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# Food Drug Cosmetic Law

## JOURNAL

Papers Presented
at the Afternoon Session
of the Sixteenth Annual Meeting
of the Section on Food, Drug
and Cosmetic Law of the
New York State Bar Association,
January 25, 1961

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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

**About This Issue.**—The concluding papers of the Sixteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association are published in this issue of the JOURNAL. Papers delivered at the morning session of the January 25 meeting were presented last month; the concluding papers are from the afternoon session.

The first speaker was *William J. Condon,* attorney for Swift & Company, who spoke on the developments with respect to product liability laws, followed by *George M. Burditt,* a Chicago attorney, whose subject was "The Interrelation of Food Standards and Food Additives Provisions of the Federal Food, Drug, and Cosmetic Act."

Continuing the speeches were *Vincent A. Kleinfeld,* a Washington D. C., attorney, whose subject was the legislative history of the Hale Amendments, and *Thomas W. Christopher,* attorney for the Corn Products Company, who spoke on "Conflicts Between State and Federal Food and Drug Laws."

*Franklin M. Depew,* president of The Food Law Institute, Inc., concluded the speeches with an address on the need for uniformity in food legislation.

Also included in this issue of the JOURNAL is a paper by *Alan G. Kitchell* on the regulations concerning food additives in the United Kingdom. The author serves as liaison officer for food research and development of the British Defence Staffs in Washington, D. C.

**Food Law Institute Board.**—Lee S. Bickmore, president and chief executive officer of National Biscuit Company, and Frank R. Armour, Jr., president of H. J. Heinz Company, have been elected to the board of trustees of The Food Law Institute, it was announced by Franklin M. Depew, president of the institute.

Mr. Bickmore was born in Utah and began his career with his company in 1933 at Nabisco's sales branch at Pocatello, Idaho. In 1959 he was elected executive vice president and a member of the board of directors. He was elected president in April of 1960 and became chief executive officer in January of this year. Mr. Bickmore is a member of the marketing committee of the National Association of Manufacturers, chairman of the marketing committee of the Grocery Manufacturers of America, and a member of the marketing committee of the American Management Association.

A native of Pittsburgh, Mr. Armour began his career with the Heinz company as a plant guide in February, 1928, and was made president of the company in January, 1959. In November, 1958 he was elected secretary of the Grocery Manufacturers of America. He has taken part in the activities of the American Management Association, the National Restaurant Association, the National Canners Association, the Brand Names Foundation, the American Institute of Food Distribution and the American Hospital Association. He is a member of the executive committee of the Pennsylvania Economy League.

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Food·Drug·Cosmetic Law
Journal

# Product Liability Cases–1960

By WILLIAM J. CONDON

**This Annual Review of Reported Cases Was Presented Before the Section on Food, Drug and Cosmetic Law at the New York State Bar Association Meeting in New York City on January 25. This Study Indicates a Case Range Which Embraced Foods, Beverages, Bottles, Drugs and Cosmetics.**

A CAREFUL PERUSAL of this year's list of cases will lead one to the shocking discovery that there was a little more than a 50 per cent decrease in the number of reported cases in 1960 as compared to 1959. The cause of this phenomenon completely escapes me. However, for reasons which will appear as we go on, I suggest that this fact alone should not be cause for any substantial celebration on the part of those concerned with product liability matters on behalf of food, drug or cosmetic companies. The list of cases, grouped according to subject matter, follows:

## Foreign-Substance and Contaminated Food Cases

*Adams v. Great Atlantic & Pacific Tea Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,639 (N. C.).

*Eisel v. Columbia Packing Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,641 (DC Mass.).

*Rollo v. Royal Bakeries, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,643 (N. Y. City Ct., N. Y. Co.).

*Sullivan v. H. P. Hood & Sons, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,651 (Mass.).

*Kennedy v. Pepsi-Cola Metropolitan Bottling Company, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,652 (N. Y. S. Ct. App. Term 1st Dept.).

## Foreign-Substance Beverage Cases

*Macon Coca-Cola Bottling Company v. Chancey*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,637 (Ga. CA); ¶ 22,657 (Ga.).

*Elledge v. Pepsi-Cola Bottling Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,647 (N. C.).

*Mitchell v. Coca-Cola Bottling Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,649 (N. Y. S. Ct. App. Div. 3d Dept.).

*Milligan v. Coca-Cola Bottling Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,655 (Utah).

*Valdosta Coca-Cola Bottling Works, Inc. v. Montgomery*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,660 (Ga. CA).

*Paul v. Rodgers Bottling Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,661 (Calif. Dist. App.).

## Exploding-Bottle Cases

*Bash v. Hinsdale Bottling Corporation*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,636 (N. Y. City Ct., N. Y. Co.).

*Braccia v. Coca-Cola Bottling Company of Philadelphia, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,640 (Pa.).

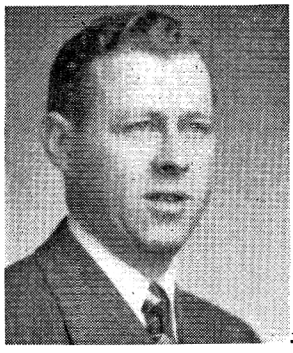
*Canada Dry Bottling Company of Florida, Inc. v. Shaw*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,642 (Fla. Dist. CA).

*Joffre v. Canada Dry Ginger Ale, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,644 (Md. CA).

*Wolf v. S. H. Wintman Company*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,650 (R. I.).

*West v. Burgermeister Beer, Inc.*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,656 (Calif. Super. Ct.).

*Meglin v. H. P. Hood & Sons*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,662 (Conn. Ct. of Comm. Pleas).



Mr. Condon, a Member of the New York Bar, Is Attorney for Swift & Company, in New York City.

## Cosmetic Cases

*Rexall Drug Company, Inc. v. Nihill,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,645 (CA-9).

*Kennedy v. General Beauty Products, Inc.,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,648 (Ohio CA).

*McGuinness v. Roux Distributing Company, Inc.,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,653 (N. Y. S. Ct. App. Term 1st Dept.).

*Bleacher v. Bristol-Myers Company,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,658 (Del. Super. Ct.).

## Drug Cases

*Fine v. Hoffman-La Roche, Inc.,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,646 (Pa. Ct. of Comm. Pleas).

*Ex Parte Laura H. Emerson,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,654 (Ala.).

*Gottsdanker v. Cutter Laboratories,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 22,659 (Calif. Dist. CA).

## Device Case

*Orthopedic Equipment Company, Inc. v. Eutsler,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7601 (CA-4).

Strangely enough, in addition to the paucity of cases, there is little of a startling nature in this year's list. I am sure it will come as a surprise to no one that the district court of appeals in California affirmed the judgments in the *Cutter* cases, holding that privity of contract is not required in California to support an action for breach of implied warranty in the case of a deleterious drug.

The only real departure in 1960 is to be found in the case of *Orthopedic Equipment Company v. Eutsler.* This case was brought in a federal district court sitting in Virginia to recover for injuries sustained through the use of a surgical nail which was not of proper size. Plaintiff had broken his leg and his doctor sought to treat the fracture by means of the so-called Kuntscher process. This involves driving a surgical nail into the medullary canal of the thigh bone in order to stabilize the broken fragments. The canal is cleaned of marrow by a reamer of appropriate size and the nail is then inserted. In this instance the doctors used a reamer made by one manufacturer and a nail marked with the same size as the reamer, manufactured by the defendant. It developed that the nail was somewhat larger in diameter than the markings indicated and the doctors were unable to get it all the way into the canal, even with the aid of a hammer. They were also unable to get it out. The upshot of plaintiff's experience is that he has lost the use of his leg and ultimately may lose the leg itself.

The essence of plaintiff's case was that this surgical nail was a device within the meaning of the Federal Food, Drug, and Cosmetic Act and, because of the incorrect labeling in the form of measurements, the nail was misbranded. The opinion we have is by the United States Court of Appeals for the Fourth Circuit on appeal from a judgment in favor of the plaintiff. This court held that the numbers 9 x 40 were meant to indicate a diameter of nine millimeters by a length of 40 centimeters; that this nail, whose diameter varied between 9.27 millimeters and 10.12 millimeters, was misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act; and that this misbranding constituted negligence per se under Virginia law. In reaching this result, the court noted that the Virginia Supreme Court of Appeals had not had occasion to determine the civil effect of a violation of Virginia's own food act or its statutes dealing with misbranding and adulteration of drugs and cosmetics. However, the court of appeals pointed out that the Virginia court had indicated that the violation of a motor vehicle statute constituted negligence per se. From this, it was easy for the court to determine that the Supreme Court of Appeals of Virginia would hold a violation of the federal statute also to be negligence per se.

The court of appeals apparently was not concerned with the fact that no cases were cited to it in which any state court had found negligence per se in the violation of a federal statute, nor was it concerned with the fact that prior to its adoption, the bill which became

the Federal Food, Drug, and Cosmetic Act had contained a specific provision for civil liability arising out of violations, which provision failed to survive the legislative process. So far as I know, this is the only case wherein it has been held that a misbranding under the Federal Food, Drug, and Cosmetic Act constitutes negligence per se.

We could review several of this year's cases and point out the fanciful flights of some of the courts in the awkward appplications of timeworn doctrines, such as *res ipsa loquitur*. We could also review the departures from timeworn doctrines such as privity of contract. However, if we did, I would have the feeling that I had said it all before, and you would begin to suspect that I was using the same material over and over again. Therefore, with your indulgence, may I embark upon a slight divergence from our usual norm and discuss with you a couple of cases which arose in other fields.

For years, we in the food and drug fields, and more recently in the cosmetic field, have taken a certain masochistic pride in being the unwilling ground breakers in products liability. Through our blood and our tears, we tended to boast a little that our products liability problems were more severe than anyone else's because the courts treated us differently. Privity of contract was not required in negligence actions involving food and drugs long before *McPherson v. Buick*. The abolution in almost half of our states of the privity requirement in actions for breach of warranty is generally restricted to food and drugs. And the benefits of inferences, presumptions, extensions of *res ipsa loquitur*, liberalizations of the burden of proof, have been extended more freely by the courts in cases involving food and drugs than in other cases. And, as I say, while we have complained about these encroachments, we have been like the little boy with a broken arm. While he bemoans his inability to play ball with his fellows, he enjoys the attention he gets by being the only one wearing a cast.

It, therefore, comes as something of a blow to discover that the two most significant product liability cases of 1960 have nothing to do with food, drugs or cosmetics. Nevertheless, if these two cases mean what I think they mean, and if their principles spread to other jurisdictions, then we will awaken some day with the unhappy feeling that we have exchanged the cast on our forearm for a hospital bed.

The first of these cases, *Henningsen v. Bloomfield Motors, Inc.*, 161 A. 2d 69 (N. J., 1960), arose in the State of New Jersey. The facts are simple. Mr. Henningsen purchased a new Plymouth automobile from

the defendant Bloomfield Motors. Within ten days, after the car had only been driven a few hundred miles, Mrs. Henningsen was driving on a New Jersey highway when she heard a loud noise "from the bottom by the hood." The car turned sharply to the right, ran into a brick wall, and Mrs. Henningsen was severely injured. She sued both Bloomfield Motors and the Chrysler Corporation for breach of implied warranty. Her recovery at the hands of a jury was affirmed by the Supreme Court of New Jersey. The case is significant for a number of things, although I propose to dwell at length on only one. It is one of those cases that has something for everyone. For those of you who are fond of disclaimers and limitations of liability the court held that the standard new car warranty is ineffectual to limit either the dealer's or the manufacturer's liability for damages resulting from a breach of implied warranty. For those of you who are students of privity, the court held that privity of contract will no longer be required in New Jersey to support an action for personal injuries based on a breach of implied warranty. This is rare because New Jersey had been one of our remaining bastions of privity and because the breakthrough occurred in a case which did not involve food or drugs. Ordinarily, these two facets would be sufficient to propel me into a passionate prelection of purple prose. However, the third aspect of this case is so startling as to render me relatively unmoved by these two otherwise remarkable departures.

The third aspect of the case has to do with the matter of proof. The record discloses that the front end of this automobile was severely damaged. Plaintiff, of course, had the problem of proving that the car contained a defect which was the cause of her injury. For this purpose, plaintiff employed an expert witness. This "expert" was a man of 11 years experience, divided between being an automobile mechanic and being an appraiser for insurance companies. Now, did he testify as to the cause of this unusual behavior of the automobile? On the contrary, he testified that the front of the car was so badly damaged that it was impossible to tell what part had been defective. However, based upon the plaintiff's version of the occurrence, he gave as his opinion that something definitely went "wrong from the steering wheel down to the front wheel" and that the action of the car must have been due to mechanical defect or failure. This, said the Supreme Court of New Jersey, was enough to raise a question of fact for the jury as to whether or not there was something wrong with the car. It is noteworthy that he limited the area of possible

deficiency from the steering wheel down to the front wheel. Apparently, in his judgment, the two feet or so immediately behind the steering wheel could not have been the seat of the trouble.

Observe, then, what we have: Instead of having an examination made of the parts of the car, and instead of isolating in some fashion the area of the defect, plaintiff essentially proved that she could not prove what caused her injury. Not only was there no effort to prove the specific cause, or the particular defect, but also there was no effort to eliminate any other possible causes of this happening. The court admitted that the testimony of the insurance appraiser was "not entitled to much probative force." Actually, it had just enough probative force to win the case for the plaintiff. We will return to a discussion of the significance of this holding after we have the second case before us.

This second case to which I refer has to do with dynamite. (One of my associates has suggested that it *is* dynamite.) The case is *Dement v. Olin-Mathieson Chemical Corporation,* 282 F. 2d 76 (CA-5, 1960). The plaintiff was a driller's helper involved in seismic explorations in Texas. On the day which gave rise to this unfortunate saga, the charges being used for the creation of shock waves were composed of sticks of dynamite manufactured by Atlas Powder Company but sold by Olin-Mathieson Chemical Corporation under its trademark, a metal cylinder booster manufactured by E. I. DuPont deNemours & Company and an electrical blasting cap manufactured by Olin-Mathieson. All three articles contained high explosives. Plaintiff bundled five sticks of dynamite together and gave them to the driller. The driller punched a hole in one of the dynamite sticks preparatory to inserting the booster and attaching the cap. At this point, plaintiff walked from the driller to a truck some 18 feet away to get a drink of water. While he was at the truck, the charge exploded, the driller was killed, and plaintiff was seriously injured. As far as the record discloses, no one knows any more about this occurrence than that.

At the trial, in the United States District Court in Texas, the jury returned a verdict for all three defendants: Atlas, Olin-Mathieson and DuPont. Plaintiff appealed, and the Court of Appeals for the Fifth Circuit reversed and ordered a new trial as to Atlas and Olin-Mathieson. The ground for reversal was that the district court had erred in failing to charge the jury on the applicability of the doctrine of *res ipsa loquitur.*

As the court said, "plaintiff's expert and lay witnesses advanced several hypotheses as to what probably happened."

For example, it was suggested that if the dynamite had an oily exterior, this might be due to a leakage of nitroglycerine which could be set off with a minimum amount of friction. Plaintiff's testimony that the dynamite being used that morning was not oily was discounted by the court because plaintiff only had three days experience. Another hypothesis was that if the cap were made of a material that was subject to deterioration under the hot Texas sun, a minimum amount of friction might have set its charge in motion. There was no evidence that the cap was so constructed. The only claim against the booster appeared to be that it was negligence to manufacture and sell a booster known to require insertion into a hole in the end of dynamite. The hole, necessarily, had to be enlarged to accommodate the booster. Plaintiff's expert was unable to concoct any theory concerning a defect in the booster itself. Accordingly, the court felt that DuPont should not be held.

However, as to Atlas and Olin-Mathieson, the situation was quite different. The court seems to suggest that, on the basis of the hypotheses indicated above, the jury would have had a right to infer, first, that these defective conditions, or either of them, did exist; and, second, that these defective conditions, or either of them, did in fact cause the explosion. All of this the jury might have inferred if it had been properly instructed concerning the doctrine of *res ipsa loquitur*.

Now to some, this doctrine might present some problems in a situation such as this. But to the United States Court of Appeals for the Fifth Circuit it was easy. First of all, one might wonder about the requirement of exclusive control. Accordingly, the court pointed out that: "The critical point of time is not necessarily the precise time of injury. Rather, it obviously refers to the time the probable negligence inferred from the occurrence of the event took place." However, even if we accept this bit of judicial tail-chasing, we might inquire as to when Atlas had control of the cap or the booster. On this, the court blithely said: "Here there can be no doubt that the components of the explosive charge were under the exclusive control of the defendants at the critical manufacturing stage." Defendants contended that *res ipsa loquitur* was not available to aid plaintiff because no particular cause could be severed out and identified. In other words, the application of *res ipsa loquitur* is precluded by the fact that, on this record, the explosion could have resulted from any one of two or more causes, and it was not more reasonably probable that it was due to one rather than another. The court characterized

this as a "musical chairs" argument. It went on to say: "Here from a physical standpoint the injury was caused by a combination of the three products. Where the consequences are so devastating and the risk to human life so great, manufacturers of products which are components designed to be used with other known products may not thus evade the responsibility to come in and explain. That is basically what the res ipsa doctrine requires."

Thus, from the fact that an explosion occurred, plus otherwise unsupported hypotheses as to the cause, this court would permit a jury to infer the existence of a defect in either the dynamite, or the cap, or both.

These hypotheses were advanced by plaintiff's expert witness. Here, as in *Henningsen,* the expert, in effect, was allowed to speculate as to the cause of the accident. This would seem to be, at best, a very dangerous and unhealthy practice which ought not to have any place in the law. However, if it is to be permitted, a very basic requirement should be that the qualifications of the witness be such as to provide a practical safeguard against irresponsible testimony. In this connection, we have already alluded to the minimal qualifications of the mechanic who testified as an expert in *Henningsen.* By coincidence, another 1960 federal decision involved a discussion of the qualifications of the expert who testified in *Dement.* This was the case of *Smith v. Hobart Manufacturing Company,* 185 F. Supp. 751. This case involved injuries allegedly resulting from the defective design of a meat grinding machine, and the cited opinion is on defendant's motion for a new trial following a verdict for the plaintiff. The ground for the motion for a new trial, which incidentally was granted, was that the court erred in permitting this particular witness to testify as an expert. After carefully reviewing the witness' testimony as to his qualifications, the district judge agreed that he had committed error. The witness described himself as "a consulting materials engineer and a consulting safety engineer." The evidence disclosed that he had been graduated from Long Island University in 1939 with the degree of Bachelor of Science, majoring in history. Thereafter, he had pursued a course in mathematics for part of a year at Columbia University. This was the full extent of his formal education. The rest of his testimony concerning qualifications was general. For example, he "filed for application approximately 350 patent disclosures." He had written "approximately 150 technical articles on various subjects."

None of the patent applications was identified, nor were any of the technical articles. Then the court said this:

> Further, and reluctantly, we note that in his direct testimony that he, at least in the early days of his activities following college, seemed to change his employment almost yearly and that thereafter his testimony revealed working and associating with firms of such a vast number it is difficult for the Court without more direct evidence to determine what, if any, was his association with these firms or what type of organizations they were. For example, he stated, "I do work for our Government, various branches of the Government; I do work for French firms, German firms, industrial machine equipment firms here and abroad" and also, "Well, a lot of my safety consultant work is in utilities: Jersey Central Power and Light Company uses me; Public Service of New Jersey uses me; the New Jersey Natural Gas Company uses me; Florida Power & Light Company uses me; various manufacturing equipment members of the American Gas Association use me in manufacturing various industrial and domestic appliances, gas consuming equipment. Also industrial machine tool equipment."

One searches this opinion in vain for any reference to the witness' experience with dynamite or other explosives. The court, following this lengthy quotation, indicated that it had difficulty ascribing a specific meaning to the phrase "uses me." One might wonder if they used him for the same purposes for which the two plaintiffs used him. It is more than a little frightening to consider that the Court of Appeals for the Fifth Circuit is willing to permit a jury to speculate on the cause of plaintiff's injury, with nothing more to go on than hypotheses concocted by an "expert" whose experience and qualifications are such as we have just reviewed.

Let us now compare this *Dement* case with the *Henningsen* case. *Dement* was negligence; *Henningsen*, breach of implied warranty. Yet, both are concerned with an element common to all product liability cases—indeed, the most important element—that of causation. In neither case was there any proof as to the existence of a defect in the product. In both cases the existence of a defect was essential to plaintiff's recovery. In both cases, the courts permitted juries to speculate concerning the cause of the difficulty on the basis of completely unsupported opinions of what appeared to be, at best, poorly qualified experts. And what is worse, the courts permitted these so-called experts to speculate as to causes concerning which they actually knew nothing.

Is it any wonder, then, that we call on all of you to take heed? Can we be blamed for suggesting that the insurance concept of liability has come to full flower? For what these cases do is to point the way to a new standard of proof—a standard which differs vitally and

drastically from any that we have previously known. In the past, even in food cases, plaintiff has had to show facts from which could properly be inferred some neglect or default on the part of the defendant which was the cause of plaintiff's injury. Even with the aid of inferences, presumptions, *res ipsa loquitur;* even with the relaxation of the privity concept, plaintiff still carried this burden of proving causation, and to sustain this burden he had to have evidence which tended to exclude other reasonably probable causes for his injury. It is significant that this requirement was not present in either case.

All the jury really knew about the *Henningsen* case was that Mrs. Henningsen, like a magician, turned a Plymouth automobile into a brick wall. The New Jersey jury thought that Chrysler and the dealer should underwrite that performance. All the jury in the *Dement* case knew was that there had been an explosion and that the only one who really had knowledge as to what happened was not available to testify. That jury did not think that the various companies who had been invited to participate should bear the loss. But the court of appeals wants another jury to pass on that, armed with the instruction that this is the kind of occurrence that does not normally happen without negligence on the part of someone; and that this new jury should decide whether to infer negligence on the part of either, or both, of the remaining defendants. Just a statement of the facts of the occurrence places on these manufacturers the responsibility to explain.

This principle could prove interesting in food poisoning cases. Normally today, plaintiffs select the main course in their meal as the target when they become ill. Possibly, we can look forward to a lawsuit arising out of one illness wherein will be joined as defendants: a meat packer, bread manufacturer, frozen food packer, salad dressing maker, butter manufacturer, and even, perhaps, a spice maker. Will plaintiff be permitted to say: "I ate a combination of food manufactured by each of you and I became ill. Now each of you must come in and explain"? And if so, will the jury be permitted to speculate as to which, or how many, of the defendants failed to live up to their warranties, or failed to use reasonable care?

Over the past several years, I have often urged defense counsel to approach products liability cases as though the burden of proof were on the defendant. I now have an uneasy feeling that, for all practical purposes, this suggestion is not only tactically valid, but also technically accurate. **[The End]**

# The Interrelation of Food Standards and Food Additives Provisions of the Federal Food, Drug, and Cosmetic Act

By GEORGE M. BURDITT

This Paper Was Given at the 1961 Meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association. The Author Is a Member of the Chicago Law Firm of Snyder, Chadwell, Keck, Kayser & Ruggles.

A LESS HIGH-SOUNDING and pompous title for this paper would be "Standards and Additives." However, such a simple title might lead you to conclude that either the subject or the author was simple, neither of which a lawyer likes to admit! In any event, I have been asked to discuss with you the effect of the Food Additives Amendment [1] on standardized foods.

One who wishes to add a food additive to a food which has been standardized under Section 401 of the Federal Food, Drug, and Cosmetic Act [2] must eventually accomplish two things: an amendment to the standard in order to satisfy Sections 401, 403(g) and 701 of the Act,[3] and a food additives regulation in order to satisfy Sections 402(a) (as amended on September 6, 1958) and Section 409.[4] The petition for an amendment to the standard must show that the amendment "will promote honesty and fair dealing in the interest of consumers" as set forth in Section 401, and the food additives petition must follow the requirements of Section 409(b).[5] The Commissioner has indicated

[1] P. L. 85-929, 85th Cong., approved September 6, 1958.
[2] 21 USC Sec. 341.
[3] 21 USC Secs. 341, 343(g) and 371.
[4] 21 USC Secs. 342(a) and 348.
[5] 21 USC Sec. 348(b).

his willingness to accept one set of data, rather than two separate petitions, on the product for which a food additives regulation and a food standards amendment are requested. In response to such requests, FDA will issue a joint publication covering both the food additives regulation and the food standards amendment. This procedure was recently followed in connection with azodicarbonamide as a maturing agent in flour.[6]

After the petitions are filed, notices of the petitions must be published within 30 days. Section 121.8(a) of the regulations[7] provides:

> Where a petition is received for the issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a food additive in such definition and standard of identity, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the food additive. Since section 409(b)(5) of the act requires that the Secretary publish notice of a petition for the establishment of a food additive regulation within 30 days after filing, notice of a petition relating to a definition and standard of identity shall also be published within that time limitation if it includes a request, so designated, for the establishment of a regulation pertaining to a food additive.

With the strict time limits imposed by the Food Additives Amendment, and the overwhelming amount of work which has been thrust upon the Food Standards Section of FDA, resulting in very substantial delays, one can't help but think that perhaps the best way to get a new standard, or an amendment to an old standard, promulgated, is to include a food additive in the proposal! Then all the proponent has to do is prepare and successfully prosecute a food additives petition. With 19½ years between the first frozen desserts standards hearing and the issuance of a standard, and almost five years already passed since the filing of the mozzarella cheese standard proposal and 2½ years since the hearing, perhaps we should throw a food additive into the next proposal for a standard so that the strict food additives time schedule will have to be followed.

If the petition for a standard or for an amendment to a standard contains a proposal for a food addtives regulation, and the petition fails to designate it as such, Section 121.8(b) of the regulations[8] requires the Commissioner to so notify the petitioner and then to proceed in accordance with the food additives regulations. In other words, if the Commissioner concludes that one of the ingredients of a product for which a standard is proposed *is* a food additive, even though the petitioner thinks the ingredient is *not* a food additive, the Commis-

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[6] 25 *Federal Register* 10064 (October 21, 1960).

[7] 21 CFR Sec. 121.8(a).

[8] 21 CFR Sec. 121.8(b).

sioner merely advises the petitioner that a food additive is involved and that clearance under the Food Additives Amendment is required.

Several petitions for amendments to standards to permit the use of food additives have been filed along with food additives petitions. For example, the cream and neufchatel cheese standards have been amended to permit the use of propylene glycol alginate,[9] and the French and salad dressing standards have been amended to permit the use of hydroxypropyl methylcellulose.[10] A proposal has been made to amend the French dressing and mayonnaise standards to permit the use of the food additive oxystearin.[11] Several other proposals have been filed, and, of course, many more similar amendments may be anticipated.

One interesting situation has arisen in connection with hydrogen peroxide in various standardized cheeses. A petition for an amendment to the Swiss and cheddar-type cheese standards was filed, asking that hydrogen peroxide and a catalase be permitted in the manufacturing process.[12] A proposed order was issued [13] and duly objected to, and a hearing held. One of the grounds for the objection was that hydrogen peroxide was a food additive, since it affects the characteristics of the food and is not "generally recognized as safe," to use the words of Section 201(s) of the Act,[14] and no food additives petition had been filed covering this use. FDA did not offer any witnesses at the hearing, and has not indicated whether it will require a food additives petition. Perhaps because the proponent alleged that none of the hydrogen peroxide remains in the finished product, although there is at least some scientific evidence to the contrary, FDA may conclude that no food additives petition is necessary.

Now let's turn to another interesting standards and additives matter. Simultaneous publication of the frozen desserts standards and a food additives order, the effect of which was apparently to amend the frozen desserts standards, indicate both the reasonable attitude of FDA in considering the interrelation of the food additives and food standards provisions of the act, and the alertness of counsel in making the proposal to FDA.[15] Hearings on the frozen desserts standards were conducted in 1942 and again in 1952 and 1953, but at neither

[9] 25 *Federal Register* 8947 (September 17, 1960); 21 CFR Sec. 19.515(b)(2) and 21 CFR Sec. 19.520(b)(2).

[10] 25 *Federal Register* 8949 (September 17, 1960); 21 CFR Sec. 25.2(c)(1) and 21 CFR Sec. 25.3(d).

[11] 26 *Federal Register*, January, 1961.

[12] 24 *Federal Register* 4495 (June 2, 1959).

[13] 25 *Federal Register* 1016 (February 5, 1960).

[14] 21 USC Sec. 321(s).

[15] 25 *Federal Register* 7099, 7126 (July 27, 1960).

hearing was data on the safety of Tweens 65 and 80 sufficient, in the opinion of FDA, to justify inclusion of these emulsifiers in the standards. But after passage of the Food Additives Amendment, a food additives petition was filed and the Food and Drug Administration was convinced of the safety of Tweens 65 and 80. The petitioner then requested FDA not only to issue a food additives regulation authorizing the use of these Tweens in frozen desserts, but also asked for an amendment to the standard. FDA in response, being now convinced that both Section 401 and Section 409 [16] were satisfied, issued a food additives regulation permitting the use of Tweens 65 and 80 in frozen desserts,[17] and the regulation appeared in the same *Federal Register* as the frozen desserts standards.[18] The regulation states that "the Commissioner has considered Section 401 of the Act and has concluded that these additives in frozen desserts will be in conformity with that section of the act as well as Section 409." While this procedure is certainly expeditious, it is subject to criticism on the ground that two optional ingredients which FDA apparently intends to permit are not listed in the standards. The result of FDA's convenient but perhaps confusing action—if the interpretation which has been generally given to the action is correct—is that the standard was amended without any notice of the proposed amendment.

The frozen desserts standards have since apparently been further amended to permit the use of propylene glycol alginate as an emulsifier, stabilizer or thickener, on substantially the same basis as the Tweens amendment.[19]

Now let's turn to another very interesting aspect of standards and additives. Until December 4, 1959, Section 121.8(c) of the regulations [20] provided:

> A regulation will not be issued allowing the use of a food additive in a food for which a definition and standard of identity is established unless its issuance is in conformity with section 401 of the act.

This takes no specific recognition of the possibility of an application for an experimental permit, under Section 3.12 of the regulations,[21] to permit the temporary use in a standardized food of an ingredient not permitted in the standards. Since experimental permits have been found to promote honesty and fair dealing in the interest

[16] 21 USC Secs. 341, 348.
[17] 25 *Federal Register* 7099 (July 27, 1960).
[18] 25 *Federal Register* 7126 (July 27, 1960).
[19] 25 *Federal Register* 9532 (October 5, 1960).
[20] 21 CFR Sec. 121.8(c).
[21] 21 CFR Sec. 3.12.

of consumers, and have been advantageous to both FDA and to industry, it appears highly desirable to combine a food additives regulation with a temporary permit in connection with a standardized product. The Commissioner corrected this situation by amending Section 121.8(c) on December 4, 1959 by adding the following:

> . . . or with the terms of a temporary permit issued under § 3.12 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the food additive regulations will be conditioned on such compliance and will expire with the expiration of the temporary permit.[22]

This procedure has recently been followed in connection with ethylenediaminetetraacetate, which, I might add with a gentle needle to the Commissioner, is the chemical name of a substance, the *common* name of which is EDTA. The calcium disodium form has been approved for use under the food additives amendment in several non-standardized foods, and a food additives petition has been submitted to FDA for the disodium dihydrogen form.

The calcium disodium EDTA petition is noteworthy in at least two ways. First, the food additives petition was, of course, prepared primarily by the manufacturer of the product. But customers of the manufacturer, who wanted to use EDTA in such standardized products as margarine, salad dressing, French dressing and mayonnaise, cooperated closely with the manufacturer in preparing data concerning technical effect, normal usage and other facts peculiarly within the knowledge of the manufacturer of the standardized foods in which it was desired to use EDTA. The manufacturers of the standardized products submitted data to the manufacturer of EDTA, who in turn submitted this data to FDA as part of its food additives petition. In other words, manufacturers at two different levels of production cooperated closely in submitting data in support of a food additives petition.

The second way in which the EDTA situation is noteworthy is that the food additives regulation authorizes use in a standardized product without an amendment to the standard, in accordance with the amendment to Section 121.8(c) of the regulations. Two manufacturers of these standardized products who are interested in EDTA chose to submit applications for temporary permits under Section 3.12 rather than apply for an amendment to the standards, and FDA has

[22] 21 CFR Sec. 121.8(c); 24 *Federal Register* 9730.

now issued a food additives regulation authorizing the use of calcium disodium EDTA in margarine, salad dressing, French dressing and mayonnaise,[23] and has issued temporary permits authorizing the use of EDTA in specific brands of these four standardized foods. This same procedure was followed in connection with the food additives petition and an application for temporary permit to use acetone peroxide in flour and bread.[24]

Such a situation could conceivably lead to temporary confusion. A margarine manufacturer who wants to use EDTA can find a food additive regulation which permits calcium disodium EDTA in margarine in an amount not to exceed 75 parts per million.[25] He would also find, however, that EDTA is not permitted in the margarine standard as an optional ingredient. The apparent dilemma is, of course, solved when the manufacturer finds that one of his competitors holds a temporary permit to use EDTA in his brand of margarine, and his recourse is obviously to apply for his own temporary permit, or for an amendment to the standard.

Note, however, the rather interesting comparison between these two situations: first, a food additives regulation permitting EDTA in salad dressing, but no provision in the salad dressing standard permitting EDTA; second, a food additive regulation permitting Tween 65 in ice cream, but no provision in the ice cream standard permitting Tween 65. The two situations appear to be identical: but they are not. Salad dressing manufacturers may not use EDTA, but ice cream manufacturers apparently may use Tween 65. The fault, I believe, lies in the short-cut method used to permit Tweens 65 and 80 in ice cream, but can easily be remedied by a publication in the *Federal Register*.

A temporary permit is normally valid for one year or until the standard is amended, whichever occurs first. Thus the manufacturer is enabled to test his product containing the food additive, under actual conditions of interstate use, and can acquire information necessary for a sound decision on whether or not to petition for an amendment to the standard. The Commissioner, I believe, deserves the thanks of the consuming public and manufacturers in his forward-looking decision to allow the use of temporary permits to deviate from a standard by the addition of approved food additives.

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[23] 26 *Federal Register* 25 (January 5, 1961).

[24] 25 *Federal Register* 10092 (October 22, 1960).

[25] 21 CFR Sec. 121.1017.

When a temporary permit expires by virtue of the clock, without a petition for an amendment to permit the use of the food additive having been filed, it remains to be seen what action if any the Commissioner may take. Conceivably he might leave untouched the food additives regulation authorizing the use of the substance in the standardized food, even though neither the standard nor a temporary permit authorized the use. Or he might conclude that since use of the substance in the standardized food is not authorized, the food additives regulation should be revoked. If the substance is one which is in great demand for other foods in which use has not been authorized, because the Commissioner feels that the total quantity in the diet is at the desired maximum, then I see no reason for not revoking the food additives regulation, at least as soon as a petition for permission to use the additive in another type of food is filed.

On the other hand, if the maximum amount has not been approached for use in other foods, no harm would be done by leaving the food additives regulation in effect in case someone wishes to file another application for a temporary permit or petition for an amendment to the standards.

A word should also be said about food standards and indirect additives, for example, substances which may migrate from packaging material. While, to the best of my knowledge, no official statement has been issued by the Commissioner, FDA has apparently taken what is obviously the correct position that indirect additives may occur in standardized foods as well as nonstandardized foods, without any effect on the standards, as long as the indirect additives are approved under the Food Additives Amendment.

## Conclusion

In conclusion, it appears that the food additives and food standards provisions of the Act have been administered well and liberally, if not with the greatest alacrity, by the Food and Drug Administration, and the absence of dispatch is due to the fact that if anyone at FDA is more overloaded than the food *additives* section, it is the food *standards* section. The beneficiaries of this proper administration are consumers who will benefit by having better standardized products available to them, additives manufacturers who will have wider markets for their products, and manufacturers of standardized foods who will be able to improve the quality of their products. **[The End]**

# The Hale Amendments— A Pyrrhic Victory?

By VINCENT A. KLEINFELD

The Author, a Member of the Washington, D. C., Law Firm of Bernstein, Kleinfeld & Alper, Presented This Paper at the Afternoon Session of the Annual Meeting of the New York State Bar Association, January 25.

THE HALE AMENDMENTS [1] to the Federal Food, Drug, and Cosmetic Act, sponsored by the affected industries, were enacted with the blessing of the Food and Drug Administration. It seemed clear that the amendments were most advisable in order to simplify the procedure for amending regulations, particularly by not requiring a hearing where industry did not object to a proposed regulation.

This aim was accomplished by the amendments, and the procedure with respect to making changes in definitions and standards of identity under Section 401, for example, was considerably simplified. The question remains whether, by reason of the *Dyestuffs and Chemicals* case [2] and the interpretation placed upon it by the government, more was lost by industry than gained.

In the *Dyestuffs and Chemicals* case, the Deputy Commissioner of Food and Drugs had published a notice of the government's proposal to amend the applicable regulations by removing certain coal-tar colors from the approved list for unrestricted use. After receiving comments, the Commissioner published an order removing the colors from that list because they were not "harmless and suitable for use" within the meaning of Section 406(b), then included in the Act. The order was to become effective 90 days after publication unless stayed by the filing

[1] P. L. 335, 83d Cong., 2d Sess.; P. L. 905, 84th Cong., 2d Sess.

[2] *Dyestuffs and Chemicals, Inc. v. Flemming*, 271 F. 2d 281 (CA-8, 1959).

of objections. The petitioner filed objections within the time provided by law, and requested a hearing pursuant to the provisions of Section 701(e).

The hearing was sought primarily on the ground that, in issuing the order, the government had failed to consider whether the colors were harmless and suitable for use under the intended conditions of use, and that the colors could so qualify when used within stated tolerances. Other objections were generally to the effect that the colors served a useful purpose; that there were no reports of injury to humans; that there was no fear of such injury from use by humans; and that the Commissioner should bar only excessive concentrations. The government refused to grant a hearing and review was sought in the United States Court of Appeals for the Eighth Circuit.

After the objections had been filed, but before decision by the Court of Appeals, the Supreme Court handed down its decision in *Flemming v. Florida Citrus Exchange*.[3] The Supreme Court held that under the Act, while the scientific tests and standards upon which the government had relied in precluding the use of another coal-tar color were required to be "toxicologically significant" (a term reeking with ambiguity), nevertheless, the tests did not have to depend upon a showing that the color was harmless when taken in a particular way, and in particular quantities, by humans. (Whether the Supreme Court adopted *in toto* the late, unlamented per se rule urged by the government is debatable, but that is not the subject of this paper.)

Upon the basis of this holding, the Court of Appeals for the Eighth Circuit concluded that it could not, of course, reverse the Supreme Court, and that it was now settled law that an order prohibiting the use of coal-tar colors in foods was not required to be based upon tests showing that the colors were harmful to humans in the context of the particular intended use. Accordingly, the court held that the objections of the petitioner were without legal substance and that a hearing would have been futile.

The court of appeals, in reality, concluded that objections of an affected industry requesting a hearing must raise an issue which the Food and Drug Administration can legally consider under the statutory mandate. After quoting from the Supreme Court's opinion in the *Florida Citrus Exchange* case to the effect that a system of tolerances

[3] *Flemming v. Florida Citrus Exchange*, 358 U. S. 153 (1958).

and consideration of particular intended use are not prerequisites of testing basic to the Secretary's order, and after declaring that the industry objections before it raised only that issue, the court of appeals stated:

> The hearing is solely for the purpose of receiving evidence "relevant and material to the issues raised by such objections". Certainly, then, the objections, in order to be effective and necessitate the hearing requested, must be legally adequate so that, if true, the order complained of could not prevail. The objections must raise issues. The issues must be material to the question involved; that is, the legality of the order attacked. They may not be frivolous or inconsequential. Where the objections stated and the issues raised thereby are, even if true, legally insufficient, their effect is a nullity and no objections have been stated. Congress did not intend the governmental agencies created by it to perform useless or unfruitful tasks. If it is perfectly clear that petitioner's appeal for a hearing contains nothing material and the objections stated do not abrogate the legality of the order attacked, no hearing is required by law.

Thus, both in concept and language the court of appeals merely held that while the Act requires a hearing upon objections, the objections must, in effect, state a cause of action not subject to demurrer. Just as at common law if the facts stated in a complaint, assuming their truth, could not withstand a demurrer, so too, if there was nothing whatever for the Secretary to consider on the merits, a hearing would necessarily be futile.

The holding of the Court of Appeals for the Eighth Circuit is understandable. But the government apparently reads much more into the opinion than seems warranted. For the position subsequently taken by the government in connection with 17 other coal-tar colors seemed to be that if a conclusion is reached by it on a scientific question, a hearing is not required even if there are factual allegations to the contrary by the affected industries. In other words, we know we are correct and a hearing would, therefore, be a futile gesture.

By order published in 24 *Federal Register* 8065, the Deputy Commissioner of Food and Drugs proposed to remove these colors, used widely and for many years in various drugs and cosmetics, from the list of colors theretofore permitted by the Food and Drug Administration for unrestricted use in such products. Prior to the order, the agency had informally advised the industries that its proposal to delist these colors would be the subject of a public hearing.

Immediately after the *Dyestuffs and Chemicals* decision, however, it became clear that the government now proposed to change its mind and issue, without any hearings, a delisting order vitally affecting the regulated industries. The reasoning behind this is not entirely clear,

for that case did not, after all, establish new law. It merely held that the position which the Food and Drug Administration had taken, in the context of the facts present in the case, was correct.

The government proposed not to grant a hearing with respect to the 17 colors, many of which were vital to the affected industries, and which the government acknowledged presented no hazard,[4] notwithstanding that the industries had submitted objections to the factual and scientific bases of the Commission's proposed action. The industries asserted that the Commissioner's order was objectionable because, *inter alia*, the tests upon the basis of which the order had issued were not scientifically proper. The industries alleged that the evidence of any potential injury from the use of the colors was entirely inadequate from a pharmacological and toxicological standpoint because the method of testing relied upon by the government was not scientifically proper in the circumstances, and that reliable conclusions could only be drawn from chronic toxicity tests at levels which were pharmacologically significant, and not from 90-day sub-acute feeding tests. Affidavits of experts to that effect were submitted by the industries.

With the greatest reluctance, a decision to grant a hearing was reached by the government. This may have been due to the fact that in their objections the industries also pointed out that tests had been conducted by the Food and Drug Administration on only some of the colors, and that others had been outlawed without any testing whatever on the assumption that they were chemically related to those which had been tested so that the same results could be assumed. The industries challenged this assumption, and submitted further affidavits of scientists supporting this objection. Apparently because of these objections, the government then conducted tests which disclosed that some of these "related" colors did not, in fact, have the same effects

[4] See, for example, the *Annual Report of the Food and Drug Administration, 1959*, where the following appears:

"Because of injury to test animals, a proposal was made to remove 17 colors from the list of those certifiable for use in drugs and cosmetics, while continuing to certify 13 for use in externally applied drugs and cosmetics. Some of these colors are widely used in lipsticks, which are not considered 'externally applied' because they are partially ingested and absorbed through the mucous membranes. The proposal has been opposed by drug and cosmetic manufacturers who would be seriously affected by the delisting. Although there is no evidence that lipsticks now employing these colors are injurious, there is no authority under the act to establish tolerances for a coal-tar color found not 'harmless' in any concentration."

on test animals as the colors which had been tested. This, in itself, would seem to highlight the necessity for hearings and the value of cross-examination.[5]

It is difficult to understand the reluctance to grant such hearings, particularly where the effect of an order proposed by the government will often have a profound effect upon industry. The language of Section 701 of the Act, as passed in 1938, was clear and specific. It was mandatory that a hearing be held upon objections to an order proposed by the Food and Drug Administration, that any order issued after the filing of objections be based upon substantial evidence of record at the hearing, and that the order be supported by detailed findings of fact. The Congressional purpose was obvious. Because orders proposed by the Food and Drug Administration are 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.[6]

Thus, the original pertinent provisions of the Federal Food, Drug, and Cosmetic Act, set forth below,[7] required a hearing upon any pro-

[5] Cf. the recent case of *Certified Color Industry Committee et al. v. Flemming*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 7620, 283 F. 2d 622 (CA-2, 1960), where the United States Court of Appeals for the Second Circuit stated, with respect to the Secretary's order withdrawing the outstanding certificate approving the use of FD&C Red No. 1:

"The objections filed by the Committee, quoted above, were certainly sufficient to raise the issue of the harmless or non-harmless character of Red 1, which is a question of fact. As no underlying factual determination of a sort sufficient to justify withdrawal of certificates had been made, the objections raised more than a 'legal issue.'"

[6] See, for example, H. Rept. 2139, 75th Cong., 3d Sess., accompanying S. 5. Congressman Lea, in charge of the bill on the floor of the House of Representatives, said:

"The regulation that is adopted in this bill in section (e) of 701, in my opinion, is of more importance to orderly procedure and in aid of the government departments in passing regulations than the court review section itself. This provision in our bill was written before the Supreme Court made its famous decision in the *Morgan* case, but it, in substance, provides that the legislative agency shall do the very things that the Supreme Court said they should do in the *Morgan* case." (83 *Congressional Record* 9096 (1938)).

[7] "The Administrator, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the foregoing sections of this Act: 401, 403(j), 404(a), 406(a) and (b), 501(b), 502(d), 505(h), 405 and

posal initiated by the Secretary to issue or alter any regulation, even, apparently, 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. Theretofore, the adoption of general regulations by administrative action, even where penal consequences attached to their violation, had not been surrounded by the safeguards that attend a judicial proceeding or an administrative proceeding of a quasi-judicial character. In the Act, the major requirements of quasi-judicial proceedings, including the holding of a hearing, were explicitly incorporated into Section 701(e) of the Act as passed.[7]

Experience under the Act subsequent to 1938 demonstrated 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 suggestion of industry and with the support of the Secretary, the Act was amended to require a hearing only for those proposed regulations to which industry specifically objected. The amendment has been converted by the government,

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*(Footnote 7 continued)*

604. The Administrator shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404(a) may be held within a reasonable time, to be fixed by the Administrator, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Administrator shall by order make public his action issuing, amending, or repealing the regulation or determining not to take such action. The Administrator shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Administrator finds that emergency conditions exist necessitating an earlier effective date, then the Administrator shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Administrator shall specify therein to meet the emergency."

[8] "*Hearings.* — A proposal to issue, amend, or repeal any such regulation [listing of harmless coal-tar colors and certification of batches thereof for foods, drugs, or cosmetics] is to be made by the Secretary of Agriculture on his own initiative, or by the interested industry or a substantial portion thereof, and the Secretary is required to set the proposal for hearing. The proposal is to be set forth in general terms so that the Secretary will be free to frame the precise language of the regulation or amendment or repeal in the light of the evidence developed at the hearing." H. Rept. 2139, 75th Cong., 3d Sess. (1938).

however, into an authorization for the Secretary to grant or withhold a public hearing at his absolute discretion. This was not the intent of Congress.

## Legislative History of Administrative Hearings Provisions of Federal Food, Drug, and Cosmetic Act, as Amended

The legislative history of Section 701 of the Act reveals in the clearest and most unambiguous language that Congress meant what it said in explicitly requiring a hearing where objection is taken to action instituted by the Secretary to issue, modify or repeal an order. In view of this, it is difficult to understand the position taken by the government that amendments of the section, proposed by industry and recommended by the government for the specific purpose of not requiring hearings where objections are not raised, removed the right to a hearing where factual objections are asserted.

## Legislative History of Section 701 of Act as Enacted in 1938

The most hotly contested provisions of the many bills which were introduced and debated during the five years it took to pass the original 1938 Act were those pertaining to administrative proceedings and judicial review. As stated, the intent was clearly expressed that Congress was going to see to it that the procedures traditionally encompassed only in judicial and quasi-judicial doctrines were to apply to the rule-making powers granted to the Secretary.[9]

The Federal Food, Drug, and Cosmetic Act consequently embodied the growing tendency on the part of Congress to impose strict procedural requirements upon regulatory agencies in the exercise of rule-making powers. Under the Federal Food, Drug, and Cosmetic Act, as passed in 1938, 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.[10] 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. In fact, Congress felt so strongly about the necessity for preventing arbitrary action and providing for a record based on the traditional concepts of examination and cross-

[9] See 83 *Congressional Record* 11830 (June 13, 1938).

[10] Fuchs, "Procedure in Administrative Rule-Making," 52 *Harvard Law Review* 259, 276-280 (1938).

examination, that it apparently required a public hearing even where there was no objection by industry to a proposed order of the Secretary.

## History of First Amendment of Administrative Provisions of Act

The first amendment was designed to revise Section 701 of the original Act, 21 USC 371, only with respect to regulations dealing with definitions and standards of identity for foods (Section 401, 21 USC 341). The legislative history is explicit in explaining that the amendment was designed merely to remove the necessity for a hearing where there are no objections.

Only two witnesses testified at the Hearing Before a Subcommittee of the Committee On Interstate and Foreign Commerce, House of Representatives, Eighty-third Congress, First Session, on H. R. 5055, "A bill to amend Sections 401 and 701 of the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures governing the establishment of food standards." Mr. Michael Markel, appearing on behalf of the Food, Drug and Cosmetic law section of the New York State Bar Association, testified as follows:

P. 7. In brief, Congressman Hale's bill would do two things:

(1) It would eliminate the requirement that food standards be promulgated on the basis of evidence of record at a formal hearing unless such a hearing is desired by any party who wishes to make a formal record for the purpose of possible judicial review. This change would greatly reduce the time and cost to both Government and industry involved in issuing food standards.

P. 9. The law [the original Act] requires that all regulations, whether challenged or not, be based "only on substantial evidence of record at the hearing". . . . However, all that can be done about this has been done by liberalizing the procedures as much as possible in the presence of statutory mandate that a regulation must be based "only on substantial evidence of record at the hearing", whether the regulations be controversial or not. . . .

P. 11. Paragraph (b)(2) of the bill serves to preserve the present safeguards by providing that anyone dissatisfied with the proposal as issued under (b)(1) my [may] file objections and, by so doing, invoke the full formal procedures now available under the law. In other words, the present provisions would remain in full force and effect in favor of any dissatisfied party who would be adversely affected by a regulation.

The following colloquy occurred with regard to the situation where objections are filed:

P. 14. Mr. Springer (reading):

Shall, by order, act upon such proposal and make such order public.

Mr. Markel. Yes sir. That order would then include the proposed regulation, that may be identical in wording with the proposal but its status now would be that of a proposed regulation.

Mr. Springer. But she [the Secretary] does issue the order?

Mr. Markel. Yes.

Mr. Springer. Is that the effect of a regulation?

Mr. Markel. If no objections are filed within the specified time.

Mr. Springer. I have not gotten to that point. At this point, she issues a regulation if she wants to.

Mr. Markel. Yes.

Mr. Springer. But it cannot become effective for 30 days.

Mr. Markel. Right.

Mr. Springer. At that point, is there a stay of all proceedings?

Mr. Markel. Correct.

Mr. Springer. Then she must call a public hearing?

Mr. Markel. Right.

Mr. Springer. A witness or anyone can be heard?

Mr. Markel. Yes.

Mr. Springer. Now at that point if she issues an order "such order shall be based only on substantial evidence at such hearing." Now in that kind of a case she must base her order only on the record?

Mr. Markel. Right.

Mr. Charles W. Crawford, then Commissioner of the Food and Drug Administration, was the only other witness. He stated at page 16:

I would like to say merely that the Department endorses this legislation. It believes that it will simplify the proceedings, speed them up; it will sacrifice no rights, public or private, and will save the Government a lot of money in my judgment.

The House Report, 934, Eighty-third Congress, First Session, accompanying H. R. 6434, "Amending Sections 401 and 701 of the Federal Food, Drug, and Cosmetic Act With Respect To Establishment of Food Standards," was equally clear in pointing out that the right to a hearing was preserved where controversy exists:

Pp. 2, 3. The consensus of opinion, as expressed in these communications and by the witnesses appearing before the committee may be fairly stated to be that (a) the procedural requirements of the present law are unnecessarily burdensome in that they require formal hearings and all that this implies, whether a proposed regulation is controversial or not, with the resultant unless expenditure of time and money by both the Government and the interested industry, even when all are in agreement as to the proposed regulation; and (b) the proposed legislation is favored by them 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.

Appended to the report was a letter dated July 13, 1953, transmitted to the committee by the Secretary of Health, Education, and Welfare. That letter stated, in pertinent part:

> The bill would provide for issuing, amending, or repealing food standards regulations by a procedure comparable to that specified by section 507(f) of the act for regulations concerning the certification of certain antibiotic drugs. This bill would greatly facilitate non-controversial changes in food standards regulations. It would eliminate the necessity for public hearings and the establishment of a record of testimony and exhibits where, after due notice, it developed no one opposed the change. A further advantage would be to simplify hearings on regulations containing both controversial and non-controversial issues by separating and eliminating the non-controversial.

The same explanation of the purpose of the bill was made by the Senate Committee on Labor and Public Welfare. The committee declared:

> The consensus of opinion among all the leading food producers, as well as Food and Drug Administration officials, is that the existing standard-making procedures are slow and cumbersome. The procedural requirements of the present law are unnecessarily burdensome in that they require formal hearings and all that this implies, whether a proposed regulation is controversial or not, with the resultant useless expenditure of time and money by both the Government and the interested industry, even when all are in agreement as to the proposed regulation. Enactment of this bill would provide 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.
>
> The Commissioner of Food and Drugs, together with counsel representing the interest of leading food producers, appeared before members of the Subcommittee on Health of this committee and strongly urged the early enactment of this legislation. All communications received by the committee concerning this measure have been unanimous in favor of the bill's enactment and the committee knows of no opposition thereto (S. Rept. 1060, 83d Cong., 2d Sess.).

The brief debate on the floor of the Senate on the bill again highlighted the clear intent of Congress to preserve the mandatory right to a hearing where objections were asserted to a proposed order (pages 4287-4288, *Congressional Record*, April 5, 1954):

> Mr. Purtell: Mr. President, the main purpose of the bill is to facilitate the making of noncontroversial changes in food standards regulations. The bill is designed to—
>
> First. Simplify the procedures governing the issuing, amending, or repealing of regulations fixing and establishing definitions and standards of identity, standards of quality, or standards of fill of container for foods as authorized by section 401 of the Federal Food, Drug, and Cosmetic Act by restricting the requirements for the formal type of hearings, as now prescribed in section 701(e) of that Act, to instances where this procedure is desired by a party who would be adversely affected if the regulation, as proposed, were to be effective. . . .
>
> . . . .

Mr. Gore. The distinguished Senator from Connecticut has made an able explanation of the bill. Does he consider it in the public interest that formal hearings be waived, even though no direct controversy is involved? Would not it be in the public interest to have available to the public the reasons formally stated, for such regulations?

Mr. Purtell. Public hearings are not to be waived, in the sense that there are to be no public hearings, when anyone at all objects to the proposed regulations. The bill provides that time for the filing of objections will be allowed, and then a hearing will be held before any such regulation on the part of the Food and Drug Administration will become binding on the public.

(The bill passed the House without debate (page 10753, *Congressional Record*, July 20, 1953).)

## History of Subsequent Amendment of Section 701 of Act

The experience under the first amendment was gratifying to both the Secretary and industry. It was determined, therefore, to extend to all the types of regulations specified in Section 701(e), and not merely to food standards regulations, the procedure whereby hearings would not be required because objections had not been raised. Again, the legislative history of this subsequent amendment (putting the administrative proceedings provisions of the Federal Food, Drug, and Cosmetic Act in their present form) reveals clearly the mandate of Congress to do away with hearings where there was no objection, and to retain them when there was controversy.

The report of the House Committee on Interstate and Foreign Commerce (H. Rept. 2623, Eighty-fourth Congress, Second Session) accompanying H. R. 9547, which became law, and the Secretary's letter to the committee with respect to the amendment, were explicit. The report pointed out:

The purpose of the bill is to simplify the procedures followed by the Food and Drug Administration in making regulations under certain provisions of the Federal Food, Drug, and Cosmetic Act. The bill would remove in specified situations, where the proposed regulations are not controversial, the mandatory requirement of following formal rulemaking procedures.

The legislation would extend the procedural simplification provisions of Public Law 335, 83d Congress. Public Law 335 was limited in its application to regulations establishing standards of identity, standards of quality, or standards of fill of container, for food products. The experience under Public Law 335 has been so gratifying to both industry and government that all concerned desire to have this simplified procedure apply to all regulatory procedures referred to in section 701 of the Federal Food, Drug, and Cosmetic Act. These include labeling for special dietary foods, tolerances for necessary and unavoidable poisonous and deleterious substances in foods, listing of coal-tar colors which may be certified for use in food, drugs, and cosmetics, and other provisions calling for rulemaking by the Food and Drug Administration.

The procedural requirements of the present law are unnecessarily burdensome. They require formal hearings, whether a proposed regulation is controversial or not. This results in useless expenditures of time and money by both the Government and the interested industry.

The communication directed to the committee by the Secretary of Health, Education, and Welfare (pages 2 and 3 of the report) was equally specific. The Secretary stated:

The bill would greatly facilitate the establishment of regulations insofar as they are noncontroversial. It would also simplify hearings on regulations containing both controversial and noncontroversial issues by separating and eliminating the noncontroversial. On the narrow issues about which there is controversy, any interested person affected by a proposed regulation could, by filing a petition, initiate the formal procedure, including a public hearing, establishment of the public record on which our action would be based, and review of our action in the United States Court of Appeals. Thus, no substantial rights of any person would be relieved of protection, while government, the public, and industry are relieved of the costs and expenditure of time in holding hearings on points about which all agree.

Your committee's report on H. R. 6434 (which becomes Public Law 335) stated in regard to the proposal to simplify the procedure for food standards issued under section 401 of the act:

"All of the communications received by the committee, including many not a part of the record, and both of the witnesses appearing before the committee, favored the proposed legislation and urged its early enactment. There is no known opposition.

"The consensus of opinion as expressed in these communications and by witnesses appearing before the committee may be fairly stated to be that (a) the procedural requirements of the present law are unnecessarily burdensome in that they require formal hearings and all that this implies, whether a proposed regulation is controversial or not, with the resultant useless expenditure of time and money by both the Government and the interested industry, even when all are in agreement as to the proposed regulation; and (b) the proposed legislation is favored by them 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 (H. Rept. 934, 83d Cong., 1st sess.)."

We believe that the amendment of section 701(e) contained in the bill, which makes the simplification effected by Public Law 335 applicable to the procedure for the other regulations governed by section 701(e), will prove as noncontroversial in its extension to other regulations as was the prior amendment affecting only the food standards procedure.

The existing law is unnecessarily burdensome, and the proposed bill would afford the required relief. We recommend that it be considered favorably by your committee.

In a communication to the committee from the Deputy Attorney General, attached to the report, the Department of Justice pointed out, similarly:

The purpose of the bill would be accomplished by eliminating the present requirement of the Federal Food, Drug, and Cosmetic Act that hearings be conducted in certain cases although no controversy exists.

The act now provides for two separate procedures pertaining to the issuance of regulations. Section 401(b) relates to regulations pertaining to standards of identity, quality, and fill of container for food. Section 701(e) relates to regulations issued pursuant to eight other sections of the act. Under this latter provision a public hearing is required as a condition precedent to the issuance, amendment, or repeal of any regulation covered. Under section 401(b) a public hearing need be held only when requested by a person adversely affected by a proposed rulemaking action.

The bill would establish a uniform procedure for the issuance of regulations under the listed sections, and would adopt the provisions of section 401(h) with respect to public hearing as applicable to all of the sections.

The testimony at the Hearings Before a Subcommittee of the Committee on Interstate and Foreign Commerce, House of Representatives, Eighty-fourth Congress, Second Session, on H. R. 4785, H. R. 9547 (the bill in question), H. R. 9725 and H. R. 10519, had specifically set forth the same views. Congressman Hale, the sponsor of the bill, made the following explanation of the bill to the committee:

The bill would amend the Federal Food, Drug, and Cosmetic Act so as to simplify the procedures required to be followed under the act in promulgating formal regulations. Specifically, the bill would do only one thing; it would eliminate the requirement for formal procedure and a formal record when all concerned are in agreement, but would preserve the present procedure where a hearing is desired by any disagreeing party. Thus there would be no need for expensive and costly hearings except in instances which involved controversial questions where any adversely affected party wishes to make a formal record as the basis for administrative action and judicial review. . . .

The bill has been prepared by Mr. Allen Perley, our legislative counsel, after collaboration with both Government and industry representatives. To the best of my knowledge, there is no objection to it.

The fact that the Secretary not only did not object to the bill and its purposes, but favored it, was brought out in a letter from the Secretary, dated June 6, 1956, to the President of the Senate, a copy of which was attached to the record of the hearings at page 16. The Secretary declared:

The bill would greatly facilitate the establishment of regulations insofar as they are noncontroversial. It would also simplify hearings on regulations containing both controversial and noncontroversial issues by separating and eliminating the noncontroversial. On the narrow issues about which there is controversy, any interested person affected by a proposed regulation could, by filing a petition, initiate the formal procedure, including a public hearing, establishment of the public record on which our record would be based, and review of our action in the United States Court of Appeals. Thus, no substantial rights of any person would be relieved of protection, while Government, the public and industry are relieved of the costs and expenditure of time in holding hearings on points about which all agree.

The Deputy Commissioner of Food and Drugs testified before the committee. He did not object to the bill or to the explicit explanation that there was no desire to remove the requirement for a public hearing where there were objections to a proposed regulation by the Secretary. Rather, the Deputy Commissioner stated briefly at page 38:

> I would like to have the record show that we have had experience with a similar provision applicable to food standards alone, and that experience has convinced us that extending it to other forms of rulemaking is highly desirable. We are very much in favor of that piece of legislation.

## Conclusion

It is not too frequent that explicit statutory language is buttressed by equally clear language in the applicable debates, Congressional hearings and reports. The mandatory provisions for a hearing in advance of administrative action affecting personal or property rights is the statutory embodiment of a legal concept of fair play fundamental to our system of jurisprudence.[11] This concept was specifically insisted upon by Congress in connection with the rulemaking authorization vested in the Secretary by Section 701(e) of the Act, and Congress reasserted its intent in the legislative history of the Hale Amendments of the section. It would appear abundantly clear, therefore, that if any factual issue whatever is raised with respect to an order proposed by the Secretary under Section 701, a hearing is required as a matter of law. **[The End]**

## CHICKEN VACCINE MANUFACTURER SUED

An action brought against the maker of a dust vaccine for the immunization of chickens was dismissed by the New York Supreme Court for want of privity between the plaintiff and the defendant. The plaintiff alleged that certain warranties contained in the defendant's advertising literature were untrue, and that damage had resulted from the plaintiff's reliance on them. The court said:

> "It is clearly established as the law of this State that an action for breach of warranty, express or implied, does not lie in the absence of a contractual relationship. . . . Even if such a course were desirable it is not within the province of this court to change existing law or to make a determination contrary to binding precedents."—*Canter v. American Cyanamid Company*, New York Supreme Court, December 2, 1960, 12 NEGLIGENCE CASES (2d) 53.

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[11] See, for example, *Standard Airlines, Inc. v. Civil Aeronautics Board*, 177 F. 2d 18, 21 (CA of DC, 1949).

# Conflicts Between State and Federal Food and Drug Laws

By THOMAS W. CHRISTOPHER

This Paper Was Presented at the Afternoon Session of the Annual Meeting of the Section on Food, Drug and Cosmetic Law, New York State Bar Association. The Author Is an Attorney for the Corn Products Company in New York City.

THERE ARE A NUMBER of concepts for dealing with situations where both the state and the federal government have statutes on the same subject. Some areas are reserved exclusively to the national government, the issuance of money being an example. Some areas which normally are open to state regulation have been pre-empted by federal legislation and thus closed to state controls, aspects of labor problems being examples.

A third concept permits state regulation in areas where Congress has not acted or where it has acted so long as there is no conflict, and this is the concept that generally applies to state food and drug legislation. Thus, barring questions such as due process and equal protection, so long as there is no conflict, the federal Constitution does not interfere with state statutes dealing with narcotics and other drugs and with foods; the important federal question in these cases is whether there is conflict. There are several landmark decisions by the United States Supreme Court on the conflicts problem and these lay down fairly clear guides.

## Conflicts in Fact

The first of these is *Savage v. Jones*,[1] decided by the Supreme Court in 1912. There, an Indiana statute required a tag on commercial

[1] *Savage v. Jones*, 225 U. S. 501 (1912).

animal feeds giving the ingredients and the minimum percentages of crude fat and crude protein: this information was not required by the Federal Food and Drug Act. We thus have a situation where a state law requires additional information on the labeling.

In its decision upholding the Indiana requirement, the Supreme Court points out that the federal statute does not prohibit the giving of the information in question, and, further, that requiring this information does not interfere with the federal control. So, the state is free to act. This decision is very much in point in considering state requirements which call for additional information.

Another decision on this issue is *Corn Products Company v. Eddy*.[2] Unlike the federal law, a state statute required that the label of syrup disclose the ingredients and proportions, thus adding to the federal requirements. As in the *Savage* case, the Supreme Court had no trouble upholding this statute as not violating federal prohibitions.

These decisions pretty well settle this issue. Today, we have examples of additional state requirements in the margarine field when several states demand special labeling in addition to the federal specifications, and such demands do not raise serious legal questions so long as they are merely additive in nature.

A somewhat similar issue arises when a state outlaws an ingredient or a product which is not prohibited by the federal statutes. For example, may a legislature proscribe colored margarine, or plain unenriched flour, or cigarettes, or coal tar dyes in food?

*The Weigle*[3] case in 1919 involved a state statute which banned foods containing benzoic acid—an ingredient not illegal under the federal acts. The plaintiff shipped fruit products containing benzoic acid in interstate commerce into the state in question. The local prohibition applied only to retail sales in single jars or bottles. The Supreme Court upheld the statute, saying that it applied only to retail sales within the state and, thus, did not interfere with interstate commerce.

On a slight variation, another state statute was upheld which prohibited the retail sale of lard otherwise than in bulk or in one-, three- or five-pound packages or pails.[4] The Court also held that the statute does not violate the due process or equal protection clauses of the Fourteenth Amendment.

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[2] *Corn Products Company v. Eddy*, 249 U. S. 427 (1919).

[3] *Weigle v. Curtice Brothers Company*, 248 U. S. 285 (1919).

[4] *Armour & Company v. North Dakota*, 240 U. S. 510 (1916).

In the narcotic field a state act required physicians to treat drug addicts by prescription and not from the physician's own supply of narcotics, the federal regulation permitting treatment either way. This cutting down by the state was upheld.[5]

These decisions point to the interesting question arising where a state law prohibits an ingredient which is positively permitted under a federal regulaton. A required or optional ingredient in a standardized food would be an example. An opinion by the Attorney General of Wisconsin[6] indicates that such a state act is void on federal grounds. My own feeling is that the mere fact of conflict in this manner is not enough to invalidate the state regulation. Thus, unless Congress has occupied the field, as in certain labor matters, or has clearly said that no state can interfere, I see no reason why a state cannot prohibit an article regardless of its acceptability under federal rules. I would suppose that a state could completely proscribe unenriched bread, for example. The Fourteenth Amendment, of course, may act as a restraint here but this is a different issue and I am talking only of the conflict doctrine.

## Conflict of Enforcement

So far we have dealt with conflicts in fact—one permits, the other restricts or prohibits. There is another aspect of the conflict doctrine. This is that a state statute may fall because it interferes with the *enforcement* of the federal act. The classic decision on this point is *McDermott v. Wisconsin*,[7] a 1913 Supreme Court case. In this case, a Wisconsin statute required that the product at hand be labeled "Glucose flavored with Refiner's Syrup." By the federal law the product could be labeled as "Corn Syrup with Cane Flavor." The result was that a retailer in Wisconsin was required to remove an interstate label and substitute a local one. The Supreme Court cites the *Savage* decision with approval but holds the Wisconsin statute to be void. The crux of the holding is that the state requirement unduly interferes with the enforcement of the federal act. By the removal of the interstate label prior to the last retail sale, the federal authorities are limited to inspection prior to that time; yet the federal act contemplates inspections down through the last retail sale. The Court says that the "real opportunity of Government inspection may only

[5] *Minnesota v. Martinson*, 256 U. S. 41 (1921).

[6] Opinion of Attorney General, Wis., Dec. 5, 1950, CCH FOOD DRUG AND COSMETIC LAW REPORTS, ¶ 85,127.

[7] *McDermott v. Wisconsin*, 228 U. S. 115 (1913).

arise when . . . the goods as packed have been removed from the outside box in which they were shipped." [8]

The lesson of the *McDermott* decision is, then, that a state regulation may fall by reason of its conflicting with the enforcement of a federal law, as well as by reason of a conflict in requirements.

Another decision on this point is *Cloverleaf Butter Company v. Patterson*.[9] There, a federal statute authorized seizure of the finished product made from packing stock butter but not the original packing stock butter. An Alabama statute authorized the seizure of the packing stock butter itself, even in the plant. Thus, the Alabama regulation applied to an area of the manufacturing process not covered by the federal enactment.

A divided Court struck down the Alabama statute on the theory of interference with the federal enforcement. The majority said that Alabama could seize the product before it arrived at the plant, but state intervention at the plant interferes with federal discretion regarding ingredients. Thus, we have the *McDermott* situation.

## Conflict with Federal Directive

Up to this point we have considered the "add to" and the "interfere with enforcement" problems. In the background of both these facets is the situation where the state rule is in clear conflict with a federal directive. An example would be where the federal regulation requires that all ingredients on the label be in type of the same size and boldness, and a state statute specifies that certain ingredients shall be printed on the label in larger or bolder type than others. As to interstate commerce, you have here a clear conflict and the state requirement must give way. This is true even though the state perhaps could prohibit the product altogether.

Another situation when state statutes may run afoul of the federal courts is where the restriction interferes with interstate commerce. The best decisions on this point involve milk. In the much discussed *Dean* [10] case, a city ordinance required that milk be pasteurized within five miles of the city, and this was struck down as interfering with perfectly good milk in interstate commerce. The lesson of such decisions as *Dean* is that intrastate and interstate commerce must receive equal treatment.

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[8] Case cited at footnote 7, at p. 136.

[9] *Cloverleaf Butter Company v. Patterson*, 315 U. S. 148 (1942).

[10] *Dean Milk Company v. City of Madison*, 340 U. S. 349 (1951).

## Fourteenth Amendment

Finally, we may spend a moment on the Fourteenth Amendment, for it places some restriction on what a state may do in the food and drug fields. In simple terms, the rule here is that a state may not act arbitrarily to prohibit a perfectly good product. There must be some reason founded in health or public welfare; welfare here may include economic considerations, such as fraud or consumer deception. The filled milk acts are examples of valid prohibitions.[11]

Of course, in this connection, a valid statute today may become invalid in a decade due to advances in scientific knowledge. Normally, a legislature cannot outlaw a product without rhyme or reason; there has to be some basis—health, economic, fraud, and the like. Scientific advances, thus, may supply a basis for a law where there was none in the past; and it is likely that in the next half century we will have valid regulatory action—even prohibitions—as to certain foods we now commonly eat. Thus, so far as the Fourteenth Amendment and similar state constitutional provisions are concerned, there is interplay between science and constitutional law. Simple examples are drugs which are found to be harmful and foods which are found to cause disease.

Not to be overlooked as a possible way around the Fourteenth Amendment question is the taxing power. This item is an effective device for regulation of a product and its use may avoid the health or public welfare requirement. **[The End]**

## • MISREPRESENTATION—COSMETICS •

**Colognes** . . . A Commission hearing examiner issued an order which would require a mail-order distributor of miscellaneous merchandise in Atlantic City, New Jersey, to stop misrepresenting colognes as perfumes, as charged in the complaint.

Acting on the FTC's complaint of last August 25, the examiner found that the concern's advertising for Arpege and Chanel No. 5 colognes falsely represented that the products offered were the perfumes of the same names. Although the company did not use the word "perfume" in its advertising, it did use the brand names without disclosing that the products offered were colognes.

Furthermore, the examiner asserted, the fact that Arpege and Chanel No. 5 colognes, unlike the perfumes of the same names, are not normally sold in units as small as one dram, "leads to the conclusion that many buyers could easily be led into believing that the products offered were perfumes." (Released March 1, 1961.)—CCH TRADE REGULATIONS REPORTS ¶ 29,409.

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[11] *See Hebe Company v. Shaw*, 248 U. S. 297 (1919).

# The Need for Uniformity in Food Legislation

By FRANKLIN M. DEPEW

**This Paper, Presented by the President of the Food Law Institute at the Recent Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, Stresses the Need for Uniformity Between State and Federal Regulations of Food Products.**

IN RECENT YEARS there has been a widespread interest in a modernizing revision of the existing food laws, regulations and standards of many countries throughout the world. Interested officials and international governmental and nongovernmental organizations and national associations of the various professions and industries concerned, regard this as desirable in order to protect the consumer's health, to assure high quality and to eliminate objectionable trade barriers. The existing diversity in these laws has created serious impediments in the development of international trade in food products. When these barriers have not completely banned the movement of a particular food product, they have added a burden of expense to the ultimate consumer in the cost of special labeling, packaging, etc.

In addition to old-time barriers, many of which were created by selfish interests, is the relatively new barrier created by the chaos of legislation relating to food additives. In a recent article by C. L. Hinton (*Food Processing and Packaging*, July 1960, p. 247), the following comment was made, relative to food additives and the European Free Trade Association:

> In regard to the legally permissible use or prohibition of many food additives, such as chemical preservatives, alkalisers, colouring matters, antitoxidants, emulsifiers, etc., the seven countries afford a good random sample of the extraordinary diverse ways in which this question is dealt with the world over. And

as for the quantitative tolerances allowed for particular additives, the diversity becomes so wide as to suggest that they have often been fixed on the basis of suspected health hazards with no supporting evidence worth talking about.

The author reports that the tolerance limit for benzoic acid varies from 320 p.p.m. in Switzerland to 2000 p.p.m. in Denmark.

Such diversity of toxicity tolerances has seriously impeded international trade in the past, and will continue to do so unless corrected. If these barriers are not abolished, and if new tolerances are not made on a sound and reasonable basis, it is the considered opinion of nutritional scientists that they will hasten the day of food shortages and the higher cost of food for all of us.

These reasons have brought about a movement toward uniformity of food standards and the drafting of uniform international food codes which could eventually be adopted on a regional or international scale.

In the international field the following developments toward this end can be reported for the year 1960:

The Official Revised Spanish Edition of the Latin-American Food Code as adopted by the Seventh Latin-American Chemical Congress on April 3, 1959, was published in Spanish in August, 1960. Dr. Carlos A. Grau, chairman of the drafting commission of this code, has advised that the earlier distribution of a preliminary draft of the code brought forth some 400 comments through The Food Law Institute and the United States Department of Commerce, and that some 300 changes had been made in the code to conform to these comments. Dr. Grau further stated that the balance of the comments are still under consideration. The latest revised copy of the code will be submitted to the Eighth Latin-American Chemical Congress which will be held in 1962; at which time it is expected that a further revision of the code will be made to accommodate additional comments and suggestions.

In November, 1960, Dr. Grau reviewed this code with the Pan-American Federation of Pharmacy and Bio-chemistry at its meeting held in San Diego, Chile. It is our understanding that the code was approved in principle, and that it was suggested that this code might well be made the basis for a Pan-American food code.

In September of 1960 the Fifth International Congress on Nutrition was held in Washington, D. C., under the auspices of the International Union of Nutritional Scientists. Dr. Charles Glen King, president of the congress, reports that these nutritional scientists feel

that unless the tolerances for food additives are established on a sound and reasonable basis, conditions will be created which will greatly increase the difficulties of feeding our world population. While this particular subject was not discussed in any of the papers read at the congress, it was a source of considerable informal discussion among the members in attendance.

Later in September the British Pure Food Centenary was held in London, England. This centenary conference was formally opened by the Rt. Hon. The Earl Waldegrave, T. D., Parliamentary Secretary (Lords), Ministry of Agriculture, Fisheries and Food. Lord Waldegrave in his opening remarks strongly recommended the adoption of universal standards of food purity throughout the world. In addition a number of papers read at the centenary stressed the desirability of uniformity in food legislation. The paper of Dr. Norman C. Wright, Deputy Director-General of the Food and Agriculture Organization of the United Nations (FAO), in particular, mentioned the progress that was being made in respect to the European and Latin-American food codes and reported that the FAO-World Health Organization (WHO) joint program on food additives was an example of work along these lines on a world-wide basis.

Early in October, Dr. Hans Frenzel, president of the Council for the European Food Code, reported at the Convention of Officials held at Klagenfurt, Austria, that it appeared that the best way of furthering acceptance of the code was to work in cooperation with WHO and FAO. Later that month at the FAO European Regional Conference the question of cooperation with the Council for the European Food Code was reviewed, and it was noted that certain European countries had tried to establish a European Food Code. After some discussion the following proposal was adopted:

> On the proposal of a number of delegations, the Conference considered the problem of coordination presented by the growing number of food standards programs undertaken by many organizations. The desirability of international agreement on minimum food standards and related questions (including labelling requirements, methods of analysis, etc.) was recognised as an important means of protecting the consumer's health, of ensuring quality and of reducing trade barriers, particularly in the rapidly integrating market of Europe.
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> The position was clearly reflected in the interest shown in such activities as the joint FAO/WHO Program on Food Additives, the joint FAO/ECE programs on standards for perishable foodstuffs, and the FAO code of Principles on milk and milk products. The recent formation of the European Council of the *Codex Alimentarius* with a valuable and farseeing program in which some twenty countries cooperated, was a further example of this trend.
>
> The advantages to be obtained by integrating and simplifying the various projects under way and by avoiding the creation of new independent bodies were

recognised, both as a measure of economy and as an effective mechanism for covering other food products as and when required. In view of the primary role of FAO in such programs and the need for collaboration with WHO where the health aspect is concerned, it was felt that a valuable step forward would be achieved if the Director-General of FAO, in collaboration with the Director-General of WHO and after consultation with the international governmental and non-governmental organizations active in this field, could submit to the 11th Session of the Conference (in October 1961) proposals for a joint FAO/WHO program on food standards and associated requirements, with particular reference in the first instance to the principal foodstuffs offered for sale on the European Market.

From the foregoing we can safely conclude that the FAO-WHO will work with the Council for the European Food Code in furthering the adoption of uniform laws, standards and regulations throughout Europe. In the meantime there are four intergovernmental organizations working in the food standards field. They are FAO, WHO, the Economic Commission for Europe of the United Nations (ECE) and the Organization for European Economic Cooperation (OEEC and EAP). All four organizations work closely together. In some cases FAO programmes are actually joint FAO/WHO undertakings (for example, food additives and milk hygiene), whilst the ECE is in close contact with its fellow European organization, OEEC. The earlier difficulties, due to the fact that eastern European countries were not included in some of these organizations, now belong very largely to the past. The standards now being worked on by these organizations are as follows:

FAO—Milk and Milk Products, Food Additives (with WHO), Milk Hygiene, Rice, Cocoa, Citrus Fruit;

ECE—Fruit and Vegetables (about a dozen already issued), Eggs, crating and packaging;

OEEC—Fruit and Vegetables (with ECE), Meat and Meat Inspection, Fish (with ECE).

In addition, the European Common Market is working on new food standards and there is a considerable quantity of nongovernmental or semigovernmental organizations active in the field. In all important cases they have an understanding with FAO on a cooperative exchange of documents, etc.

From the foregoing, we can conclude that the countries in the principal foreign markets of the world have recognized the need for uniformity in food laws and are seriously endeavoring to achieve this goal.

On the home front, while our situation is by no means as grave as that existing in foreign countries, it is necessary that we should avoid falling into the errors exemplified by the situations discussed above. With the statesmanlike efforts that are being exerted toward correction of these barriers in the international field, it is even more important that we should not take a parochial viewpoint here in the United States. We must avoid Balkanizing our local trade in food products, by renewing our efforts toward the goal of uniformity. Uniform state laws, adequately enforced and uniformly interpreted, are of prime importance to the citizens of the several states and to the operation of industry as a whole.

We have had one striking example of ill-considered legislation in the law recently enacted in Florida. That statute permits the commissioner of agriculture to require the registration of foods and their labels, and the state board of health to require the registration of drugs and cosmetics and their labels, upon the payment of specified registration fees. (Laws of 1959, H. B. 1093, approved June 15, 1959, effective January 15, 1961.) The commissioner of agriculture has not yet implemented the statute. The enforcement of the food and drug laws has historically been carried out by the use of funds raised by general taxation, which were not in any way earmarked for that specific purpose. The distribution of food and drugs, so vital to our consuming public, should not be made a source of special revenue. Furthermore, it is difficult to see what enforcement purpose this required registration will achieve. Its cost to industry appears to be out of all proportion to any possible aid in enforcement, and it is bound to be reflected in higher costs to the consumer.

In our search for the goal of uniformity we must recognize that the federal Act only applies to foods, drugs, therapeutic devices and cosmetics that have moved in interstate commerce. Also, the states naturally have a great interest in protecting the health of their citizens and feel the need to have freedom of action to handle problems peculiar to their states.

Mr. Timothy E. Sullivan, Director, Division of Food and Drugs, Indiana State Board of Health, and a long-time advocate of uniformity, in his paper delivered at the 1960 Joint National Conference of the Food and Drug Administration and The Food Law Institute, pointed out the difficulties facing the states in connection with the adoption of uniform food laws. In the course of that paper he stated:

State regulatory agencies, state legislators and state attorneys feel that the prerogative of states to act for themselves when the need arises must be preserved in any amendments to state laws which seek to promote the uniformity we all agree to be desirable.

Mr. Sullivan's comments reflect the position taken by the Committee on Revision of the Uniform Food, Drug and Cosmetic Bill in its Report to the Sixty-fourth Annual Conference of the Association of Food and Drug Officials of the United States, last June. This report stated in part:

> The Committee has reviewed the proposed amendments to the Uniform Food, Drug and Cosmetic Bill which has been submitted to the Council of State Governments by the Department of Health, Education, and Welfare, and the State members of the committee believe that a number of the proposals are not compatible with State laws and would be objected to by state attorneys.

At the same conference the Committee on Chemical Additives and Dietary Foods made the following statement as part of its report:

> The Committee also had requests for model legislation to bring the Uniform Bill up to date with respect to Chemical Additives and Dietary Foods. Some of the requests dealt with enabling legislation and were referred to the "Committee to study Proposed Revisions of the Uniform Food, Drug, and Cosmetic Bill recommended by AFDOUS."
>
> This Committee wholeheartedly supports the efforts of this Association to obtain uniform laws, increased appropriations, adequate modern facilities and equipment, and improved status for enforcement agencies and personnel particularly in the areas of chemical additives and special dietary foods.

From the foregoing it can be safely concluded that the Association of Food and Drug Officials of the United States is wholeheartedly in favor of the doctrine of uniformity, but that there are certain problems of legal draftmanship which must be solved in order to make this doctrine work as a practical proposition.

I think that lawyers and other representatives of industry have made it clear that they favor uniform food legislation. Additionally, it is in the public interest that such legislation should be uniform from the viewpoint of consistent enforcement and from the viewpoint of the consumer's pocketbook. If we had differing label packaging requirements in each state, the cost of complying therewith would have to be passed on to the consumer. The same is true of registration fees and any other cost. It must be recognized that these are all added costs to the consumer. The Food and Drug Administration has long favored uniformity. As a matter of fact, it would be difficult to find anyone who objects to the principle of uniformity. So long as the Federal Act safeguards the health and pocketbook of the consumer, no sound reason exists for objecting to uniformity. There appears to be no constitutional reason why a state legislature may not make

appropriate findings of the need for uniformity in the area and require the state agency to seek this uniformity where practicable. (See Christopher, "May a State Adopt Federal Regulations?" 15 FOOD DRUG COSMETIC LAW JOURNAL 373-381.) The adoption of such a general policy by a state would not seem to, in any way, deprive the state agency of its freedom of action to handle as it sees fit any problems relating to local products, if it should be necessary to do so.

As everyone who is interested in this problem is seeking the same objective, I am confident a solution will soon be found with respect to language appropriate to securing that objective. We have delayed too long in the past. (See Mensor, "Snafu in State Food Laws," 12 FOOD DRUG COSMETIC LAW JOURNAL 690. Fortunately, to date, the good sense of the state officials has prevented the occurrence of any major difficulty. Now, the changes in the Federal Act make it imperative that the Uniform Food, Drug and Cosmetic Bill be brought up to date and that the state legislatures be encouraged to adopt it.

In an effort to meet these objectives I suggest that the chairmen of the standing Committees for Uniform State Food, Drug and Cosmetic Laws of the American Bar Association and the New York State Bar Association appoint subcommittees to work closely with the Committee on Revision of the Uniform Food, Drug and Cosmetic Bill of the Association of Food and Drug Officials in drafting language which will accomplish basic uniformity without sacrificing the principles of state sovereignty. I advance this proposal in the hope that it may be worthy of consideration by the Association of Food and Drug Officials of the United States. I am confident that if these committees work together they will be able to draft language which will provide a satisfactory solution.

The basic need for state laws which are uniform in principle with the Federal, Food, Drug, and Cosmetic Act is a general one which urgently requires prompt attention by the state legislatures. If the foregoing proposal should in any way aid in the drafting of language which is acceptable to the state legislatures it will have served its purpose.

In closing I would like to quote from Dr. Norman C. Wright's paper presented at the British Pure Food Centenary last September. While this comment related to mutual understanding between nations, it is my belief that the concept is equally applicable to a mutual understanding of our states and with the federal government as it relates to uniformity in food legislation. His statement was as follows:

We live in an international age; it must be our responsibility, as well as our privilege, to further in the field of pure food legislation the mutual understanding between nations, which is one of the outstanding concepts of the twentieth century, and which I firmly believe will be ranked as one of its greatest and most beneficient achievements.

I cannot let this occasion pass without commenting on a related subject—the need for an extension of the Food Additives Amendment of 1958, as it relates to food additives which were in use before January 1, 1958. Such an extension is needed in behalf of the consumer so that he will not be deprived of the food additives which have contributed to his pleasure and convenience; or which have decreased his food costs. Such extension is needed by industry to avoid the forced removal of products from the market and the later struggle to re-enter them in the market if the food additive is finally approved. It would be most unfortunate if hardships were imposed on the consumer and industry, unless a real question of public safety were involved. Such extension should be allowed without circumscribing the authority of the Food and Drug Administration beyond the requirement that adequate safeguards be provided to protect the public health and that future action be taken with reasonable promptness.

Recent legislation has placed an enormous responsibility on the Food and Drug Administration. They have used this responsibility wisely to assist industry in solving many of the perplexing problems that have been created by this legislation. Such joint action has been in the public interest as it has made foods available to the consumer in accordance with his needs. Thus, it is only appropriate that the Administration should exercise this responsibility without any crippling restrictions which might result in depriving the consumer of desirable foods just because of a lack of diligence in the past on the part of the supplier. **[The End]**

## PHYSICAL AND EMOTIONAL INJURY INSEPARABLE

The Kansas Supreme Court sustained verdicts for two plaintiffs whose injuries arose entirely from an emotional revulsion and nausea at finding a decomposed centipede in the soft drink they were sharing. The plaintiffs, who were sisters, had obtained the drink from a vending machine in a hospital. As a consequence of their qualmish experience, both plaintiffs suffered mental and physical reactions requiring a doctor's attention. One of them lost a week's work.

Pleadings in the trial court relied upon a theory of the inseparability of mental anguish of this kind from its concomitant physical reaction. The state supreme court approved the plaintiffs' theory and held that a bottler of beverages is an insurer that its product will cause no harm.—*Connell v. Norton Coca-Cola Bottling Company, Inc.*, Kansas Supreme Court. December 10, 1960. 12 NEGLIGENCE CASES (2d) 39.

# Control of the Use of Food Additives in the United Kingdom

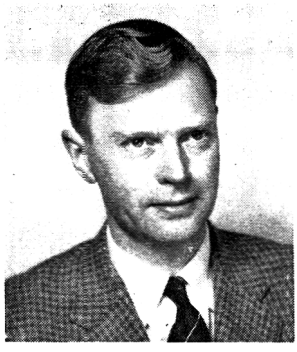
By ALAN G. KITCHELL, M.A., B.Sc., Ph.D.

**This Article Discusses the British Food and Drug Regulations and the Various Governmental Agencies. A Comparison Is Made Between the British Food Laws and Our Food Additives Amendment with Respective Methods of Enforcement.**

THE FOOD LAWS which have evolved since the first Adulteration Act of 1860 are couched in general terms intended to embrace all foods. Clarification of the status of distinct groups of additives—preservatives, antioxidants, colours, emulsifying agents, metals, etc.—has been achieved by regulations made during the past 35 years.

## Food and Drugs Act

The Food and Drugs Act of 1955 contains some 135 sections dealing, *inter alia*, with food hygiene, regulation of markets and slaughterhouses, and the designation of milk. The first nine of these sections contain all the weapons of the enforcing authorities for controlling the composition of foods. Section 1 deals with the sale of, or preparation of, foods, and prohibits "the addition of any substance to food and the abstraction of any constituent from food so as to render the food injurious to health." Section 2 concerns the general protection of the purchaser and states that "if a person sells to the prejudice of the purchaser any food or drug which is not of the nature, or not of the substance, or not of the quality, of the food or drug demanded by the purchaser, he shall be guilty of an offence." The wide scope of these sections constitutes a deterrent to the haphazard or wanton introduction of additives into food.



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Section 4 confers on the responsible Ministers wide powers which can be used to make regulations when this appears necessary or expedient to them in the interests of public health or otherwise for the protection of the purchaser. The regulations can require, prohibit or regulate the addition of any substance to any food, any ingredient in the preparation of food, any process or treatment in the preparation of food and prohibit or control the sale or possession of any food. In order to acquire the information to frame regulations, the Ministers may make orders under Section 5 of the act requiring that the particulars of the chemical composition of any additive which has been selected for control, the manner in which it is to be used, and details of any investigations as to toxicity or its effect on health be furnished by any person who proposes to use it. Sections 6 and 7 deal with false labelling and advertising of food, and Sections 8 and 9 deal with food unfit for human consumption.

## Regulations Made Under Act

Regulations made under Section 4 of the act render more precise certain aspects still covered by the more general clauses of the act, and enable a whole class of functional additives to be controlled. Foods containing preservatives may come within the scope of Section 1 or Section 2, according to the chemical nature of the preservative added, but it is obviously an administrative advantage to define "a preservative" and then control the use of all those substances falling within the definition. This scheme of control originated in 1925 when the Public Health (preservatives, etc., in food) Regulations were issued. The "etc." included colouring matters in food and thickening agents in cream and, hence, was our first attempt at the control of

food additives. The matters dealt with under the original regulations have now been split up. Thus we have the antioxidants in food regulations, the colouring matters in food regulations, and there are likely to be new preservatives in food regulations if the recommendations made in November, 1959, in the Report of the Food Standards Committee (*vide infra*) are followed. There are also regulations covering mineral oil, fluorine, artificial sweeteners, and arsenic in food.

In addition, there are a number of foods covered by standards of composition which are published in the Food Standards (General Provisions) Orders, such as margarine (vitaminisation), soft drinks, preserves, meat and fish pastes, etc. The Flour (Composition) Regulations of 1956 under which we add calcium carbonate to all except wholewheat flours (for nutritional reasons and not to dilute the Strontium 90) are currently under review.

Advances in particular legislation designed to protect the consumer usually follow consideration of the subject by the Food Standards Committee which the responsible Ministers have created for the sole purpose of advising them. This is a completely independent body. It does not include members representative of the Ministries concerned, though the Government Chemist's Department which has special responsibilities under the Food and Drugs Act is represented. The committee, under an independent chairman, is made up of three trade members, three scientific members (including the Government Chemist) and three independent members. Apart from this committee, advice on related subjects is given by the Advisory Committee on Poisonous Substances used in agriculture, and the Ministry of Health's Committee on the Medical and Nutritional Aspects of Food Policy which deals with medical questions, including carcinogenicity.

A brief comment on the way that flour improvers were dealt with will serve to exemplify the general procedure adopted in the United Kingdom when reviewing the use of additives. The Food Standards Committee, at an appropriate stage in its general deliberations on bread and flour, referred the matter of flour improvers to a subcommittee. This group, which includes pharmacologists and nutritionists, appointed as assessors the Directors of the Research Association of British Flour-Millers and the British Baking Industries Research Association. Together they reviewed the field, making wide contact with current commercial practices and research, and prepared a draft report. A questionnaire was then formulated to provide answers to those aspects of their report which were thought still to be unsatisfac-

tory, and it was sent to appropriate commercial interests. An invitation was also extended to the recipients of the questionnaire to present oral evidence to the subcommittee; these were not public hearings. In the light of these discussions, and after further deliberation in committee, the report on flour improvers was revised and submitted to the main committee. These recommendations were included in the main committee's Report on Bread and Flour which has been submitted to the Minister for use as a basis for any revision of the regulations which he may wish to make.

## Enforcement

The enforcement of the act, and regulations made under the act, is the duty of Food and Drugs Authorities. These include county and metropolitan boroughs and those boroughs or districts having a population of 40,000 or more. Thus the County of Lancashire is itself a food and drugs authority, as is each of the big cities within the county, for example, Manchester, Liverpool, etc., each being independent of the other. Each authority appoints a medical officer, a public analyst, and one or more sampling officers and is responsible for the quality of the food and drugs sold within its boundaries. In England and Wales there are 308 authorities.

Samples of foods and drugs taken by the sampling officer are submitted by the authority to its public analyst for examination. If it is decided that the seller or manufacturer shall be proceeded against, a summons is issued and the case may be heard in the courts before lay magistrates and summarily dealt with. Although appeals to higher courts may be made by either party, in most cases the local verdict is accepted.

The sampling officer must subdivide the purchased article into three equal portions, one is given back to the vendor, one is sent for analysis by the public analyst and the third is retained by the sampling officer. This last sample must be produced in court and, in the case of a dispute on scientific or analytical grounds, either party can request the magistrate to direct the third sample to be sent for analysis to the Government Chemist whose decision is normally accepted as final.

If the Government Chemist is not involved, the opinion of the public analyst is considered by the court. His opinion will be based on any official pronouncement made on the issue in question, for example, Food Standards Orders or any other pertinent regulation. Where, however, no such pronouncement exists, the public analyst

bases his opinion on experience and formulates, for the benefit of the magistrates, a standard which is temporary and only valid for that court at that time.

It does not follow that an "opinion" successful in one court will be accepted by another, or that the opinion of one public analyst will be identical with that formulated by the public analyst of another authority. In theory, because of the numerous authorities and the changing composition of the magistrates' benches, there could be great diversity of opinion of what should be the characteristics of a genuine article of food. In practice, this is not so. The public analysts reach agreement within their professional association. Also, one bench of magistrates usually takes note of the decision made by another. Nevertheless, awkward situations can arise. Against this background of enforcement of the act, manufacturers are chary of employing novel manufacturing aids or uncommon ingredients of food, unless they can secure an opinion from a public analyst or eminent consultant that the use of such substances is within the law.

## Comment on Future

You will now appreciate some of the differences between our food laws and your own Food Additives Amendment of 1958, and between our respective methods of enforcement. The most important are perhaps that we have not laid down tolerance levels for chance contaminants, such as pesticide residues; we have a system of permitted lists which is not comprehensive; and that enforcement in the United Kingdom is in the hands of local authorities, through the local courts, and is not the responsibility of the government departments which promulgate the statutory instruments, namely, the Ministry of Agriculture, Fisheries and Food and the Ministry of Health. Thus it is that the Ministry of Agriculture, Fisheries and Food is not always able to answer questions about the acceptability in the United Kingdom of certain food additives since interpretation of the act and the regulations is a matter for the courts.

Are we satisfied with the current Food and Drugs Act and our methods of enforcement? In attempting to answer this question, I will, of course, be expressing my own personal opinions and my comments do not represent official thinking on the subject. In general, I would say that the manner of enforcement, though odd in your eyes, is considered by us to be satisfactory. In the United Kingdom there

is always strong resistance to the transfer of authority out of local hands into those of a government department.

As to the law itself, it is recognized that the reviewing of groups of food additives must continue, not only with a view to embracing more classes of additives but also to reconsider, in the light of further technological and pharmacological developments, compounds already covered by regulations. For example, the Flour (Composition) Regulations of 1956 are, as I mentioned, under revision and it has recently been announced that the Antioxidant Regulations of 1958 are to be reviewed. Advisory committees, such as the Food Standards Committee, do a good job.

The regulations, based on their recommendations, are usually sound, and fair to both trade and public interests. Further, all interested parties have, by the terms of the Food and Drugs Act, to be consulted on proposals for regulations. However, progress is very slow. For example, in the case of the subcommittee's review of flour improvers, the first approach was made by the parent committee in March 1959. In spite of meeting almost every month, the subcommittee's report was not available to the main group until June 1960. Such delay must mean that it will be a long time before we can adopt a comprehensive system of permitted lists which are held under continuous review.

Also, the requirement for biological testing of new additives and also of some of long standing, will become more acute in the United Kingdom. At present, within our current framework of regulations and the manner of their enforcement, facilities may perhaps be adequate and the costs, although high, are less than in the United States. Nevertheless, it is clear that to implement a system of permitted lists would require much additional biological testing and for such a programme new facilities would almost certainly be required.

## Principle of Permitted Lists

Earlier this year the Committee on Medical and Nutritional Aspects of Food Policy came out in support of the principle of permitted lists as advocated by the FAO/WHO Committee on Food Additives. They consider, therefore, that *all* substances proposed for use as food additives should be subjected to tests for carcinogenicity. They outline in their report a scheme for such tests. They propose

the use of males and females of two species of test animals in groups sufficiently large to permit survival of 12 animals for 80 weeks and at least another 12 for two years. Histological reports will be required on all animals. The preferred route of administration is oral.

## Final Recommendations

Their final recommendations, however, do not add up to a Delaney clause. They are as follows:

(a) As a general principle, no substance shown to be a carcinogen when administered *orally* to animals should be added to or allowed to contaminate food.

(b) If a substance is shown to be a carcinogen to animals by any other route of administration, or if it attracts suspicion of carcinogenicity solely on clinical grounds, the scientific standing committee should decide whether, as a food additive or contaminant, it constitutes a carcinogenic hazard to man.

(c) Support should be given to research studies in this field which may have a bearing on the prevention of cancer.

Thus, Professor Frazer, who is a member of that medical committee, has recently made a plea for the building of a national biological testing station on the lines of a research association supported both by public and industrial funds. Such a facility has been under discussion for many years in the United Kingdom but, under the stimulus of the changing pattern of our food laws, it is possible that action will soon be taken.*

**[The End]**

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* Since this paper was read to the Division of Agricultural and Food Chemistry, American Chemical Society, in September, it has been announced by the Department of Scientific and Industrial Research (*The London Times*, November 22, 1960) that a new research body, the British Industrial Biological Research Association, has been formed. It will have facilities at Leatherhead, Surrey, near the British Food Manufacturing Industries Research Association and should be operational by mid-1962. Ninety companies have pledged support for a total of $64,000 a year for five years. In addition, the Department of Scientific and Industrial Research has agreed to match industry's contribution dollar for dollar up to a total grant of $131,000 per year.

The Association's main object will be the investigation of chemical compounds added to food in processing or contaminating the food through contact with agricultural sprays, packaging materials, etc. Further development of tests using experimental animals is seen to be needed. An advisory and information service will make available to members the results of related research in other establishments throughout the world. **[The End]**

# WASHINGTON—

## ACTION AND NEWS

## In the Food and Drug Administration

**February Report of Food Seizures.**—A total of 749 tons of contaminated food was seized in 62 federal court actions during January. Of this total, 144 tons became contaminated in warehouses while the food was being held for sale after shipment in interstate commerce.

Frozen seafood comprised the largest tonnage involved in seizure actions. Approximately 364 tons of contaminated seafood was seized in six court actions. In three of the cases 340 tons of shrimp contaminated with dirt and smoke during a fire were seized.

The second largest category was soybeans contaminated with crotalaria seeds. Over 103 tons of soybeans were seized in two federal court actions.

An unusual food seizure was made this month of 2½ tons of kangaroo meat imported from Australia. The meat, intended for use in pet food, was found to contain insect fragments, animal hairs and decomposed meat.

Approximately 33 tons of food seized in 15 federal court actions were found to be economic cheats because the products contained less weight than declared on the label, fell below standards of quality, or were not as represented on the labels.

**Drug and Device Seizures.**—Twenty-four federal court actions were taken against drugs and devices in the month of January.

Vitamin preparations were involved in six of the 24 actions. One vitamin preparation asked of the consumer in its brochure, "Can you banish those weary blues caused by a nutritional deficiency?" It claimed to treat middle-age decline, premature aging and depression, poor eyesight and teeth and bones, and to "boost the blood" and revitalize the system.

**Voluntary Actions by Industry.**—A candy company in Chicago, which had serious rodent infestation, destroyed and converted to animal feed over 80 tons of candy, nuts and sugar, and improved plant sanitation practices at an annual cost of over $25,000.

Wheat became contaminated with rodent excreta in storage at Lewiston, Idaho. The company skimmed approximately 52 tons of wheat off the top of the bin and converted it to animal feed. In addition, the storage bin was destroyed and a new concrete elevator was erected at a cost of $201,500.

All told, during the month, over 1,794 tons of adulterated food were destroyed or converted to animal feed in 147 actions by industries voluntarily seeking to avoid violations of the law.

Drug firms voluntarily destroyed $13,374 worth of adulterated drugs in 14 separate actions. The largest of these involved the destruction of $7,000 worth of drugs. A fire broke out in the prescription area of an Omaha, Nebraska, drugstore. Prescription and nonprescription drugs and vitamin preparations were badly damaged by heat, fire, smoke and water. Many drug bottles were broken, labels burned off and drugs melted. All the damaged goods were destroyed by burning.

Voluntary plant improvements totaled $583,104 in value at 28 establishments.

# Use This Check List to Add to Your Permanent Food and Drug Law Library

Wherever things happen of importance to Food and Drug Men, you'll find CCH there with handy desk helps on food, drug and cosmetic law. Each of these books was written by an outstanding authority in the field and published by Commerce Clearing House, Inc., for The Food Law Institute. They serve as a chronicle of the development of food law, including the associated drug and cosmetic laws; provide an adequate library for everyone concerned.

## Some BOOKS IN THE FOOD LAW INSTITUTE SERIES:*

- ✓ General State Food and Drug Laws—Annotated, by David H. Vernon and Franklin M. Depew. Table of contents; 816 pages. Price: $17.50 a copy.
- ✓ Constitutional Questions in Food and Drug Laws, by Thomas W. Christopher. Topical index; 128 pages, 6" x 9", heavy paper covers. Price: $3.50 a copy.
- ✓ Federal Food, Drug, and Cosmetic Act—Judicial and Administrative Record, by Vincent A. Kleinfeld and Charles Wesley Dunn. All these publications include indexes and case tables.

  1953-1957, 1,444 pages. Price: $25.00 a copy.
  1951-1952, 588 pages. Price: $12.00 a copy.
  1949-1950, 543 pages. Price: $10.25 a copy.
  1938-1949, 922 pages. Price: $17.50 a copy.
- ✓ Legislative Record of 1958 Food Additives Amendment to Federal Food, Drug, and Cosmetic Act. Topical index; 160 pages, 6" x 9", heavy paper covers. Price: $3 a copy.
- ✓ Product Liability Cases, by Frank T. Dierson and Charles Wesley Dunn. Table of contents; 1,182 pages. Price: $12 a copy.
- ✓ Canada's Food and Drug Laws, by Robert E. Curran, Q. C. Topical index, case table; 1,138 pages. Price: $19.50 a copy.

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