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Food Drug Cosmetic Law JOURNAL

The Problems of Advocacy in Food and Drug Litigation

. . . . . Vincent A. Kleinfeld

International Developments in the Food Law Field

. . . . . Franklin M. Depew

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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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REPORTS

TO THE READER

Charles Wesley Dunn Lecture.—The presentation of the *Charles Wesley Dunn Lecture* by *Vincent A. Kleinfeld* at the Law School of Harvard University on March 9, 1962 afforded an opportunity for students to join with a distinguished group of faculty members, government representatives and interested attorneys in an informal meeting. Mr. Kleinfeld discussed "The Problems of Advocacy in Food and Drug Litigation" (or how to live with the axiom that he who is against the Food and Drug Administration is for evil). The speaker was introduced by Associate Dean *David F. Cavers* of the law school. Dean Cavers has long had a vital interest in matters of food and drug law. He was one of the group of nongovernment experts selected to aid in the drafting of the bill which eventually became the Federal Food, Drug and Cosmetic Act of 1938.

Dean Cavers observed that Mr. Kleinfeld had had a fruitful association with the late Charles Wesley Dunn over the years. He was co-editor with Mr. Dunn of a number of volumes in the Food Law Institute Series and served as Adjunct Associate Professor at the New York University Law School Center in its graduate program under Professor Dunn. He went on to say that Mr. Kleinfeld has become recognized as a leading scholar and practitioner in this field of law.

Dean Cavers then announced that the Charles Wesley Dunn lecture had been made possible through the generosity of the Pharmaceutical Manufacturers Association, which had established these lectures at five leading law schools, in honor of Mr. Dunn, their counsel at that time. He continued with a tribute to Mr. Dunn, pointing out that Mr. Dunn became interested in food and drug law early in his professional career. In 1927 he published a treatise on the Food and Drugs Act of 1906, and in 1939 he published treatises on the Food, Drug and Cosmetic Act of 1938 and the Wheeler-Lea Amendments to the Federal Trade Commission Act. It was through Mr. Dunn's efforts that the Sections on Food, Drug and Cosmetic Law and on Antitrust Law were organized in the New York State Bar Association and also in the American Bar Association. Mr. Dunn was instrumental in bringing about the founding in 1949 of The Food Law Institute, for the purpose of encouraging instruction and research in the field of food and drug law. Through his guidance the Institute was able to establish courses of instruction in this field of law at a number of law schools. At the same time Mr. Dunn did much to spread comparative study of this field of law by arranging national and international conferences and symposia under the sponsorship of the Institute. He also traveled and lectured widely in this field of law, both in this country and abroad.

Mr. Kleinfeld's paper appears at page 404 of this month's JOURNAL.

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Food·Drug·Cosmetic Law
Journal

The Problems of Advocacy In Food and Drug Litigation

By VINCENT A. KLEINFELD

This Charles Wesley Dunn Lecture Was Presented at the Harvard University School of Law on March 9, 1962. Mr. Kleinfeld Subtitled His Lecture "Or How to Live With the Axiom That He Who Is Against the Food and Drug Administration Is For Evil." Mr. Kleinfeld Is a Member of the Washington, D. C. Law Firm of Bernstein, Kleinfeld & Alper.

AN ASSOCIATE OF MINE, a graduate of this law school and 20 years younger, shook his head dolefully after reading my rather disjointed paper. He did not criticize the accuracy of either my statements or analysis. He felt, nevertheless, that students should not be disillusioned so soon with respect to the manner in which laws, even criminal laws, are sometimes administered and construed.

I feel that law students are sufficiently mature, and perhaps sophisticated enough, not to be startled by a few sad facts of life. Actually, my criticisms are not particularly harsh—they merely point up the fact that it seems to be inherent in all government agencies to strive ceaselessly to expand their authority. To a lesser extent this is undoubtedly true in industry as well. The difference, of course, is that industry can't ordinarily send you to jail—it has enough trouble staying out of jail. I must plead guilty to the soft impeachment, too, that, unlike Daddy Warbucks and his little monster, I distrust bigness, particularly when coupled with vast power and when found in government. This is regardless of the political affiliation of those sitting in the seats of the mighty. Bigness and power almost inevitably tend to corrupt, in my opinion, although I do not use the term in any venal sense. And unfortunately those in power are mortals with human failings and weaknesses, and again as in industry some of these mortals may be superior, some may be average, and some less than average.

The title of my lecture is more than a bit verbose. What I mean to convey by it is merely that litigation in the food and drug field is different from that in any other legal area.

Passage of New Law Required Compromises

Dean Cavers was one of the group of dedicated men who strove diligently, for five years against serious odds, to persuade Congress to pass a food and drug law which would give real protection to the consumer. In the passage of social legislation of this character, compromises are always inevitable if some law is to be enacted. There are many conflicting groups. On one side you have the Neanderthal portions of industry who are against any effective legislation of this character as being communistic or socialistic, or even worse, "new dealish." On the other extreme, you have earnest consumer groups and their publications which strive for legislation which would unnecessarily hobble industry and which, from a realistic viewpoint, just doesn't have a chance of passing. Then you have those I call the "yes, but" element; those who commence their testimony before a Congressional committee by saying that they are in definite agreement with the lofty purpose of the legislation to protect the public, and then offer so many amendments, so many qualifying adverbs and adjectives, as virtually to emasculate the law. Fortunately, you also have a few dedicated and reasonable people in industry and the government who seek legislation which will, in fact, give the public a large measure of additional protection, even though some compromises are essential in order to get a law passed.

When the Federal Food, Drug and Cosmetic Act was finally passed in 1938, after five years of weary struggle, there were many consumer groups which threw up their hands in horror at some of the compromises that had been made. They stated that it would have been better not to have had any legislation rather than the "weak," "ineffectual" law that had been enacted. I might say that Dean Cavers did not agree with that point of view. He realized that a fairly decent law had been passed—certainly one that was much stronger than the predecessor Food and Drug Act of 1906.

A number of compromises have been reached in order to forestall such serious opposition as might have prevented the passage of any bill. Many weaknesses seemed to remain. I do not know whether anyone realized (I feel sure Congress did not) what the executive and judicial branches of the government would do with the statute. The tremendous desire of the courts, from the Supreme Court down,

has been to convert this compromise statute into an extremely strong law. I have said that the hair on the heads of many of the Congressmen who voted for the Act would have stood on end if they had realized what the executive and judicial branches were going to do with this law.

Justice Frankfurter's Opinion

I am sure that there are very few lawyers who pay too much attention to legal generalizations. Most of us realize that these generalizations are usually convenient pegs on which lazy judges who have reached prior conclusions hurl their hats. In the food and drug field this just is not so. The generalization that the Federal Food, Drug and Cosmetic Act must be construed liberally is virtually a substantive rule. One of the early and leading cases which reached the Supreme Court involved the criminal prosecution of a small corporation and its president for having shipped a misbranded drug in interstate commerce. The president had had no direct or active part in the shipment, and in fact was out of the state when the offense occurred. What little legislative history there was on the problem indicated that Congress had probably decided not to provide for the prosecution of corporate officers and agents in such circumstances. To complicate the picture, the jury found the corporation not guilty and the officer guilty. With respect to this latter point, Mr. Justice Frankfurter, who wrote the majority opinion in a five-to-four decision affirming the conviction of the officer, shrugged his shoulders and said this was one of the vagaries of the jury system.

In the usual Frankfurter fashion, he used language which was of tremendous value to the Food and Drug Administration in all its future cases. He said: "The purposes of the legislation thus touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislative if it is to be treated as a working instrument of Government and not merely as a collection of English words."

Opinion Strengthens Government Position

Now this was just beautiful from the government's viewpoint. What Mr. Justice Frankfurter was saying (I am certain he would not have said so five years later, but that is another story) was that practically any construction of the Act by the government which would strengthen the consumer protection offered by it would be upheld. At that time, I was in general charge of food and drug litiga-

tion for the Department of Justice and an earnest advocate, being much younger and much less cynical. One did not have to be brilliant to realize what the Supreme Court was doing. I recall saying to the attorneys in my section of the Justice Department (and only half jokingly) that from that point there was no particular need for preparing briefs in food and drug cases; all we would do was to mimeograph Mr. Justice Frankfurter's language, hand that to the courts and we would undoubtedly win. As a matter of fact, we almost did that. I think I am correct in saying that no brief in any food and drug case ever was filed in any court from that point on without quoting the go-ahead language of Mr. Justice Frankfurter.

The result was to be expected. The government won some amazing decisions. In many cases the district courts and the courts of appeals were obviously influenced by the language and apparent philosophy of the Supreme Court. In opinion after opinion, the inferior courts, in holding for the government, would say "As stated by the Supreme Court in *United States v. Dotterweich*," and then they would parrot the language I quoted a few moments ago.

This has continued. That is why I introduce my courses by talking about the fact of life (a very sad one from the viewpoint of those opposing the Food and Drug Administration in litigation) that attorneys in this field have to accept the maxim that he who is against the Food and Drug Administration is for evil. To be trite —there are already two strikes against you.

Intent Need Not Be Proved

One of the factors which makes litigation in this area so difficult, and which makes attorneys so hesitant in going to trial, is the holding of the courts that the government need not prove intent to obtain a conviction on a criminal charge. This rule of absolute liability is based on the public policy consideration that in the food and drug field the public is entitled to great protection, and that this will be best brought about by placing the strictest liability on distributors. The reason appears to be that where the public health is concerned, in an area where the consumer obviously cannot protect himself, the hazard must be cast upon the distributor.

Concept of Absolute Criminal Liability Questioned

It may be questioned whether this concept of absolute criminal liability is sound, particularly since many violations are minor in nature, and many involve economics and not health or even decep-

tion. The charge may be that a food has been made to appear better or of greater value than it is, or that it is an imitation of another food, or that it purports to be a standardized food and, although truthfully labeled, violates the law because it contains a wholesome ingredient not specifically permitted by the standard. And the possible penalty for each violation, each shipment, can be a year in jail or a fine of $1,000 or both.

This real hazard to industry is augmented by the fact that a corporate officer or agent may be held personally liable, criminally, for having had a responsible share in the furtherance of the illegal act, even though he may not have participated in the transaction or even known about it. This would seem to place the corporate officer in a rather difficult position. Just what is this "responsible relation" which will cause a corporate officer to be held guilty of a criminal offense? (By the way, the second offense is a felony, and for each count the defendant may get three years in jail, a fine of $10,000, or both.) Isn't this "responsible relationship" concept just a bit vague? Mr. Justice Frankfurter was not bothered by this. He said to attempt a formula "embracing the variety of conduct whereby persons may responsibly contribute" in furthering a forbidden transaction "would be mischievous futility." He concluded by saying that "in such matters the good sense of prosecutors, the wise guidance of trial judges and the ultimate judgment of juries must be trusted." As a former prosecutor, I shudder at this. Interestingly enough, Mr. Justice Frankfurter made his statement in the very case where the corporation had been acquitted and the officer convicted, although the officer was the man who was not there.

An ameliorating factor might be the provision in the Act providing for an informal administrative hearing before apparent criminal violations are forwarded to the Department of Justice for prosecution. At least at these hearings good faith, or lack of intent or knowledge, may be raised. This might well persuade the hearing officer to recommend against prosecution. But the Supreme Court has ruled, in its august wisdom, that the failure to provide the hearing, even though a hearing is required by the statute, does not bar prosecution. This, in my view, is unrealistic.

Actions Which May Result in Imprisonment

This is all difficult enough. But let us look at some of the acts for which one may be imprisoned, regardless of intent. A food is adulterated if it consists of any filthy, putrid or decomposed sub-

stance or "if it is otherwise unfit for food," or if it has been held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. A food is also adulterated if any substance has been added to it or packed with it "so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is." A drug is misbranded unless its labeling bears adequate directions for use, and "such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health." A "new drug" is one not "generally recognized among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling." How can one possibly advise his client, for example, that his product is not a "new drug"? What it comes down to, and this is what my clients are told, is that to be safe, the definition must be changed to "a new drug is a drug which the Food and Drug Administration says is a new drug." This concept of absolute liability under the Federal Food, Drug and Cosmetic Act is a questionable one, in my opinion, but it is here to stay. I question the necessity for it largely because of the ambiguity of much of the language, the size of the penalties and the so-called "liberal construction" of the statute by the courts.

Another Peril

To add to the manufacturer's peril is the fact that important positions are taken by the Food and Drug Administration in "Statements of General Policy or Determination," again without a hearing, and sometimes even more informally by a press release. These may be changed from time to time, so that which the Food and Drug Administration would consider not to be a criminal offense at one time, may turn into an offense at another. For example, the government originally took the position that there could be legal imitations of standardized foods if properly labeled. Years later, an exactly contrary position was taken. It might be said, and this is correct, that when the government finally instituted regulatory action based upon this changed concept it was by means of a civil seizure proceeding rather than by criminal prosecution. But that was an administrative decision which theoretically at least might have been otherwise. As I have said, fortunately or unfortunately, those in the government service are human beings, sometimes with the same predilections, frailties and weaknesses of those in industry.

To add to the distress of the attorney in this field desperately attempting to keep his client out of litigation, or to foresee what might be the consequences of some action by his client, is the fact that the government possesses other sanctions which can be used not only in substitution for, but also in addition to, criminal prosecution. A single seizure may be made of his product; and an injunction may be sought. In addition, if the charge is adulteration, or upon the basis of an administrative determination reached without a hearing and which can not be judicially reviewed, multiple seizures of the product can be made throughout the United States. The client, therefore, can be ruined before he ever gets his day in court. True, the sanction is used sparingly, but it is there and it can be a dreadful one. Let us not forget, also, the extra-legal, dreadful sanction of the press conference and press release. If you will recall the cranberry and stilbestrol incidents of a few years ago, you can recall the tremendous publicity that ensued as a result of press releases. As a matter of fact, there are few who believe that any emergency existed which required the use of the press release and the press conference. Stilbestrol, for example, had been specifically approved by the Food and Drug Administration and used for many years, and there was no actual evidence of any hazard.

Act's Broad Coverage Shown in Cases

I have mentioned the *Dotterweich* case. A brief mention of a few other cases may be helpful to indicate the broad coverage given to the Federal Food, Drug, and Cosmetic Act by the courts, even in criminal prosecutions. In the *Sullivan* case, sulfathiazole pills had been shipped by the manufacturer from Illinois to Georgia. A small retail druggist in Georgia purchased a portion of the tablets in that state and sold a few of them in his store in that state to a Food and Drug Administration inspector without getting a prescription. The regulations, which were most ambiguous, required a prescription. The five years of legislative history of the Act contained not the slightest mention of the prosecution of retail druggists. Sullivan's conviction was affirmed by the Supreme Court as a violation of a section of the Act which made it an offense to alter, multilate, destroy, obliterate, or remove in whole or in part the labeling of, or the doing of any other act with respect to a food or drug that had been shipped in interstate commerce which caused it to become misbranded.

In the leading *Kordel* case, the Supreme Court affirmed the conviction of the defendant for having introduced into interstate commerce a drug alleged to be misbranded because it had been accompanied

by labeling containing false and misleading therapeutic claims. In one of the counts of the criminal information, the literature which was held to be labeling which had accompanied the drug in interstate commerce was shipped a year and a half after the drug.

In the *Spectrochrome* case, Olson, in Oregon, had purchased a fantastic device from its manufacturer in New Jersey. False and misleading therapeutic claims had been made for the device by the manufacturer. Olson paid for the device and kept it in his home, where it was used only by him and his mother. It was seized in his home since the seizure section of the Act provided that a drug or device shipped in interstate commerce in a misbranded condition could be seized "at any time thereafter." Solely because of that language, the United States Court of Appeals for the Ninth Circuit found no difficulty in declaring that the seizure and condemnation of the device was proper. I am not saying that the court was wrong. My point is that the court hardly adverted to the problems which were presented.

"End Justifies the Means"

The Food and Drug Administration is by far one of the better and more competent federal agencies and is less influenced by political considerations than most other agencies. Its approach, however, is sometimes what can be called the "end-justifies-the-means" approach. In other words, since the John Smith Company is putting out a product which we think is bad, or for which we think false claims are being made, any approach which the courts may possibly accept is justified. This may not be considered to be a particularly harsh criticism from the layman's viewpoint, for the end sought and usually accomplished may result in greater consumer protection.

My own personal philosophy does not approve the "end-justifies-the-means" approach anywhere, even in a field such as the food and drug area, where the public is obviously an amateur requiring vigilant protection by the state. Let me mention a few examples of this approach. As I have mentioned, a section of the Act provides that before any violation is reported by the Food and Drug Administration to the Department of Justice for criminal prosecution, the person against whom prosecution is contemplated must be given appropriate notice and an opportunity to present his views. Notwithstanding the holding of the Supreme Court that the failure to give such notice does not act as a defense in a criminal prosecution, the Congressional mandate to the Food and Drug Administration is clear—a hearing must be given. It is one thing for a mistake to happen so that in some particular situation the Congressional directive is not followed.

But this is what has occurred. Several years ago, the Food and Drug Administration found that a real evil was arising in connection with the sale of amphetamines, "pep pills" or "bennys," to truck drivers by gas station attendants. It is true that giving these prospective defendants the informal administrative hearing required by the law might have alerted them to prosecution and caused them to skip. This could have been met by having the investigations of the violations made by the Department of Justice, for under those circumstances the statutory requirement for a hearing would not have been applicable. It was much simpler, however, for the government to take the position that, since the Supreme Court had ruled that the failure to give the statutory notice and hearing was no defense to a prosecution, the notice and hearing did not have to be given at all. The logic of this fails me completely.

Authority Limited In Scope

The authority given to the Food and Drug Administration under the factory inspection provision of the Act is quite limited in scope. Yet inspectors constantly request data in their inspections which do not have to be submitted, with no mention of the fact that the information sought may be voluntarily given but certainly need not be. Of course, the data may lead to criminal prosecution, with resulting imprisonment.

Calculated advantage is taken of ancient happenings. The government may claim that a product is a new drug for which the manufacturer has not obtained the requisite prior clearance. Government counsel and their briefs will dwell eloquently on the fact that it was the death of over 100 persons from an untested drug product (in that case it was the solvent) in 1938 that caused Congress to provide for the licensing of new drugs as far as safety is concerned. It is easy to comprehend the effect this has on the judge.

Peculiar Clause Concerning Arsenicals

Under a provision of the Food Additives Amendment of 1958, providing for the licensing of additives in food (it is licensing although a euphemism is employed for that nasty word), no ingredient may be used if it is found, after appropriate tests, to induce cancer. There is not an iota of scientific evidence that organic arsenicals, used in animal feed, have caused cancer in man or animal. Because of a somewhat peculiar "grandfather" clause, manufacturers using such arsenicals when the Food Additives Amendment was passed may

continue to do so, and so far this has not been challenged by the government. By what most attorneys believe is an extremely strained interpretation, the government has taken the position that no new manufacturer may market the identical organic arsenical which may be used by their competitors who happened to have been marketing the product in 1958 when the Amendment was passed. Attorneys (and their clients) would like very much to test the government's position in court. It has been rumored, however, that if judicial determination of this legal question was ever sought, the government would make the walls of the court resound with the dread word "cancer." You can appreciate the emotional effect this would have on a judge who is presumably middle-aged or elderly and, like most people, has had friends or relatives die from this scourge. At the very least, he reads periodically of the death from cancer of prominent personalities. You may say that this is merely advocacy on the part of the government. The question remains (but that is not the subject of this talk), whether the government of the United States, and its attorneys, should be as advocate-minded and utilize the same tactics as private litigants and their counsel.

Administrative Hearings of FDA

In a speech made by the Chairman of the Federal Trade Commission a couple of months ago, he said, and I quote: "Fairness having been assured [by the Administrative Procedure Act], the inquiry has become: How well is each administrative agency performing" its task? But has fairness been assured? Let me talk for a few minutes about the administrative hearings held by the Food and Drug Administration. There are two types: one is in connection with the agency's rule-making powers; for example, the agency is authorized to promulgate definitions and standards of identity for foods. These hearings are supposedly impartial. Notice is given, a hearing is held, an opportunity is given for examination and cross-examination of witnesses, there are findings of fact, an order is made and judicial review is available. It is unfortunately true, however, that in some instances the proposed order is one which the government has definitely made up its mind to issue. It is obvious at the hearing that this is so and the hearing is factually, if not theoretically, an adversary proceeding. The Food and Drug Administration has one of its attorneys present who acts as an earnest advocate, strongly attempting to sustain the proposed order. Who is the examiner before whom he pleads? It is another attorney in his office, a member of the General Counsel's office doing the legal work of the Food and Drug Admin-

istration. At times, the Food and Drug Administration attorney at the hearing is the Hearing Examiner's superior in the General Counsel's office. This may perhaps be within the letter of the Administrative Procedure Act since the hearing is being held in connection with rule-making. Whether it makes good sense is another matter. Also, the legislative history of the Federal Food, Drug and Cosmetic Act reveals the clear intent of Congress that the pattern of judicial and quasi-judicial proceedings was to be pursued in connection with the rule-making power granted to the Secretary.

A couple of years ago, the Food and Drug Administration designated such an examiner as I have just mentioned. Again, the advocate for the government would have been one of his confreres in the General Counsel's office. When the drug company protested that this at least seemed to be in violation of the Administrative Procedure Act, the examiner was withdrawn and a theoretically more impartial examiner was borrowed from another bureau of the Department of Health, Education, and Welfare.

Reluctance to Grant Hearings

Perhaps because rule-making hearings under the Federal Food, Drug and Cosmetic Act are time consuming and costly, and probably because in most instances the government has made up its mind anyway as to the final regulation which will be issued, there is a growing reluctance to grant hearings at all, notwithstanding the clear intent of Congress that there be hearings even in connection with rule-making.

The original pertinent provisions of the Federal Food, Drug, and Cosmetic Act, enacted in 1938, required a hearing upon any proposal initiated by the Secretary to issue or alter any regulation, even where there was no dispute. Congress chose to adopt an unusual approach by imposing on the rule-making powers of the Secretary the safeguards customarily applied in quasi-judicial proceedings.

The Federal Food, Drug, and Cosmetic Act embodied the growing tendency on the part of Congress towards the end of the New Deal era to impose strict procedural requirements upon regulatory agencies in the exercise of rule-making powers. Under the Act, the Secretary was required to observe a careful procedure in promulgating regulations. The resulting process resembled the previous machinery for prescribing public utility rates, rather than that employed in devising

health and safety regulations. The major requirements of quasi-judicial proceedings, including the holding of a hearing, were explicitly incorporated into rule-making under the Act.

Obvious Purpose

The Congressional purpose was obvious. Because orders proposed by the Food and Drug Administration are ordinarily unilaterally conceived, and because such proposed orders generally have serious and widespread impact upon industry as well as the consumer, Congress created a specific mechanism to test, by public hearing, by the production and evaluation of evidence and by the orderly processes of examination and cross-examination, whether the order should properly issue. In fact, as I have pointed out, Congress felt so strongly about the necessity for preventing arbitrary action and providing for a record based upon the traditional judicial and quasi-judicial concepts of examination and cross-examination, that it required a public hearing even where there was no objection by industry to a proposed order of the Secretary.

Experience under the Act subsequent to 1938 demonstrated, however, that it was unnecessarily burdensome, time consuming and expensive to require a hearing in every instance, since many proposals were outside the zone of contention and were satisfactory to both the Secretary and industry. Accordingly, at the specific suggestion of industry and with the support of the Food and Drug Administration, the Act was amended to require a hearing only for those proposed regulations to which industry specifically objected. This was the reason for the amendment.

The legislative history of the original Act revealed in the most clear and unambiguous language that Congress meant what it said in explicitly requiring a hearing in connection with a proposal of the Secretary to issue, modify or repeal an order. There was no dispute whatever that, where industry objected to a proposed order of the Secretary, Congress had insisted that fair play and justice necessitated a hearing.

The legislative history of the amendment to the hearing provisions is equally clear in pointing out that the right to a hearing was to be preserved where a controversy existed, and that the amendment was sought only in order to prevent the necessity of a hearing on any proposal, or portion of a proposal, by the Secretary *to which no objection was taken.* For example, the pertinent House Committee report stated that the proposed legislation was favored by both government

and industry "because it should provide the needed relief from these unnecessary burdens by eliminating the requirement for formal hearings *except* in instances where such a hearing is desired for the purpose of providing a basis for the judicial review as now provided in the Act, should the objecting party find the ultimate regulation still objectionable." Yet the amendment to the Act, clearly designed to aid industry, to expedite hearings and remove the necessity for them *only* where industry does not object to the contemplated regulation, has been converted by the government into an authorization to the Secretary to grant or refuse a public hearing in his discretion, on the basis of whether the objections advanced could possibly change his mind.

What Attorney Can Do

Well, what is the attorney in this field going to do about all this, assuming it is true? The first thing he must do is to accept this sad fact of life and try desperately to avoid litigation if humanly possible, even if concessions have to be made which he feels are legally not required. He must know, also, that if he is forced into litigation, or cannot possibly avoid it, he must prepare his case with even greater zeal than cases in other statutory areas. He is aware of the fact that the burden in a civil case under the Act is upon the government to prove its case by a preponderance of the evidence and, in a criminal prosecution, beyond a reasonable doubt. He realizes, nevertheless, that the courts may take it upon themselves to shift this burden; although they may not say so or even realize what they are doing. Discovery proceedings are particularly important. In many instances, it may be advisable to demand a jury; perhaps he can win over at least one of them who is benighted enough to believe that even the government may, on some extraordinary occasion, be wrong.

An Unexplored Avenue

One avenue of exploration has not been explored to any real extent. In the ordinary civil seizure action, the Food and Drug Administration has taken the position, which has been sustained without exception by the courts, that if the government makes any number of charges in its complaint and prevails on one, the government must as a matter of law obtain a decree of condemnation in its favor. With its usual strong advocate approach, therefore, the Food and Drug Administration may make a seizure predicated on some substantial charge of misbranding. A real and important issue of fact and law may be presented. However, the government, in order to make absolutely certain that it must get a judgment, even if it

really hasn't proven the substantive part of its case, may add several other charges. For example, it may allege that some fairly insignificant ingredient is called on the label by its generic name, such as "emulsifier," rather than by its "common or usual name" as the statute requires. It may charge that the ingredients are not specified in large enough type. All these are thrown in so that the government must prevail, even though the jury may come to the conclusion that the really substantive charge has not been proven.

This is an ideal situation for special verdicts, so that the jury may decide each of the factual issues presented by the complaint. In the few instances where special verdicts have been requested by the claimant, however, the government has fought this bitterly. Of course, the government may not realize that it is possible that it will be hoist on its own petard by this gambit, for if the government obtains a general verdict in such a situation, and the claimant then makes one change in its labeling, can the government claim that the judgment acts as an estoppel in future cases? In any event, it seems to me that if the point I make is forcefully presented to a trial judge, and if he can only be persuaded to listen (most judges just don't listen in this field), he may see that special verdicts are virtually required in such a situation. If this is accomplished, counsel for the claimant may have gained tremendously, not only because he may really be entitled to a verdict in his claimant's favor on some of the charges, but also because of the tendency of many juries to compromise. These latter points have not, in reality, been litigated.

Publicity Feared

One other reason, of course, for avoiding litigation is the desperate fear of publicity on the part of most segments of the regulated industries. This is readily understandable. If industry, however, can reach the conclusion that it must get rid of this fear when it sincerely believes as a matter of law that it is right and the government is wrong, it is possible that this may have a somewhat braking effect on the constant effort to extend the boundaries of the authority conveyed by the Act. Further, I am by no means sure that the Supreme Court would be quite as liberal in its construction of the Federal Food, Drug and Cosmetic Act today as it was 10 or 15 years ago. Mr. Justice Frankfurter, for example, who wrote the majority opinion in the *Dotterweich* [1] case, has certainly moved to the right (this does not necessarily mean "correct") in subsequent food and drug cases.

[1] *U. S. v. Dotterweich*, 320 U. S. 277 (1943).

Another Opinion by Justice Frankfurter

Early in my talk I quoted from Mr. Justice Frankfurter's opinion in the *Dotterweich* case, decided in 1943. His language which had proven so helpful to the government, was as usual handed back to him in the government's customary fashion in a case before the Supreme Court eight years later. The case involved the government's attempt to bar from interstate distribution products purporting to be standardized foods, regardless of the fact that here they were labeled as "imitation" in conformity with a section of the statute which authorizes the distribution of food products truthfully labeled as "imitation." The Court, through Mr. Justice Frankfurter, refused to accept the government's position. In countering his own language in the *Dotterweich* case, he now just as seriously said: "In our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." Yet this was a civil action and the *Dotterweich* case a criminal prosecution.

The inferior courts may be lagging somewhat behind the Supreme Court. The government lost the last two cases to reach the Supreme Court, and in my opinion these might well have been won if they had come before the Supreme Court several years earlier. In any event, the client in this field should be advised that litigation should not be entered into unless he is prepared to appeal.

I must conclude by making one recommendation. In many areas, a careful and thorough lawyer is customarily willing to stick his neck out and give a definite opinion to his client. The specialist in the food and drug area, however, although he may have concluded that his client's position is legally correct, must now try to speculate whether the government will differ and whether the courts, by some miracle, will take issue with the government's position. It is this factor which makes specialization in the food and drug field an intriguing, yet sometimes frustrating experience. **[The End]**

Weights and Measures Control at the Federal Level

By CHESTER T. HUBBLE

The Author, Director of Division of Case Control, Bureau of Enforcement of the Food and Drug Administration, Delivered This Address at the Forty-seventh National Conference on Weights and Measures, in Washington, D. C. on June 7, 1962.

I AM COMPLIMENTED to be invited to appear on the program of another of your National Conferences on Weights and Measures. There is a great area of common interest in the work that you and your associates are doing on a daily basis and the kind of enforcement actions under the Federal Food, Drug, and Cosmetic Act that flow from our field offices through the Division of Case Control in the Bureau of Enforcement.

When Commissioner Larrick spoke at your meeting last year he referred to our inability to increase our efforts in investigating short-weight practices to the extent that would be desirable because of our enforcement obligations in the health field. As a suggested means of assisting in bridging this gap he invited your requests for commissions so that you could assist in enforcement of federal requirements in your states and cities. This idea has been acted on by the officials of four states and the District of Columbia thus far.

Number of Violations Increasing

Meanwhile we have been able to give regulatory attention to violations in the area of short weight and inconspicuously labeled foods to a significantly greater extent than originally contemplated. The number of violations has been running rather high in this relatively neglected area. During a 10-month period extending from the middle of June, 1961 to the middle of April, 1962 we removed from the market by seizure action 162 lots of short-weight foods and 63 lots of foods bearing inconspicuous declarations of net contents, ingredients or firm name and address. In approximately 30 other instances violations were encountered that warranted seizure, but the goods were dis-

แผนกห้องสมุด กรมวิทยาศาสตร์
กระทรวงอุตสาหกรรม

tributed and perhaps consumed before the lots could be attached by the United States marshals following preparation of the necessary legal documents. You recognize, of course, that we have no direct embargo or seizure authority, and it is not always possible to make a final decision as to the legal status of a lot in time to arrange a state or local embargo through cooperating enforcement officials, though such arrangements are used to great advantage on many occasions.

These short-weight and/or short-volume foods just about ran the gamut of the market basket. They included anchovies, beer, black pepper and numerous other spices including 16 in one seizure; blueberry pie filling, bread, breaded oysters, cake mix, candied watermelon slices, candy mints, candy bars, cane sirup, canned green beans, canned mixed nuts, canned mushrooms, canned pork and beans, canned sweet potatoes, cashew nuts, caviar, cheese sticks snacks, chocolate flavored sirup, concentrated fruit sirup, coffee, cookies, dates, dried beans, fried pork rinds, frosting mix, frozen flavored ice suckers, frozen pizza, fruit preserves, glace fruit, grenadine sirup, honey and ice cream topping. Also included were instant coffee, instant tea, macaroni, maraschino cherries, matzo crackers, nonfat dry milk, noodles, oleomargarine, olive oil, olives, onion soup mix, orange juice, peanut butter, pecans, pickle chips, pickle relish, popcorn, potato chips, pretzels, puffed rice, puffed wheat, salad dressing, sauerkraut, sesame chips (crackers), shrimp cocktail, shoestring potatoes in cans, sorghum, spaghetti, sugar tablets, tea, tea bags, toasted pumpkin seeds, tortillas, vinegar, walnuts in sirup, wheat germ cereal and zweibach toast, and of all things, a short weight "weight control" liquid.

Legal Charge Is Misbranding

Since the legal charge against short-weight foods is one of misbranding, it is usually limited to a single action for each product. As you perhaps know, our law provides for multiple seizures on the same alleged misbranding only after the adjudication of one such charge in favor of the government unless the Secretary makes a finding of fact that the article is dangerous, or the labeling is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. This is interpreted to include economic damage. We did make a finding in the case of some nationally distributed puffed wheat and puffed rice that ranged up to 15 per cent short weight in the wheat and 6 per cent in the rice product. The manufacturer had developed a process by which it could puff the grain to a substantially greater volume than had previously been the

practice. Placing the product with increased volume in the same size cartons without change in weight declaration resulted in the shortages mentioned above. Although the company was aware of the short-weight problem as early as April, 1961, it continued distribution of the short-weight packages until action was started by the Food and Drug Administration in July. Routine reports received by our Division of Federal-State Relations suggest that legal action was taken some months ago by the State of New Jersey resulting in a $500 fine on 10 counts.

The amounts of the net contents shortages were not always large, percentage wise. In fact, in the 162 libel actions filed only 8 per cent showed shortages above 10 per cent; 26 per cent were from 5 to 10 per cent, and 66 per cent were less than 5 per cent. Under the federal law in order to establish criminal liability we must be able to conclude that the product was short weight when shipped. This poses no particular problem in the case of such containers as hermetically sealed cans, while in others such as paper or cloth bags considerable weight must be given to the age of the lot sampled, moisture content (as compared to normal moisture levels when this is known), storage conditions, temperature and humidity.

Some of these problems can be overcome by check-weighing the same items in the same size packages as packaged at the factory prior to shipment; the weighing at the time a shipment is delivered to a common carrier for introduction into interstate commerce or by other similar techniques. There are apparently some tightly sealed containers that should not lose moisture such as heat-sealed pliofilm bags, but our scientists tell us that there is great variation in the porosity of various films that appear tight and the moisture loss through them can be significant.

A further word of caution—it is not always easy to determine the tare weight accurately. We have experienced several examples of glass jars used as containers where the variation in weight of individual jars is greater than the average shortage in net weight of the contents, for example, a 2 per cent shortage in a 2-ounce jar is only .04 ounce and the glass jars may easily vary up to .08 ounce, so we must be sure we are measuring actual shortage and not container variation.

The number of seizure cases involving inconspicuous labeling has not been as great as for short weight cases but the percentage increase over previous years has been about the same. We understand that the impact on industry has been great. Some of the larger firms in

the country have been involved. Many have hastened to bring about corrections that would meet our objections and thus far only two or three firms have decided to contest the issues in court. One such case was lost by the government earlier this year because of the difficulty in proving to the satisfaction of the court as a fact that the accused statements were inconspicuous because of the inherent difficulties in such subjective measurements.

Avoiding Easy Detection of Required Labeling Information

Those responsible for the make-up of food labels have shown us there are many resourceful ways to avoid easy detection of mandatory label information. Here are a few of the more common ways that have been used—through inadvertence or by deliberation. The ink color selected for such information on clear bags or wrappers is that of the product so that there is no contrast and thus the wording can not be readily seen, if at all. Black ink is used for licorice candy bags, brown ink for bags of chocolate candy or brown dried beans, white for marshmallows, and green for green colored gum-type candies. Similarly the ink does not contrast with the label background such as in the case of black printing on very dark green cardboard. The size type used, even when there is ample room on the label, is too small to be easily read and, often the fraction of a net weight declaration such as 1¼ ozs. can not be read. Sometimes the printing is so blurred in the case of mandatory information (but never in the case of a brand name) that it can not be read.

Required information is encountered on package wrappers of a metallic type so highly reflective that the words, especially if small, can be read only with difficulty in good light and at one certain angle. Mandatory information has been found camouflaged by a background of variegated colors or submerged in nonrequired information such as recipes and "trade puffery," of the same color, size and style of type. Sales promoters of "free" portions of a product or a "free" prize such as a ball point pen or a cook book sometimes overlook legal requirements in attaching the gift to the original package in such a way that at the time of purchase it completely obscures the quantity of contents statement or other information. Many times unit items of a food bearing proper labels are packed six or more together in an open faced opaque carton which is sealed in a wrapper in such a way that the mandatory information on the individual units can not be seen and is not repeated on the outer wrapper.

Although we have sought through discussions, expressions of opinion, in correspondence, and so forth, to have required information appear plainly and conspicuously on the main panel of the label, in order to be certain of compliance, we find considerable body of opinion among industry people that this is not necessary since the Act itself does not contain such a specific requirement. Also the interpretive regulations thus far issued have not specified an exact location or type size. Perhaps revised regulations in more specific terms may be needed to spell out packaging and labeling criteria more clearly. These matters, as you know, have been given much attention in the hearings conducted by Senator Hart's Subcommittee on the Antitrust and Monopoly of the Senate Committee on the Judiciary. And in case any of you did not have the opportunity to read this significant portion of President Kennedy's March 15, 1962, message on protecting the consumer let me quote him as follows:

President Kennedy Speaks on Consumer Protection

Just as consumers have the right to know what is in their credit contract, so also do they have the right to know what is in the package they buy. Senator Hart and his subcommittee are to be commended for the important investigation they are now conducting into packaging and labelling practices.

In our modern society good packaging meets many consumer needs, among them convenience, freshness, safety and attractive appearance. But often in recent years, as the hearings have demonstrated, these benefits have been accompanied by practices which frustrate the consumer's efforts to get the best value for his dollar. In many cases the label seems designed to conceal rather than to reveal the true contents of the package. Sometimes the consumer cannot readily ascertain the net amount of the product, or the ratio of solid contents to air. Frequently he cannot readily compute the comparative costs per unit of different brands packed in odd sizes, or of the same brand in large, giant, king size, or jumbo packages. And he may not realize that changes in the customary size or shape of the package may account for apparent bargains, or that "cents-off" promotions are often not real savings.

Misleading, fraudulent or unhelpful practices such as these are clearly incompatible with the efficient and equitable functioning of our free competitive economy. Under our system, consumers have a right to expect that packages will carry reliable and readily usable information about their contents. And those manufacturers whose products are sold in such packages have a right to expect that their competitors will be required to adhere to the same standards. Upon completion of our own survey of these packaging and labelling abuses, in full cooperation with the Senate Subcommittee, I shall make recommendations as to the appropriate roles of private business and the Federal Government in improving packaging standards and achieving more specific disclosure of the quantity of ingredients of the product inside the package in a form convenient to and usable by the consumer.

Our enforcement actions in the field of deceptive packaging are still marked by lack of success in contested cases. We have appealed to the Circuit Court of Appeals twice in the well known Delson thin

mint candy case previously discussed with you and only recently lost our last attempt to gain a decision favorable to the government and we think to the consuming public. It now appears that in the absence of any further legislation in this area we might have more success by developing some standards of fill of container, as now provided for in the Act, even though this certainly would be marked with difficulty in view of the great number and variety of packages that would be involved even for a single food industry or product.

"Giant Economy Size" Misleading

In a somewhat different area of economic cheating we recently seized in possession of a large retail food chain in Chicago, stocks of 10 ounce size jars of instant coffee labeled by a nationally prominent food firm as "Giant Economy Size." This representation was charged to be false and misleading since the cost per ounce of product was 14.4 cents when buying the giant economy size but only 12½ cents when buying the smaller (6 ounce) size of the same product in the same stores.

In addition to participating in each of your National Conferences we have, primarily through our Division of Federal-State Relations, attempted to keep you up to date on our day-to-day activities so that our work would be coordinated to the greatest extent possible.

Following last year's conference we sent you lists of seizures of foods that were found to be short weight, short volume or inconspicuously labeled. Beginning February 1 of this year we started sending out consolidated lists of all seizures, prosecutions and injunctions by us on all products covered in the enforcement of the Federal Food, Drug and Cosmetic Act and the Federal Hazardous Substances Labeling Act. We hope this information, which is now being supplied every two weeks, is helpful and informative.

Many of you will recall that when we started sending this information to you we supplied a number of blank forms and suggested that you might wish to reciprocate by sending us information of a similar nature. A number of weights and measures officials responded and have been keeping us advised of their actions on a periodic basis. This has been extremely helpful in the development of our short weight and short volume programs.

We hope that each of you will join in a two-way exchange of this information and that such an exchange will lead to an accurate appraisal of the nationwide consumer protection afforded by our joint efforts in this area. **[The End]**

International Developments in the Food Law Field

By FRANKLIN M. DEPEW

Mr. Depew Is President of the Food Law Institute.

THERE HAVE BEEN a number of interesting developments in the food law field not only in Europe, but in Latin-America, since I last reported on European developments.*

The Official Revised Spanish Edition of the Latin-American Food Code, as adopted by the Seventh Latin-American Chemical Congress on April 3, 1959 and published in Spanish in August, 1960 has been translated in part into English. The English translation of the Introduction was published in the October, 1960 issue of the FOOD DRUG COSMETIC LAW JOURNAL; Chapter IV in the February, 1961 issue; Chapter X in the May, 1961 issue; Chapter XVI in the November, 1961 issue; and Chapter XII in the June, 1962 issue. Comments by representatives of American industry were invited and received. These were passed on to Dr. Carlos A. Grau, President of the Permanent Commission for the Code, who has graciously made revisions in accordance therewith. The revised copy of this Code will be submitted to the Eighth Latin-American Chemical Congress in Buenos Aires in September, 1962, at which time it is expected that further revision of the Code will be made in the light of suggestions and comments received in the meantime.

Inter-American Bar Association Meeting in Columbia

At the Twelfth Conference of the Inter-American Bar Association held in Bogotá, Colombia, on January 31, 1961, Dr. Enrique E. Bledel reported to the members of the Food, Drug and Cosmetic Law Sec-

* "Recent European Food Law Developments," 15 FOOD DRUG COSMETIC LAW JOURNAL 817.

tion of the Association on developments in the food, drug and cosmetic field since the Eleventh Conference. A copy of this report and the minutes of the meeting are attached (Annexes A and B).

The following resolution with respect to the Latin-American Food Code was adopted:

RESOLVED, that the Section highly commends the outstanding work done by the Drafting Committee for the Latin American Food Code under the chairmanship of Dr. Carlos A. Grau in revising the Preliminary Draft of the Latin American Food Code and in publishing a printed edition of the Revised Code.

FURTHER RESOLVED that the Section devote its special attention to a continued study of the 1960 edition of the Code and contribute comments and suggestions to the Permanent Drafting Committee for the Latin American Food Code so as to further improve and elaborate the text of the Code to keep it dynamic and closely related to the continuous evolution of food technology and to make it a modern model food code designed to stimulate international trade and commerce; and

FURTHER RESOLVED that the Section submit the 1960 edition of the Latin American Food Code to the Directors General of F. A. O. (Food and Agricultural Organization of the United Nations) and W. H. O. (World Health Organization) and to other national and international organizations concerned in food, drug and cosmetic law, for their study and comments on the legal aspects of the Code.

Results of Santiago Meeting

At the meeting of the Pan American Pharmaceutical and Biochemical Federation held in Santiago, Chile, November 10-19, 1960, an effort was made to secure that organization's sponsorship of a Pan-American Food Code. This rival project did not find any support among the delegates, primarily because the Latin-American Food Code, drafted by Dr. Carlos A. Grau and his committee, was already complete and was the work of a committee representative of most of the Latin-American Republics. Consequently, the only food code under active consideration in this hemisphere is the Latin-American Food Code.

Definition Adopted

However, the following definition, formulated by a commission consisting of Dr. Schmidt-Hebbel, Dr. Celsi and Dr. Grau, was adopted unanimously at the Symposium on Food Additives, held as part of the program of the Santiago meeting:

The term "added extraneous substance" (additive) means any substance which, lacking any nutritional value or serving no nutritional purpose, is added to foods in order to improve their appearance, their organoleptic characteristics or their conditions of preservation. By extension, physical agents which serve the same purposes shall likewise be considered additives.

The use of an additive may be authorized only on condition that it meet the following requirements:

a. If its harmlessness for the human health has been proved conclusively;

b. If it does not affect the hygienic, nutritional or technological conditions of the foods containing it and does not lend itself to covering up a possible fraud;

c. If it is truly indispensable from the technological point of view; above all, if it cannot be avoided, or replaced by a natural product of known harmlessness.

d. If its control is practically feasible.

All countries ought to adopt a positive list of additives. This list should be temporary and subject to revisions.

This definition was approved, likewise unanimously, by the plenary closing session of the Federation.

Meeting of European Food Code Council

A meeting of the Council for the European Food Code was held on February 13, 1961. At that meeting a resolution was adopted to associate the Council for the Code with FAO/WHO (Food and Agricultural Organization-World Health Organization-United Nations) and to form a "Joint Committee" which would include representatives of both agencies. The Joint Committee was to be responsible for furthering food standardization and for food law codes in Europe and throughout the world. The Resolutions were then communicated to the Directors-General of FAO and WHO with a note explaining how the functions of the present Code Organization would be continued under the proposed joint FAO/WHO program. The proposals were approved by the Directors-General and a note setting forth the general plan of the proposed program was sent to Dr. Hans Frenzel, President of the Council, for the consideration of the Fourth Conference of the Council for the European Code held in Vienna on May 31-June 3, 1961.

Resolution Adopted for Affiliation With FAO/WHO

At this conference a resolution was adopted by the delegates for affiliation of the Council with the new Joint Committee of Food and Agriculture Association/World Health Organization basically in accordance with the proposed plan approved by the Directors-General of FAO and WHO. Industry representatives urged that they and private scientific organizations be given an opportunity to present their views to the Joint Committee so that industry problems would receive proper consideration. The plan provides that funds to carry out the program will be made through a Special Trust Fund. The

funds will be advanced by national *Codex* committees of the various interested countries. Contributions may be made to the committees by industry or other interested organizations. The contributions of each participating country will be consolidated by its national *Codex* committee so that one single national contribution can be made for each country through or with the approval of the government concerned.

As it appeared that the Council for the Code had not been brought up to date with respect to developments in this hemisphere, I sent Dr. Frenzel a copy of the current edition of the Latin-American Food Code prior to the Vienna meeting and informed him that the Pan-American Food Code project had been abandoned, with the result that the Latin-American Food Code was favorably received at the Fourth Conference and a letter was sent to Dr. Grau congratulating him and his committee on the work which had been accomplished.

Program of ISO/TC 34

In August, 1961, the American Standards Association (ASA) sent an invitation to about 75 food trade associations located in the United States, to the United States Department of Agriculture, and to the United States Food and Drug Administration, to attend a general conference to be held on October 6, 1961 to discuss the role that the United States, through the ASA, should play in activities of the International Organization for Standardization (ISO) for the international standardization of products of agricultural origin and for human and animal feeding purposes with special emphasis on those which enter international trade. This international standardization activity has been carried on for a number of years under the auspices of the International Organization for Standardization (ISO), which is a federation of national standards associations of 45 countries. Standardization of agricultural products has been handled by a technical committee known as ISO/TC 34. The recommended program of work for ISO/TC 34 limits its activities to: (1) terminology, (2) methods of testing and sampling, (3) packing, and (4) storage, handling and transportation. Since 1957 seven subcommittees of ISO-TC 34 have considered standardizing the following agricultural commodities: (1.) propagation materials, (2.) oil seeds and vegetable oils, (3.) fruits and vegetables, (4.) cereals and pulses, (5.) milk and dairy products, (6.) meat and meat products, (7.) spices, condiments and stimulants (such as coffee and tea). Work is now under way in all seven subcommittees.

The ASA meeting was held on October 6, 1961, on which occasion those present failed to indicate a desire to participate to the extent of forming a United States National Advisory Committee for ISO/TC 34. Certain organizations have, since that time, advised ASA that they would like to participate in the work of the subcommittees to the extent of naming an advisory group to the subcommittee. The ASA plans to keep these American organizations informed of these activities so that they may be represented in the work of the subcommittees. Unless American industry is represented by a National Committee for active participation in ISO/TC 34, it seems possible that standards may be formulated which are unsatisfactory from the American viewpoint. The American Standards Association will not urge such participation unless American industry expresses an active desire to participate. A letter from ASA to organizations attending the meeting, dated March 13, 1962 is attached, together with a copy of Mr. Boerma's letter (Annexes C and D). The report referred to is not included here because it has already been published in 17 FOOD DRUG COSMETIC LAW JOURNAL 131, February, 1962. Any views on the subject should be sent to the American Standards Association, 10 East 40th Street, New York 16, New York. The importance of participation in such work is augmented by the fact that ISO is one of the organizations mentioned as qualified to do preparatory work on Standards in the Report of the Conference held in Rome on November 23, 1961, dealing with the Joint FAO/WHO Program on Food Standards referred to in Mr. Boerma's letter and published in full in 17 FOOD DRUG COSMETIC LAW JOURNAL 131, February, 1962.

New *Codex Alimentarius* Commission Needed

The report of this conference is very interesting and important as it shows that the FAO and WHO may be expected to embark on the venture of an International Food Code which may be expected to supersede the Council for the European Food Code as well as a program which aims at simplifying and integrating food standards work on an international level. The resolution adopted by the conference, as set forth in its report, specifically endorses the proposals made by the Directors General of FAO and WHO, with one exception. This exception concerns the initial period of four years during which time the acceptance of any standard by European governments alone will be a necessary and sufficient condition for its publication in the *Codex Alimentarius*. The conference drew specific attention to the

need for the new *Codex Alimentarius* Commission, which takes over the original Council for the *Codex Alimentarius*, to study the need for more than one standard for a given product so as to harmonize special requirements of certain regions. The conference also urged all interested member nations to contribute to the Special Trust Fund and to consult with the Directors General as to the amount of this contribution. The United States government has established an inter-agency *Codex* committee for the purpose of considering a United States contribution; it is made up of representatives from the Departments of Agriculture, Commerce, and Health, Education and Welfare. Jacob M. Schaffer, Director of the Food Industries Division, Business and Defense Services Administration, Department of Commerce, has been appointed to serve as chairman of a subcommittee which has been charged with responsibility to report on two assignments, namely: (1) the mechanism by which United States participation will be coordinated, and (2) the manner in which business, foundation, and other business contributions to the Trust Fund may be encouraged and sought.

In the meantime the original Council for the Code has continued to function and in a recent address the West German Minister of Health, Dr. Elizabeth Schwartzhaupt, said:

> As you know, efforts have been made for about six years to achieve the creation of a *Codex Alimentarius* for all of Europe. It was the President of the Austrian Food Code Commission, former Federal Minister Dr. Frenzel, who paved the way for this thought. The Federal Republic of Germany has collaborated energetically on the European Food Code Council. At the last general meeting of the European Food Code Commission at Vienna the merits of the German Council members about the creation of the chapter on principles were given particular credit. This acclaim found expression also in concrete honors. The Federal Republic of Germany will be perfectly happy to continue developing the work of the European Food Code Council with every means available. It believes, however, that if this body is to operate as successfully as it has done in the past it must keep its autonomy and maintain the flexible working methods applied thus far. We feel hopeful and confident that the work commenced by Austria will be pursued successfully also after next month when the chairmanship of the Council goes into Swiss hands, because the recommendations supported by eighteen European countries will orient the harmonization of the European food legislations.

Thereafter on March 26, 1962 as mentioned by Dr. Schwarzhaupt in her address, First President Dr. Frenzel inducted his successor, Professor Dr. Högl of Switzerland into his office of Chairman in the Chambers of the Court of the Exchequer at Vienna. The ceremony was attended by the Federal Minister for Social Administration, a

representative of the Federal Minister for Land and Forest Economics, the Swiss Ambassador to Austria and many outstanding representatives of public authorities and public life.

Finally, I have been informed that a Joint FAO/WHO Conference on Food Standards will be held in Geneva on October 1-6, 1962.

ANNEX A

This Is a Report on Developments in the Food, Drug and Cosmetic Law Section Since the Eleventh Conference of the Inter-American Bar Association Held at Miami in April, 1959. *Enrique E. Bledel,* Secretary of the Section, Presented the Report at the Twelfth Conference of the Association Which Was Held in Bogota, Colombia, January 27-February 3, 1961.

In my capacity of Secretary of the Food, Drug and Cosmetic Law Section of the Inter-American Bar Association, it is my privilege to report to this conference on all developments and events of particular interest which have taken place in our special field since April, 1959, that is, since the time at which the Eleventh Conference was held at Miami.

In the first place, it is my sad duty to report that since then the Association has lost one of its outstanding members, Charles Wesley Dunn, who passed away in November, 1959, and whose demise was received with deep sympathy by all circles in which he had been active. It was Mr. Dunn who, in 1957, at the Tenth Conference held in Buenos Aires, first formulated the idea of creating a separate Food, Drug and Cosmetic Law Section within the Inter-American Bar Association and who must therefore be given credit for having been the true founder of this movement which is to stimulate and intensify the interest in and study of food, drug and cosmetic regulations in the Americas. The remembrance of his strong personality and of the competence he achieved in this particular field in years of experience—as a member of the legal profession, university lecturer and member of professional organizations in the United States and other countries—will serve as an inspiration and guide for all who seek to contribute to the development of this new specialty within the health laws of our countries.

New Officials Chosen

With the passing away of Mr. Dunn, the office of Vice President of our Section had become vacant. Mr. Warren S. Adams was chosen to take his place. Mr. Adams is an eminent member of the New York

State bar, who, because of the orientation he has given to his professional activities, has gained a well-deserved prestige among the jurists engaged in the study of food, drug and cosmetic laws.

The office of President of The Food Law Institute, New York, likewise previously held by Mr. Dunn, was filled by Franklin M. Depew, a lawyer who has behind him many years of extensive experience in the food industry and is also actively interested in the study of food, drug and cosmetic laws. Mr. Depew is a member of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association and of the Division of Food, Drug and Cosmetic Law in the Section on Corporation, Banking, and Business Law of the American Bar Association and of its Committee on Food Standards. He has collaborated in the past on the publication of The Food Law Institute: FOOD, DRUG, COSMETIC LAW JOURNAL, and has given lectures on this particular subject at New York University, under the sponsorship of The Food Law Institute.

Our section is happy to welcome Mr. Depew as one of its members. His success in his new office is assured by his professional prestige and his remarkable experience in our field of law.

Mr. Samuel A. McCain was elected Chairman of the Subsection for the United States of America. Mr. McCain is a distinguished jurist who has been extremely active in the field of food and drug legislation. We can therefore expect of him valuable contributions to the progress and development of our food, drug and cosmetic laws.

Dr. Jorge E. O'Farrell was appointed Treasurer of our Section. In this capacity he is to administer whatever funds may be collected in the future in order to publish papers and cover whatever other expenses may be caused by the activities of our Section. Dr. O'Farrell is going to fill this new office of Treasurer without prejudice to his activities as Chairman of our Section.

Newly Formed Groups to Play an Important Part

Finally, I am happy to state that subsections have been formed within the local bar associations of several countries, which will engage in the study of local laws and serve as a source of information. They will also facilitate the exchange of the documentation required to undertake comparative studies of our special laws in all American countries. At this time, about 35 Latin-American lawyers have enrolled in our Section and have already begun to cooperate actively towards the development of its program.

In order to set up a compilation of the basic information on food, drug and cosmetic laws which may serve as a practical guide for lawyers, industrialists and merchants, that is, all persons whose activities are related to the food, drug and cosmetic laws, a questionnaire was addressed to all members of our section in the different countries. This questionnaire was to supply information on the most important questions germane to this special field.

On the basis of the answers received, a first compilation has been prepared which will be distributed to the members of our Section in both Spanish and English, with special mention of the professionals who lent their cooperation to this work. Although this compilation must be considered incomplete, it may serve as a starting point for comparative studies of the subject.

I attended, as an observer, the meetings which the Division of Food, Drug and Cosmetic Law of the American Bar Association held in Washington in 1960. This gave me an opportunity to appreciate the number of North American professionals who attended the meetings, the quality of the papers presented and the interest shown by the participants in discussions of a great variety of subjects all dealing with our specialty. The Subsection for the United States already has 24 regular and three associate members, as I understand from its Secretary, Dr. Julius G. Zimmerman, who is also the Editor of Foreign Laws of the FOOD, DRUG, COSMETIC LAW JOURNAL.

I also wish to point out that the Latin-American Food Code which was approved at the Seventh Latin-American Chemical Congress held in Mexico City from March 28 to April 3, 1959, has now been published. Its published edition contains a number of amendments suggested by authoritative experts and approved by the Permanent Editing Committee, whose Chairman is Dr. Carlos A. Grau of Argentina. As far as I know, this Code has been widely distributed to specialists in the Americas, who were happy to receive it and commented on it in the most favorable terms. We have been informed that in several Latin-American countries, government committees whose task it is to revise the food legislation, have taken the text of the Code as a guide on which to pattern more modern regulations. It must be hoped that the Code will become known still more widely and in the end be instrumental in bringing about greater uniformity and consistency in the food laws of all American countries. Be it said in this connection that the members of our Section are in a position and will be happy to lend their assistance in spreading the Code not

only among professional groups, but also among those members of governments who are to propose and pass legislation in line with the latest findings and standards.

The first text of a Pan-American Bromatological Code, drafted by Dr. V. Colobraro and Dr. S. A. Celsi of Argentina, and containing the general and special regulations to be met in particular by foods and beverages of world-wide consumption, was to have been debated at the Fifth Pan-American Congress of Pharmacy and Biochemistry held at Santiago, Chile, from November 12-19, 1960. It did not come up for discussion, however, since its authors withdrew it from the agenda of the Congress.

These are, as far as I know, all the matters of importance concerning our Section which have developed since the Miami Conference. Now, if any of the members here assembled have any comments to make which they consider of interest or as likely to contribute to the achievement of our purposes, I shall be happy to yield the floor.

ANNEX B

Minutes of the Meeting Held in Bogota, Colombia, on January 31, 1961, During the Sessions of the Twelfth Conference of the Inter-American Bar Association, Food, Drug and Cosmetic Law Section.

At 15 o'clock the meeting of the Section was declared open with the following members present:

Argentina: Enrique E. Bledel, Buenos Aires, Secretary of the Section; Carlos María Gamas, Buenos Aires, representative of the Argentine Federation of Bar Associations.

Colombia: Ramiro Castro-Duque, Secretary of the meeting.

Ecuador: Diego Bustamante, Quito.

United States: John Dahlgren, Washington, D. C.; Franklin M. Depew, New York, New York, President of the Food Law Institute of New York; Victor C. Folsom, Boston, Massachusetts, Vice-President of the Section, acting President; John V. Guigon, New York, New York; Samuel A. McCain, New York, New York, President of the United States Subsection; Julius G. Zimmerman, New York, New York, Secretary of the United States Subsection.

Peru: Alberto L. de Guevara, Lima; Juan Velásquez F., Lima; Jorge Mercado, Lima.

Also present was Rafael Gutiérrez C. of Bogotá, who recorded in shorthand the subjects discussed in this meeting.

Victor C. Folsom declared the meeting open and welcomed all present. He stated that in the absence of Dr. J. E. O'Farrell, President of the Section, who unfortunately was not able to attend, he as Vice-President would take the chair.

Further, he appointed Dr. Ramiro Castro-Duque of Colombia as secretary of the meeting. He also expressed his appreciation to Rafael Gutiérrez C. for helping the secretary in his duties.

Introduction of Officers

Making reference to the agenda he stated that although it was not very long, it was interesting. He further stated that the Food, Drug and Cosmetic Law Section was honoured by the presence of Dr. Carlos María Gamas of Buenos Aires who had been chosen to represent the Argentine Federation of Bar Associations in the absence of Dr. O'Farrell. He expressed himself in the same terms about other officers also present—the distinguished and dynamic Secretary of the Section, Dr. Enrique E. Bledel, so well known by all; Mr. Samuel A. McCain, President of the United States Subsection, who was host at luncheon to members of the Section and welcomed them in Spanish; Dr. Julius G. Zimmerman, Secretary of the United States Subsection; Dr. Juan Velásquez F., Secretary of the Peruvian Subsection and Dr. Ramiro Castro-Duque, member resident in Bogotá and Secretary of the meeting.

Further, Mr. Folsom proceeded to appoint the following officers of the Committee for Resolutions and Appointments: President—Dr. Ramiro Castro-Duque, Messrs. Samuel A. McCain and Enrique E. Bledel.

Before proceeding with the reading of the report on the activities of the Food, Drug and Cosmetic Law Section since the XI Conference of the Inter-American Bar Association held in Miami in April, 1959, (Annex A) the Secretary of the Section, Dr. Enrique E. Bledel, thanked Mr. Folsom for his kind words and stressed that if his own work proved of value, this was mainly due to the wonderful leadership of Dr. Jorge E. O'Farrell and to the constant and intelligent cooperation shown by the Secretary of the United States Subsection, Dr. Julius G. Zimmerman.

In addition to the report proper, Dr. Bledel made an interesting reference to the efforts which made this constructive work possible,

stating that the work accomplished so far proved that the members of the Section fully and efficiently cooperated in order to reach their objective.

In connection with the Latin-American Food Code to which detailed reference was made in Dr. Bledel's report, he stated that it would be recommended that our Latin American colleagues give ample publicity to its text in order to achieve progressively a greater uniformity in food legislation.

With reference to the compilation of the basic information on Latin American Food, Drug and Cosmetic Legislation to which reference was made in his report, but without making a detailed analysis of the subject, Dr. Bledel stated that copies were available to those present of the questionnaire and of the respective answers given by lawyers of the different countries (Argentina, Brazil, Chile, Mexico, Peru and Uruguay) who collaborated in this task.

Later Dr. Bledel asked Franklin M. Depew, President of the Food Law Institute, to give a short account of his experiences in Europe with regard to this subject. In brief, Mr. Depew stated that there existed in Europe a committee engaged in the drafting of a food code which has asked for the cooperation of the World Health Organization and of the FAO (Food and Agriculture Organization); their work is in the preliminary stage and is not expected to be terminated before two or three years' time. In this respect the Latin American countries are much more ahead.

When asked by the Chairman about the progress made in Colombia, Dr. Ramiro Castro-Duque stated that the situation seems rather confused due to a recent government regulation which unfortunately will have to be changed. He added that notwithstanding the more or less serious studies of the subject which are at present being made, it would be well to take advantage of the conclusions of this conference to make recommendations to the Colombian government. These recommendations could be taken into consideration by the government for the drafting of a food code.

Mr. John O. Dahlgren, after apologizing for the lack of a Spanish translation, read a paper entitled "Principal International Agreements Relating to Control of the Narcotic Drug Traffic," by Alfred L. Tennyson, formerly Chief Counsel, and Carl De Baggio, Chief Counsel of the Bureau of Narcotics, Washington, D. C. Making corresponding explanations, Mr. Dahlgren expressed the hope that the conference would adopt some definite program in order to obtain the cooperation of all the countries in the fight against narcotic drug traffic.

Narcotic Drug Control in Peru

While discussing this subject the Chairman asked Dr. Juan Velásquez F. of Peru to explain the present situation in his country regarding narcotic drug control. At the present time, said Dr. Velásquez, Peru has a special tribunal (*tribunal privativo*), a dependency of the Ministry of Interior, which not only controls the proper use of the drugs and narcotics by the laboratories but the improper use in all its forms as well. This tribunal operates under the chairmanship of the Minister of Interior and has various advisors from the Ministry of Public Health as well as from the Ministry of Interior, which are in charge of the vigilance and control of the drug traffic. This tribunal has powers to order arrests and impose economic sanctions on the syndicates for the improper use of drugs.

Dr. Velásquez is convinced that in his country the campaign that is being conducted is beneficial to the poorest sections of the population, to which belong, in particular, the Indian, who unfortunately, is the greatest consumer of coca, which drug forms part of his daily food. "It is to be regretted that in our country the Indian cannot work well without his daily ration of coca," said Dr. Velásquez.

This special tribunal (*tribunal privativo*) which watches over the use of narcotic drugs is doing a meritorious job.

When asked what a "special tribunal" was, Dr. Velásquez explained that it was an organization which is not subject to any political control. It is constituted of lawyers, doctors and other professionals, and has the power to impose sanctions. It is legally recognized.

Following Dr. Velásquez's statements, the Secretary of the Section, Dr. Enrique E. Bledel, read the draft of a resolution in which various recommendations are being made to the American countries with regard to the campaign against illegal traffic in narcotic drugs.

Treatment of Drug Addict Discussed

In the discussions that followed, Dr. Carlos María Gamas suggested with regard to the point concerning the treatment of drug addicts that it would be better to word it in the affirmative, that is, "to recommend the treatment of narcotic drug addicts be carried out under official control." Dr. Gamas added that the form proposed was, in his opinion, negative. It only contained one moral sanction and on the other hand tended to restrict the private practice of medicine. This observation of Dr. Gamas gave rise to a lively discussion, es-

pecially among Messrs. Gamas, Velásquez, Folsom, McCain, Dahlgren and Castro-Duque, as to the advisability of modifying the article under discussion or eliminating it completely, as some of the members claimed that Dr. Gamas's suggestion was included in the subsequent clause. Finally the Chairman proposed that the point under discussion be submitted to a special committee; this suggestion was unanimously accepted, Messrs. Carlos María Gamas, Juan Velásquez F. and John O. Dahlgren being appointed to form the committee.

Franklin M. Depew then read in English his paper entitled: "Current Food Law Developments in the United States," expressing the honour he felt in succeeding Charles Wesley Dunn as President of the Food Law Institute. While he was reading this paper, the Spanish translation of which was followed very closely by the attendants, Mr. Depew gave several explanations and at the end the Chairman congratulated Mr. Depew for his interesting work and submitted to the consideration of the members the final recommendation of this work. This was approved with one amendment, proposed by Dr. Carlos María Gamas, and unanimously accepted. The amendment proposed that the inquiry contained in the last part of the paper must be addressed to the merchants and manufacturers specializing in this subject, as the term "trade" to which this recommendation refers is too generic and includes activities totally different from those to which the recommendation refers.

When discussing the last point of the agenda, Dr. Ramiro Castro-Duque read the Spanish text and Dr. Julius G. Zimmerman the English text of each of the proposed resolutions which were individually discussed and unanimously approved.

In closing, Dr. Enrique E. Bledel in his capacity as Secretary of the Section thanked Samuel A. McCain for the splendid luncheon he offered to the attendants as well as for the facilities obtained for the meeting.

There being no other matters for discussion, the Chairman closed the meeting at 6 p. m.

ANNEX C

March 13, 1962

To Organizations Interested in ISO/TC 34

Gentlemen:

In view of your indicated interest in International Organization for Standardization/Technical Committee 34, Agricultural Food Prod-

ucts, we felt you would like the opportunity to see a letter received by Admiral Hussey from Mr. Boerma of the Food and Agriculture Organization. A copy of Mr. Boerma's letter is enclosed.

You possibly will recall that a representative of the Food and Agriculture Organization addressed the International Organization for Standardization/Technical Committee 34 conference on October 6.

At the moment, there is no plan for another conference on the question of participation in International Organization for Standardization/Technical Committee 34. There has been a show of interest in participation in the work of at least two subcommittees and perhaps three. However, should these areas of the food industry concerned decide on active pursuit of this work, such participation can be handled at the subcommittee level.

We shall keep you informed of any further developments on International Organization for Standardization/Technical Committee 34.

Sincerely,

Rose V. White, Secretary [signed]

Consumer Goods Standards Board
Home Economist

RVW:MTB
Encl.

ANNEX D

Dec. 27, 1961

Vice-Admiral George F. Hussey Jr. (Ret.)
Managing Director
American Standards Association
10 East 40th Street
New York 16, N. Y.
U. S. A.

Dear Admiral Hussey,

The comprehensive and most interesting minutes of the meeting held under your chairmanship in New York on 6 October to discuss possible United States participation in the work of ISO/TC 34 have now been received and carefully studied here.

You will recall that the Food and Agriculture Organization representative at the meeting stated that proposals for a joint Food and Agriculture Organization/World Health Organization Program on

Food Standards were to be presented in November to the Eleventh Session of our Conference. These proposals have now been approved by the Conference and I am attaching a copy of the relevant sections of its report.

I would also like to add a point concerning the work of ISO in relation to the new program, with particular reference to the United States. In the first place, I share your opinion expressed on page 13 of the Minutes that FAO will seek full ISO co-operation. The small amount of overlap in the work of ISO/TC 34 existing at present —concerning methods of analysis of milk products—is now in process of being overcome. As I stressed in a circular sent to all interested organizations, including ISO, prior to preparation of our detailed proposals, it is not our intention to take over existing work already well done elsewhere, but rather to encourage, coordinate and simplify work in the whole field of international food standards to the advantage of all concerned.

Technical Committee 34 of ISO is with one exception (Sub-Committee 7, where there is no danger of overlap) not concerned with quality or health standards, but only with sampling and analysis, and with the technical aspects of packaging and labelling. ISO has earned its reputation in handling technological questions of this sort in other fields, and I feel they deserve every encouragement in their present project.

I am particularly interested in the possibility of active United States participation in international food standards work. At the present time, to the best of my knowledge and with the possible exception of Pan American activities, the United States does not take part in any *preparatory* work on international food standards. This has the result that participation in the finalization stage alone—for instance in the case of our Code of Principles concerning Milk and Milk Products—often involves the consideration of amendments which might more easily be handled in earlier stages of the work, in the present example, through active membership of the International Dairy Federation and of ISO/TC 34/SC 5. United States membership of the Organization for Economic Co-operation and Development may well encourage participation in work on the fruit and vegetable standards worked out by the Economic Commission for Europe, in particular those projected for fruit juices, in accordance with the proposed program now under consideration by O. E. C. D. By and large, however, I am convinced that international food standards

would stand greatly to gain from further United States participation at all levels, by whatever means and agencies may be found appropriate.

We have frequently stressed, as underlined by the Food and Agriculture Organization representative at your meeting, the need for close co-operation in food standards work between government, research bodies, industry and, wherever practicable, the consumer. On the other hand, it is of course for each country alone to determine how best this co-operation can be achieved under its own conditions.

I shall be most interested to hear the results of action taken following the meeting held on 6 October.

Yours sincerely,

A. H. Boerma [signed]
Assistant Director-General
(Program and Budget)

[The End]

FAKE ARTHRITIS CURE BANNED

A federal court has banned further sales of a nationally promoted hormone cream with false and misleading claims for the treatment of arthritis and many other ailments.

Promoters of the product consented to an injunction ordered by Judge James H. Meredith of the District Court at St. Louis, Missouri. The ban on sales of the epinephrine hydrochloride ointment, which is of no help to victims of rheumatic diseases, brought this comment by FDA Commissioner George P. Larrick:

"There are millions of arthritics in this country who will grasp at any straw. Many are led to believe in so-called cures because of the remissions which naturally occur in the disease. By taking advantage of this, unscrupulous promoters can profitably sell any product falsely claimed to offer cure or relief. This injunction action is part of FDA's continuing effort to stop dealers from making money by preying on the hopes of the suffering through false and misleading claims."

Mail-order sales of the adrenal hormone cream had soared in recent years because of false claims in promotional literature.

False claims included relieving or overcoming rheumatism; arthritis; pains of fibrositis due to sprains, strains, fractures, postoperative adhesions; knots and swellings; lumbago; pain of shingles; skin blemishes—keratoses of the aged; gout; painful skin and nerve conditions; migraine headaches; frozen nerves; neuritis; sciatica, Charley horse; neuralgia; and osteo-arthritis.

Some Comments on Packaging

By GEORGE P. LARRICK

The Author Is Commissioner of Food and Drugs, U. S. Department of Health, Education and Welfare. He Delivered This Talk at a Meeting of The Food Group, Washington, D. C., on February 14, 1962.

LATELY WE HAVE BEEN HEARING a lot about packaging and so you may be interested in a brief review of the way the Food and Drug Law has applied to packaging from its beginning.

The Pure Food Act of 1906 had a very far-reaching effect on packaging practices. One thing it did was to help promote the public acceptance of packaging. In those old-fashioned "cracker barrel days" there were many sanitation-minded people who were very quick to appreciate the advantages of containers that protected their contents from the store cat and her kittens and which at the same time provided the consumer with important information on their labels. The Pure Food Law was a very popular measure, and it was right in line with the times to put out products that were packed in a sanitary way and "untouched by human hands."

The provisions against adulteration and misbranding frequently involved the package. A great many labels, especially drug labels, were extensively revised after the law was passed. And over the years there were a number of cases where adulteration of foods was caused by contamination from the packages. For example, there was contamination by lead foil in tea caddies, and arsenic in vinegar and olives which had been packed in used barrels. Another early problem was lead solder for tin cans.

The 1906 law defined a food or drug as misbranded if it did not have the weight or measure "plainly and correctly stated on the outside of the package." But there were no requirements as to conspicuousness of label statements, nor was there any provision against slack-filling. In 1930 the law was amended to authorize food standards, including standards of fill of container.

When the law was rewritten in 1938 it was made to apply directly to packaging materials and practices. It spelled out the labeling requirements in greater detail. Required label statements had to be conspicuous, and authority was again provided for standards of fill in food packaging. A special provision defines foods, drugs and cosmetics as adulterated if their containers are "composed in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health." Another new provision defined foods, drugs or cosmetics as misbranded if their containers are "so made, formed or filled as to be misleading." All these provisions showed that Congress realized that the packaging was an integral part of the product as sold to the consumer and could be an instrument for consumer deception or injury as well as for consumer protection.

Twenty years later, in 1958, Congress enacted the Food Additives Amendment. Substances used in packaging are specifically included in the definition of food additives under this law, if their use may directly or indirectly result in their becoming components of food or otherwise affecting the characteristics of food. The effect of this is that for the first time package materials are covered by a plan of regulation designed to insure their safety to the consumer. And, as you all know, much of the work under the food additive law has dealt with packaging materials.

Current FDA Problems

Today, however, I want to talk about three other broad areas of packaging that concern industry and the Food and Drug Administration. These are the problems of inconspicuous display of required label information and the related problems of slack-fill and short weight of package contents.

Under the law a food, drug or cosmetic is misbranded if its container is "so made, formed or filled as to be misleading." Labels must bear "an accurate statement of the quantity of contents in terms of weight, measure, or numerical count." Regulations are provided to exempt small packages and to allow reasonable variations. Other regulations under this section spell out the proper terminology for declaring weight, measure or count on different types of products.

After the law was passed there was a wave of reform in packaging. Many deceptively shaped bottles, such as the old-time "panel"

extract bottle, disappeared from the market. Industry groups worked with the Food and Drug Administration to eliminate deceptively packaged items. For example, there was voluntary action to develop proper practices in measuring the drained weight of products like pickles and olives, and the correct fill for spices. The size of cartons used for collapsible tubes was voluntarily reduced by the toothpaste manufacturers. They worked out machinery for turning the tube so that the clip went into the box in a diagonal position.

Many court actions were started against deceptively packaged products. Most of these cases were settled by default; in other words, the cases were not contested, and the bad practices were stopped. But then there was a series of three cases which we lost because we were not able to prove in court what seemed to be obvious from the slack-filled packages themselves. After these reverses there were no court actions against deceptive packages for a number of years. We simply did not have the money to spend on this problem when there were many more pressing problems to handle. Now, as you know, we are again engaged in litigation under the deceptive package provision of the Act. In one case we have a decision from the United States Court of Appeals which we believe provides very clear guidance in determining whether or not a package is deceptively made, formed or filled. Very briefly, this decision says that when the package will hold more than is contained in it, the person using the package has the burden of justifying the deception by proof that the package is necessary *and* that there is no reasonable alternative that is less deceptive. The question still to be answered in this case is whether the evidence shows that the padding in the container was necessary to protect the contents and that there was no less deceptive alternate available to the manufacturer.

If necessary, we can deal with the problem in the food field at least, by issuing standards of fill of container for the products that are being packed in oversize containers. This would require added manpower in our Food Standards Unit.

Over the years, the packaging industries have been very successful in developing equipment and methods for accurate weighing and filling of packaged products. Today, net weight or volume can be controlled with great precision and there is a strong incentive to do this, especially in large operations where small variations may be quite costly. But this precision can be abused.

Proper Weight Surveys

Beginning several years ago the Food and Drug Administration made a number of surveys to see whether foods were being packed according to their declared weight. We found a surprising number of samples that were very slightly below the declared weight, and we found some that were seriously short in weight. You know, of course, that we allow for weight loss that normally occurs after packing due to climatic conditions. But this did not explain the net weight shortages that we found in our survey.

The results of these surveys were announced at the National Conferences on Weights and Measures in 1959, 1960 and 1961. There were court actions and there was publicity, both in the trade press and to some extent in the general press. In the trade press, particularly, we warned the industry that there were too many manufacturers who were shooting too close to the line in filling their packages. I am sure this warning put the industry on notice and that some firms did check on their packaging operations to insure correct fill. Nevertheless, during this past year when we expanded our enforcement program in this area we found a surprising number of companies, including some well-known companies, who had short weight products on the market. And I am sorry to say we found several who were deliberately short-weighting their customers by reducing the fill and continuing to use the same packages without changing the net weight statement.

Misbranding Defined

The Federal Food, Drug, and Cosmetic Act declares that a food, drug or cosmetic shall be deemed to be misbranded "if any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use."

These words did not get into the law by accident. They were directed toward a problem which existed long before 1938, and as you know, it still is a problem.

Congress evidently had in mind that packages which are designed to act as salesmen in self-service supermarkets should play fair with the consumer by telling her certain things about their contents. No

detailed directive was given but the principle was stated very clearly and here again there was marked improvement after the 1938 law was passed. Over the years, however, we have seen a great deal of back-sliding in this area. The selling function of the package has been emphasized to such an extent as to obscure its function as a source of public information. Such information as the net weight of contents or the ingredients of the product too frequently is relegated to the far corners of the fine print so that the consumer has to search carefully, and may even need a magnifying glass.

The last sentence, incidentally, is a direct quote from a statement that I made back in 1959. At that time I said, "We believe the pendulum has swung too far in the direction of de-emphasizing required information. Some corrective actions have been undertaken and the program is being expanded." We suggested that the package designers should familiarize themselves with the requirements of the law and with the interpretive regulations regarding conspicuousness of required information in the labeling of foods, drugs and cosmetics.

Findings of Senate Subcommittee

Within the past year this problem has been studied by a Senate subcommittee. At the same time the Food and Drug Administration has taken legal action in a number of cases where required information was so inconspicuous that we did not think it was "likely to be read and understood by the ordinary individual under customary conditions of purchase and use." For instance, we found net weight on a spaghetti package printed in black ink on a very dark green background. We found transparent bags of licorice candy with the net weight statement in black ink, and raspberry candy with the net weight in purple ink. Such techniques are very effective in making the information as unnoticeable as possible without omitting it altogether.

Since last July the Food and Drug Administration has filed around 200 court actions against short weight and inconspicuously labeled food products. Further checking is underway. We hope that it will show that there has been substantial improvement, but if we continue to find violations of this kind, we are going to have more seizures and more prosecutions.

Senator Hart's hearings have brought out the fact that today the public is buying "by the package" instead of by the pound or the pint or the peck as we used to. This has made it easier to use the

package as a method of changing prices. And this is why so much attention is being given to the importance of the required information on the label. Informed consumer choice of products is essential in the operation of a free competitive economy.

We have seen some trade press editorials which suggest the desirability of regulations which would spell out in detail what is considered to be correct fill or conspicuous labeling. And we seem to be moving in this direction. Under the new Federal Hazardous Substances Labeling Act, we have issued regulations specifying type size and location on the label required to make the information sufficiently conspicuous. Currently we are considering regulations to specify the size of type that will be considered legible in circulars accompanying prescription drugs. If necessary, regulations of similar character can be issued with regard to the ingredient statements and net weight statements on food products.

Experience teaches that laws and regulations come in response to public problems. The conditions are constantly changing, and this is true of packaging practices as well as other matters.

It seems clear that we have reached a point where another forward movement is necessary to improve our packages from the consumer standpoint. This will require a combined effort consisting of voluntary action, regulatory action, and possibly new legislation.

[The End]

"LOW CALORIE" CLAIMS RESULT IN SEIZURE

Cottage cheese and tomato bouillon promoted with "low calorie" claims have been seized in FDA's program to correct false and misleading claims in the "nutritional" and "weight reducing" field.

A shipment of cottage cheese shipped from Chicago, Illinois was seized at El Paso, Texas on charges that it was falsely labeled as an uncreamed, low calorie cottage cheese, effective to promote slimness. FDA further charged that it failed to conform with the established standard for cottage cheese since it was made with a cream product containing 6 per cent fat. The definition and standard of identity for cottage cheese requires it be made from sweet skim milk, concentrated skim milk or nonfat dry milk. The cheese was manufactured from cottage cheese and a cream product containing 6 per cent fat.

A shipment of tomato bouillon prepared by a Pennsylvania company was seized at Thornton, California. FDA charged it was falsely promoted as low in calories and high in nourishment and supplied all of the body's daily protein needs for growth, health and vitality. The product was essentially a tomato cocktail made with tomato paste, water, beef extract and other substances to add flavor to it. It contained only 0.9 per cent protein, an amount which is of little value as a primary source of protein.

WASHINGTON

ACTION AND NEWS

In the Food and Drug Administration

July Food Seizures Report.—Over 1,200 tons (2,575,116 pounds) of contaminated food were seized in 33 federal court actions during June. Of this total, 312 tons (635,130 pounds) involved rodent-infested wheat, and 23 tons (66,290 pounds) of wheat and wheat bran were seized on charges of containing nonpermitted chemical residues. Food products which had become contaminated by insanitary storage conditions accounted for seizures of 833 tons (1,667,110 pounds). Sugar imported from Mexico and stored in a Texas warehouse where it was subject to rodent infestations furnished the largest tonnage—790 tons. Other food products seized on charges of filth or decomposition were canned kidney beans prepared under insanitary conditions, moldy cheese, decomposed eggs (1 truckload of 600 cases), fish fillets containing parasitic worms, and insect-damaged cherries and nuts.

The majority of food seizures in the ecomomic violations category involved short weight products and inconspicuous labeling.

Drug and Device Seizures.—Charges of adulteration, inadequate directions for use and misbranding with false and misleading claims resulted in 46 seizures of drugs and devices. Included were a number of food supplements and vitamins, claiming to be of value in weight control; a drug for increasing the milk production in dairy cattle; a diethylstilbestrol mix for treatment and prevention of bloat and disease in general; various subpotent drugs, tablets, capsules, injections; prophylactics of substandard quality; and an electric gum massaging device which failed to bear adequate warnings to insure safe use.

Six of the seizures involved antibiotics which had not been certified, and new drugs without a safety clearance.

Cosmetic Seizures.—One counterfeit of a name-brand hair preparation was seized in New Jersey.

Hazardous Substances. — Failure to bear precautionary labeling required by the Federal Hazardous Substances Labeling Act resulted in the seizure of soldering solutions, wood turpentine and carbon tetrachloride.

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