VOL. 17, NO. 8 AUGUST 1962

# Food·Drug·Cosmetic Law JOURNAL

## Federal Pre-emption

. . . . . MICHAEL F. MARKEL

## New Drug Applications

. . . . . RALPH C. SMITH

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD LAW INSTITUTE, INC.

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.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: $20 per year. Single copies are $2 each. Editorial and business offices, 4025 W. Peterson Ave., Chicago 46, Ill. Printed in United States of America.

August, 1962
Volume 17 • Number 8

Second-class postage paid at Chicago, Illinois.

# FOOD DRUG COSMETIC LAW JOURNAL

## Table of Contents . . . . . August, 1962



VOLUME 17 NUMBER 8

# REPORTS

## TO THE READER

**Doctrine of Federal Pre-emption.**—The reason for the growing interest in the doctrine of federal pre-emption in the last decade is ". . . because the most frequent issues raised by alleged conflicts between federal and state laws have involved highly controversial social questions." *Michael F. Markel,* a former FDA Hearing Examiner and present chairman of the Division of Food, Drug and Cosmetic Law of the American Bar Association, presents a critical review of the application of the doctrine in cases of alleged conflict between federal and state food and drug regulations in his article which begins at page 453.

**Of Interest to the Cereal Chemist.**—At the annual meeting of the American Association of Cereal Chemists in St. Louis, *L. L. Ramsey* of the Division of Food, Bureau of Biological and Physical Sciences of the FDA gave a brief account of the progress in clarifying the status of substances used by the cereal industry and the progress of the FDA toward meeting its increased regulatory responsibilities under the Food Additives Amendment and other recent legislation. His address begins at page 485.

**California's Food and Drug Legislation.**—An outline of the methods used by the State of California to make its food and drug laws uniform because of its extensive exportation of California products through interstate commerce is included in the article by *Milton P. Duffy* which is at page 492. Mr. Duffy is Chief of the Bureau of Food and Drug Inspection of the California Department of Public Health.

**New Drug Applications.**—*Ralph G. Smith,* the Director of the Division of New Drugs, Bureau of Medicine, Food and Drug Administration, in his article beginning at page 497 discusses new drug applications in a broad outline and dwells in some detail on certain recent developments in the field. He advises that any manufacturer who is uncertain as to whether or not his drug is technically "new" request the opinion of the FDA. He states that "after a new drug is on the market under an effective new drug application it is still of concern to us and with increasing staff we are able to keep in touch with it more closely than in previous years . . . . Distribution experience frequently warrants changes in labeling and on rare occasions removal of the drug from the market." Mr. Smith says that effective surveillance can only be achieved by mutual cooperation.

**93,496,000 Barrels of Beer.**—Of interest to the brewing industry is the report by *Einar T. Wulfsberg* on the relationship of the FDA and that industry which is presented at page 505 of this issue of the JOURNAL. Mr. Wulfsberg, an officer of the Food and Drug Administration, illustrates three aspects of interest—the safety of the adjuvant chemicals that are used in food production, the requirement of the law for sanitary practice even as an aesthetic consideration and the matter of full measure in what is offered to the consumer.

# WASHINGTON

## ACTION AND NEWS

## In the Food and Drug Administration

**August Report of July Seizures.**—Over 1,657 tons of food (3,314,546 pounds) were seized on charges of contamination during July.

Chemical contamination led to seizure of 391 tons of wheat and barley containing a poisonous mercury compound and nonpermissible DDT residues. Flour and meat seasoning were seized because they contained additives that had not received safety clearance.

Filthy and spoiled foods included 1,181 tons of insect- and rodent-contaminated wheat, flour macaroni and rice. Other products seized for filth contamination included 27 tons of decomposed frozen eggs and 11 tons of seafood containing parasitic worms.

Seized as economic cheats were canned beans and margarine not complying with official standards; canned cocktail shrimp and sweet yams containing broken pieces substituted for whole products; short-weight horseradish and hot sauce; and inconspicuously labeled candy and sandwich spread.

**Drug and Device Seizures.**—Thirty-nine federal court actions were instituted against misbranded and adulterated drugs and devices.

Among the products seized were a number of devices falsely promoted for diagnostic and therapeutic purposes; defective prophylactics; subpotent liver injections; veterinary drugs which failed to carry proper label warnings to assure safety of human foods from the treated animals; repackaged physicians' samples; and a dandruff medicine containing an uncertified blue color additive which had not been established as safe.

**Cosmetics.**—Two cosmetics were seized in Vernon, California. A deodorant stick was seized on charges of inconspicuous labeling; and toothpicks for containing toxic cinnamon oils.

**Hazardous Substances.** — Soldering salts and gum spirits of turpentine were seized because of failure to bear precautionary warnings required by the Federal Hazardous Substances Labeling Act.

**Voluntary Actions by Industry.**—A total of 783,941 pounds of adulterated food was voluntarily removed from human consumption in 98 actions to protect the public from unfit products.

A grain and seed company voluntarily destroyed 544,570 pounds of wheat which had become rodent-contaminated in rail cars.

A cereal company ordered 45,000 pounds of flour to be taken to the city dump for destruction, where the warehouse showed evidence of insect infestation.

A packing company arranged for destruction of approximately 19,000 pounds of oleomargarine which had become contaminated while in transit. A steel drum holding a chemical had ruptured during the shipment, spilling the chemical on the truck floor.

Vol. 17, No. 8 August, 1962

Food·Drug·Cosmetic Law
Journal

# Federal Pre-emption

By MICHAEL F. MARKEL

This Is a Critical Review of the Application of the Doctrine of Federal Pre-emption in Cases of Alleged Conflict Between Federal and State Food and Drug Laws and Regulations. Mr. Markel, a Former FDA Hearing Examiner, Is Now Chairman of the Division of Food, Drug and Cosmetic Law of the American Bar Association. He Is a Leading Practitioner of Food and Drug Law in the United States. This Paper Was Presented Before the P. M. A. Law Section Meeting Which Was Held in White Sulphur Springs, West Virginia, May 7-9, 1962.

IT IS INDEED AN HONOR to have been invited to speak to such a distinguished group of lawyers on the rather thorny suggested subject of "Federal Pre-emption." I was happy to accept your kind invitation because, as many of you know, I have heretofore been critical of the application of the doctrine in the area of regulation of the production and distribution of foods and drugs. A critical review of the application of the doctrine in this area of regulation would seem most appropriate for this occasion. Therefore, I have taken the liberty of narrowing my subject accordingly.

The doctrine of federal pre-emption has attracted greater public attention in the last decade than possibly ever since the early days in the history of our country when the United States Supreme Court rendered some of its first decisions in construing the pertinent constitutional provisions from which the doctrine derives. The reason for this is, no doubt, because the most frequent issues raised by alleged conflicts between federal and state laws have involved highly controversial social questions.

Some of the decisions of the last decade have aroused widespread public debate on various platforms of the question of the proper

spheres of regulation by state and federal government. Criticism of the United States Supreme Court has been that it has indulged in judicial legislation by extending the application of the doctrine of federal pre-emption, hence exclusive federal jurisdiction, to many new areas theretofore regarded as areas of concurrent federal-state jurisdiction.

## Debates on "States Rights Bill"

The controversy reached its pinnacle in the introduction in the 86th Congress, 1st Session, of H. R. 3, the so-called "States Rights Bill," and the ensuing debates on this Bill, both on the floor of Congress and on public platforms.

The following cases were listed as examples of unwarranted nullification of state laws by the extension of the doctrine: *Pennsylvania v. Nelson,* 350 U. S. 497 (1956); *Phillips Petroleum Company v. Wisconsin,* 347 U. S. 672 (1954); *Slockower v. The Board of Higher Education,* 350 U. S. 551 (1956); *Railway Employees' Department v. Hanson,* 351 U. S. 225 (1956); and *Cloverleaf Company v. Patterson,* 315 U. S. 148 (1942).

The more recent cases involving food and drug laws in the area selected for this critical review will not serve as examples of judicial legislation. Indeed, one cannot help but speculate that perhaps some of the reasoning and attendant prejudices on both sides, engendered during these debates, particularly of the social issues involved, are being carried over to the area of federal regulation of the production and distribution of food and drugs.

In any case, no complaint of over-extension of the doctrine of federal pre-emption in the area of regulation of the production and distributiton of food and drugs is heard from any member of these most highly regulated industries. On the contrary, the special interests of your industry, and others similarly situated, in the doctrine of federal pre-emption stems from complaints that the courts have been too reluctant to apply it realistically in this area of regulation.

Basic to these complaints is the fact that uniformity in the administration and enforcement of laws which regulate the production and distribution of food and drugs is of greatest importance to such highly regulated commerce. Multiplicity of regulation and diversity of procedures are not uncommon in this area. A realistic application of the doctrine would go far to insure the desired uniformity. This, in turn, would be of enormous benefit, not only to the regulated industry, but also to ultimate consumers since it would promote common

understanding, hence more intelligent buying, and would also result in substantial savings in costs of distribution, which, under the highly competitive conditions which exist, would ultimately be passed on to the consumer.

A critical review or some of the more recent cases selected for consideration does not call for a detailed briefing of this general subject. Indeed, this would be an impossibility for our purposes, since volumes would be required to deal fully with the subject, and indeed have been written on it. An outline of basic principles as reflected by a few selected Supreme Court decisions should suffice for present background purposes.

## Doctrine of Federal Pre-emption

The doctrine of federal pre-emption, stated as a basic legal principle, in the abstract, appears very simple. It is most simply stated in the "supreme law of the land" clause of the federal constitution from which it is derived. This provides:

"This Constitution, and the Laws of the United States which shall be made in pursuance thereof; and all Treaties made, or which shall be made under the Authority of the United States, shall be the Supreme Law of the Land; and the Judges in every State shall be bound thereby, anything in the Constitution or Laws of any State to the Contrary notwithstanding." (Clause 2 of Article VI of the constitution.)

About the first case, if not *the* first, in which this principle of "supreme law of the land" was the basis for nullifying a state law, was the classic *Gibbons v. Ogden,* 9 Wheat 1 (1824).

Ogden was the assignee of Livingston and Fulton of the right, granted by the New York legislature, for the exclusive navigation of the waters of New York with boats moved by fire or steam. Gibbons operated two steamboats between New York and Elizabethtown, New Jersey, in violation of the New York legislative acts, but under license to carry on this kind of trade authorized by act of Congress of the United States. The New York legislature had granted this exclusive right because it wanted to reward Fulton for his contribution to navigation by developing the steamboat.

The New York Chancery Court granted an injunction against Gibbons on petition of Ogden, forbidding Gibbons to enter New York waters with his steamboats. The decision by the lower court, holding the acts of the New York legislature invalid, was affirmed

on appeal. The case came to the United States Supreme Court from this decision.

One of the arguments, here pertinent, made in the case was that New York undertook only to regulate its internal affairs within its own territorial waters by granting the exclusive license and that this was a proper exercise of its inherent police power to regulate its domestic affairs. The Supreme Court rejected this argument and, after having concluded that these laws had come in "collision" with the act of Congress from which the appellant derived his right, Chief Justice Marshall said:

"Since, however, in exercising the powers of regulating their own purely internal affairs, whether trading or police, the states may sometimes enact laws, the validity of which depends on their interfering with, and being contrary to, an Act of Congress passed in pursuance of the Constitution, the court will enter upon the inquiry, whether the laws of New York, as expounded by the highest tribunal of that state, have, in their application to this case, come into collision with an Act of Congress, and deprived a citizen of a right to which that Act entitles him. Should the collision exist, it will be immaterial whether those laws were passed in virtue of concurrent powers to regulate commerce with foreign nations and among the several states, or in virtue of a power to regulate their own domestic trade and police. In one case and the other, the acts of New York must yield to the law of Congress; and the decision sustaining the privilege they confer, against a right given by a law of the Union, must be erroneous."

## Federal Pre-emption Invoked

The most frequently cited case and regarded as the leading case, (usually cited by both sides in cases in which the doctrine of federal pre-emption is invoked) is *Sinnot v. Davenport*, 22 How. 227, (1859).

This case also arose under the navigation laws. The steamboat, of which Sinnot was master, had been seized by virtue of penalties prescribed by the Alabama law for failure to comply with certain registration requirements with respect to all vessels docking in Alabama ports.

These requirements were that the mate of a steamboat carrying on trade within her own waters should file a sworn statement with the probate judge of the county where it docked, in this case Mobile County, Alabama, setting forth; (1) the name of the vessel; (2) the name of the owner or owners of the vessel; (3) the places of resi-

Iowa were commodities which its owners had a right to transport in interstate commerce, and that, therefore, the state could not interfere while they were being held after such shipment. *Leisy v. Hardin,* 135 U. S. 100 (1890).

## "Local Option Law"

After this decision, Congress passed specific legislation, the so-called "local option" law, granting states the power to regulate the sale of alcoholic beverages within their own jurisdiction. A Kansas law was upheld as valid in a criminal case where the defendant was arrested on the day after this federal legislation became effective.

The decision in *Leisy v. Hardin,* cited above, has not been without subsequently developed limitations. It was followed in *Schollenberger v. Pennsylvania,* 171 U. S. 1 (1898), where the Court held that a Pennsylvania statute, prohibiting the sale of oleomargarine, could not be applied to the first sale of uncolored oleomargarine in its original package, received in interstate commerce and a proper article of commerce. The Court reached the same result in *Collins v. New Hampshire,* 171 U. S. 30 (1898), which similarly limited the application of a New Hampshire statute prohibiting the sale of oleomargarine unless colored pink. But even as applied to first sales in the original package, the Court has upheld state statutes prohibiting the sale of oleomargarine colored yellow, on the general ground of likely customer delusion and fraud upon the general public. (*Plumley v. Massachusetts,* 155 U. S. 461 (1894).)

These, and other cases turned on the basic holding that a commodity, lawfully shipped in interstate commerce, could not be prevented from crossing state borders and could not be interfered with while being held for sale after shipment except when justifiable as a proper exercise of police power.

## Original Package Criterion Qualified

However, the original package criterion was later qualified from the opposite direction. The Supreme Court held that a state may not in certain circumstances condition the sale of out-of-state goods even after it becomes the subject of local commerce. A frequently cited case supporting this premise is *Baldwin v. G. A. F. Seelig, Inc.,* 294 U. S. 511 (1935).

This case involved a New York law enacted for the purpose of regulating milk production and marketing in that state. The pertinent

provisions in the New York Milk Control Act (New York Laws of 1933, Ch. 158 and 1934 Ch. 126), prohibited the sale of milk imported from outside of the state unless the price paid to the out-of-the-state producer from whom it was obtained was not less than the minimum price prescribed by New York.

With obvious design to circumvent the original package doctrine, the legislative intent was spelled out in this law as follows:

"It is the intention of the legislature that the instant, whenever that may be, that the handling within the state by a milk dealer of milk produced outside of the state becomes a subject of regulation by the state, in the exercise of its police powers, the restrictions set forth in this article . . . shall apply . . . ."

The law went on then to provide that, "After any such milk so produced shall have come to rest within the state," any sale of such milk purchased at a lower price than the minimum price prescribed by the New York law was unlawful and that violation subjected the violator to a penalty.

## Law's Validity Defended

The validity of this law was defended as having been enacted by valid exercise of police power in an area of concurrent jurisdiction. It was argued that New York was greatly dependent on an adequate milk supply and that it was essential, in the administration of its internal affairs, to do what was necessary to insure an economically stable and prosperous milk industry so as to have available at all times a sufficient milk supply to insure protection of public health.

Mr. Justice Cardozo, responding specifically to this argument, said that the legislation touched in an area where the nation would have to "sink or swim" together and that the whole nation should enjoy the economic prosperity as well as be subjected to economic depressions together.

In setting the New York laws aside as being in conflict with the federal powers to regulate commerce, the Court said, among other things, that the manner in which the police power had been exercised served to set a barrier to traffic in legitimate commerce between states just as effectively as if customs duties had been laid upon the transported commodities. This, the Court said, was patently an unconstitutional exercise of power and was no less so when cloaked

in the guise of exercise of police power to protect consumers' health, or to insure a healthier economy in this selected industry.

## *Nelson* Case Noted

Finally, the case which sparked the charge of "judicial legislation," *Commonwealth of Pennsylvania v. Nelson,* cited above should be especially noted in this background-outline of basic principles as applied by the United States Supreme Court in certain key cases.

In the *Nelson* case, the sole question before the Court was whether the Smith Act of 1940, as amended in 1948, which prohibits the advocacy, knowingly, of the overthrow of the government of the United States by force and violence, superseded the Pennsylvania Sedition Act which proscribes the same conduct, to the extent that the latter is not enforceable against the conduct proscribed by both laws.

Nelson was convicted of violation of the Pennsylvania Sedition Act by reason of seditious conduct against the United States government. The intermediate appellate court affirmed the conviction.

On appeal, the Pennsylvania Supreme Court decided the case on the narrow issue of the validity of the state law in the presence of the federal law, the Smith Act. It held that the state law had no application in the area covered by the Smith Act, reversing the lower courts and quashing the indictment. The United States Supreme Court granted certiorari on petition of the Commonwealth of Pennsylvania.

The Court affirmed, holding that the Smith Act superseded the Pennsylvania Sedition Act.

In reaching this conclusion the Court stated that in cases where Congress had not stated specifically whether the federal law is intended to pre-empt the field, "different criteria have furnished touchstones for decision." (Quoting the above quoted language from the *Davidowitz* case.)

## Pertinent Tests

The Court believed that in this case "each of several tests of suppression is met." The tests applied included the test, whether the "scheme of federal regulation" is so pervasive as to make reasonable the inference that Congress left no room for state supplementation.

After reviewing the history of federal espionage legislation the Court said (p. 504):

"We examine these Acts only to determine the congressional plan. Looking at all of them in the aggregate, the conclusion is inescapable that Congress has intended to occupy the field of sedition. Taken as a whole, they evidence a congressional plan which makes it reasonable to determine that no room has been left for the States to supplement it. As was said by Mr. Justice Holmes in *Charlston & Western Carolina R. Company v. Varnville Furniture Company,* 237 U. S. 597 . . .:

" 'When Congress has taken the particular subject matter in hand, coincidence is as ineffective as opposition, and the state law is not to be declared a help because it attempts to go farther than Congress has seen fit to go.' "

The second test which, in itself, would support the Court's conclusion was said to be the test whether the federal laws touched a field in which federal interest was so dominant that the federal system must be assumed to preclude enforcement of state laws on the same subject.

The third test, and one as pertinent to this discussion as the first, was whether state legislation would present a conflict with the administration of the federal program.

After pointing out the areas of likely conflict in the practical administration of such laws if the several states were to enjoy concurrent jurisdiction, the Court continued, p. 509:

"When we were confronted with a like situation in the field of labor-management relations, Mr. Justice Jackson wrote:

" 'A multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law.' " (Citing *Garner v. Teamsters . . . Union,* 346 U. S. 485.)

## *Nelson* Decision Remains

The *Nelson* case remains controversial; *but it remains!* The fact that the Congress rejected proposed legislation intended to nullify, or at least highly restrict, this decision serves to dilute the argument of the critics significantly.

Whatever may be said about the decision in its application to the particular area of regulation before the Supreme Court, however, the principles upon which decision turned appear to apply particularly, and more so, to the area of regulation of the production and distribu-

tion of goods in interstate commerce. Indeed, the strong dissent in the case recognizes this distinction.

Mr. Justice Reed, speaking for the minority and responding to the argument that the Smith Act occupied the "field of sedition," said:

"The 'occupation of the field' argument has been developed by this Court for the Commerce Clause and legislation thereunder to prevent partitioning of this country by locally erected trade barriers. In those cases this Court has ruled that state legislation is superseded when it conflicts with the comprehensive regulatory scheme and purpose of a federal plan. *Cloverleaf Butter Co. v. Patterson,* 315 U. S. 148 . . . ."

The distinction was also recognized by the proponents of H. R. 3 in the majority report wherein was stated:

"It is argued that H. R. 3 may have the effect of giving validity to State regulatory laws which could be onerous and costly to nation-wide industries doing business in many States. The Committee believes that this argument is not well founded and does not intend H. R. 3 to create such onerous burdens on interstate industries." (Committee on Judiciary Report No. 422, 86th Cong., 1st Sess.)

Indeed, on debate of the Bill, the Federal Food, Drug and Cosmetic Act was singled out for special assurance that H. R. 3 was not intended to restrict the application of the existing case law to cases arising under that Act. (Congressional Record, Monday, June 22, 1959, pp. 10449-773.)

## Review of "Congressional Plan"

A brief look at the "congressional plan" or the "scheme of federal regulation" as revealed by the history of the legislative pattern of the Federal Food, Drug and Cosmetic Act is now in order since it is obvious from the foregoing that such a review is a most important factor in determining extent of federal pre-emption.

That the Congress possesses the constitutional power to regulate the production and distribution of food and drugs was settled long ago, *Hipolite Egg Company v. United States,* 220 U. S. 45 (1911), and is no longer being questioned. That this power extends from the point of production of a commodity which is subject to the Act, up to the point of sale at retail where the commodity is handed to consumers is also well established. *McDermott v. Wisconsin,* 228 U. S. 115 (1913); *United States v. Sullivan,* 332 U. S. 689 (1948). The courts have held

in these and a host of other cases that the purpose of the Act is to protect consumers against health hazards and economic exploitations.

The historical development of federal food and drug laws as compared to the historical development of the federal espionage laws would seem to establish even more clearly a "congressional plan" or a congressional "scheme of federal regulation" to regulate the production and distribution of the commodities subject to these laws in the greatest detail to the outer limits of congressional jurisdiction, namely, from production of the commodities, including their ingredients, up to and including the point where the finished product is delivered to the persons who are to consume these products; that is, the person for whose protection the Congress has undertaken to "appropriate the field."

## Demand for Federal Regulation Arose in Early 1900's

It was about the turn of the century that public demand for federal regulation arose. This demand was founded on the basic premise that the states were unable to regulate effectively because of the increased complexities of the commerce of producing and distributing these commodities.

The Congress responded in 1906 by enacting the Federal Food and Drug Act and the Meat Inspection Act. Both of these Acts had as their basic purpose the protection of ultimate consumers, wherever located, against unsafe and unclean commodities and against false representations, directly or indirectly, of these products in promoting their distribution and sale. As deficiencies were revealed which indicated that this ultimate objective could not be readily achieved in the practical administration and enforcement of the laws, Congress always responded to such demonstrated needs by amending the law in the particulars indicated so as to insure the most complete protection which, in its judgment, was then required.

Finally, in 1938 the Federal Food, Drug and Cosmetic Act was enacted, completely revising the law to meet the increased needs for closer federal supervision of the production and distribution of foods, drugs and cosmetics. Of special significance was the inclusion of administrative powers to pass on the safety of drugs, to insure safety of foods by establishing tolerances for "poisonous and deleterious substances" when these were required in the production of foods or could not be reasonably avoided in following good manufacturing practices, and to promulgate standards of identity, quality, and fill of container

for foods, "whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers."

## Amendments Extend Federal Control

Soon after this comprehensive revision it became evident that the potency of insulin had to be federally controlled. The Congress again responded with unprecedented speed by adopting the necessary amendment within one or two days from the time the bill was introduced. Thereafter followed the Antibiotic Certification Amendments, then the Pesticide Chemical Amendment, then the Food Additives Amendment, then the Color Additive Amendments, and there are presently additional amendments suggested which would extend federal control even further.

A review of the historical development of these laws and the succeeding congressional action taken, compares most favorably with a like review by the court of the statutory development in espionage legislation and would seem surely to warrant the same conclusion. Indeed it is difficult to find any other federal legislation regulating commerce which is so intricately interlaced in the minutest details in order to insure as complete protection of consumers as is, *in the judgment of Congress*, reasonably required.

## Starting Point of Alleged Conflict

Unfortunately the courts have not always agreed. The two leading cases arising by virtue of provisions in the old Federal Food and Drug Act are, in their chronological order, *Savage v. Jones*, 225 U. S. 501 (1912) and *McDermott v. Wisconsin*, 228 U. S. 115 (1913). These cases mark the starting point in any consideration of the application of the doctrine of federal pre-emption to any alleged conflict of the Federal Food, Drug and Cosmetic Act and regulations promulgated under it, and state laws and regulations which undertake to regulate in the same area.

*Savage v. Jones* involved an Indiana law which required the disclosure of ingredients and other detailed information on the labels of feeds received in interstate commerce and offered for sale in Indiana. After an extensive review of the doctrine of federal pre-emption the court held that the federal act restricted its labeling requirements to prohibition "of any statement, design, or device . . ., false or misleading."

The Court then found that, since Congress had not exercised its constitutional power to extend its requirement to such detailed regu-

latory requirements as were required in the Indiana law, it was proper for Indiana to so extend it and that its action was not *inconsistent* with the more general federal requirements, but merely an *extension* thereof.

It should be noted parenthetically, however, that the present much more detailed branding provision in the federal law may well serve to distinguish a current case involving the same issue.

*McDermott v. Wisconsin* represents the other side of the coin. This case involved a Wisconsin law which made it unlawful "to sell any syrup, maple syrup, sugar-cane syrup, sugar syrup, refiners syrup, sorghum syrup or molasses, mixed with glucose," unless its original container bore the specifically prescribed label statements.

McDermott was prosecuted because he had in his possession and offered for sale Karo syrup consisting of a mixture of 90 per cent corn syrup and 10 per cent sugar-cane syrup.

The contention that this designation was proper labeling and conformed to the branding requirements of the Federal Food and Drug Act was supported by a communication signed by the Secretaries of Treasury, Agriculture, and Commerce and Labor, each having certain administrative authority in the administration of the Act, which communication stated that it was the judgment of all three of the Secretaries that the mixture of syrup labeled "corn syrup with cane flavor" was not misbranded under the branding requirements of the Federal Food and Drug Act.

In discussing the application of the doctrine of federal pre-emption to the facts before it and after having referred to *Savage v. Jones* as deciding that the state could make regulations concerning the same subject matter "reasonable in their terms and not in conflict with the acts of Congress," the Court continued:

"While this is true, it is equally well settled that the state may not, under the guise of exercising its police power or otherwise, impose burdens upon or discriminate against interstate commerce, nor may it enact legislation in conflict with the statutes of Congress passed for the regulation of the subject, and if it does, to the extent that the state law interferes with or frustrates the operation of the Acts of Congress, its provisions must yield to the superior Federal power given to Congress by the Constitution."

". . . Conceding to the State the authority to make regulations consistent with the Federal law for the further protection of its

citizens against impure and misbranded food and drugs, we think to permit such regulation as is embodied in this statute is to permit a State to discredit and burden legitimate Federal regulations of interstate commerce, to destroy rights arising out of the Federal statute which have accrued both to the Government and the shipper, and to impair the effect of a Federal law which has been enacted under the constitutional power of Congress over the subject."

## Further Application of Doctrine of Federal Pre-emption

The next Supreme Court decision, highly significant in the pattern of the application of the doctrine of federal pre-emption to alleged conflicts between federal and state laws is *Cloverleaf Butter Company v. Patterson,* 315 U. S. 148 (1942).

In this case, federal statutes provided for the inspection, manufacture, storage, and marking of process of renovated butter and for confiscation of the finished product if found unwholesome. An Alabama statute authorized state officials to condemn adulterated and misbranded articles.

Petitioner, engaged in Alabama in the manufacture of renovated butter 90 per cent of which was shipped out of the state, sued for a declaratory judgment to prevent Alabama's officials from determining the wholesomeness of renovated butter made from the raw material in petitioner's hands, from inspecting its raw materials and plant, and from seizing petitioner's packing stock butter.

The Supreme Court reversed the denial of declaratory relief and held that since "there was Federal regulation of the material and composition of the manufactured article, there could not be similar state regulation of the same subject." (p. 169) In so doing, the Court used language which has been quoted and relied on in most decisions where pre-emption is in issue. The most frequently quoted language is the following:

"The power of Congress to exercise exclusive control over operations in interstate commerce is not in dispute here. Nor is this power limited to situations where national uniformity is so essential that lacking Congressional permission all state action is inadmissible notwithstanding a complete absence of Federal legislation. Exclusive Federal regulation may arise, also, from the exercise of the power of Congress over interstate commerce where in the absence of Congressional action the states may themselves legislate. It has long been recognized that in those fields of commerce where national

uniformity is not essential, either the state or Federal government may act . . . Where this power to legislate exists, it oftens happens that there is only a partial exercise of that power by the Federal government. In such cases the state may legislate freely upon those phases of commerce which are left unregulated by the nation. But where the United States exercises its power of legislation so as to conflict with a regulation of the state, either specifically or by implication, the state legislation becomes inoperative and the Federal legislation exclusive in its application.

"When the prohibition of state action is not specific but inferable from the scope and purpose of the Federal legislation, it must be clear that the Federal provisions are inconsistent with those of the state to justify thwarting of state regulation." (315 U. S. at 154-56.)

These three Supreme Court cases are always cited by both sides on the issue of the application of the doctrine of federal pre-emption in the area of regulation of the production and distribution of food and drugs. Advocates of both sides of the question usually quote freely from all three opinions.

## Cases Involving Issue of Conflict

The cases decided against this background of statutory pattern, and the three cases regarded as the leading cases dealing with this general subject matter, which have involved the issue of conflict between federal and state regulations, direct or implied, do not provide even a reasonably uniform rule of application of the doctrine. Cases are to be found on both sides and the soundness of some is questionable.

The first case of special interest to this group, and the only case involving a drug, is *Whitehall Laboratories v. Wilbar*, 397 Pa. 223, 154 A. 2d 596, (1959) CCH Food Drug Cosmetic Law Reporter, ¶ 85,188. This case is better known to this audience as the "Primatene" case. In this case the issue of conflict was raised on petition for declaratory judgment that the federal law governing the labeling of dangerous drugs pre-empted this area and that, therefore, the Pennsylvania law, claimed to be in conflict with the federal law, had to yield.

Whitehall manufactured a drug containing a barbituric acid derivative which drug, therefore, was required to bear the warning legend required by Section 502 of the Act "Warning, may be habit forming." However, federal regulation duly issued exempted a drug of the composition involved in the case from the requirement that it be sold only on prescription and that it bear the prescription legend.

The Pennsylvania law required that barbituric acid derivatives, or any drug which contained such a derivative, should be sold only on prescription.

Citing the *Cloverleaf* case, the Court noted that the Federal Food, Drug and Cosmetic Act was silent on whether it was intended to preclude state action in the sale and dispensing of drugs. The Court observed "the mere fact that Congress has taken action in this field does not justify the assumption that the federal system was intended to dominate the field." According to the Court, the Pennsylvania act did not produce results inconsistent with the purposes and objectives of the federal Act. It said there was "common recognition" that drug users be warned by the label that the drug might be habit forming, but that the Pennsylvania statute proceeded a step further than the federal statute by requiring also that the drug could be sold only on prescription.

The Court stopped with the comparison of the two statutes and, after finding no conflict in their wording, proceeded to find that the record included abundant evidence to support a conclusion of likely dangers to users of barbituric acid derivatives and that, therefore, the extension of the control in the sale of the drugs was a valid exercise of the state's police power to protect its citizens against health hazards. The Court said, in part, (154 A. 2d 602) :

"In the health and welfare of its citizens, the Commonwealth has a vital interest; a necessary concomitant of such interest is the protection of its citizens from drugs containing active ingredients the use of which, without proper supervision, may be harmful and even dangerous. It is not only the right but the duty of the Commonwealth to surround the use of such drugs with such safeguards that they may be used, if at all, safely and properly. When the Commonwealth in the exercise of such duty, does act, its actions should not be held to be suspended or superseded by Federal action unless the Congress has clearly and unmistakably revealed its intent to pre-empt the field and to render dominant the Federal control . . . In the Federal Food, Drug and Cosmetic Act the Congress, neither by expression nor implication, has indicated any such intent; in the absence of the revelation of any such intent the state statute and the regulations promulgated thereunder should not be held to be suspended or superseded. Until such time as the Congress clearly and unmistakably evidences an intent to pre-empt the field of regulation of the sale of such drugs, each state has the right and the duty as a police measure

to take such action, not inconsistent with Federal law in that field, for the protection of the health and safety of its citizens."

It is difficult to understand how the same Court which had no difficulty in reaching the conclusion that the Federal Espionage Act had pre-empted the field and that therefore the Pennsylvania Espionage Act had to yield, could reach an opposite conclusion with respect to a federal act much more detailed in its control of the subject matter than was the Espionage Act.

It would seem that the fallacy in this case lies in the fact that the Court stopped with comparing statutory language. However, this is not the test. It is well established that administrative regulations, even though only advisory, must be recognized in applying the doctrine. The conflict must be determined on the basis of their requirements. (*McDermott v. Wisconsin,* above.) In this case the determination of federal control was based on the letter signed by the three Secretaries. There the Court said:

"Whether the Secretaries had the power under the Food and Drug Act to make the regulation set out above is not now before us. It is enough for the present purpose to say that so far as this record discloses, it was undertaken in good faith to label the articles in compliance with the act of Congress, and, if they were not so labeled, . . . whether the labels complied with the Federal law was not for the state to determine. This was a matter provided for by the Act of Congress and to be determined as therein indicated by proper proceedings in the Federal Courts."

## Conclusions of Administrative Agencies Opposed

A like comparison of the state and federal regulations in the instant case suggests that this decision is erroneous because the conclusions of ultimate fact reached by the respective administrative agencies undertaking control of this drug were diametrically opposed.

The federal regulation was to the effect that the drug of the composition which was the subject of the case before the Court was exempt from the requirement that it be sold only on prescription. This exemption is, and can be, supported only upon the conclusion of ultimate fact that making the drug available to consumers for self medication will not involve any health hazards for such consumers when the directions for use appearing on the label are followed.

On the other hand, the testimony of experts on which the Court relied altogether on the question of reasonable exercise of police power

because of inherent health hazards, was to the effect that the drug was too dangerous to permit self medication.

Comparison of the administrative conclusions of ultimate fact, the real test of impact of the questioned regulation, shows a clear conflict. The evidence in the case fails to establish a valid basis for the state regulation in that all the evidence regarding health hazard on which the court relied was a discussion of general hazards and did not include any showing of circumstances peculiar to Pennsylvania and its citizens which required the special treatment demanded by the regulation. Assuming the hazards existed, the remedy was not to contradict the federal agency in the guise of exercise of police power, but rather to amend the federal regulations. It is on this basis that I regard this case as an unsound decision and, in my opinion, a decision which is in direct conflict with a prior decision by the same court in the espionage case.

## Food Cases

The remaining cases are all food cases. Note should be taken of some of these also, because they are subject to similar criticism.

A New York Supreme Court refused to dismiss a complaint alleging a misbranding violation under state law in *Casey v. Standard Brands, Inc.*, N. Y. Sup. Ct. April 9, 1959, CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 85,185. The complaint alleged that defendant's Royal Gelatin dessert was misbranded because the labeling conveyed the impression that the product contained only natural raspberry juice, whereas in fact it contained also artificial fruit essence. Holding that the state had jurisdiction, the Court said:

"This statute was enacted by the Legislature within the scope of the police power of the State to safeguard the public against misrepresentation or deception in its sale. It appears that the Federal Food and Drug Administration has not established a standard of identity for powdered gelatin desserts and has not undertaken to deal with this type of alleged mislabeling under the Federal Act. . . . The state statute is not in conflict with its Federal counterpart."

The Attorney General of California has ruled that a California Olive Oil Law prohibiting the manufacture, sale or possession of imitation olive oil is not in conflict with the Federal Food, Drug and Cosmetic Act although a possible effect of the law may be to prohibit the introduction into interstate commerce of olive oil not meeting the California standard. (Opinion of the Attorney General

of California, May 21, 1947, 9 Attorney General's Opinions 236, CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 7057 (Transfer Binder)).

The Attorney General noted that no standard of identity, quality, or fill of containers for olive oil had been promulgated under federal law, and that the mere existence of a federal law on the "general subject does not necessarily mean that a statute enacted under a proper and reasonable exercise of the police power of a State is inoperative if it adversely affects interstate commerce. This is especially true where the application of State and Federal food and drug acts is in question."

The language of the opinion probably reflects the views of most state officials in this area:

"Where the Federal statute makes certain requirements to prevent misrepresentation and adulteration of food, unless the Federal statute expressly or by necessary implication shows an intention to exclude regulation of the same subject matter by the states, the individual states may make additional requirements to prevent misrepresentation and adulteration. Such requirements may have the effect of wholly preventing the manufacturing of an adulterated product within the State. Because the statute prevents such manufacturing and, thus, prevents the introduction of such product into interstate commerce after it comes into being within the State is not a violation of the commerce clause of the Federal Constitution."

"In the case of a regulation falling short of prohibition, such as label requirements, size and fill of containers, etc., there is no objection to the provisions of a State statute or regulation extending or enlarging upon the provisions of the Federal statute or regulation unless, of course, it is determined that Congress has occupied the entire field of regulation. Such entire dominance of the field is unusual in cases of the regulation of the interstate and foreign commerce in foods. Thus, whatever additional labeling or container requirements exist in the Olive Oil Law as compared to the Federal Act are supplemental in nature and not in conflict with the Congressional action. . . ."

## Issue of Validity of State Standard

But even where a standard of identity has been promulgated, there is no assurance that a food complying with the federal standard will be free from higher requirements imposed by state law. A difference in federal and state standards for the minimum butterfat

content for ice cream was the issue in *Borden Company v. Liddy*, 200 F. Supp. 221 (S. D. Iowa 1961) CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 7731. The federal standard of identity prescribes a 10 per cent minimum; the Iowa law, 12 per cent. The court saw no reason why the more stringent Iowa Standard should not apply to ice cream manufactured outside the state and shipped into Iowa for sale. It was conceded by the state that Borden could manufacture ice cream in Iowa not meeting the state standard for shipment into other states.

The court dismissed Borden's complaint for a declaratory judgment claiming that the federal government had pre-empted the field of standards for frozen desserts, and that enforcement of the Iowa statute would constitute an undue burden on interstate commerce.

On the pre-emption point, the court stated that Congressional intent to bar state action in an area not covered by federal legislation was not to be implied unless there was an actual conflict between state and federal law. Moreover, said the court, federal regulations only prescribe a minimum standard and do not prohibit states from setting a higher fat content for ice cream sold within their borders. No undue burden on interstate commerce was found, on the theory that a state may in the exercise of its police powers deal with adulterated food if there is no conflict with federal law.

The issue raised in the *Borden* case as to the validity of a state food standard which is more rigid than the federal was also involved in *Pepperidge Farm v. Foust,* 117 N. E. 2d 724, (Ct. Com. Pleas Ohio, 1953) CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 7289. This was a suit by a Connecticut corporation selling in 44 states, to enjoin the Ohio Director of Agriculture from prohibiting the sale of "Brown and Serve French Rolls." Under Ohio law and regulations, the minimum weight for bread is 16 ounces and, by regulation, the maximum weight of "rolls" is three ounces. Under the federal bread standard, the minimum weight for bread is one-half pound and rolls are anything less than one-half pound. Citing the *Cloverleaf* case for the proposition that a state can freely legislate on those phases of commerce which are left unregulated, so long as there is no conflict, the court decided that the Ohio statute was a valid exercise of the police power, and that the fixing of a federal standard of identity did not preclude the state from fixing a different standard of identity.

"If a state may supplement the prohibition of misbranding contained in the Federal Food and Drug Act, by requiring publication of ingredients, then it stands to reason that the state may also

supplement such Federal act, by legislation to prohibit the sale of bread under a certain weight unit to prevent frauds and require honest weights in the sale of such food product." (117 N. E. 2d at 729).

In addition, the court rejected the contention that compliance with the state standard meant a violation of federal law. Under the federal standard, rolls may weigh one-half pound but they need not; there is therefore no conflict, the court noted, if Ohio requires rolls to weigh less in the "interest of honest weight" and an upper limitation of three ounces is set.

## State Statutes Upheld

In *People v. Breen,* 326 Mich. 720, 40 N. W. 2d 778 (1950), the court upheld a Michigan statute prohibiting the sale of colored oleomargarine against the argument that the 1941 federal standard of identity for margarine permitting the use of artificial coloring had left no room for state regulation. Relying on the *Cloverleaf* language, the court held that the federal government had only partially preempted the field because use of a coloring ingredient is optional, not mandatory. There was therefore, in the court's view, no conflict with the Michigan statute absolutely barring the sale of colored margarine, and whose purpose was to prevent deception and confusion.

*Florida Lime and Avocado Growers v. Paul,* 197 F. Supp. 780 (N. D. Cal. 1961) was a suit by Florida avocado growers to enjoin enforcement of the California law which requires avocados to contain not less than 8 per cent oil by weight excluding skin and seed. Florida avocados do not meet this standard. Under a Florida avocado order issued under the Federal Agricultural Marketing Agreement Act of 1937, Florida avocados may not be marketed unless picked and shipped in accord with certain shipping dates. This order, a three-judge court held, did not prevent application of the California eight per cent oil content requirement to Florida avocados, because there was no clear conflict between the two.

Said the court (197 F. Supp. at 787):

"California has lawfully applied an 8% oil content to avocados marketed by her own producers, which may be applied to any state not covered by the Federal order. If the implication of Federal preemption is read into Florida Avocado Order No. 69 and the act under which it was issued, Florida producers alone will be privileged to avoid compliance with that test. Such an implication should not be lightly made (*Cloverleaf Butter Company v. Patterson,* 315 U. S. 148).

Congress, not having covered the whole field of interstate transportation of avocados, has left a wide field for the protection of consumers by the states by the appropriate exercise of the state police power. . . . The case would be different if the Federal Government had established a complete and uniform regulatory scheme which covered the whole problem . . . but this Congress has not done."

The court adverted to the language in *Cloverleaf* saying that where a federal statute does not in specific terms prohibit state action, it must be clear that the federal provisions are inconsistent with those of the state before prohibition of state action may be inferred.

The *Lime Growers* case is the remand from a Supreme Court ruling that the District Court had erred in dismissing the complaint for failure to state a cause of action. Judging from the nature of the issues, it is likely that the case will again be appealed to the Supreme Court.

These are some of the cases and rulings representative of the judicial and administrative reasoning in upholding state laws and regulations in situations where I believe the doctrine has not been given realistic recognition.

For example, promulgation of state food standards for foods for which the Secretary has not promulgated standards under the federal Act is, in my opinion, not a warranted "supplementation" or "extension" of administrative regulation. It is an "interference" in an area appropriated by the Congress.

## Secretary Given New Responsibility

The cases rested on this point fail to take note of the statutory authority that a standard may be promulgated for any food "whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers." It is obvious that Congress wished "judgment" to be exercised at the federal level and that to the extent to which it became necessary to do this administratively, the authority to do so was delegated to, and the responsibility was placed upon, the Secretary.

As noted earlier in *Leisy v. Hardin,* the court rejected the argument that the state prohibition law was valid because Congress had failed to act specifically in that area and held that, on the contrary, by its failure to act Congress had merely indicated that there was no need for specific regulation in this particular area. It would seem that the reasoning and the holding in that case is particularly pertinent to

absence of federal food standards, because of the more specific statutory language. There may well be, and indeed there have been, instances where the Secretary concludes that no standard should issue. His exercise of judgment, though this may be informal and within the confines of his own chambers, should control. It should not be permitted to be thwarted by state action under the guise of needed "supplementation" or "extension" because the Secretary has failed to act.

Nor is the line of reasoning sound which is founded on the argument that where the federal requirements are only "optional" or "minimum" a state may regulate specifically, because compliance with different or higher state standards will not involve a violation of the federal law. This is rested on the basic premise that a state law may stand as long as compliance with it will not require a violation of the federal law. However, as stated in *Hines v. Davidowitz,* (cited above) and quoted with approval by the Supreme Court in later cases, there is no "distinctly marked formula" in the application of the doctrine. If the reasoning in the cases such as the *Borden* case, for example, is sound, then we would have available such a formula since this would supply a simple test applicable to *any* situation.

## Can State Interfere with Federal "Right"?

However, the test is not whether the state requirements might involve a violation of federal law. The test, in my opinion, is much more basic than this. It is whether a *right* existing by virtue of the federal law, both in the federal government and in the regulated industry, may be "interfered" with or qualified by the states. As successfully argued by Daniel Webster in *Gibbons v. Ogden* (cited above), "All useful legislation does not consist in restraint; that which Congress sees fit to leave free is a part of its regulation as much as the rest."

Any state regulation which, in its impact, interferes or qualifies a right existing under the federal law should yield to the federal law. Once a commodity is qualified for shipment under the United States flag, there may be no interference with its movement to the outermost reaches of interstate commerce. In our area of concern, this means the point at which it is handed to the consumer. This is a matter of *right.* Such a right may not be interfered with or qualified by requirements that the composition, weight, labeling directions, or some other

aspects of the commodity be varied from the federal requirements simply because the required variation would not involve a violation of the federal law.

## Single Exception

The only exception which may be recognized to this general statement is when the state interference is rested on the exercise of its police powers to meet a *demonstrated special need* of its own citizens as distinguished from the need of the public at large. However, it will not do simply to assert that the state action is taken in the exercise of police power without demonstrating, precisely, the basis for exercising police power. Thus there must be a good and sufficient reason to answer basic questions such as, for example—

(1) Why the citizens of California's interests require that their avocado pears should contain not less than 8 per cent fat in the presence of government regulations which recognize as a legitimate commodity of commerce avocado pears from other areas containing less fat?

(2) Why do the citizens of Iowa require 12 per cent of fat in their ice cream when the Secretary has concluded that "honesty and fair dealing" is promoted for the citizens at large when ice cream contains a minimum of 10 per cent fat?

(3) Why may the citizens of Pennsylvania not safely use a product which the Secretary has found that consumers generally, wherever located, may use safely?

Merely asking the pertinent questions serves to answer them. Obviously the police power in all these situations is used merely as a cloak to serve objectives which are not the proper subject of state regulation in the presence of a federal regulation. It is respectfully submitted that the decisions and rulings discussed are not sound. It is hoped and predicted that both the avocado pear case and the ice cream case, still in the courts, will be resolved by holding that the state regulations challenged in these cases must yield to the federal regulations.

## Cases Supporting Criticism

This criticism is not without judicial support. The following are some of the selected cases which, in my judgment, support the criticism:

The only case so far as appears which directly involves the Federal Food, Drug and Cosmetic Act is *Gorolin Corp. v. City of New York* (S. D. N. Y. 1949), CCH FOOD DRUG COSMETIC LAW REPORTER,

¶ 7116 (Transfer Binder). This was a suit for declaratory judgment by an Illinois manufacturer of a hair dye containing a coal tar color which had been seized under the New York City Sanitary Code. The New York law prohibited sale of all hair colorings unless the hair dye was from a certified batch or bore a caution statement and instructions for a patch test. Federal law requires the cautionary statement and instructions without regard to whether the hair dye is from a certified batch. The seizure was based on the presence of an uncertified coal tar dye.

The court concluded that federal law, particularly Section 601, had pre-empted the field, and denied the City's motion to dismiss the complaint, saying:

"Inasmuch as the City's local law prohibits the sale in New York City without a warning of any coal tar hair dye and then excepts from that prohibition a hair dye containing a coal tar color from a batch certified by the Federal security agency, it conflicts with the Federal statute, even if that statute (21 U. S. C. A. 361) were construed as the Corporation Counsel construes it to mean that every coal tar hair dye must be considered an adulterated cosmetic . . . . But to decide this motion the Court need not construe the statute nor even reflect on the intrinsic defects of the local law so ably argued by plaintiff. The Federal act is constitutional and under it Congress properly exercises a power which governs the intrastate sale of the products affected by it, including the final sale. *U. S. v. Sullivan,* 332 U. S. 663; *McDermott v. Wisconsin,* 228 U. S. 115; 21 U. S. C. A. 331 and 334. Thus the regulation envisaged and effected by the Federal statute is thorough and complete and the legislation attempted by the city and whose enforcement is threatened by the individual defendants infringes on the policy of the Federal statute which it thereby discredits. For this reason the city's local law is unavailing against the product of this plaintiff whatever be its merits or demerits since it arrived here in the court of interstate commerce."

## Case Pertaining to "Minimum" Requirements

Another New York case particularly pertinent to the question of "minimum" requirements of federal regulations is *Kansas Packing Company, Inc. v. The City of New York, et al.,* 127 N. Y. S. 2d 107, 205 Misc. 1077 (Supreme Ct. Spec. Term, New York County, December 4, 1953). This case involved a New York City ordinance which prohibited the importation into New York City, and the sale therein, of

any processed beef which contained more than 10 per cent of added water. The plaintiff brought about 77 per cent of its beef into New York from out of the state and did so lawfully under United States Department of Agriculture regulation which provides for the use of a curing solution for beef briskets in a manner so that it will not result in an increase in weight of the uncured product of more than 20 per cent.

The city sought to sustain its regulation on the ground that a city the size of New York had to have more stringent requirements for the protection of its citizens and that, therefore, this was a proper exercise of its police powers. The Court agreed that a colorable case could be made for this contention from the various expressions in the many cases dealing with this subject. However, it disagreed with the application of this doctrine to the instant case, saying:

"But a state or municipal statute must fall if in terms or practical administration it either conflicts with the Federal law or infringes on its policy, . . . . This ordinance does both. In terms it prohibits importation of a product which has received the imprimatur of approval from that authority. In practice it renders nugatory the inspections conducted by the Federal authority and effectually substitutes a different standard. Trading pursuant to the sanction thereby given is infringed upon to an extent that can render it impossible. The statute is, therefore, unconstitutional and the plaintiff is entitled to judgment so declaring."

*Quaker Oats v. City of New York,* 295 N. Y. 527, 68 N. E. 2d 593 (1946), did not involve a food and drug problem, as such, but an asserted conflict between the federal and New York City standards governing the sale of horsemeat. The New York City ordinance required the decharacterization of horseflesh by the addition of ground bone and harmless coloring. The federal regulation permits, in lieu of decharacterization, the use of hermetically sealed containers. Quaker Oats (a user of containers), in a suit for declaratory judgment claimed that the local ordinance was inconsistent with federal law because it forbade to interstate commerce what the federal government authorized. The court agreed that the local ordinance as applied to Quaker Oats burdened commerce, relying on *Cloverleaf.*

## Wisconsin Attorney General's Opinion

The Wisconsin Attorney General has issued an opinion ruling that Wisconsin statutes providing standards of identity for canned

vegetables, and standards of identity for fruits and jams, are invalid because they conflict with federal standards. Opinion, Attorney General of Wisconsin, Dec. 5, 1960, CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 85,127.

With respect to canned vegetables, the federal standards permit as *optional,* ingredients barred by the Wisconsin standards. Elimination from canned vegetables of the optional ingredients so barred would not result in a violation of the federal standard.

Similarly the federal standards for canned fruits and preserves permit the use of *optional* ingredients not recognized in the state standards for these foods.

In the opinion of the Attorney General, the Wisconsin statute could not validly be enforced to bar the sale of canned vegetables conforming to the federal standard but containing optional ingredients not recognized in the state standards. These Wisconsin standards were, in the Attorney General's view, invalid under *McDermott v. Wisconsin.*

## Recent Supreme Court Decision

The most authoritative decision which would appear to cast considerable doubt on the soundness of at least some of the criticized cases is a United States Supreme Court decision, more recent than any of the cases discussed. This is *Campbell v. Hussey,* 368 U. S. 297 (1961).

Though the Federal Food, Drug and Cosmetic Act was not in issue, a distinction not without significance, the *Campbell* case is an important precedent because the facts present a rather striking parallel to the standard of identity as well as the drug labeling problem and because of the comprehensiveness of the language used.

This was a suit by tobacco owners in Georgia to enjoin Georgia officials from enforcing certain provisions of the Georgia Tobacco Identification Act. Under the Federal Tobacco Inspection Act, Congress provided for the establishment of uniform standards of classification and inspection of tobacco and authorized the Secretary of Agriculture to "establish standards for tobacco by which its type, grade, size, condition or other characteristics may be determined, which standards shall be the official standards of the United States."

A regulation issued thereunder prescribed that all tobacco possessing the same characteristics shall be treated as one type regardless of geographical origin. Accordingly Type 14, which was grown prin-

cipally in southern Georgia and "to some extent" in Florida and Alabama, was required to be identified by a blue tag which stated the grade and type. The Georgia law specified that Type 14 grown in Georgia must have a white tag.

The Supreme Court—five to three—held that the federal law pre-empted the field even though the Georgia law did no more than "supplement" the federal law. Mr. Justice Douglas, speaking for the majority, said:

"We do not have here the question whether Georgia's law conflicts with the Federal law. Rather we have the question of pre-emption. Under the Federal law there can be one 'official' standard —one that is 'uniform' and that eliminates all confusion by classifying tobacco not by geographical origin but by its characteristics. In other words, our view is that Congress, in legislating concerning the types of tobacco sold at auction, pre-empted the field and left no room for any supplementary state regulation concerning these same types. . . ."

"We have then a case where Federal law excludes local regulation, even though the latter does no more than supplement the former. Under the definition of types or grades of tobacco and the labeling which the Federal Government has adopted, complementary state regulation is as fatal as state regulations which conflict with the Federal scheme." (368 U. S. at 200, 302.)

## Strong Dissent by Three Justices

There was a strong dissent, written by Mr. Justice Black, who ordinarily votes with Douglas, and Justices Frankfurter and Harlan. The dissent asserted that there was no conflict between Georgia and the federal regulation, and that the definition of Type 14 in both meant the same thing. The full effect of the Georgia law, Justice Black said, is simply to assure that bidders at the Georgia auction markets located in Type 14 area will be able to distinguish between officially classified Type 14 tobacco grown only in Georgia and other types of tobacco grown in other states.

## Drug Registration Requirements

The issues in all of the cases involving federal food and drug laws which have been discussed have arisen in connection with regulations pertaining to commodities shipped interstate. However, there is another aspect to this whole consideration which is of special interest to your industry, not touched directly by these cases. This is the

requirement by some states that drug firms, or their detail men, or both, which ship specified types of drugs into their state meet certain registration requirements. This is a subject which is deserving of special treatment, as such.

I regret that I have not researched this question specifically for this occasion. However, on the basis of the discussion had, I think it can be said that the principles here outlined are equally applicable to such attempted state regulation. I see no distinction in principle, for example, between such state requirements and a state requirement that a mate of a steamboat, duly qualified under the federal navigation laws, carrying on trade within the waters of Alabama file a certificate of ownership in the county where his boat docked, a requirement set aside by the Supreme Court as an unlawful interference with the federal regulation in *Sinnot v. Davenport* (cited above).

Whatever may remain debatable under the divergent judicial and administrative determinations in particular circumstances, it is well settled that if state action does, in fact, constitute interference with interstate commerce the state requirement must yield. It is also well settled, as we have seen in the *Sullivan* case, that interstate commerce in this field reaches up to the point where the drug is handed to the ultimate consumer. A detail man, or anyone else serving in the promotion of the sale and transportation of a drug up to the point of retail sale is, therefore, engaged in promoting interstate commerce. It would follow from this that any registration requirements should be treated the same, in principle, as the requirement that a mate of a vessel file a certificate of registration of ownership.

The question may properly be asked, then, where the line should be drawn between federal control and state control. In my opinion that line should be drawn at the point of retail sales in the case of food and drugs shipped interstate. Everything done to deliver the product to the person who will ultimately deliver it to consumers is promotion of interstate commerce.

However, the state may well impose requirements on the person who is the ultimate go-between in the final delivery of the drug to consumers, depending always on the nature of the drug and the purposes for which it is sold. Thus the state may well establish the qualifications for the person who is the recipient of such commodities provided this can be justified by the proper exercise of state police power. However, as Mr. Justice Cardozo said in the *Seeley* case, the police power may not be invoked as a veil for the protection of special interests.

## Restrictive Sales

This latter comment introduces still another subject: that of restrictive sales. My own opinion is that the principles which we have discussed permeate this whole area subject only to exceptions which can be justified by the *proper* exercise of state police power; that is, by a showing wherein the citizens of the particular state need the additional protection claimed.

I am not unmindful of the lack of uniformity in judicial decisions as well as the strong dissents in the cases on which my criticism is rested. Indeed, there have been few, if any, Supreme Court decisions on this subject which have been by a unanimous Court. However, I believe these should be regarded merely as symptomatic of an evolving judicial system founded on precedents. In any case, the courts should keep pace with ever increasing complexities of technology and commerce in order to insure the fullest realization of the purposes of the laws which come before them for construction. Consumers are entitled to this because, in the language of Mr. Justice Jackson quoted earlier, "A multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law."

One more point should be noted in connection with the discussion. This is the need for supplementation of a realistic application of the doctrine of federal pre-emption by state laws which are uniform among themselves and with the federal law and the need for a uniform administration and interpretation of such laws.

## Effective Enforcement Essential

While a realistic application of the doctrine would serve to achieve susbtantial uniformity, this would in any event be only half the job. Effective enforcement is highly essential to a full realization of statutory objectives and benefits. It is well known to all concerned that neither the federal government nor any one state government is adequately manned and equipped to provide the maximum enforcement desired. Coordinated enforcement programs between federal government and the states as well as among the various states are indispensable to any effective enforcement plan. However, in order to make possible unified action among regulatory officials, they must first have uniform laws and regulations.

The Association of Food and Drug Officials of the United States is presently developing a recommended uniform state law. I think

the regulated industry, and particularly its lawyers, should do everything they can to promote the adoption of such legislation. In my opinion, uniform laws and regulations would serve to virtually eliminate controversies over the application of the doctrine of federal pre-emption of the nature such as have been reviewed.

My recommendations, therefore, are first, that the regulated industry be more litigious and take well selected cases to the highest tribunals possible in the hope that greater uniformity and more clearly defined rules of application of the doctrine of federal pre-emption in areas of food and drug laws will result; and, secondly, to actively promote the adoption of the uniform state laws and regulations. Constant vigilance and aggressive action on both fronts are essential in order to avoid useless duplication and divergence of regulation.

[The End]

## FDA ROUNDS UP FAKE HEALTH DEVICES

Fifty-two "Micro-Dynameter" machines were taken out of operation during July as a result of the nation-wide FDA campaign to round up these fake medical devices.

Forty-two of the "Micro-Dynameters" were reported to have been voluntarily destroyed by the users. Of these, 24 were reported by FDA's Boston District and 18 by the Minneapolis District. The "Micro-Dynameter" is an electrical gadget widely promoted for the diagnosis of disease. A recent federal court decision banned it as dangerous because it is incapable of diagnosing any disease.

Ten of the machines in possession of health practitioners were seized during the month.

During the same period, FDA also seized five "Neurolinometer" devices. The "Neurolinometer," like the "Micro-Dynameter," is also an electrical device promoted with claims for diagnosis, treatment and prevention of disease. It, too, has been banned by a recent federal court injunction.

In new court actions, FDA also charged that false health claims were made for a massage machine promoted for various ailments, an electrical gadget for removing wrinkles, and a compound to be used with a vacuum cleaner to treat and prevent disease. Following are details on the new actions:

Sanitizing Crystalline Preparation to be used in Electro Hygiene Vacuum Cleaner was charged with false claims in accompanying literature. The literature stated that the crystals, used with the firm's vacuum cleaner, are effective for relieving asthma and bronchitis, guarding against pneumonia, tuberculosis, influenza, whooping cough, polio, measles and scarlet fever.

Firmatone claimed to rejuvenate the face by eliminating poor skin texture, dry skin conditions, sagging facial contours, flabby facial muscles and to create a healthier, more youthful appearance.

Massage Master Model VII claimed it was adequate and effective as a treatment for ailments of the nerves, muscles, skin, vascular system, entire body structure and for other purposes.

# Progress Under the Food Additives Amendment of Interest to the Cereal Chemist

By L. L. RAMSEY

The Annual Meeting of the American Association of Cereal Chemists in St. Louis, Missouri, May 20-24, 1962 was the Scene of This Talk. Mr. Ramsey Is With the Division of Food, Bureau of Biological and Physical Sciences of the Food and Drug Administration.

THE FOOD ADDITIVES AMENDMENT has been a part of the Food, Drug and Cosmetic Act for almost four years, now. During this time the Food and Drug Administration, as well as various industry organizations and associations, has carried on a comprehensive informational program designed to acquaint all those interested with the provisions of the new law. I believe it would be almost an insult to your intelligence for me to dwell on the provisions of the Amendment. To be familiar with the law of course does not mean that there are no differences of opinion over interpretation of its various provisions or over administrative handling; but these matters lie within the province of the lawyer and the administrator rather than that of the chemist. However, I do believe that a brief account of progress under the Food Additives Amendment in two major areas will be of interest to you: first, progress in clarifying the status of substances used by the cereal industry and second, progress by FDA toward meeting its increased regulatory responsibilities under the Food Additives Amendment and other recent legislation through its building construction and laboratory modernization program, and through personnel expansion.

Upon passage of the Food Additives Amendment in 1958 the cereal industry was using a rather large number of substances as

additives in its products. Fortunately, a joint effort by the industry and the FDA several years earlier had culminated in the promulgation of regulations prescribing definitions and standards of identity for the basic cereal foods. Thus, most of the common direct additives in cereals were excluded from the clearance provisions of the Amendment because they were either generally recognized as safe, prior sanctioned, or both.

It is a little difficult to arrive at an exact figure for the total number of chemical agents permitted by the standards for use in standardized cereal products. For example, iron and calcium where permitted may be added in any form in which they are harmless and assimilable; and a rather indefinite number of agents is encompassed by the term "spice." Moreover, there is the problem of distinguishing between chemical agents and other substances. Nevertheless, it appears that the cereal standards gave prior sanction status to a total of approximately 40-50 chemical agents.

The publication in the *Federal Register* of January 31, 1961, of the comprehensive GRAS list of substances added directly to food clarified the status of about 250 items. Also, during 1961 supplementary GRAS lists of approximately 278 natural flavoring agents and 27 synthetic flavoring agents were published.

## Intentional Cereal Product Additives

Further, I note that your industry and your food additive suppliers have been quite active in submitting petitions and obtaining clearance by regulation for the use of a wide variety of agents: emulsifiers in shortening and in cake mixes, modified starches, cottonseed flour, acetylated monoglycerides, antioxidants in breakfast cereals, fatty acids and their salts, the stearyl lactylates, anticaking agents, pesticides for use in flour mills and directly in flour and even one new bleaching and maturing agent for flour. Thus, there are about 40 food additive regulations which prescribed the safe conditions of use for substances added to cereal products or to the cereal product ingredients used by your industry. This is almost half of the regulations which have been promulgated to date dealing with direct additives in human food.

What remains to be accomplished in the area of intentional cereal product additives? One task is obtaining clearance for many modified starches having utility when added directly to certain foods. As many

of you know, there are some unresolved problems here with regard to identity, methodology and possible safety data. Another task remaining in which you are interested, if not actually involved, is that of obtaining clearance for the synthetic flavoring agents; there are almost 1000 of these. The Administration is studying the proposal of the Flavoring Extract Manufacturers Association to place the majority of these flavors in the GRAS category, but I have no information as to when a decision on the individual substances in this list may be reached. About 200 natural flavors are also awaiting clearance. And finally in this area I anticipate that your research and development people have several new additives which show promise. These, of course, are subject to the full preclearance provisions of the Amendment.

## Unintentional Additives

In the area of unintentional additives the problem of developing suitable specifications for a food processing grade mineral oil and food packaging grade petroleum wax is under intensive study by both the American Petroleum Institute and the Food and Drug Administration. Although this work is not yet complete, the findings to date are quite reassuring and the outlook promising.

With publications of regulations covering such basic packaging materials as can enamels, cellophane, polyethylene, polypropylene, the nylons, polyurethane, textiles, the paper chemicals used in slimicides, defoamers and polymeric and resinous coatings, a great deal of the area has been covered, but we realize there are some major troublesome spots such as rubber and dispersion coatings on paper as well as a large number of individual substances having utility in food packaging or in food processing equipment that remain to be cleared. You have perhaps noted that most of the petitions filed have been concerned with this area.

In brief, we believe a great deal of progress in clarifying the status of your food additives has been made, but there are some rather knotty scientific and administrative problems remaining. Although your industry as well as most of the food industry appears to be able to operate satisfactorily under the current extensions of the effective date of the Amendment while data supporting safety of the additives are being obtained, we would urge you to exercise due diligence in pursuing your remaining food additive problems either directly yourselves or indirectly through your suppliers. Only two years remain to accomplish this job.

## FDA's New Responsibilities

Let's turn our attention now to the second part of this paper: the progress FDA is making toward meeting its new responsibilities under the Food Additives Amendment and other recent legislation. The basic requirement in this area, of course, is an adequate staff. Our personnel just prior to the passage of the Food Additives Amendment numbered about 1400. Today, our authorized strength is almost double that figure and an increase to approximately 3,200 is proposed for the next fiscal year beginning July 1, 1962. Another basic requirement in this area is adequacy of the physical facilities, that is, the buildings and equipment. At present we have new buildings in four of our districts; new buildings are currently under construction in six of our districts; and within two years we shall have new buildings for our field personnel in 17 districts. The one remaining district will have a completely renovated building.

A new building for our Washington staff is also scheduled for occupancy well within this two-year period. It will be supplemented by a new building for certain of our operations to be built in nearby Beltsville, Maryland.

## Specialized Instruments Are Essential

The laboratories in these new buildings in the field and in Washington are, of course, being furnished with modern conventional equipment and utilities. But beyond the use of conventional analytical equipment and techniques, the Director of the Bureau of Biological and Physical Sciences of FDA has set as our goal the development and maintenance of scientific leadership in food and drug research. To this end our Washington laboratories are now equipped with or are acquiring the most advanced instrumentation for fundamental research and investigative purposes. It may be of interest to mention some of the specialized instruments we now have in the BPS Bureau: a mass spectrometer, Craig countercurrent apparatus, molecular stills, Warburg manometric apparatus, liquid scintillation counter for radioactivity, spectrophotofluorometer, spectrophotophosphorimeter, X-ray diffraction and fluorescence equipment and so forth. These will be supplemented soon by a nuclear magnetic resonance instrument, a spectrometer, a Raman spectrometer, an ultracentrifuge, a recording spectropolarimeter, neutron activation analysis equipment and an electron microscope.

This list is in addition to the newer instrumentation which has been established as essential to our district laboratories in their methodology research and day-to-day regulatory operations. Each of our 18 district laboratories has the following modern instrumentation available: recording spectrophotometers for the visible, the ultraviolet, and the infrared ranges, flame photometer, titrimeter, grain X-ray inspection units, electrophoresis apparatus, gas-liquid chromatographic equipment, microwave heater, cameras including a photomicrographic camera and a polarizing microscope. Additionally, certain laboratories have other equipment for specialized work. For example, seven of the district laboratories are equipped with bacteriological facilities, four have polarographs, and three have bioassay facilities. All of these will become standard equipment in each of the new district buildings. Ten of the districts are each equipped with two beta counters for radioactivity.

## Specially Trained Personnel Needed

In order to utilize this new instrumentation to our best advantage, it is necessary to have specially trained personnel. In addition, therefore, to our continuous in-service training on a wholly informal basis, we are, as the need arises, holding comprehensive training sessions or schools for our chemists in such areas as infrared spectrophotometry, gas-liquid chromatography, radiology and so forth.

Instrumentation developments are proceeding at a rapid pace and certainly are having a tremendous impact upon methodology in the total field of chemistry. As evidence we note that at the recent national meeting of the American Chemical Society in Washington there was a symposium of one and one-half days on mass spectrometry with a total of 15 research papers presented. This meeting also included a symposium of five research papers on the ultracentrifuge; the Zechmeister symposium on chromatography and electrophoresis with five research papers; and the Fisher Award Symposium on instrumental analysis with seven papers honoring Dr. Liebhafsky. The Fisher Award Symposium was devoted almost entirely to the impact of instrumental analysis on the various industries including the aluminum industry, the communications industry, the petroleum industry, the photographic industry and the pharmaceutical industry. Although the cereal industry was not included in the discussion, your industry also has undoubtedly been affected. Automation was the keynote in the discussion both with respect to plant production control and with

respect to the analytical work required in research and development. For example, this trend is illustrated by the fact that the central control staff of a huge aluminum plant now includes only 10 per cent of conventional or so-called wet chemists. All plant site testing has been abandoned because the new instrumental analytical techniques permit transmission of sample, complete analyses and a report back in a fraction of the time formerly required using conventional techniques at the site.

## Ideal Tools for Chemists Being Developed

Several of our chemists attended the recent annual meeting of the Pittsburgh Conference on Analytical Chemistry and Applied Spectroscopy and returned slightly starry-eyed. They reported that recent advances in instrumentation and automation almost border on the miraculous. Certainly, this industry is making remarkable strides towards developing ideal tools for the chemist.

As briefly alluded to a few moments ago, we have compelling reasons for being vitally interested in modern instrumentation. Much of the scientific data and other information offered in support of food additive petitions as well as other submittals to us has been obtained with the aid of recently developed instruments. Data establishing the identity of a substance, its freedom from toxic impurities and its fate in food or in the animal body, have often been acquired using advanced technics and a new instrument. Also, the practicable analytical method proposed by the petitioner for regulatory purposes may itself employ such an instrument. Therefore, in order for our scientists intelligently to evaluate the soundness of such data and the practicability of such an analytical method, it is quite essential that they have more than a nodding acquaintance with the instrumentation employed. In fact, it is imperative that they themselves have ready access to it and be using it in their research. Otherwise, they possibly may not have the depth of understanding to do justice to the problems confronting us.

Although the Food Additives Amendment requires that a practicable method be furnished by the petitioner where a tolerance is required and the Administration has adopted the same policy with respect to the Pesticide Chemicals Amendment, these methods are seldom ideal. The most common weakness is lack of rapidity for efficient routine regulatory work. We in the laboratories of FDA are continually working toward the developent of new methods and the improvement of existing methods for purposes of greater rapidity

without loss of accuracy, greater convenience, and increased suitability for routine use. If the consumer is to be afforded optimum protection against unsafe amounts of food additives or other substances in his diet, more samples of food in interstate commerce must be analyzed and at a lower cost per unit. In moving toward this goal our plans call for expanded coverage of the food additive area as well as related areas.

In conclusion then, we propose to exploit modern instrumentation to the fullest degree in order first, to afford the consumer the maximum protection against possible hazards in his food supply for the funds spent; and second, to facilitate the administration of the Food, Drug and Cosmetic Act in the interest of the consumer as well as in fairness to industry by making informed and valid appraisals of scientific data, other information and methodology submitted to us in support of a new chemical usage. **[The End]**

## INTERNATIONAL FOOD CONGRESS AND EXHIBITION

Secretary of State Dean Rusk recently said, "No more pressing problem faces the world than providing adequate nourishment for its many peoples."

"The food industries have made significant contributions in aiding efforts to resolve this problem," Secretary Rusk stated in a letter to Hans J. Wolflisberg, Chairman of the Fifth International Food Congress and Exhibition being held at the New York Coliseum from September 8 to 16.

He expressed hope that the International Food Congress will serve to increase knowledge of basic food science so that "the nutritional advantages we enjoy may be shared by all."

This international food festival, at the New York Coliseum September 8 to 16, will include dramatic displays under thematic areas portraying the full scope of the world-wide food industry. The theme of the Fifth International Food Congress and Exhibition is "The Life Line of Humanity—Food from Farm to Table." Key food industry executives from all parts of the world will gather and exchange information during a four-day series of trade sessions and seminars. These will be held on the Coliseum's fourth floor. Each of these sessions will be conducted by leaders of the United States food industry and other world authorities.

United States Government participation in this huge food exposition includes displays by the United States Departments of Agriculture, Commerce, Interior, Labor, as well as the United States Public Health Service and the United States Food and Drug Administration.

# California's Approach to Uniformity of Food and Drug Law Standards and Regulations

By MILTON P. DUFFY

The Author, Chief of the Bureau of Food and Drug Inspections, California Department of Public Health, Presented This Paper at the Stanford Law School Symposium on Food and Drug Law on April 27, 1962.

FOOD AND DRUG LAWS are designed to protect the consumer's health and pocketbook, as well as to prevent unfair competition among manufacturers and distributors. These laws are of great social and economic importance, for they deal with the entire course of the production, manufacture and distribution of foods and drugs, and they touch upon the lives of the entire consuming public and influence a larger segment of commerce than any other body of laws.

## Early Legislative Measures

California has had a long, illustrious history of food and drug legislation which commenced with the first session of the California Legislature meeting in San Jose in 1849. From the turn of the century, California has experienced a very rapid growth of its population and a corresponding growth of its food and drug producing capabilities. We became an exporting state and soon found the need for uniformity in our food and drug laws and regulations in order that our products would not meet interstate barriers.

On March 11, 1907, just one year after the passage of the Wiley Food and Drug Law, our forward-looking legislators approved the first California Pure Foods and Pure Drugs Acts. In 1939, California became one of the first states to adopt the "Uniform Food and Drug Act," often referred to as the Copeland-type act.

California has always been a strong proponent of food and drug legislation which is on a par with federal legislation. Indicative of

this is the adoption of the Food Additive Amendment in 1959 and the Color Additive Amendment and Hazardous Substances Labeling Act in 1961. To further advance this uniformity, the State Board of Public Health has made it a point to maintain standards and regulations governing the production of foods and drugs which are consistent with standards and regulations adopted at the federal level.

My remarks today will be directed to a discussion of the authority for adoption of standards, the procedures we must follow here in California, and some of the problems we encounter.

## Authority

The authority to adopt standards and regulations for the efficient enforcement of the Pure Foods and Drugs Act is vested in the California State Board of Public Health. In the case of standards, the law states "whenever in the judgment of the Board such action will promote honesty and fair dealing in the interest of the consumer, the Board may promulgate. . . ."

It should be noted, however, that authority to adopt standards is not without its limitations. First of all you will note the word "may," which gives the board the discretion of adopting or not adopting. Secondly, the law uses the term "reasonable."

The use of the terms "may" and "reasonable" places the adoption of standards in the discretion of the state board, a duly constituted state body. These phrases were undoubtedly added to preserve the freedom of the state to take such action as it considers necessary to protect the health of its citizens and to act upon problems peculiar to this state. I feel that such freedom of action must be preserved.

To show its interest in uniformity, the state legislature placed other mandates in the Pure Foods and Drugs Acts. They state that regulations must "conform insofar as practicable" to those promulgated under the federal act, and further, that in no instance shall such standards require a higher standard than the standards required pursuant to definitions currently promulgated by the United States Food and Drug Administration, or the United States Department of Agriculture.

## California Sets Its Own Wine Standards

There is one exception to the foregoing however, for California reserves the right to adopt its own standards for wine. We define

wine as the normal alcoholic fermentation of the juice of sound, ripe grapes. California-produced wines, particularly table wines (dry wines) are of the highest quality.

## Procedures in California

The administrative staff of the State Department of Public Health is generally responsible for the preparation of the regulations and standards which are to be presented to the State Board of Public Health. Such preparation is usually a resultant of one or more of the following conditions:

1. An addition to, revision of, or a deletion from federal standards and regulations.

2. A departmental determination that such action is necessary for the protection of the public health of the citizens of California, and/or that it will promote honesty and fair dealing in the interest of consumers. This usually covers areas of control not subject to federal control.

3. Interested groups may contact the department requesting standards or regulations which will promote honesty and fair dealing.

Once the standard or regulation is drafted it is submitted to the Attorney General's office for review. The Attorney General's office gives legal advice as to compatibility with other federal or state laws, and for construction and terminology.

## Publication of Proposed Regulation

When these preliminary steps have been completed the regulation or standard is transmitted to the Director's office, who, as executive officer of the state board, publishes the proposed regulation.

This notice of proposal to promulgate a regulation is published at least 30 days prior to the date of hearing. All interested parties are also sent copies of the regulation to be adopted. This notice includes the time and place of the board hearing.

## Hearings Explained

The next step, of course, is the hearing before the State Board of Public Health. The administrative staff of the Department of Public Health is usually called upon to justify the adoption of the proposed standard. Expert testimony may be required, in which case scientists and leaders in industry may be called upon.

Those opposed to the proposed regulation or standard also have the opportunity to express their view. I would like to again state that California's dogged adherence to uniformity has led to little or no opposition in such procedures. This is most probably due to the fact that the opposition has ironed out its objections at the federal level.

When agreement is reached, the standard or regulation is given a "do pass" recommendation. Once the board has adopted the regulation, it is forthwith transmitted to the Secretary of State for registration. The regulation so promulgated becomes effective on a date fixed by the board, but in no case prior to 90 days after it is filed with the Secretary of State.

## General Discussion

The Association of Food and Drug Officials of the United States has given wholehearted support to the principle of "Uniformity," and representatives of industry have made it clear that they favor consistency in federal, state and local laws and regulations. However, AFDOUS has expressed the need for states to preserve their prerogative to act for themselves when the need arises. This presents problems of legal draftsmanship which must be solved in order to make this principle a practical reality.

Most states have provisions in their laws which authorize adoption of standards and regulations which are comparable to those at the federal level. It should be pointed out, however, that some statutes are quite vague in their nomenclature, which leads to much confusion.

## Conformity with Current Federal Regulations Essential

Another problem which I have met as an administrator is the need for adequate funds and staff necessary to properly maintain the standards and regulations of this state in conformity with current federal regulations and standards. They must be current, or they are of little value.

The level of technology of our food and drug industries has advanced significantly. The coming of food additives and hazardous substances regulations with the resultant changes in related food standards, to authorize the new food additives, has increased the work load in this field considerably. This requires enlarged staffs not available under present budget conditions. I am sure this is also a contributing factor in many states to the lack of uniform regulations and standards.

This factor is having its effect all along the line. The state board, overloaded with these administrative procedures, is unable promptly to implement processes required by law.

## Study of Adoption Procedures Needed

It is time that a concerted study be made of the adoption procedures used. On the federal level the need for technical staffing has been recognized, and increased appropriations have been made to carry out the necessary research preparatory to adoption of standards.

In 1959 the Hale Amendment to the federal act made a step in the right direction. This amendment eliminated the need for costly and time consuming hearings in the promulgation of standards where the evidence of record was sufficient and no request for formal hearings was made by the affected parties. It appears to me that this would be a desirable addition to state statutes, one which would aid greatly in the adoption of uniform state regulations and standards.

## Incorporation of Regulations and Standards by "Reference"

Another concept which needs a great deal of study and careful draftsmanship by legal counsel is the incorporation of regulations and standards by "reference." Some states have constitutional barriers which prohibit this procedure, New York, for example. On the other hand, some state codes simply provide that the standards and regulations of the United States Department of Agriculture or United States Food and Drug Administration shall be the state standards and regulations. Such codes do, however, have the original establishment of regulations and standards in the hands of agents or agencies outside of the state's control. Accordingly, this concept presents problems and there is need for concerted research in this field.

I have been advised that, as a general rule, here in California, the adoption of standards by reference could be worked out in some cases, especially for cumbersome standards adopted by the federal government that are highly technical and subject to change. Such adoption by reference would not be an automatic procedure for all new regulations, but it could be utilized for coverage of specific subjects. It has been recommended that this subject be referred to our state's Attorney General for an opinion. **[The End]**

# New Drug Applications

By RALPH G. SMITH

The Author of This Timely Article Is Director, Division of New Drugs, Bureau of Medicine, Food and Drug Administration. It was Presented at the National Meeting and Seminar of the Drug and Allied Products Guild, Inc. at Ellenville, New York, June 14, 1962.

MY SUBJECT is a broad one and unrestricted. It is not possible to cover it fully in one address nor would it be wise to try to do so. I will attempt, however, to consider it in broad outline and dwell on certain recent developments in more detail. Those of you who have had some experience with new drug applications will already be familiar with much that I'm going to say. It is hoped that the redundancy will not bore you.

You already know that the Federal Food, Drug and Cosmetic Act of 1938 prohibits the shipment in interstate commerce of a new drug for human or veterinary use until a new drug application is effective for it. To become effective the application must show that the drug is safe in the dosages and for the purposes set forth in its labeling.

## Definition of a New Drug

Most of you also have a pretty good understanding of the legal definition of a new drug. Simply stated, *it is one which is not generally recognized as safe by experts qualified to evaluate the safety of drugs when used as directed in its labeling.* This applies not only to one or more active ingredients but to the whole dosage form which is marketed. A new solvent, excipient, suspending agent or preservative may cause a product to be a new drug. A combination of two old drugs may be a new drug or even a combination of old drugs of recognized safety may be made a new drug by a change in the proportion of its ingredients. A drug which is recognized as safe for the

treatment or prevention of one disease may be made a new drug by recommending it for treatment of another disease or for its effect on another structure or function of the body. Newness of a drug may also arise from a change in dosage or method or duration of administration.

Even though the safety of a drug under certain conditions of use is recognized as a result of investigations, it is still a new drug until it has been used for a material time or to a material extent under such conditions.

In other words, although there may be an effective new drug application for a product under which a drug firm is legally marketing it in interstate commerce, until there has been a considerable volume of distribution over a considerable period of time it is still a new drug. This is probably a wise provision because marketing experience with respect to safety does not always corroborate that of the investigational studies. In any case, there can be no general recognition of safety by experts without appreciable use of the drug. The retention of the product in new drug status for some time after it is first marketed results in requiring other firms to obtain their own effective new drug applications before marketing it within this period.

## When in Doubt Seek FDA Opinion

In most instances you will know when your new product is a "new drug." When in doubt it is advisable to request our opinion. You may, by so doing, avoid later embarrassment and perhaps more serious consequences. In order to offer a definite opinion we need the complete quantitative formula and draft copy of proposed labeling. Further background information on the product, if available, is usually helpful to us.

Although the law prohibits interstate distribution of a new drug without an effective application, it does allow an exemption for shipping it solely for investigational use to experts qualified by scientific training and experience to investigate the safety of drugs. This involves certain conditions, including the label statement "Caution: New Drug—Limited by federal law to investigational use," and a signed statement by the investigator to the effect that he has facilities for investigation and will use the drug only for that purpose. This provision is, of course, necessary to enable pharmaceutical firms to obtain the evidence for safety required in a new drug application.

## Who Is an Expert?

Although the term "expert" has not been legally defined, it is believed that it refers to physicians who have experience in drug investigation and are specialists in the field applicable to the specific drug. Furthermore, they should have adequate facilities for investigation with respect to patients, clinical laboratory services and time to give attention to such studies. This usually does not apply to the busy general practitioner. There may be a rationale in some instances for wider distribution of a drug after it has been well studied by experts in order to gain some experience with its use under conditions similar to those encountered in commercial distribution. Occasionally we become aware of abuse of this exemption for actual commercial distribution and without apparent intention of collecting data to support a new drug application. Regulation 130.3(c) provides for the voiding of the exemption for the distribution of drugs for investigational use under certain conditions of misuse.

Two groups of drugs are exempted from the new drug application requirement. Five antibiotics (penicillin, streptomycin, chlortetracycline, chloramphenicol, and bacitracin) and their derivatives are subject to batch certification by the Food and Drug Administration for safety and efficacy. The second exempted group consists of biological products such as toxins, antitoxins, vaccines and certain blood products. These are subject to license control by the United States Public Health Service, in the case of drugs for human use, and by the United States Department of Agriculture for veterinary biologicals.

## Required Information for Application

What types of information are required in a new drug application? Probably the most important part of the application, and the one that requires the greatest effort in preparation, consists of reports of investigations to show whether or not the drug is safe for use. These include data obtained by studies on both animal and human subjects.

Although the results of animal studies of a new drug have limited human application, they are certainly indicated before even cautious use on human subjects. You are probably aware of recent testimony before a congressional committee to the effect that new drugs are sometimes offered for clinical investigation before they are adequately tested in animals. Animal studies yield certain types of

information rarely obtainable in the clinic such as relationship of effective to toxic or lethal doses and the type of toxicity in case of acute or chronic over-dosage. It may be feasible to administer the drug over an appreciable part of the life span of the smaller rodents and to study the long-term effects.

## Two Determining Factors

As a general guide for required animal toxicity studies you may refer to the publication "Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics" with which many of you are familiar. It is usually advisable, however, to submit a proposed program of study for comment by our Division of Pharmacology. Different types of drugs require different methods of study. Method of administration and duration of treatment are determining factors. Combinations of drugs require special consideration. If adequate toxicity data are already available on the individual ingredients, less prolonged studies may be acceptable on the mixture to rule out possible potentiation of toxicity.

We are also interested in reports of investigations of the pharmacological action of the drug. Such reports are not as directly concerned with safety as those on toxicity. They do, however, have a bearing on this point in that they define the tissues on which the drug has its primary action and suggest what side effects might result from overdosage. The development of methods for the assay of the drug in body fluids and tissues which make possible studies of its metabolism is valuable. Besides solving problems of possible cumulative action, information is gained on the distribution and fate of the drug in the body which may have a bearing on toxicity problems.

## Widespread Investigation Preferred

The reports of clinical investigations are the most definitive part of the application in determining whether or not the drug should be marketed from the standpoint of safety. Such reports should be from several investigators rather than one or two. It is common experience that the findings of one investigator may differ from those of another. A more accurate assessment of the drug can be made from the results of reasonably widespread investigations rather than from one or two studies. It requires a real effort on the part of a pharmaceutical firm to plan a program of study and to select investigators

who will carry it out. All investigators cannot be expected to conduct liver function studies but some will be able to do so. Others may be able to make the usual clinical observations and conduct the more common laboratory procedures, such as hematologic and urine examinations. It may take a still greater effort to obtain the detailed case reports which are necessary for an evaluation of the safety of the drug. The required information is outlined in the new drug application form and a serious attempt should be made to obtain it. You will have to contend with the physician who is only too willing to test a drug and probably even to publish his results but cannot find the time to furnish detailed individual case reports.

With the continuous development of drugs of new chemical structure, new problems of safety can be expected and do occur. This increases the problem of testing for toxicity. Within the past year two well-known antibiotics have unexpectedly been shown to be capable of producing impairment of liver function and jaundice indicating that they should have been subjected to more thorough studies before marketing.

## Danger of Thalidomide

You are also aware of the recent tragedy in Europe from the hypnotic, **thalidomide**, a drug which fortunately was not marketed in this country. This forcefully calls attention to possible serious effects of new drugs on the fetus as a result of use during pregnancy. It poses the problem of what constitutes adequate animal and clinical studies to detect this potentiality. Most certainly steps must be taken to develop requirements in this connection. Since many drugs may incidentally be administered during pregnancy we believe that labeling of a new drug should include a forthright statement to the effect that its safety for use in this condition has not been shown, when such is the case. Such information to physicians may be useful in a decision on whether or not to use a drug in a female patient during the child bearing age.

## Child's Reactions Differ from Adults

Experts in the field of pediatrics have pointed out that infants and children may react to drugs differently from adults. Incompletely developed enzyme systems may result in impaired metabolism from drugs or, conversely, drugs may impair normal enzymatic processes to a greater degree in children than in adults. It is no longer considered

safe to derive children's doses from safe adult doses by an age or weight formula. Safety of new drugs for infants and children must be shown by actual use in the various age groups.

None of these examples indicates that the required testing of new drugs will become simpler or less laborious. This is an understatement.

Another section of the application which is reviewed by our staff of chemists consists of a full description of the methods, facilities and controls used in the manufacture, processing and packing of the drug. This is considered as an important part of a new drug application since it is designed to offer assurance that the product marketed will meet adequate and uniform standards.

## Factory Inspection Provision

To strengthen this requirement, the regulations have been revised within the recent past to provide for a factory inspection before an application becomes effective. The regulations now recognize that the marketing of a new drug may be delayed or prevented until inspectors of the Food and Drug Administration have been furnished an adequate opportunity to verify the adequacy of the manufacturing procedures and controls and records pertaining to them. When an inspection is considered necessary or advisable, we try to have it completed during the usual period of review. When the inspection cannot be completed within the time limits established by the Act, provision is made in the regulations for making the application conditionally effective pending completion and a satisfactory report. It is expected that this latter provision will be used rarely and only in cases when the applicant does not schedule production or the control operations within the time limits provided for processing the application.

## Submission of Samples

Still more recently the regulations have been revised to require the submission of a number of specific samples. These include samples of the dosage forms the applicant proposes to market representative of the drug employed in clinical studies, of the drug proposed for initial marketing, and of commercial scale production, together with samples of the new drug substances used in producing the batches of the drug represented by the foregoing samples, and such reference

standards and blanks as may be required to perform the assay procedures described in the application.

Specific instructions are given in the regulations and on the new drug application form of the number and amount of each sample which is required. We are authorized to waive the requirements for certain samples, either on request of the applicant or on our own initiative when they are not considered necessary. The purpose of the sample requirement is to permit verification in our laboratories of the adequacy of control specifications or test procedures for identifying or assaying the new drug or its components.

The samples should be submitted with the application along with complete information with respect to applicable laboratory results. Otherwise the application may be considered incomplete and not filed. Prompt submission is necessary to allow time for testing in our laboratories during review of the application. As with factory inspections, provision is made for making an application conditionally effective when necessary, pending satisfactory completion of our analyses.

## Submission of Proposed Labeling

As you know, the application must include specimens of the proposed labeling. In this connection I would like to refer to the regulation requiring a package insert for prescription drugs which is now effective. This regulation applies to human and veterinary drugs, both old and new. Even before the Durham-Humphrey Amendment in 1952, package inserts were required for parenteral drugs and we have for a long time required them for a few oral dosage form products such as the anticoagulants and the antileukemic drugs. During recent years under the new drug procedure this requirement has become increasingly frequent, although with some degree of inconsistency. It was general policy to require package literature for drugs with special hazards so that adequate information on them would be more readily available than the more usual professional literature on request. Consequently, as far as new drugs are concerned, this new requirement by regulation is not really a radical change for a number of pharmaceutical firms.

The only exemption from the package insert requirement is for products the uses of which are commonly known to practitioners. Exemptions have been recognized with considerable conservatism for old drugs but none to date for any in new drug status. A list of drugs

considered entitled to the exemption has been published in the *Federal Register*. We will furnish an opinion in this connection on a written request containing reasonable grounds for favorable consideration.

## Package Inserts

Package inserts must consist of so-called full disclosure information which includes indications, effects, dosages, routes, methods and frequency and duration of administration, and any relevant hazards, contraindications, side effects and precautions, under which practitioners licensed by law to administer the drug can use it safely and for the purposes for which it is intended. Furthermore, promotional literature that furnishes or purports to furnish information for use of the drug, such as indications or dosage, must also include the above full disclosure information.

When a new drug is first marketed there may be little information on it in the published literature. This is one reason why we ascribe such importance to the package labeling and promotional literature. It is often the main source of information for the physician.

## Constant Surveillance

After a new drug is on the market under an effective new drug application it is still of concern to us and with increasing staff we are able to keep in touch with it more closely than in previous years. We still are not as well informed as the distributor on newly discovered adverse effects. We believe that the latter should keep us informed as reports become available and we have been requesting this information on occasion of supplements. Distribution experience frequently warrants changes in labeling and on rare occasions removal of the drug from the market. We have an obligation to see that the physician receives as complete information as possible in the interests of his patients and of himself. This can be achieved best by mutual cooperation. **[The End]**

# FDA and the Brewing Industry

By EINAR T. WULFSBERG

The Author, a Food and Drug Officer of the Food and Drug Administration, Delivered This Paper at the American Society of Brewing Chemists Convention in Milwaukee, Wisconsin on May 21, 1962.

IT WAS ABOUT THE FIRST OF THE YEAR that your program committee chairman, Mr. Petersen, asked to have a representative from FDA at this meeting. His suggestions for topics of interest covered a broad field which might be summarized as everything from sanitation to statistics. My position is that of an administrator in charge of food additive petition processing. This is a rather confining field in that it keeps me out of the stream of the overall activities of the Food and Drug Administration. However, I did put in a good many years as an inspector and have been through my share of breweries and related industries such as grain processing. It will not be my purpose to speak as an expert on a specific phase of the relation of the Food and Drug Administration to your industry but rather to touch briefly on those aspects of the brewing industry of particular interest to us.

From the Bureau of Program Planning and Appraisal I received some of the statistics for the fiscal year ending June 30, 1961. The Treasury Department reports showed that during that year 220 breweries produced 93,496,000 barrels of beer. During that year we made 102 brewery inspections, nine of which were indicative of violative conditions. One of these violative situations involved the misuse of a rodenticide. Eight involved rodent and/or insect contamination and generally insanitary factory conditions. In connection with the inspections, two situations were encountered involving short volume or slack fill. Fair to poor sanitary conditions were observed in 33 other establishments to a lesser degree.

Legal actions included recommendation of prosecution of one brewery and three citations for insanitary operation. There were some voluntary diversions of contaminated cereal to animal feed, including one involving a half million pounds of corn grits and another, the disposition of 7,000 barrels of beer produced from insanitary grain.

Seizure actions numbered five involving the following products: malted barley, malting barley, cracked wheat, brewers rice.

On the subject of sanitation, many of you have had the opportunity to hear FDA's views from Kenton Harris of our Bureau of Biological and Physical Sciences who has addressed this group. About all I can add to the subject are the reflections of my own experience as an inspector.

## Two Schools of Thought on Inspection

I found two schools of thought in my work: those that believed sanitation was an expensive and necessary evil and those that believed it was economically profitable and paid off also in better all-around plant performance. To the Food and Drug Administration inspector the absence of a planned program of sanitation is often an indication of trouble ahead. When responsibility for sanitation is not an assigned responsibility, it gets to be "nobody's business." However, just making out a program is window dressing unless it is implemented, supervised and enforced.

Usually in a large food plant of any kind the inspector is assigned some person from the management as his contact during the inspection. Not infrequently I found that a chemist was tied in to the sanitary program. This is good because he can usually report to the upper levels of management where the responsibility lies for plant policy on sanitation. What the inspector looks for in plant sanitation is no mystery to any of you who have ever observed an inspector at work. He looks for evidence of living, crawling, flying and creeping things that defile the brewery raw materials. Once the product gets into the wet stage, sanitation is pretty well a requirement if the end article is to pass quality control and customer acceptance. The tools the inspector uses are his hands and knees to crawl into obscure places, his eyes, a flashlight, containers for samples, a camera, black light and assorted gadgets for the job at hand. There is nothing he can do that you can not do yourself. My experience has been that the key to a clean plant is to involve actively in the sanitation program employees with whom sanitation is something of a passion or at least a dedica-

tion rather than eight hours on the job. One of the handicaps is that operating personnel tend to scorn the broom and bucket and those who work with them. Cleanup is often regarded as a bottom of the ladder job and a new man who is any good soon gets picked off for what is considered a more responsible job and which pays more money. How often does management spend a few minutes in compliment or recognition for excellence in this field of effort?

## Key Man Must Be Well Informed

Another essential to sanitation is the gathering of facts for the information of the key man in the program. That undoubtedly involves some of you here today. Through personal observation, coupled with reliable reports from reliable in-plant inspectors someone who is at least one step removed from the operating area should know routinely what the score is in the plant.

Coupled with a knowledge of plant conditions a responsible person needs to know the nature of the raw materials being brought into the plant. At this point you can bring statistical concepts into play but I am not prepared to advise you in a subject you know better than I. The examination of raw materials for brewing quality factors is routine. The concurrent examination and sampling of incoming cars for sanitary factors and rejection of filthy materials is part of management's responsibility to the customer. It may not be possible to buy corn as pure as new fallen snow but neither is it necessary to take the worst that is offered. You may ask, why FDA concerns itself with the filth so long as the finished product is free of any evidence thereof. Our position historically has been this: if the raw material must inevitably contain some objectionable matter and a reasonable selection of the best materials is made, then the further cleaning of such raw material to remove filth is an acceptable practice. However, this contemplates the rejection of some raw materials that are so defiled as to be repugnant from a consumer's point of view and which are "beyond the pale" for human food use. Another problem with cereal is the diversion of seed grains, treated with poisonous fungicides, into food channels by blending with untreated grain. To this practice we devote a significant amount of time. The root of it is with the growers and elevator operators who have seed grain to dispose of. We do not think such blended grain is suitable for food use and take legal action whenever we can find it. Without cooperation from those who produce food products from grain our efforts are

probably not enough to effectively stop the practice. We have cooperated extensively in educational programs to improve farm care of grain, and sanitary care by the industry storing and handling grains. Again, unless there is some resistance and rejection of filthy grain by those who convert grain to food this effort yields minimal results.

## Chemist's Role Is Vital

From the point of view of modern food and drug control, sanitation goes beyond insuring freedom from that which may ruin the quality of the product or may endanger the health of people, whether the in-plant personnel or the customer. The concept and the law clearly contemplate freedom from practices and conditions which violate human decency or which may incorporate into the product the obnoxious and the repulsive even though it may not be an agent of disease. The whole area of sanitation involves some of the criteria of microbiology, entomology, sanitary engineering, chemistry, human psychology and some orderly management approach to the complete program. One of the places to find a composite understanding of the knowledge that is required is in the chemist. I can well imagine that those of you who can devote yourselves exclusively to the areas of pure and applied research are few and that many of you must apportion some of your time and talent to the more mundane considerations of basic plant sanitary control. From our point of view this also is good.

A review of the titles of the papers that have been prepared for this meeting indicate that you are active in areas that relate to production economics and yield, quality control of process and product, analytical techniques, the effects of trace substances on the process, and so forth. You might consider whether or not in such a busy schedule you could devote some time to a well-developed panel discussion or seminar on the planning and execution of the plant program of sanitation, correlation of the systematic procedures for the examination of raw materials as they come in the plant and go into the process, the human engineering problems of cultivating a sense of pride in cleanliness, and incentives and recognition for those whose jobs may be at the menial level of "cleaner-uppers."

In a few short words, we think the public is entitled to drink beer made from clean raw materials. There is not too much an FDA chemist can do with a bottle of beer to tell what sort of plant it was made in, so, we rely on the inspector to develop the facts.

## Short Weight Problem Discussed

The suggestion was made that something be said about short volume or slack fill. Two factors have been in part responsible for more activity on our part in that area: the gradual increase in our manpower resources and public opinion which is impatient with the idea of economic cheat. The usual procedure for an inspector examining packages, including bottles or cans for shortage, is to examine a representative sample made up of not less than 50 units—sometimes many more. Of these the average must be up to the declared amount. Some may be a little under and others a little over. There is no problem of natural shrinkage in an article packaged in a can or bottle. Volumes can be measured directly though it is easier to do it by weight. To approach the problem by weight is a matter of getting an adequate number of gross weights, an accurate tare and the specific gravity of the product. With that information at hand, the rest is arithmetic. The law requires that the article be up to the declared contents when in interstate commerce or when offered for such movement.

The problems of fill of container in a product such as yours are readily subject to statistical methods of control. If you use such methods you are aware of the differences between single service and returnable glass.

In brief, if the contents are declared as 12 ounces, the "overs" may be balanced out by the "unders" in a reasonable sample—provided also that the spread is within practical limits for the particular product.

## Food Additives Are Complex Topic

The subject of "food additives" is more than can be covered in any detail in a short session. As chemists it is probable that some of you are expected by management to keep up with the developments in that area. By definition, "a food additive" is any substance the intended use of which results or which may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food, and including any source of radiation intended for any such use). The definition then proceeds to exempt substances which are generally recognized as safe for the intended use by qualified experts, certain uses of pesticides on raw agricultural products and substances which

are used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment, either under the Federal Food, Drug and Cosmetic Act, Meat Inspection Act or Poultry Products Inspection Act.

As it must be with a legal definition, the problem of its application to a multitude of situations is no small task.

My experience has been that the people affected by the law are less concerned with where the legal definition begins or ends and more concerned about the practical question, does the government permit this chemical or substance to be used in or on, or with food or not, and what tolerances or limitations if any govern the use of the substance?

The other area of practical interest is that of nonfood articles intended for use in producing, manufacturing, packing, processing, transporting and holding food. Frankly, we have made slow progress in this area because of the complexity of the products involved and because it is in an area in which we have much to learn. The job of accurately identifying the many materials from which nonfood articles are prepared and expressing in regulations reasonable criteria which are characteristic of a safe, well-made article has required that much of the information needed must come from the industry. We have for many years directed our attention to the safety of substances used directly in the production of food. With nonfood articles we are concerned with the small amounts of substances which become components of food from the equipment and packaging used in preparation and distribution. The industry has been most cooperative and patient. In this area particularly the venture into regulations which prescribe safe conditions of use is cooperative, in that we are even more dependent on the industry than in the area of direct food additives for information concerning the substances used to create nonfood articles.

## Interesting Examples of Food Additives

In the "food additive" field we can consider a few examples which are of interest to you.

(a) We have expressed the opinion that compounds used for cleaning, scouring, and sanitizing food processing equipment under conditions of use where they are removed from the equipment by rinsing with potable water are not "food additives" within the meaning of the definition. Under those conditions of use by responsible people

we think the compounds cannot reasonably be expected to become a component of food.

(b) Glass as a food contact surface in bottles or equipment is exempt. It is not considered a "food additive." By virtue of its long history of safe common use we are of the opinion that it is generally recognized as safe by qualified experts.

(c) We consider enamels or lacquers used in beer cans food additives. Their composition is so complex and varied that it would be difficult to suppose that they are generally recognized as safe. We know the extractives become a component of food in small amounts. A regulation was proposed and has issued prescribing conditions which are believed adequate to insure safety.

(d) Gibberelic acid is a food additive as an adjuvant in malting barley. The practice is fairly new. We have no reason to believe it is generally recognized as safe by qualified experts. For this use of gibberelic acid a regulation prescribing safe conditions of use was proposed and has been issued.

These examples probably raise questions in your minds that could take much time to answer. The substances added to beer to produce desired physical or technical effects are likely to be "food additives" unless they fall into the categories of substances generally recognized as safe in food or are subject to some prior sanction or approval. We have received a number of petitions relating to chemicals for use by brewers, proposing that regulations issue prescribing safe conditions of use. Some regulations for the substances have been issued, others are pending. Under the Food Additives Amendment the regulations that issue are not proprietary to the petitioner but affect all who may wish to use the substance. You may recognize that this is in contrast to procedures relating to new drugs. The matter of keeping up with developments in this area may be the responsibility of a number of you, and I am sure it is of interest to chemists. The most rapid means to keep abreast of new regulations is through the *Federal Register* or trade publications. You can also have your firm put on the mailing list for all of the reprints of the orders that issue. They follow in about 30 days after the publication in the *Federal Register*.

From the definition which I quoted, you can see that the area of "food additives" covers a lot of ground. The chemicals which facilitate production and distribution by the food industry constitute a vast and complex technology. The area of nonfood articles used

in preparing, packaging, holding, transporting and storing food is a giant in itself. The work load imposed on the FDA by the amendment is greater than was anticipated.

In these rather brief remarks, I have endeavored to illustrate three aspects of our interest in the brewing industry and for that matter the food industry—the safety of the adjuvant chemicals that are used in food production, the requirement of the law for sanitary practice even as an aesthetic consideration and the matter of full measure in what is offered the consumer. **[The End]**

## TIME LIMIT FOR COMMENT EXTENDED

The Food and Drug Administration has announced a two-month extension of time for receiving public comments on proposed changes in the nation's special dietary food regulations. The extension was ordered because of requests which had been received for additional time to study proposals and prepare written comments for the record.

In announcing the 60-day extension, FDA said that some of the comments received to date indicate that a number of consumers have been misled about the purpose and contents of the proposals.

FDA said it is *not* true that a prescription would be needed to buy health foods or that "health food" stores would be put out of business; that consumers would be unable to buy natural foods or vitamins from natural sources, or that sellers would be unable to make truthful statements about inherent dietary properties, such as the Vitamin C content of orange juice.

It is also *not* true, FDA said, that the proposed change from the present term "minimum daily requirement" to "daily requirement" would put a ceiling on the nutritive value of special dietary foods. This change was proposed to discourage the addition of needlessly large amounts of vitamins and minerals to food supplements simply as a sales promotion device.

FDA said the proposed changes would prevent consumers from being misled by a listing of ingredients which have no value as food supplements. Such "shotgun" formulas now contain as many as 50 to 75 ingredients, only a few of which are recognized as essential in human nutrition. Such a listing may mislead the purchasers into selecting the product simply on the basis of a large number of listed ingredients of which many or most are of no value.

The proposed regulations are also directed at false or misleading labeling which may lead consumers to believe that the average American diet results in ill health and that nutritional supplements are required to prevent or cure this, FDA said.

Some consumers have called for a public hearing. Under existing procedures, the first step is to invite views and comments from all concerned, FDA pointed out. After the new date for receiving these comments—October 18—consideration will be given to all communications received by the Department of Health, Education and Welfare Hearing Clerk.

A COMMERCE CLEARING HOUSE PUBLICATION