being made using a terminal at a hospital to query the computer and receive responses to such queries. Such a system would make possible rapid retrieval, updating and usefulness of our present data. We are quite enthusiastic about its potential.

The Division of Hazardous Substances has been in existence since the Hazardous Substances Act was passed. It may not have always been known by that name, but its functions have been the same. In this Division we have the capability for determining the chemical and toxicological hazards of household products. We do have statutory authority to seize the product, or to prosecute or enjoin firms from the sale of substances which are misbranded, if such product or substance is not adequately labeled to inform the consumer of the hazards. In those cases where the product is so hazardous that adequate labeling cannot be designed, we have authority to ban the article. I previously mentioned several such actions taken by us.

The Division of Product Research, although not staffed at the present time, was established to give us the capability to examine products for mechanical, electrical, and thermal hazards. We plan to start staffing this Division this year.

I believe we can anticipate that legislation will be passed providing for control of the hazards—mechanical, electrical, and thermal —associated with all consumer products, similar to that which was enacted in the Child Protection and Toy Safety Act of 1969.

Increased Product Safety Protection

Consumerism is a healthy development which is here to stay. And trends in product safety protection are toward greater controls to benefit the consumer. According to Commissioner Edwards, FDA's activity in product safety protection is being strengthened to increase its effectiveness. Recently he stated in a speech:

> We have elevated the Office of Product Safety to the Office of the Commissioner, and we have requested from the Department that it be given Bureau status. While organizational placement in itself will not insure more effective programs, it will offer the program visibility and recognition. It indicates our intention to make product safety a strong and effective operation within the FDA. . . . **[The End]**

Remarks on Medical Devices

By LARRY R. PILOT

Mr. Pilot Is Special Assistant to the Commissioner of Food and Drugs. He Presented This Paper Before the Food and Drug Section, Federal Bar Association in Washington, D. C., September 18, 1970.

A REVIEW OF FDA'S HISTORICAL INTEREST in devices, considered in the light of our present activities, and of changes that we envision in the future, perhaps will result in a better understanding of the problems we face and provide the device industry and medical profession with some guidance.

There is, without question, a recognized need for new legislation designed to assure the safety, effectiveness and reliability of certain types of medical devices. Not too many years after passage of the 1906 Food and Drug Act, some consideration was given to the need for amending the Act to regulate therapeutic devices and cosmetics. However, little more was done until the early thirties when congressional hearings were held on Senate Bill 1944. While a definition for drugs which would have included "all devices" was prepared, it was not satisfactory, and the influence of opposition from various quarters contributed to the recognition that a separate definition for devices was needed. The groundwork for defining a device was developed early in 1935, and was continued and preserved through passage of the 1938 Food, Drug, and Cosmetic Act.

Apart from the issue relating to the safety of drugs, the increased scope of the 1938 Act to include devices and cosmetics has been described as probably the most outstanding distinction from the 1906 Act. An FDA digest of the new Act described the many changes and new provisions and, among other factors, indicated that the Act "Brings therapeutic devices under control, and subjects them to the same general requirements as are set up for drugs."

In 1938, the device nomenclature was intended to cover things like trusses, ultraviolet lights, orthopedic shoes, surgical instruments, contraceptives, prosthetic devices and the like; and the concern over these and other items considered to be devices related to the truthfulness of their labeling claims. Most of the legal actions taken over the years were based on the misbranding provisions of the Act. These involved actions against such devices as colonic irrigators, spectochromes, generators liberating chlorine gas, galvanometers, and products which delivered ultrasonic waves or electrical energy. In the meantime, drug discovery and development was proceeding at a rapid rate, and legislation, regulations and court decisions were filling in the void to provide a sound, often controversial, body of law relating to drugs.

In the device area, however, progress in terms of discovery, development and innovation was somewhat less noticeable, and the advances which occurred far outdistanced the formulation of an adequate basis in law. In the nineteen-fifties, concern was expressed over the lack of authority to properly control problems arising from the use of devices. This concern grew in the early sixties, when the device nomenclature began to fill out with such respectable terms as cardiac pacemakers; ceramic and plastic surgical implants; kidney dialysis units; defibrillators; cardiac, renal and other catheters; artificial veins, arteries, and heart valves; and others equally descriptive of the types of products that have enriched medical science.

In 1967, Congressman Staggers introduced H. R. 10726, and several more proposals have been introduced since then, with H. R. 16190 by Congressman Halpern being the latest. Administration interest is reflected by the fact that seven Presidential messages by three Presidents have carried a call endorsing legislation to improve the protection of the public health from the marketing of unsafe and ineffective medical devices. It is anticipated that the Cooper Committee report will go a long way in providing a background for the consideration of the request for legislation.

The Need for Initiative and Imagination

While it is too early to discuss what type of legislation the Department will propose, it is not too early for non-government interests to begin exercising some initiative and imagination in developing, in a very specific manner, the criteria they believe are essential. There is no room for "beating around the bush," since the need for

legislation is well-recognized and the objections to prior legislative proposals have been thoroughly exhausted. Conferences, speeches, and conversations where industry and professional groups have been parties have suggested some needs. These include registration of manufacturers and distributors, good manufacturing practices, factory inspection, adverse-reaction reporting and recall authority.

There is also a recognition that a system for review and approval and standard-setting may be essential, but there is wide disagreement over how these objectives should be achieved, and to what extent. It is at this juncture that those involved, particularly the industry, have an opportunity to display their sincerity by exhibiting an attitude consistent with progress. Certainly, the industry and the health professions have the knowledge, background and expertise to make a significant contribution. If they have the ability to devise a new system for the review and approval of certain types of devices which will be distinct from the approval process for new drugs, then make it known. If not, this must, and will, be done by the government, and non-government interests will be placed in the position of either accepting what we propose or rejecting it in favor of the status quo and further study. Perhaps this may be an overly simplistic approach and imply a harsh impression of the true intention of non-government interests, but let us recognize that progress in medical devices is continuing to occur rapidly, that a basic legislative proposal has been in existence and thoroughly discussed since 1967, and that the status quo is no longer satisfactory. Is it possible that after all this time, the industry is not sure of the extent to which government in specific areas should exercise review and approval authority? I hope not, and I would further hope, if this is true, that the industry is indeed prepared to offer some constructive suggestions and proposals that will merit the serious consideration of the government and the Congress.

I recognize that the *AMP* and *Bacto-Unidisk* decisions may create an "ominous uncertainty" as to when the new drug controls apply to items that might be regarded as devices; however, these cases do illustrate the extent to which the Federal courts are prepared to go to protect the public from current dangers or potential disasters, the likes of which have served as the precursors of prior legislation in the drug field. Of course, it goes without saying that these decisions also

provide an alternative to legislation as related to pre-market clearance for some devices.

The Need for Cooperation

Recently, a plea on behalf of a segment of the industry was made on the need for the cooperation of industry, physicians and government in device regulations. It recognized that, for once at least, government and non-government interests are in general agreement on the desirability of additional government regulation for medical devices, and that all concerned would now welcome responsible legislation. The Food and Drug Administration (FDA) and the Department are in agreement on the need to cooperate, but, in order to be consistent, it is implicit that non-government interests understand our position and recognize that the pleasure of cooperation carries with it a responsibility to exercise initiative and be creative. Instead of always waiting for the government to make the first move and then huddling in judgment over whether our proposal is reasonable or unreasonable, acceptable or unacceptable, why can't industry or the health professions use some imagination and provide us with constructive assistance and concrete proposals?

I know that Commissioner Edwards is very concerned about FDA's future in medical devices, and I know that he would welcome any opportunity to cooperate with interested parties in the development of reasonable approaches to device regulation. The problems that exist in this area have developed and collected over many years, and represent just one of many responsibilities inherited by the Commissioner when he undertook to direct this agency. It is also a problem for which we are actively seeking a solution, because time is short and the critics are growing impatient.

Legislative and Case History

Some objective perspective can be given to the tremendous burden which faces FDA if we permit ourselves to view this in another light and consider briefly what FDA has done over the past thirty-two years and where we stand now. A glance at the Food, Drug, and Cosmetic Act reveals few words about devices apart from adulteration and misbranding. Less than ten of the approximately 1700 pages in Title 21 of the Code of Federal Regulations are devoted to devices,

and only a few dozen court cases have been litigated in favor of FDA. The simple explanation for the scarcity of legal authority rests with the fact that without the law, there can be no regulations, and that without either of these and sufficient proof to sustain an allegation, there can be no court cases. Further, when a court victory has been obtained, our resources have been heavily drained.

While FDA was aggressive in its initial attempts to enforce the provisions of the 1938 Act, this effort was directed mainly toward controlling the quack-type device and promotion of medical devices which were dangerous "per se." As mentioned before, the development of new and sophisticated devices made it increasingly difficult to enforce the law; and FDA was no longer able to sustain its legal actions solely upon the basis of expert opinions, unless the expert had special skill or knowledge in the specific area of litigation. This has made enforcement of the law a time-consuming and expensive effort in every case involving litigation over a particular device. Sufficient documented evidence has to be accumulated to show that a device is being sold or offered for sale under false or misleading claims, that it is adulterated or that it is unsafe for its intended use.

A case example is represented by the recent court victory involving "The Relaxacisor," where FDA successfully maintained that this product was a hazard to health. While the judge held that there was enough danger associated with the use of this product so that it should be sold only under the prescription of a doctor, the victory was costly. The trial took five months, and FDA investigated more than 150 complaints of injury in selecting 50 complainants as government witnesses. The government's total expenditure from all sources for this litigation against the device has been estimated to be approximately $500,000.

Complicate this outdated legal process with uncertainty over the number of devices in commerce and manufacturers who produce these devices—estimates range from 5,000 to 500,000 devices produced by 1,300 to 5,000 manufacturers—and the deaths or injuries resulting from use of many of these devices, and the nature of the problem becomes more serious. The testing laboratory at Downstate Medical Center, Brooklyn, New York, found that 40 percent of incoming equipment was defective. Either the device did not meet the

manufacturer's specifications, or basic design and construction made the equipment unsafe. An FDA review of several hundred articles published since 1963 shows that nearly 700 deaths and over 10,000 injuries have occurred from the use of such devices as heart valves, pacemakers, anesthesia machines, catheters, intrauterine contraceptives and others.

Figures like these project a gloomy forecast and suggest the need for immediate change. However, it must be recognized that many more people are living useful lives as the result of these advances in medical devices and that, by and large, the device industry has acted in a responsible manner. Nonetheless, as conditions exist today, the cry for new legislation will grow stronger and louder until industry, the health professions and government agree on a proposal, or history repeats itself and legislation responsive to a crisis is approved by the Congress.

It is obvious that some type of government review and approval for certain categories of devices is necessary, but to charge this concept with the criticisms that apply to all the pre-market clearance procedures for new drugs is absurd. Further, any suggestion that FDA would require pre-clearance for nearly every type of device is out of the question. Although the Cooper Report has not been made public, some criticism already has been leveled at what have been suggested to be the recommendations of the Committee. To knock down the efforts of this Committee before the complete facts are known is not only unwise, but also poorly timed. A better approach for those involved would be to examine their present responsibility to the public and proceed in an atmosphere where the best interest of the patient is the guiding factor.

The FDA Approach

I can honestly say that we at FDA have reviewed our traditional role in this area, recognized where our efforts are weak and made plans to be more imaginative in our approach and to consider various methods of dealing with problems that confront us now. We are seeking ways of developing an inventory of medical devices so that a

more complete understanding of the various types and kinds of devices will be achieved. This cooperative undertaking with the industry should prove to be extremely helpful to the interest of the government and the device industry in Medicare and Medicade, and to the FDA in its effort to gather information on the types of devices available in the United States. In addition, we have undertaken to collect and compile all standards and specifications developed by government and non-government groups for medical devices, consistent with a recommendation of the Task Force on Standards and Standardization at the National Conference on Medical Devices a year ago.

Likewise, we plan to meet periodically with representatives of the medical profession and the device industry to discuss matters of mutual concern.

While it will be satisfactory as an interim matter to generate new approaches within FDA and to stimulate cooperative efforts with the industry and medical profession, it is obvious that this will not be sufficient. The technological growth of the device industry has not been met with a corresponding growth in legislative development. While the Radiation Control for Health and Safety Act represents some progress, it is not enough for the government to completely fulfill its responsibility.

Additional government authority, which will not unnecessarily hamper the research and development process, yet will assure the safety, effectiveness and reliability of all medical devices, is the common goal of the government, industry and medical profession. If we are to profit from past experience, deliberations over prior legislative proposals on devices, and the many conferences, meetings and conversations that have occurred, I would hope that the spirit of our mutual efforts will help to accelerate the grinding wheels of government and make the product of this venture exceedingly fine. **[The End]**

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