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Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the Twenty-first Annual Meeting of the New York Bar Association Section on Food, Drug and Cosmetic Law

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

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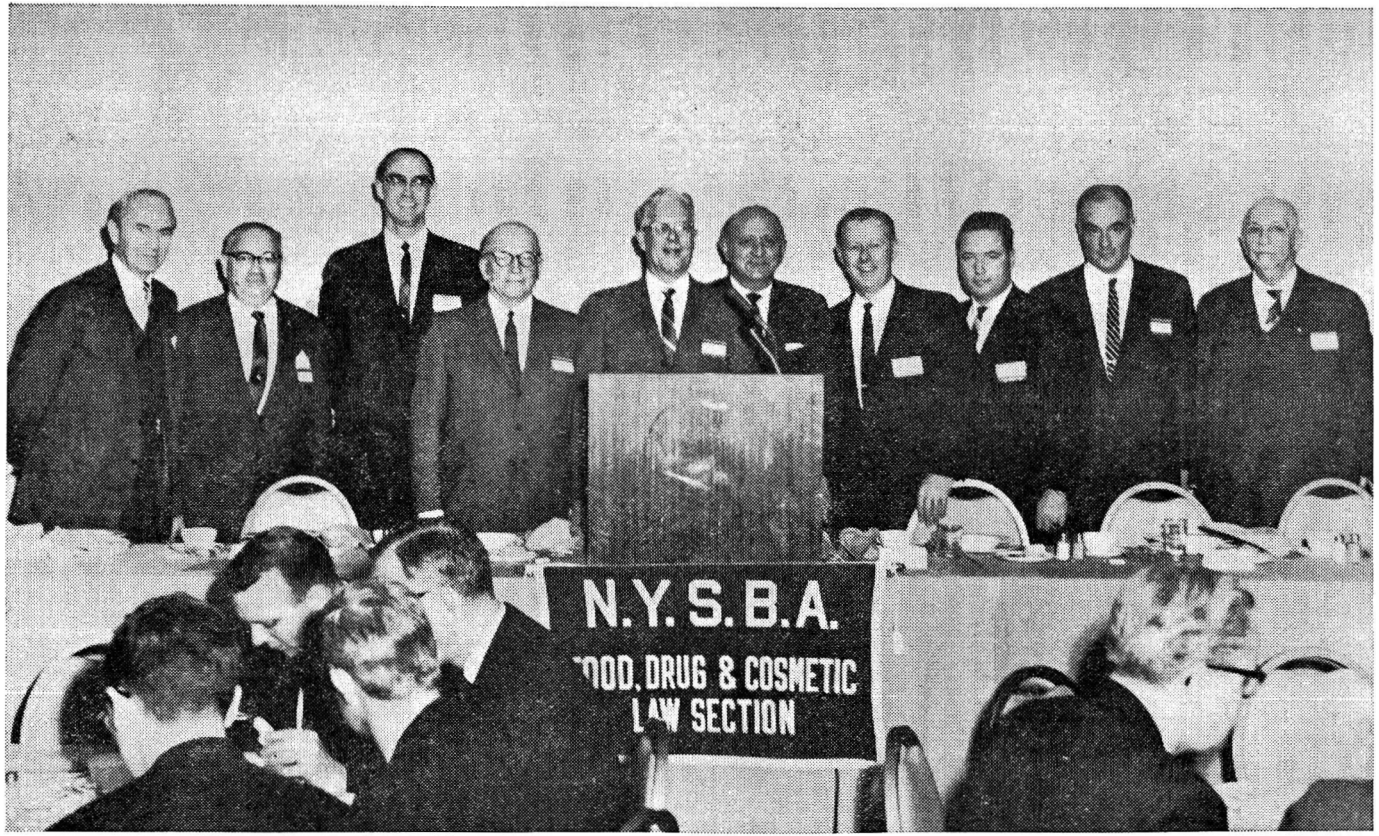
"Uniformity—A Legislator's Viewpoint" is the topic of the article beginning on page 145. *George M. Burditt,* a member of the Illinois legislature and a partner in Chadwell, Keck, Kayser, Ruggles & McLaren, Chicago, Illinois, relates how the state of Illinois achieved a degree of uniformity by the passage of the Model Food Act and how an interim Illinois legislative commission is now working in this same area of uniformity.

On page 154, the article, "Product Liability—1965," commences. *William J. Condon,* a New York attorney for Swift and Company and the author of this article, discusses four product liability cases in which the common element is the lack of evidence as to the nature of the exact defect in the defendant's product. At the end of his article, *Mr. Condon* has compiled a list of product liability cases for 1965.

"Current Problems in Food and Drug Advertising" is the topic of the paper by *James R. Dougherty,* the assistant attorney in charge, New York office, Federal Trade Commission. Beginning on page 161, the article relates three cases from the field of food and drug advertising and the significant decisions that resulted from them. *Mr. Dougherty* goes on to suggest a few principles that may be useful in determining the legality of advertising.

Third Session of the Joint FAO/WHO Codex Alimentarius Commission.—*Franklin M. Depew,* President of the Food Law Institute, reports on the third session of the Codex Alimentarius Commission held at Rome, Italy, Headquarters of the Food and Agriculture Organization, October 19-29, 1965. Included is a summary of the reports made by the different Codex Committees. The outstanding feature of this session, *Mr. Depew* believes, was the spirit of cooperation that existed between the delegates, making possible the successful establishment of food standards. The report begins on page 168.

The President's Message on Consumer Interest.—Excerpts from President Johnson's message to Congress on consumer interests begins on page 179. The President's recommendations on March 21, 1966 included three items of legislation to strengthen consumer protection. He called for legislation to protect children from danger caused by inadequate labeling and packaging of harmful substances, to protect the consumer by requiring more precise and detailed labeling of drugs, especially those drugs whose potency and purity is limited, and to broaden Federal-state-local cooperation in the field of food and drugs by giving Federal assistance to state and local communities. President Johnson also pledged to examine the laws dealing with cosmetics and medical devices and to revitalize the Food and Drug Administration.



Annual Meeting of Food Drug Cosmetic Law Section, New York State Bar Association, Feb. 1, 1966, New York Hilton Hotel. Left to right: James F. Hoge, Dr. Bernard L. Oser, George M. Burditt, Edgar J. Forio. Franklin M. Depew. A. M. Gilbert, William J. Condon, Murray D. Sayer, Peter Borie, Harold Harper.

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Food·Drug·Cosmetic Law Journal

Current Good Manufacturing Practice

By CORNELIUS D. CROWLEY

Mr. Crowley Is a Member of the New York Bar. This Article and the Following Three Were Presented at The Twenty-first Annual Meeting of The Section on Food, Drug & Cosmetic Law of The New York State Bar Association. Other Papers Delivered at This Meeting Appeared in the February Issue.

MANUFACTURING PRACTICE, I am sure, will seem to some to be a topic more appropriate to a meeting of the scientific sections of various drug associations than to a meeting of lawyers. However, the Drug Amendments Act of 1962 and Regulations issued under it, have made it most appropriate that we, as lawyers, examine this evolving field with a view to understanding where we are and where we are likely to go from here.

Statutory Provisions

Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act [1] which contains the "current good manufacturing practice" provisions was not a major battleground in the Kefauver Investigation or the legislation which developed from it. Despite the clarity of the language of the statute and the equally clear legislative history, re-

[1] "Sec. 501. A drug or device shall be deemed adulterated—(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess."

cent regulations of the Food and Drug Administration (FDA) seem to go well beyond the authority granted by Congress.

Section 501(a)(2)(B) as it read in the final enactment as signed by the President in 1962, added a new concept of product adulteration to the law. If the manufacturing, processing, packaging or equipment used in the preparation of the product do not conform to "current good manufacturing practice" to assure that the drug is safe and efficacious, the product is deemed adulterated. Neither S. 1552, as originally introduced by Senator Kefauver, nor its counterpart H. R. 6245, introduced by Congressman Celler, contained any provision comparable to that in the bill as finally enacted. Both, as first introduced, contained a provision for licensing of prescription drug manufacturers in a new Section 508 to the Food, Drug and Cosmetic Act. Subsection (b) of that section required that any establishment in which a drug was to be manufactured or processed, fulfill the requirements of such standards as the Secretary of Health, Education, and Welfare deemed necessary to insure safety and efficacy.[2]

Changes in the Proposed Legislation

This section underwent several changes as the legislation wound its way through each of the houses of Congress to ultimately evolve as Section 501(a)(2)(B).[3]

The Senate's Antitrust and Monopoly Subcommittee amended the entire section to substitute registration for licensing, and in lieu of the provision authorizing the Secretary to set standards for establishments manufacturing prescription drugs, it inserted a provision authorizing the Secretary to promulgate regulations prescribing qualifications for personnel, detailed standards for plants and plant inspection.[4]

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[2] (b) No license may be granted under this section to any person for the manufacture, preparation, or propagation of any such drug unless the applicant therefor demonstrates that the establishment in which that drug is to be manufactured, prepared, or propagated fulfills the requirements of such standards as the Secretary shall determine to be necessary to insure the continued chemical structure, strength, quality, purity, safety, and efficacy of such drug. Whenever the Secretary determines that any establishment in which any drug manufactured, prepared, or propagated under any license issued under this section no longer fulfills those requirements, he shall revoke that license, or at his election suspend that license until he has determined that those requirements have been met." (S. 1552 and H. R. 6245, Section 508(b) as introduced).

[3] See footnote 1.

[4] (b) The Secretary shall promulgate regulations prescribing the qualifications required for the manufacture, preparation, or propagation of drugs, and regulations prescribing for any plant, facility, or establishment engaged in the manufacture, preparation, or propagation of any drug or class of drugs such standards and require-

(*Continued on next page.*)

The Senate Judiciary Committee, in turn, recommended extensive further amendments to the bill and introduced for the first time in the Senate version the concept of drug adulteration. The Committee's report of July 19, 1962 suggested amendments which changed the impact of the provision from prescription drugs to all drugs and covered methods, facilities and controls used in manufacture, processing and packaging.[5]

Senator Kefauver and the other members who joined in the Minority Report of the Committee considered the revised current good manufacturing practice provisions as ones which coupled with registration requirements, inspection provisions and generic name labeling requirements, strengthened the economic purpose for the bill and could be expected to induce physicians to prescribe generically. The "current good manufacturing practice" provisions, the minority thought, would give physicians greater confidence that under generic prescribing, the patient would receive drugs of "adequate and acceptable quality."[6] It must be remembered that S. 1552 was introduced by Senator Kefauver as an economic rather than a health measure. In this context of an economic measure, it seems clear that

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(*Footnote* 4 *continued.*)
ments as he shall determine to be necessary (1) to insure the continued chemical structure, strength, quality, purity, safety, and efficacy of such drug or class of drugs, and (2) to provide for adequate inspection of such plants, facilities, and establishments. Such regulations shall include, but are not limited to, provisions relating to: the adequacy of any commercial testing laboratories which perform assays or other laboratory services related to the manufacture, preparation, or propagation of any drug or drugs; plant sanitation; raw materials used and analytical reports on such materials; formula cards and actual manufacturing working sheets; batch records; weighing and measuring controls; coding systems; facilities for maintaining separate identity for each drug; cleaning of equipment between batches; quarantine of drugs until after clearance with the control laboratory; and, the complaint file of the establishment. Any officer, agent, or employee of the Department, authorized by the Secretary for that purpose, may, during all reasonable hours, enter and inspect any plant, facility, or establishment (including warehouses, laboratories, other premises, vehicles and all records and pertinent equipment used in connection therewith) operated, or to be operated within any State by any registrant or any applicant for a registration under this section for the manufacture, preparation, or propagation of any drug." (S. 1552, Section 508(b) as approved by the Antitrust and Monopoly Subcommittee).

[5] "(B) if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packaging, or holding do not conform to current good manufacturing practice to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess." (S. Rept. No. 1744, 87th Cong. 2nd Sess. July 19, 1962, pg. 3-4).

[6] S. Rept. No. 1744, 87th Cong. 2nd Sess. July 19, 1962 (Minority Rept.) pg. 35.

the changes made by the Senate Judiciary Committee were designed to assure that the drug manufacturing techniques of the less efficient operators would be brought up to the standards then practiced by more reputable members of the industry.

The Senate Judiciary Committee version also added the words:

> The Secretary is authorized to issue interpretive regulations, upon notice and in accordance with the procedures set forth in Section 4 of the Administrative Procedure Act (5 USC 1003), which shall in any proceeding involving this paragraph, be prima facie evidence of what constitutes current good manufacturing practice.[7]

On August 3, 1962, President Kennedy suggested to the Judiciary Committee that these regulatory provisions be changed to provide to the Secretary the authority to issue substantive regulations on the basis of good manufacturing practice after hearing and judicial review. The Senate refused to accept the President's suggested revision. It did drop from the bill all references to regulations. The action was taken on the basis that Section 701(a) of the Act already contained sufficient authority to promulgate regulations for enforcement of the Act.[8]

Thus, the Senate passed S. 1552 with the language of Section 501(a)(2)(B) identical to the language now found in the Act.

In presenting the final version of the bill to the Senate on August 23, 1962; Senator Eastland (Chairman of the Judiciary Committee) explained the current good manufacturing provision. He said:

> Section 5 as it would read under the August 20 amendments is designed to assure that drugs are manufactured according to good manufacturing practices. It would deem a drug to be adulterated and thus subject to seizure if made under facilities, methods or controls that are inadequate to assure that the drug meets the *specifications of a quality product.*[9] (Emphasis added).

While S. 1552 was proceeding through hearings, arguments and debates in the Senate, H. R. 11581 was introduced in the House by Congressman Harris. In contrast to S. 1552, H. R. 11581 was never designed as an economic measure. It was clearly a public health bill from its conception. It was sponsored by the FDA and in the initial version provided that a drug would be deemed adulterated

> if it is a drug and the methods used in, or the facilities or personnel or controls used for, its manufacture, processing, packing, or holding were inadequate (as determined in accordance with regulations promulgated by the Secretary on the basis of good manufacturing practice) [10]

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[7] S. Rept. No. 1744, 87th Cong. 2nd Sess. July 19, 1962, pg. 4.

[8] S. Rept. No. 1744, Pt. 2, 87th Cong. 2nd Sess. August 21, 1962, pg. 3.

[9] Cong. Rec. August 23, 1952, pg. 16304.

[10] H. R. 11581, Sec. 101(a)(B), as introduced.

It should be noted that the word "current" does not appear in connection with good manufacturing practice in this language. The provision applied to all drugs and the regulatory power contemplated would seem to be substantive regulations requiring formal procedures under Section 701(e) before promulgation.

The bill was amended by the House Committee on Interstate and Foreign Commerce to add the word "current." [11] Congressman Schenck in explaining this amendment on the floor of the House said:

> The purpose of this provision is to enable the Secretary to require all companies producing drugs to observe the high standards that are now followed by the better manufacturer.[12]

The bill's regulatory provisions were eliminated on amendment suggested on the floor of the House by Congressman Schenck without explanation other than that it was not needed to tie this provision in with Section 701(e).[13]

The Conference Report and subsequent procedures in the Senate and House shed no further light on Section 501(a)(2)(B).

Congressional Intent

Where does all of this leave us? I submit that it is clear from the addition of the concept "current" to the bill in each House, and the rejection on several occasions of proposals that the Secretary be given the right to promulgate regulations establishing good manufacturing practice, that Congress intended the existing practice, which resulted in quality products, be required of all who manufactured drugs. The record cannot be tortured to provide authority for administrative promulgation of substantive regulations imposing standards for manufacturing practice not at the time followed in the industry.

Regulations

The first regulations issued under the new law were published in the *Federal Register* for comment on February 14, 1963.[14] It, of course, is not necessary in connection with interpretive regulations under Section 701(a) to request comments. The opportunity was gratefully accepted and acted upon. The final regulations, somewhat modified from their original form, were promulgated June 20, 1963.[15]

[11] H. Rept. 2464 September 22, 1962, pg. 7, 33.

[12] Cong. Rec. September 27, 1962, pg. 19895.

[13] Cong. Rec. September 27, 1962, pg. 19916.

[14] *Federal Register,* February 14, 1963, pg. 1495.

[15] *Federal Register,* June 20, 1963.

For the most part, these initial regulations caused no major problems for the pharmaceutical industry, since they were generally consistent with the Pharmaceutical Manufacturers Association's Statement of Principles of Control of Quality adhered to by many companies for years before the regulations were issued.

In this instance, the FDA adopted for the most part the existing practice of the better manufacturers and required that it be followed by all.

Cross-Contamination of Drugs

The next major promulgation appeared in the *Federal Register* of January 29, 1965. This time the field covered was control of cross-contamination of other drugs by penicillin. No opportunity to comment was provided this time. The regulations provided:

> Notice and public procedure and delayed effective date are not necessary prerequisites to the promulgation of this Order, and I so find, since the amendments are interpretive and since it would be contrary to public interest to delay the institution of measures to control inadvertent contamination of other drugs with Penicillin.[16]

Certainly, no reputable manufacturer would or could take the position that it should be free to contaminate its products with penicillin. However, the regulations stated to be interpretive and promulgated under Section 701(a), set maximum tolerances for penicillin permissible in parenteral and oral doses of drugs and provided for recall if such maxima were exceeded. At the time of promulgation of these regulations, the methods of assay for many drugs were not sufficiently sensitive to accurately determine the presence of such minute traces of penicillin. As a matter of fact, it is even today questionable whether assay methods for some drugs are sufficiently accurate to determine such limited tolerances. The FDA application of such standards was certainly not the imposition of the current manufacturing standards.

Obviously, this is not the type of issue which ever will or should be brought to litigation. One can only wonder, since the problem to be corrected was one which has certainly existed since the introduction of penicillin over twenty years ago, why industry comments or suggestions were not sought before issuance of the regulations in final form. This is particularly so in view of the statement elsewhere in the regulations to the effect that:

> The Commissioner, in cooperation with the pharmaceutical industry will continue to study the Penicillin cross-contamination problem, looking forward

[16] *Federal Register,* January 29, 1965, pg. 932, 933.

towards the development and adoption of manufacturing practices designed to further reduce such contamination.[17]

More Regulations?

As one looks to the future, there appears on the horizon, perhaps not too distant, a broad field for potential new "current good manufacturing practice" regulations. Are the penicillin cross-contamination regulations the opening gun in a procedure to be followed in regard to other drugs?

It has already been suggested by inspectors at drug plants that cross-contamination of one drug with another could be prevented by restricting pieces of all needed equipment and machinery to use for a single drug product. Drug plants of the future will be something to see if that theory ever takes hold. Where will all the land required and all the machinery needed come from, to say nothing of how will the consumer be able to afford to buy the drugs they produce? Stringent equipment cleaning procedures are already followed under "current good manufacturing practice." There have been public suggestions of zero tolerances and implication that white room techniques may soon be imposed upon the industry. Such techniques are not current practice in the pharmaceutical industry. Indeed, only N. A. S. A., with the unlimited financial resources of the United States to draw upon, could afford such greatly to be desired perfection.

As with penicillin cross-contamination, there, undoubtedly, will be highly respected scientific panels to recommend each new practice as it is promulgated, but it must be remembered that such panels are examining the advisability of the standards they recommend and not the question of whether what they advise are "current" practice.

Certainly, there is no doubt at all that the FDA should not be impeded in protecting the public health by picayune legalistic arguments. However, the Administration before it embarks on the issuance of new and costly requirements should be totally satisfied that the improvement it seeks is substantial and that industry is currently geared to accept it or can reasonably be expected to comply without incurring such increased costs as to cause harm to the public health greater than the improvement it seeks. It is not unreasonable to believe that such considerations, at least in part, motivated Congress to refuse to grant to the Secretary of Health, Education, and Welfare the right to issue substantive regulations in this field and confined

[17] See footnote 16.

the regulatory authority to the universal imposition of the best standards currently used in the industry.

Dr. Earl L. Meyers, Chief of Manufacturing Controls Branch, Division of New Drugs, Bureau of Medicine, FDA, has said:

> The best interpretation and enforcement of law is obtained when there is clear understanding and cooperation between Food and Drug officials and the pharmaceutical industry.[18]

To this, I am sure, the representatives of the drug industry would say in chorus "Amen!" **[The End]**

DOCTORS SADUSK AND PISANI RESIGN FROM FDA

Dr. Joseph F. Sadusk, Jr. and Dr. Joseph M. Pisani have resigned from their posts in the Food and Drug Administration. Dr. Sadusk has held the position of medical director of FDA and Dr. Pisani has been the deputy medical director. Dr. Robert J. Robinson has been appointed acting director of the Bureau of Medicine. He has been head of the Drug Surveillance Branch.

DRUG MAKERS NOT LIABLE SOLELY ON PROOF OF INJURY

According to the Texas Court of Civil Appeals and the Oregon Supreme Court, proof of injury is not a sufficient reason for a drug to be considered legally defective.

In the Texas case, a user of a drug who developed cataracts was denied recovery against the manufacturer in an action tried on the theories of negligence and breach of implied warranty. It was found by the jury that the drug was not unmerchantable or unfit for its intended use, that the cataracts resulted from an "abreaction" or sensitivity to the drug and that at the time of the injury, medical knowledge did not anticipate cataracts to result from the ordinary use of the drug. *Cudmore v. Richardson-Merrell Inc.*, Texas Court of Civil Appeals, Dallas, Texas. CCH PRODUCTS LIABILITY REPORTS ¶ 5503.

In the Oregon case, it was found that a drug manufacturer was not liable to a user, an arthritis sufferer, who lost her vision due to an idiosyncrasy which caused her to be susceptible to this uncommon reaction. The court found that there was not sufficient evidence to show the drug contained any impurities, and that the drug was reasonably safe for use in treating arthritis. The court rejected the plaintiff's contention that absolute liability should be imposed upon the maker of a product that can result in blindness. *Cochran v. Brooke,* Supreme Court of Oregon, CCH PRODUCTS LIABILITY REPORTS ¶ 5504.

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[18] Excerpt from a speech delivered at the Seminar on Control Procedures of Drug Procedures at the University of Wisconsin in August, 1965.

Uniformity— A Legislator's Viewpoint

By GEORGE M. BURDITT

Mr. Burditt Is a Member of the Illinois Legislature and a Partner in Chadwell, Keck, Kayser, Ruggles & McLaren, Chicago, Illinois.

SO MANY PAPERS HAVE BEEN WRITTEN in recent years on the subject of uniformity, some important[1] and some unimportant,[2] that a new twist to this subject is a little hard to find. As a matter of fact, it took a veto by the Governor of Illinois of a reapportionment bill passed in 1963, a deadlock in a Constitutional Reapportionment Commission, a special session of the Illinois Legislature at which rules for an election-at-large of the Illinois House of Representatives were adopted, a Republican convention called for the purpose of nominating candidates, and an election in which all 177 members of the Illinois House of Representatives were elected from one three-foot long bright orange ballot containing 236 names, to give me the opportunity to speak on uniformity with a new twist. The new twist, of course, is how this business of uniformity looks to a legislator.

I would like to review with you how we were able to achieve at least a certain degree of uniformity in Illinois by passage of the Model Food Act, and then also to discuss an interim Illinois legislative commission which is currently working in this same area.

The Uniform Food Act

Illinois, until 1965, was one of those states which had not adopted the food provisions of the Model State Food, Drug and Cosmetic Act,[3]

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[1] See footnote at end of article.

[2] Burditt, George M., "Weights & Measures, Foods & Drugs and Uniformity," *Quarterly Bulletin, Assn. of Food and Drug Officials of the United States,* Vol. 28, No. 4, October 1964, pp. 189-99;

Burditt, George M., "Recent Developments in the Field of Weights and Measures Labeling," FOOD DRUG COSMETIC LAW JOURNAL, Vol. 19, No. 5, May 1964, pp. 279-89.

[3] CCH FOOD DRUG COSMETIC LAW REPORTS, ¶ 10,100 et seq.

although the drug, device and cosmetic provisions were adopted substantially verbatim in 1959.[4] As a matter of fact, much of the Illinois food law was based on the 1906 Federal Act,[5] and substantial portions of the food law went back into the 19th century.[6] From the point of view of a legislator, therefore, Illinois was ripe for modernization—and of course for uniformity.

We had one other factor which, although technically irrelevant, helped prepare the legislative soil for the seed of uniformity. A state Senate commission under the very able chairmanship of Senator Harris Fawell (R., Naperville) had made a number of major recommendations for transferring the functions of food law enforcement from the state Department of Agriculture, where the appointment of inspectors depended on political patronage, to the Department of Public Health, which is a merit system department. You can be sure that this transfer was not welcomed with open arms in all circles, but the Senate commission's investigation, which was strongly supported by the Chicago Tribune, had uncovered enough problems to warrant the transfer in the opinion of most observers. While uniformity could have been just as easily achieved under the Department of Agriculture, the bipartisan Senate commission agreed to adopt the food provisions of the Model Act as the first bill in their package of legislation on condition that enforcement be vested in the Department of Public Health. Accordingly, after a great deal of preliminary work, 21 bills were finally introduced in the Illinois Senate on May 26, 1965, with bipartisan sponsorship, including the President *pro tem* and the Leaders and Whips of both parties.[7] Identical bills were introduced in the House substantially simultaneously.[8]

In Illinois every bill must be read three times—on three different days—in each house. This requirement, plus the normal procedure

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[4] An act defining and relating to drugs, devices and cosmetics, to make uniform the law with reference thereto, etc., July 9, 1959 (Ch. 111-1/2 IRS § 401 et seq.)

[5] An act to prevent fraud, etc., May 14, 1907 (Ch. 56-1/2 IRS 1963 § 1 et seq.)

[6] An act to regulate the sale of milk, etc., May 29, 1879 (Ch. 56-1/2 IRS § 100.1-100.6);

An act to prevent frauds in the manufacture and sale of butter and cheese, May 31, 1879 (Ch. 56-1/2 IRS § 100.7-100.9a);

An act to prevent the adulteration of butter and cheese, etc., June 1, 1881 (Ch. 56-1/2 IRS § 100.10-100.10a);

An act to prevent and punish the adulteration of articles of food, drink and medicine, etc., June 1, 1881 (Ch. 56-1/2 IRS § 100.11-100.17);

An act to prevent the adulteration of vinegar, etc., June 14, 1883 (Ch. 56-1/2 IRS § 100.18-100.20).

[7] Senate Bills 1170-1189 and 1200, 74th Illinois General Assembly.

[8] House Bills 2118-2139, 74th Illinois General Assembly.

of referring bills to committee in each house, which can take anywhere from a few days to a few months, precludes hasty passage without adequate consideration, but it also can be a mountainous hurdle for good legislation. Our Senate, incidentally, was 33-24 Republican, and our House was 118-59 Democratic, so bipartisan cooperation was essential if the food bills were to have any chance of passage. Since we were faced with a June 30th compulsory adjournment, and since we had literally hundreds of bills still to consider in both houses, time was becoming a crucial factor. The Senate bills were referred to the Senate Committee on Public Welfare and were all recommended "do pass" on June 8th.

Meanwhile, the forces which were opposed to the bills were gathering strength. Because of the necessity for bipartisan cooperation, numerous conferences were held to discuss the bills in detail. These conferences resulted in a compromise under which those bills which would have transferred enforcement over meat products from Agriculture to Public Health were to be tabled and the other bills passed. Accordingly, those bills which related to locker plants,[9] immature veal,[10] display and advertising of meat and meat products,[11] and refrigerated warehouses[12] were tabled, and the remainder of the bills, with amendments, passed the Senate without dissenting vote on June 14th and were sent to the House on the following day. There were 12 legislative days left in the session.

In the House, both sets of bills were referred to the Executive Committee and were recommended "do pass" by that Committee on June 22nd and 23rd, with some disturbing dissenting votes. There were six legislative days left, and the Democratic leadership of the House, with its two-to-one Democratic majority, was undecided and uncommitted.

By Monday, June 28th, with only three legislative days left, there were not sufficient days left to pass the House bills in the House and send them to the Senate, because of the three-readings requirement. Nevertheless, it was important to know where we stood on the bills, so we called the House bills for a vote. 89 votes, a majority of the 177 member House, are required for passage. After substantial debate, the bills received 84 votes for and 46 against, thus failing to pass by five votes. Since all but one Republican had voted for the

[9] Senate Bill 1179, 74th Illinois General Assembly.

[10] Senate Bill 1181, 74th Illinois General Assembly.

[11] Senate Bill 1183, 74th Illinois General Assembly.

[12] Senate Bill 1189, 74th Illinois General Assembly.

bills, we knew where our trouble lay. The Speaker, Majority Leader and Majority Whip, and of course many of their followers, did not vote.

The Senate bills meanwhile had been through the first and second readings in the House and were waiting to be called for a final vote on third reading, with two legislative days left. And the last two days in a legislative session, as you know, are perhaps not the best time to consider what had obviously become, by this time, controversial legislation. It was, therefore, with some regret, more uncertainty, and a great deal of trepidation, that I asked the Speaker to call the Senate bills on June 29th, the day before final adjournment.

The vote on the uniform bill was 129-32. The hours we had spent in meetings explaining the bills in detail, particularly the desirability of uniformity and modernization of the basic food law had borne fruit. The Speaker, Majority Leader, Majority Whip and even that lone Republican dissenter of the previous day, all voted in the affirmative. The Senate concurred in several House amendments on the same day.

So Illinois now has the Uniform Food, Drug and Cosmetic Act, although the food provisions are in one chapter enforced by the Department of Public Health,[13] and the drug, device and cosmetic provisions are in another chapter enforced by the Department of Public Safety.[14] The price of uniformity was a little blood, sweat and tears, and a very substantial bipartisan cooperation in the House with a tremendous assist from our colleagues in the Senate.

The Food, Drug, Cosmetic and Pesticide Laws Study Commission

But our job is not complete. An interim legislative commission, called the Food, Drug, Cosmetic and Pesticide Laws Study Commission was created in 1965[15] and is currently working to "make a thorough study of the laws and decisions of this State which pertain to food, drugs, cosmetics and pesticides and the enforcement thereof." The Governor vetoed the appropriation of the Commission, but made amends at least in part by appointing five outstanding public members to the Commission. Three of the public members are lawyers—Harvey L. Hensel of the Swift Law Department, who is an expert on this question of uniformity in food and weights and measures laws, Esther Kegan, a Chicago attorney whom many of you know as an expert in food law, and Richard W. Kasperson of the Abbott Law

[13] Ch. 56-1/2 IRS § 401 et seq.
[14] Ch. 111-1/2 IRS § 401 et seq.
[15] House Bill 984, 74th Illinois General Assembly.

Department, a drug law specialist. The other two public members are also specialists, Dr. Howard B. Petty, of the University of Illinois, one of our state's leading entomologists and a pesticides expert, and Dr. J. B. Stine of Kraft, a dairy technologist, who, among other things, is a member of the United States delegation to the Codex Alimentarius Commission. We also have five Senators and five Representatives, one of whom, Rep. Calvin Smith (D., Chicago) is a pharmacist, on the Commission. Rep. Adlai E. Stevenson, III (D., Chicago) who was a great help in those closing days of the session in securing passage of the uniform act, is vice chairman of the Commission, and I have the privilege of serving as chairman.

The Commission, I am hopeful, can be of great assistance in recommending additional legislation, both procedural and substantive, designed to promote uniformity. Let me suggest a few areas which we are considering:

1. Uniformity between Illinois and federal standards of identity

Most of us who are food and drug attorneys have at one time or another had a problem involving differences between federal and state standards of identity. One solution which has been successful in many states is a state statute automatically recognizing federal standards in one of several different ways. These may take the form of a mandate to an administrative agency to promptly promulgate from time to time such standards as are promulgated by the Federal Food and Drug Administration (FDA),[16] authorization to a state agency to adopt such standards as it deems advisable as long as they are not inconsistent with federal standards applicable to the same products,[17] authorization to a state agency to short-cut the standard-making process by accepting such federal standards as it wishes to adopt,[18] authorization to a state agency to adopt federal standards "insofar as practicable," [19] adoption of federal standards in effect at

[16] "Whenever any definitions or standards of identity . . . for any food . . . are promulgated under authority of the Federal Act . . . the state Board shall promptly promulgate said definitions and standards for Indiana." Burns Ind. Stat. ch. 31, § 35-3201 (1964).

[17] "Such standards . . . shall conform to the standards . . . if any, of purity or quality or identity adopted or that may hereafter be adopted for the enforcement of the Federal Food, Drug and Cosmetic Act, . . ." Gen'l Laws Mass. tit. XV, ch. 94, § 192 (1932, as amended).

[18] ". . . Except in cases where definitions or standards otherwise are prescribed by law, they [federal standards] may be accepted by the commissioner and if accepted, published as definitions or standards for Minnesota." 1 Minn. Stat. ch. 31, § 31.10 (1961).

[19] "The Commissioner is hereby authorized (1) to adopt, in so far as

(Continued on next page.)

the time the state law was enacted,[20] or adoption of federal standards promulgated prior to or after the passage of the state law.[21]

Obviously, the last of these is preferable from the point of view of perpetual uniformity, and if we have no Constitutional obstacles,[22] perhaps we can recommend such a statute to the 75th General Assembly which convenes in 1967.

On this subject of federal and state standards, there is one further point I would like to make. The federal government, it seems to me is uniquely qualified to promulgate a definition and standard of identity, taking into consideration a multitude of factors—geography, history, science, home economics, and other classical high school subjects—which a particular state may not be able to consider for technical, practical or other reasons. Should we not then continue to urge the *drafting* of standards of identity on a federal basis? But from this premise it does not follow that the *enforcement* of standards must be left to the federal government. Indeed in many respects, a state may be better equipped to enforce a standard than is the federal government. An inspector or a laboratory technician can just as easily determine whether a product and its labeling comply with a standard if he works for a state as he can if he works for the federal government. And state enforcement remedies are generally faster and more effective than the enforcement remedies provided in the Federal Act. Those of us who are interested in protecting states rights and in stemming the tide of power which is perpetually flowing to Washington could find a great deal of solace in *enforcement by state officials* of standards *promulgated by federal officials.* Perhaps our Commission can further this theory by recommending legislation which will strengthen Illinois's enforcement of federal standards adopted in Illinois by reference.

(Footnote 19 continued.)
practicable, the regulations fixing and establishing definitions and standards of identity . . . for foods or food products from time to time promulgated under the federal act . . . ." N. Y. Consol. Laws art. 17, § 214-6 (1964).

[20] "The definitions and standards for foods or classes of foods promulgated under the authority of the federal act as of the effective date of this act are hereby adopted as the definitions, standards of identity, standards of quality or fill of containers in the State of Nebraska." Nebraska Food Act § 9 (1965).

[21] "[Subject to exceptions] the standards of quality, purity and strength prescribed by regulations lawfully adopted from time to time by the Food and Drug Administration of the Department of Health, Education and Welfare are hereby declared to be the standards of quality, purity and strength for such foods and drugs in the State of Maryland . . . ." Md. Ann. Code art. 43, § 192 (1957, Supp. 1959).

[22] Christopher, Thomas W., "May A State Adopt Prospective Federal Regulations?" Food Drug Cosmetic Law Journal, Vol. 15, No. 6, June 1960, pp. 373-81.

2. Uniformity between Illinois and federal pesticide laws

A second subject which our Commission will study is uniformity between Illinois and federal pesticide laws. Here again the theory which I have just expounded makes sense. The federal government is obviously better equipped to establish tolerances for pesticides on all foodstuffs, without the hampering effect of local prejudice for or against a particular tolerance level for a particular pesticide on a particular raw agricultural commodity and foods made from it. But here again an analyst can check foods for residues in a state laboratory just as easily as in a federal laboratory. The states will have to provide adequate staff and facilities, which means more money on a state level, but it should also mean less money on a federal level. And here again state enforcement remedies against offending products can be quicker and more effective than federal remedies.

3. Uniformity between Illinois and federal drug laws

A third area for our Commission's consideration is uniformity between state and federal drug laws. The comments which I have made concerning food standards and pesticide residues are in general equally applicable to drug laws.

4. Uniformity between Illinois and other states weights and measures laws

A fourth area is uniformity between Illinois and other states weights and measures laws. Harvey Hensel of our Commission is also vice chairman of the Industry Committee on Weights and Measures and is speaking on this important subject at the National Conference on Weights and Measures in Denver next July. Among other things, our Commission will consider whether it is appropriate for Illinois to attempt to deal with "free" offers and "cents-off" promotions through its weights and measures regulations. No other state, to the best of our knowledge, is attempting to do so, and if necessary, we may recommend legislation to assure Illinois' uniformity with other states in this regard.

5. Uniformity among Illinois, federal and other states cosmetics laws

A fifth area for our consideration will be uniformity among Illinois, federal and other states cosmetic laws. This is also of course closely related to our food and drug considerations.

6. Improvements in the Model Food, Drug and Cosmetic Act and Model Weights and Measures Act

A final area for our consideration must be improvements in the model acts already in effect in Illinois, including the Model Food, Drug

and Cosmetic Act recommended by the Association of Food and Drug Officials of the United States (AFDOUS), the Model Weights and Measures Act recommended by the National Conference on Weights and Measures, and the Uniform Hazardous Substances Labeling Act. Changes in the model acts do not *prima facie* promote uniformity and you may question the advisability of our considering such changes. But very few written documents can remain uniform in our modern society unless they are continually reviewed for possible changes which render them better able to cope with changed circumstances. The philosophy that no change should be made would have prevented passage of the 1938 Act, the food additives amendment, the various drug amendments, and all of the other beneficial amendments to the federal act. So flexibility is necessary, whether or not we may like it for the moment, if we are to preserve our fundamental institutions. Just as a rigid building will fall in an earthquake where a flexible structure remains standing, so must our legal structure be flexible in order to withstand the shocks of advancing technology. With industries which are advancing as phenomenally as the food, drug, cosmetic and pesticide industries, we must be prepared to consider and recommend desirable changes in our legal structure governing those industries. If our Commission finds flaws in the structure, we hope to recommend repairs by the Illinois General Assembly, and of course by AFDOUS and the National Conference on Weights and Measures. One such flaw in the model law, and hence in the Illinois law, is the omission of authority to grant temporary permits to deviate from standards of identity. An amendment authorizing such permits, or better yet rendering effective in the state a temporary permit granted by FDA, appears to be highly desirable.

Other coral reefs in this sea of uniformity may be visible to you. If they are, I hope you will feel free to chart them for our Commission before we make our final recommendations in January 1967. We have a unique opportunity to promote uniformity and we need and solicit your assistance, either by letter or by oral testimony at a Commission hearing.

Uniformity, from a legislator's point of view, is perhaps not as per se a desirable goal as it is from a food and drug lawyer's point of view. But even a legislator can see its great advantages to his constituents, his industry and his state officials. It is a salable commodity because it is beneficial to all three of the interests involved in the promulgation and enforcement of food, drug and cosmetic laws—

consumers, industry and officials—and I am deeply grateful to the voters of Illinois for the opportunity they have given me to participate in a program designed to promote uniformity in Illinois.

[The End]

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Product Liability—1965

By WILLIAM J. CONDON

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THIS PAPER WILL BE FOLLOWED by a list of the cases in the area of interest to the members of this section. However, it seems appropriate to single out for discussion a few cases decided in 1965 because of a single common disturbing element found in each of them. These cases are not confined to foods, drugs and cosmetics, but the problem which they exemplify is common to all products and is of interest to any lawyer representing a manufacturer or seller.

Product Liability Cases

Let us consider first the New Jersey case of *Cintrone v. Hertz Truck Leasing and Rental Service,* CCH PRODUCTS LIABILITY REPORTS, ¶ 5441. This case is significant because it held that, in the lease of a truck, the lessor impliedly makes a continuing promissory warranty that the truck will be free of defects throughout the term of the lease. The court indicated, by way of dictum, that this would be true irrespective of which party to the lease arrangement had the responsibility for maintenance of the vehicle. The case is further of interest because it held that these warranties may be asserted without privity of contract with the lessor. Additionally, the case indicates that the lessor of such a truck may be properly sued for strict liability in tort as the result of injury brought about by a defect in the vehicle. Finally, the case has a curious fascination because the plaintiff's appeal from an adverse judgment at the trial court was certified to the New Jersey Supreme Court on that court's own motion before the Appellate Division acted upon it.

However, in spite of the obvious grist for the products liability mill which all of these points may provide, it is an entirely different aspect of this case to which I wish to draw your attention. Plaintiff was employed by the lessee of the truck, working sometimes as a driver and at other times as a helper. On the day of his injury, he

was acting as a helper. His co-worker attempted to take the 11-ft. high truck through an overpass with a clearance of 9-ft. 6-in. Plaintiff's claim was that the brakes on the truck were defective and that his driver was unable to stop. Plaintiff contended that he had complained of defective brakes on this very truck three times within the preceding week and had filed written reports to that effect with the defendant, giving a copy to his employer. Defendant denied ever getting such reports and plaintiff made no effort to produce the copies allegedly filed with his employer. There was no evidence of any kind with respect to what, if anything, was wrong with the braking system on this truck. Nevertheless, the Supreme Court of New Jersey sent this case back for a new trial on the issue of breach of implied warranty.

Let us look now at the case of *F. W. Woolworth Company v. Garza,* decided in the Texas Court of Civil Appeals. Plaintiff, a 15-year-old girl, ate a hamburger and a soda at defendant's lunch counter. Almost within moments after finishing, plaintiff began to feel sick to her stomach and broke out in a rash. She was taken to a doctor's office immediately, and upon arriving there, she fainted, her face and body were swollen and had red spots over them. She had no pulse or blood pressure and was turning blue. The doctor gave her a shot of adrenalin and transferred her to a hospital where she stayed for three days. The treating doctor testified that food poisoning can cause an allergic reaction and that a severe reaction like she had would come soon after eating. Her parents and the plaintiff testified that she had eaten hamburgers before and after this incident but had never had a reaction from them and indeed had never had any prior illness. On the strength of this evidence, the court held that plaintiff had established a *prima facie* case. Hence, the jury could properly find that the hamburger eaten by the plaintiff was unfit for human consumption at the time it was sold to her by the appellant.

Compare this, if you will, with the case of *Berke v. J. L. Hudson Company,* CCH PRODUCT LIABILITY REPORTS, ¶ 5416. Plaintiff purchased a white cotton slip from the defendant. She wore it the next day, new and without prior washing. Other clothes worn at the time were said to be the same as were constantly worn. Her breakfast that morning was an ordinary one consisting of juice, toast and coffee. During the day, plaintiff felt something like pin pricks on her back and subsequently that evening broke out into a rash and her eyes and tongue were badly swollen. Her treating physician diagnosed the ailment as severe dermatitis. At the trial an allergist testified that the wearing of such a cotton garment, as this slip, containing an

irritant "could cause a severe dermatitis condition". On these facts, the Supreme Court of Michigan held that plaintiff had established a *prima facie* case. A jury might reasonably have found that there was an irritant in the cloth at the time of the purchase and that that irritant was the cause of plaintiff's injury. Accordingly, the trial court erred in directing a verdict for the defendant at the conclusion of plaintiff's case.

The final case in this series is *Thomsen v. Rexall Drug and Chemical Company,* decided in the California District Court of Appeals. Plaintiff suffered from what appeared to be our old friend periarteritis nodosa, but which the California Court, happily, chose to call vasculitis. Plaintiff's claim was that she suffered this condition as the result of the erroneous refilling of a prescription by the defendant. The prescription in question was originally filled by an agent of defendant with small pink pills. Her first refill was filled with "large yellow or white pills completely different from the small pink pills." When plaintiff returned for a subsequent refill, she still had some of these large yellow or white pills left. Another agent of defendant told her that they were wrong and that she shouldn't take any more. He took back from her the large yellow or white pills that remained and substituted the small pink pills. No one ever saw the large yellow or white pills again. Medical knowledge concerning the cause of vasculitis is sparse. There was considerable agreement among the various medical experts who testified in this case about the nature and extent of plaintiff's illness. However, there was some disagreement about its cause. Plaintiff's expert testified that a certain type of vasculitis, which he believed plaintiff to have, had been associated in medical literature with penicillin and sulfa drugs. He further testified that both penicillin and the sulfonamides are sometimes dispensed in large white pill form. The California Court held that this evidence was sufficient to support the jury's verdict in favor of plaintiff because the jury had a right to infer from this that the unknown drug was the cause of plaintiff's vasculitis.

Need for Proof of Causation

The common element in each of these four cases is the complete lack of any evidence as to the nature of the exact defect in defendant's product. In *Cintrone,* we have no idea what, if anything, was wrong with the brakes on defendant's truck. Indeed, the dissenting justice felt that the failure to charge the jury on the doctrine of implied warranty, even if error, was not prejudicial because he felt that the jury

had clearly indicated by its verdict that it didn't believe there was anything wrong with the truck. Again, in *Garza,* we are not enlightened by the proof as to what was contained in defendant's hamburger which might have been responsible for plaintiff's severe reaction. Indeed, the court indicated very clearly that if it were called upon to determine this case on the basis of insufficient evidence, as opposed to no evidence, it would have been compelled to reverse the verdict for the plaintiff and dismiss the case. The distinction is a technical one based upon Texas practice. However, it is very difficult for a casual observer to distinguish the proof necessary to sustain a prima facie case from the proof necessary to be legally sufficient in a case of this type.

Similarly, in *Bronson,* the only evidence of a deleterious substance in the cotton slip sold by defendant was the testimony of the allergist to the effect that such a garment could cause a reaction such as the plaintiff suffered, *if it contained an irritant.* Since plaintiff suffered a reaction following the use of the garment, the court permitted the jury to infer that such a reaction must have come from an irritant which must have been in defendant's garment. Finally, in *Thomsen,* the jury was permitted to speculate as to what the unknown drug must have been which was erroneously given to the plaintiff by defendant and on the basis of this speculation, to conclude that that drug caused plaintiff's vasculitis.

The vice in these cases requires little elaboration. Heavy though the burdens imposed by warranty without privity or strict liability in tort may be, they are as a bag of feathers compared to the thrust of a doctrine which permits the plaintiff to get to a jury upon a mere showing of injury following the use of one's product. This is essentially the principle for which these cases stand. Even though the courts do not express the doctrine that nakedly, it boils down to that, and no more. When plaintiff is relieved of his burden of proving the defect in defendant's product, or when juries are permitted to infer a defect from the fact of an injury, the standards of proof are so eroded as to render a seller or manufacturer a true insurer, not only of his product, but of the safety of any one who uses his product, whether it be defective or not.

Unfortunately, no program comes readily to mind by which we might combat this trend, if trend it be. Our only hope at the moment is to prick the consciousness of those concerned with the defense of product liability cases to the end that minds more fertile

than ours might combine to bring forth some means by which to preserve our last remaining bastion, proof of causation.

PRODUCT LIABILITY CASES FOR 1965

The list of cases for 1965, grouped according to classification, is as follows:

FOREIGN SUBSTANCE AND CONTAMINATED FOOD CASES

Industrial Sugars, Inc. v. Standard Accident Insurance Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5343 (CA-7)

Dickens v. Horn & Hardart Baking Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5391 (Del. Super. Ct.)

F. W. Woolworth Company v. Garza, CCH PRODUCTS LIABILITY REPORTS ¶ 5413 (Tex. Ct. Civ. App.)

O'Brien v. Comstock Foods, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5431 (Vt.)

Brockett v. Harrell Bros., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5449 (Va.)

Ray v. Deas, CCH PRODUCTS LIABILITY REPORTS ¶ 5450 (Ga. Ct. App.)

Love v. New Amsterdam Casualty Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5456 (La. Ct. App.)

Hardin's Bakeries, Inc. v. Kelly, CCH PRODUCTS LIABILITY REPORTS ¶ 5477 (Miss.)

Musso v. Picadilly Cafeterias, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5483

FOREIGN SUBSTANCE BEVERAGE CASES

Terry v. Double Cola Bottling Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5346 (N. C.)

Dr. Pepper Bottling Co. v. Harris, CCH PRODUCTS LIABILITY REPORTS ¶ 5457 (Ga. Ct. App.)

Chattanooga Coca Cola Bottling Co. v. Johnson, CCH PRODUCTS LIABILITY REPORTS ¶ 5484 (Tenn. Ct. App.)

BURSTING BOTTLE CASES

Brown v. Hardware Mutual Casualty Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5373 (La. Ct. App.)

Renninger v. Foremost Dairies, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5374 (Fla. Dist. Ct. App.)

Jenkins v. Harvey C. Hines Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5382 (N. C.)

Hood v. P. Ballantine & Sons, CCH PRODUCTS LIABILITY REPORTS ¶ 5486 (U. S. D. C., S. D., N. Y.)

DRUG CASES

Berry v. American Cyanamid Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5350 (CA-6)

Tytel et al. v. Richardson-Merrell Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5354 (U. S. D. C., S. D., N. Y.)

Foley v. Weaver Drugs, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5367 (Fla. Dist. Ct. App.) ; ¶ 5398 (Fla.)

DiBelardino v. Lemmon Pharmacal Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5383 (Pa.)

McLeod v. W. S. Merrell Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5400 (Fla.)

Cornish v. Sterling Drug, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5415 (U. S. D. C., W. D., Mo.)

Thomsen v. Rexall Drug and Chemical Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5438 (Cal. Dist. Ct. App.)

COSMETIC CASES

Quist v. Bressard Distributors, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5455 (N. Y. App. Div., 1st Dept.)

Horan v. Klein's-Sheridan, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5473 (App. Ct., Ill.)

Corneliuson v. Arthur Drug Stores, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5480 (Conn.)

Doutre v. Niec, CCH PRODUCTS LIABILITY REPORTS ¶ 5485 (Mich. Ct. App.)

ANIMAL FEED CASES

Henry v. Eshelman & Sons, CCH PRODUCTS LIABILITY REPORTS ¶ 5386 (R. I.)

Nelson v. Boulay Bros. Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5408 (Wis.)

Burrus Feed Mills Inc. v. Reeder, CCH PRODUCTS LIABILITY REPORTS ¶ 5446 (Tex. Ct. Civ. App.)

Savage Bros. v. Peterson Distribution Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5463 (Mich. Ct. App.)

INSECTICIDE CASES

Hubbard-Hall Chemical Company v. Silverman, CCH PRODUCTS LIABILITY REPORTS ¶ 5347 (C. A. 1)

Golden Gate Hop Ranch, Inc. v. Velsicol Chemical Corp., CCH PRODUCTS LIABILITY REPORTS ¶ 5432 (Wash.)

Gonzalez v. Virginia-Carolina Chemical Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5448 (U. S. D. C., E. D. S. C.)

TOBACCO CANCER CASES

Pritchard v. Liggett & Myers Tobacco Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5430 (C. A. 3) **[The End]**

DRUGS LABELED AS SAFE BEFORE 1962 MUST BE PROVED EFFECTIVE

The Food and Drug Administration has announced that all drugs labeled as safe before 1962 must now prove that they are also effective. It was in 1962 that procedures were initiated requiring drug manufacturers to prove not only that their drug is safe but that it also does what they claim. For some drugs this will be apparent from clinical tests that have already been published. But for others, new tests will have to be started.

SIXTEEN DRUGS BROUGHT UNDER THE DRUG ABUSE CONTROL AMENDMENTS

It was announced by the Food and Drug Administration that sixteen drugs in addition to amphetamines and barbiturates have been brought under the new Drug Abuse Control Amendments. These sixteen drugs include tranquilizers, stimulants, and drugs that stimulate hallucinations. They must be labeled with a "C" symbol to show that special control and accounting procedures are required of them. All persons handling the drugs must keep detailed records in an attempt to keep them out of illegal channels.

The order bringing these sixteen drugs under the new law was reported in the 31 *Federal Register* 4679, March 19, 1966.

Current Problems in Food and Drug Advertising

By JAMES R. DOUGHERTY

Mr. Dougherty Is Assistant Attorney in Charge, New York Office, Federal Trade Commission.

THERE ARE THREE SUBJECTS THAT I would like to cover and they are: (1) a few of the more significant decisions of the past year as they may relate to food, drug and cosmetic advertising; (2) some rule of thumb guidelines that may be useful in establishing the validity of advertising within the meaning of the Federal Trade Commission Act, and, (3) some suggestions that may be useful in the future in helping you evaluate the legality of advertising, particularly in connection with what I perceive to be an increasing tendency on the part of the Commission to require affirmative disclosures in certain situations.

The *Colgate* Case

This past year the Supreme Court reversed the Court of Appeals and sustained the Commission order in the well-known Colgate-Palmolive Company[1] "sandpaper" case. As you will remember, the Commission challenged the television commercial involving "Rapid Shave" shaving cream. The evidence disclosed that actual sandpaper could not be shaved as depicted in the commercial by applying Rapid Shave cream without soaking it for a period of approximately eighty minutes. Instead, the advertising agency for *Colgate* used a "mock-up" made of plexiglass to which sand had been applied. The merits of Rapid Shave shaving cream as such were not challenged. The deception charged was that the television viewer was given the impression that he was witnessing an actual demonstration of shaving sandpaper after the sandpaper had been moistened with the shaving cream. In my view, *Colgate* is going to be as much a landmark case in advertising

[1] *F. T. C. v. Colgate-Palmolive Co., et al.* 380 U. S. 374 (1965).

law as *Lawrence v. Fox* is in contract law. The *Colgate* case will be historic too because for the first time the supreme court upheld the right of the Commission to name an advertising agency as a respondent when the circumstances so warrant. The *Colgate* case is also important because the Supreme Court recognized the far-reaching economic effects of Federal Trade Commission (FTC) activity involving advertising and emphasized that orders issued by the Commission must be definite and precise. In other words, shotgun complaints and orders will not do.

As mentioned, the merit of Colgate Rapid Shave shaving cream as such was never an issue in the case. The salient provision in the *Colgate* case reaffirmed once again that the misrepresentation of any fact so long as it materially induces a purchaser's desire to buy is a deception prohibited by paragraph 5 of the Federal Trade Commission Act. Thus, deceptive television "mock-ups" or props of any kind fall into the same category under the Federal Trade Commission Act as those cases where the seller has an arguably good product but misrepresents his line of business or simulates the trademark of another, and so forth.

Based on the reasoning in the *Colgate* case, it is my conviction that advertisers should be particularly cautious in the future in regard to endorsements by well-known persons, particluarly if the advertisement creates the impression that the endorser actually uses the product. In certain types of cases it may well be construed to be a material fact inducing the purchaser to buy conditioned solely on the fact that the product is used by the endorser. The Commission has had in recent years some relatively obscure cases involving endorsements by major league baseball players in connection with products not actually used by them. One such case that I have in mind concerns a famous baseball player who sold the use of his name and picture in connection with the sale of milk (of all things) for an association of independent dairymen each operating through the use of different private labels. This 40-member association encompassed dairies in approximately 14 states and upon inquiry it was determined that the baseball player, during the period of the advertising, had never been in most of the states nor could he have been because of the major league schedule. The quality of the milk itself was not being challenged by the commission. However, it was alleged that the name and the picture of the baseball star on the carton and in the advertising was causing people to buy a particular brand of milk based on the statement that he was drinking the particular brand of milk.

The respondents were not helped in their case when the major league player could not recall what dairy his family was currently purchasing from in his home town and the fact that the processing plant of one of the association members was located in the player's home town and used his endorsement, while his family was really purchasing milk on a home delivery basis from a competitor. At his peak, the player in question was the epitome of speed and power. His endorsement of milk as a nutritious beverage for growing youngsters was not open to objection. However, that he regularly drank the milk products of 40 dairies located in 14 states would call for speed and mobility that even he could not have possessed.

The *Libbey-Owens Ford* Case

In *Federal Trade Commission v. Libbey-Owens Ford Glass Co. and The General Motors Corp.*,[2] the Sixth Circuit Court of Appeals disposed of the "mock-ups" issue in a single paragraph by citing *Colgate* and remarked "the undisclosed use of mock-ups was a deceptive practice even though the test, experiment or demonstration actually proved the product claim." At the time Libbey-Owens Ford was the sole supplier of glass for General Motors cars. The case involved 22 television commercials purporting to show the superiority of safety plate glass used in all of the windows of General Motors cars over safety sheet glass used in the side windows of non-General Motors cars. General Motors itself had only telecast one of the 22 commercials in issue on two separate occasions.

The television commercial depicting the quality of glass in non-General Motors cars was planned to convey the impression to the viewer that the sheet glass was no better than glass used in house windows. The Commission found that the scenery distortion depicted through the non-General Motors car glass was achieved through the use of "mock-ups" or props including smearing vaseline on the glass as well as using a different camera lens. In filming scenery through a moving General Motors car as compared with the non-General Motors car more desirable camera angles were used in some of the commercials. Of course the purpose of all 22 of the commercials was to convey the impression that Libbey-Owens Ford glass in General Motors cars was superior to glass being used in non-General Motors cars.

[2] *Libbey-Owens Ford Glass Company and General Motors Corp. v. F. T. C.*, 352 F. 2d 415 (1965).

The zeal to prove the superiority of Libbey-Owens Ford glass was carried to the extent in commercials of actually photographing through an open window whereas the television viewer was given the impression that the clearer picture was achieved by photographing through Libbey-Owens Ford glass.

Libbey-Owens Ford is an important case because in addition to the rules set down in *Colgate* concerning tests, demonstrations and so forth, it holds that trick photography, quality of a camera, lens, angles and so forth cannot lawfully be used to disparage the quality of a competitor's product. In other words, the deliberate use of different photographic techniques resulting in misrepresentation of material facts that influence the purchaser's decision to buy was prohibited. This was so regardless of the quality of Libbey-Owens Ford glass which was not an issue as such in the proceeding.

The court also upheld the right of the Commission to issue an order against Libbey-Owens Ford comprehensive enough to stop any future misrepresentations in glass products whether used in automobiles or not. The coverage of all glass products of Libbey-Owens Ford in the order was under the doctrine set down in the *National Lead* case to the effect that the respondents having been caught violating the Federal Trade Commission Act "must expect some fencing in."[3] In the continuing demand of the court for precise and definite orders, the circuit court struck a certain portion of the order as it pertained to General Motors as "too vague and indefinite to warrant enforcement." The General Motors Corp. order was also specifically confined to automobile glass.

The *Geritol* Case

The Commission's decision in the matter of J. B. Williams Company[4] involving the product Geritol is, to my mind, a good example of the extension of the affirmative disclosure doctrine. The Commission contended in the *Geritol* case that the television commercials gave the viewer the over-all impression that Geritol was an effective remedy for tiredness, loss of strength, and so forth, even though at one point in the commercial the announcer does state that Geritol is effective if the tired feeling is caused by iron deficiency or a lack of any of the vitamins contained in the Geritol formula. The television com-

[3] *F. T. C. v. National Lead Co., et al.* 352 U. S. 419 (1957).

[4] In the matter of The J. B. Williams Company, Inc., and Parkson Advertising Agency, Inc.; F. T. C. Docket 8547 (September 28, 1965.)

mercial also stressed that Geritol would be in the bloodstream within 24 hours, but the medical testimony on behalf of the Commission's case indicated that even if the person had iron deficiency the minute portion of Geritol in the bloodstream within the 24-hour period would be of no measurable benefit. The medical testimony was also to the effect that even if a person had iron deficiency that there would be no apparent loss of that tired feeling in less than a two week period. In sum, the Commission found and objected to the fact that respondent's advertising is directed to the entire population of whom, it said, less than 10% have iron deficiency and less than 1% are deficient in the vitamins contained in the Geritol formula. I have touched on the facts of the *Geritol* case but briefly because I am more interested in the type of order issued by the Commission, which is currently being appealed by the respondent. The order prohibits any *unqualified* advertising in any media that claims that Geritol is an effective remedy for tiredness, loss of strength, etc., or that by taking Geritol there will be a restoration of strength or energy which will be felt in any part of the body in any amount of time less than that which the consumer may actually knowingly experience.

In the event that the respondents desire to continue their present type of advertising based on a valid contention that some portion of less than 10% of the population may have iron or vitamin deficiency, they may not disseminate such advertising and I quote:

> Which represents directly or by implication that the use of such preparation will be beneficial in the treatment or relief of tiredness, loss of strength, rundown feeling, nervousness or irritability, unless such advertisement expressly limits the claim of effectiveness of the preparation to those persons whose symptoms are due to an existing deficiency of one or more of the vitamins contained in the preparation, or to an existing deficiency of iron or iron deficiency anemia, and, further, unless the advertisement discloses clearly and conspicuously that (1) in the great majority of persons who experience such symptoms, these symptoms are not caused by a deficiency of one or more of the vitamins contained in the preparation or by iron deficiency or iron deficiency anemia; and (2) for such persons the preparation will be of no benefit.

Geritol's advertising was apparently disseminated in reliance on the case of *Alberty v. the Federal Trade Commission*[5] decided by the District of Columbia Circuit in 1950. In that case, advertising representing that Oxorin tablets were an effective remedy for that weary, tired, rundown feeling, was in issue and in that case as in *Geritol* there was a passing qualification in the advertising that Oxorin tablets would be helpful if the tiredness was the result of iron defi-

[5] *Alberty et al. v. F. T. C.*, 182 F. 2d 36 (1950).

ciency in the blood. The court, by a two-to-one decision struck from the FTC order an affirmative disclosure clause which would have required Alberty to disclose that less than 10% of the population experienced tiredness as a result of iron deficiency in the blood. However, the circuit court did acknowledge that the Commission could require an affirmative disclosure when (1) failure to make such statement is misleading because of the consequences from the use of the product or (2) the failure to make such statement is misleading because of the opinions claimed in the advertising. In the *Alberty* case, the court struck the affirmative disclosure clause because they said that no such findings had been made. Needless to say, the Commission has attempted to overcome this shortcoming in the *Geritol* case. The dissenting judge in *Alberty* took the position that the Commission would have ignored its statutory mandate if it had not required the affirmative disclosure clause in the order. He said:

> The Federal Trade Commission Act, as amended in 1938, specified that ". . . in determining whether any advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also *the extent to which the advertisement fails to reveal facts material in the light of such representations* or material with respect to consequences which may result from the use of the commodity to which the advertisement relates under the conditions prescribed in said advertisement, or under said conditions as are customary or usual."

The Legality of Advertising

I recognize that many of you here today are quite familiar with the fundamentals of advertising law under the Federal Trade Commission Act, but yet each year brings new members to your section or regular members who, for one reason or another, now have a more particular interest in this phase of the law. Hence, a few principles in making a determination as to the legality of advertising within the meaning of the Federal Trade Commission Act:

1. Advertisements must be considered in their entirety and as they would be read by those to whom they appeal.

2. Advertisements as a whole may be completely misleading although every sentence separately considered is literally true. This may be because things are omitted that should be said, or because advertisements are composed or purposely printed in such way as to mislead.

3. Advertisements are not intended to be carefully dissected with a dictionary at hand, but rather to produce an impression upon prospective purchasers.

4. Whether or not the advertiser knows the representations to be false, the deception of purchasers and the diversion of trade from competition is the same.

5. A deliberate effort to deceive is not necessary to make out a case of using unfair or deceptive acts or practices within the prohibition of the statute.

6. Laws are made to protect the trusting as well as the suspicious.

It seems to me that the *Colgate* case, *Libbey-Owens Ford* and more recently *Federal Trade Commission v. Mary Carter Paint Company*[6] and *Geritol,* represents a progressive requirement that an advertisement in any media must contain the full truth, particularly as to material facts that induce the purchaser to buy. There seems to be little doubt that the Commission will follow the reasoning in these cases in the future, particularly with food, drug and cosmetic products, because of the direct involvement of the health of the consumer. I believe that the old days of playing a game with the Commission, by using a false advertisement until prohibited with a deficient substitute advertisement ready before the ink is dry on the original final order are gone. In the future, it is going to be painful and expensive for a client to have to drop an entire advertising theme or to engage in negative advertising in order to correct a false impression given the public as a result of prior unlawful advertising. Under such circumstances, it seems to be unsafe for attorneys to merely analyze words or sentences because we are now clearly involved with the over-all impression of the advertisement and full truth in regard to material facts inducing the purchaser to buy.

Think for a moment of the power that *Colgate, Libbey-Owens Ford, Mary Carter* and more recently, *Geritol* (if affirmed) gives the hard-line enforcer who knows no other route but litigation. Yet, in contrast, we find the modern day Commission vigorously attempting to step up voluntary compliance with the law and, wherever practical, on an industry-wide basis.

I think the FTC in recent years has demonstrated its sincerity in its endeavor to achieve voluntary cooperative compliance with the laws the Commission administers. I would, therefore, like to encourage members of the bar to more fully use the services provided by the Bureau of Industry Guidance and particularly in those areas where honest differences of opinion can exist, to seek advisory opinions. The personnel in the field offices of the Commission are cooperating very closely with the Bureau of Industry Guidance and we stand ready to cooperate with you in regard to initial discussion and preparation in connection with matters handled by this bureau. When appropriate, I hope you will see fit to use these services which, as you know, are dedicated to the public interest. **[The End]**

[6] *F. T. C. v. Mary Carter Paint Company, et al.* 333 F. 2d 654 Cert. 379 U. S. 957.

Report of the Third Session of the Joint FAO / WHO Codex Alimentarius Commission

By FRANKLIN M. DEPEW

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THE THIRD SESSION of the Food and Agriculture Organization (FAO)/World Health Organization (WHO) Codex Alimentarius Commission was held at FAO Headquarters, Rome, Italy, October 19-29, 1965. The session was attended by some 130 registrants including representatives and observers from 37 countries and observers from 20 international organizations.

Composition of Third Session

The United States Delegation consisted of eleven representatives from government and industry including Mr. John L. Harvey (Commission Chairman), Deputy Commissioner, Food and Drug Administration (FDA), Department of Health, Education, and Welfare and Mr. Nathan Koenig (Delegation Chairman), Special Assistant to the Administrator, Consumer and Marketing Service, U. S. Department of Agriculture.

The outstanding feature of this session was the spirit of harmony with which the delegates attacked the many problems brought before them at this meeting. When there were differing points of view the matters were calmly and logically discussed in an atmosphere of seeking a solution that would be for the benefit of all. This was a marked improvement over the previous sessions which had been marred on occasion by governmental rivalries. Thus, the standards program ap-

pears to be greatly strengthened, and we have reason to expect the adoption of sound standards which will protect consumers' health, assure fair practices in food trade and facilitate international trade.

This spirit of cooperation was reflected in the fact that the new officers of the Commission were elected unanimously. Their nominations were seconded by what amounted to acclaim. The new officers elected to serve from the end of the third session until the end of the fourth session are: Professor Dr. M. J. L. Dols of the Netherlands, as Chairman and Mr. H. V. Dempsey of Canada, Mr. G. Weill of France and Mr. J. H. V. Davis of the United Kingdom as Vice Chairman of the Commission. Mr. John L. Harvey, who was ineligible for re-election as Chairman, presided.

The Commission also elected the following Members of the Commission to represent the indicated geographical locations on the Executive Committee of the Codex Alimentarius Commission: for Africa, Ghana; for Asia, India; for Europe, Poland; for North America, U. S. A.; for Latin America, Cuba and for Australasia, Australia. In the cases of Asia and Australasia the countries previously representing the geographical locations were re-elected for a second term. The Commission also during the session, on a recommendation from the Co-ordinating Committee for Europe, appointed Min. a. D. Dr. H. Frenzel (Austria) to be Co-ordinator for Europe for a period of three years.

The following briefly reports the principal action taken by the third session of the Commission:

General Principles

The Commission received a progress report from the Codex Committee on General Principles, chaired by France. After discussing the recommendations in this report it was decided to adopt them as the General Principle of the Codex Alimentarius and to publish them as part of the Procedural Handbook recommended by the Commission at its Second Session. The text of the General Principles as adopted is as follows:

Purpose of the Codex Alimentarius

1. The Codex Alimentarius is a collection of internationally adopted food standards presented in a uniform manner. These food standards aim at protecting consumers' health and ensuring fair practices in the food trade. Their publication is intended to guide and promote the elaboration and establishment of definitions and require-

ments for foods to assist in their harmonization and in so doing to facilitate international trade.

Scope of the Codex Alimentarius

2. The Codex Alimentarius is to include standards for all the principal foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined. The Codex Alimentarius is to include provisions in respect of food hygiene, food additives, pesticide residues, contaminants, labelling and presentation, methods of analysis and sampling.

Nature of Codex Standards

3. Codex Standards contain requirements for food aimed at ensuring for the consumer a sound, wholesome food product free from adulteration, correctly labelled and presented. In particular a Codex Standard for a given food product lays down the special requirements for that product, it being understood that the general provisions contained in the Codex Alimentarius shall apply except to the extent otherwise expressly provided for in a specific standard.

A Codex Standard should, therefore, for any food or foods:

(1) incorporate by reference the applicable hygiene, labelling, methods of analysis and other general provisions adopted by the Commission, and

(2) specify in whole or in part the following criteria, as appropriate:

(a) *Product designation definition and composition*—These should describe and define the food (including its scientific name when necessary) and cover compositional requirements which may include quality criteria.

(b) *Hygiene requirements*—These should include such factors as specific sanitary and other protective measures and safeguards to assure a sound, wholesome and marketable product.

(c) *Weight and measure requirements,* such as fill of container, weight, measure or count of units based on an appropriate method of criterium.

(d) *Labelling requirements*—These should include specific requirements for labelling and presentation.

(e) *Sampling, testing and analytical methods*—These should cover specific sampling, testing and analytical procedures.

Acceptance of Codex Standards

(4) A *Codex Standard* so defined may be accepted by a country—in respect of trade and distribution of the food within its territory—in its entirety, or accepted with a declaration of more stringent requirements, or accepted as a target which will be put into effect after a stated number of years. Acceptance in its entirety or target acceptance would imply an undertaking by the importing country not to hinder within its territorial jurisdiction the distribution of food which conforms to the standard by interposing any legal provisions relating to the health of the consumer or to other food standard matters.

Regarding the future work of the Codex Committee on General Principles concerning the definitions of terms required for use in the Codex Alimentarius, the Commission at the suggestion of the United States Delegate requested FAO and WHO to prepare draft definitions for these terms and to send them as soon as possible to Governments for comment with a closing date for comments by the end of February 1966. A small working group convened by the Chairman of the Codex Committee on General Principles in cooperation with FAO and WHO would examine government comments and prepare a working paper for the second meeting of the Codex Committee.

Guidelines for Codex Committees

After completing its consideration of the progress reports of Codex Committees, the Commission concluded that the preparation of guidelines to assist Codex Committees to operate on a uniform basis is essential. The Commission requested the Secretariat to prepare a paper on this subject and to issue it as a provisional document inviting comments from Member Governments which would in turn be referred to the Codex Committee on General Principles so that recommendations could be placed before the Commission at its next session.

Food Hygiene

The Codex Committee on Food Hygiene, chaired by the United States, presented a report on its work. This document had reached Step 3 of the Commission's procedure for the elaboration of standards, that is the draft had been sent to governments and international organizations for comments. The Commission recommended that this Committee should give priority to hygiene standards for those foodstuffs which are being standardized by other Codex Committees and for those other foodstuffs which might present a special health hazard to the consumer. In its outline of future work the Committee pro-

posed to deal with hygenic problems in the retail handling of food. The need for close cooperation between this Committee and other Codex Committees was recognized.

Methods of Analysis and Sampling

The Codex Committee on Methods of Analysis, chaired by the Federal Republic of Germany, presented a report on its work. The Committee reported it had agreed upon a general framework for its work and how this should appear in the chapter of the Codex Alimentarius on Methods of Analysis. The Committee decided to give priority to the elaboration of referee methods and intended to take account of work already done in specific fields. An essential part of the establishment of priorities would be the drawing up of a bibliography of existing methods of analysis. The participants of the Committee had been requested to assist in this, and it was stated that information from other members of the Commission and from international organizations would be welcomed by the secretariat of the Committee. The Committee reported that it was receiving valuable cooperation from the International Standards Organization (ISO). The participants at the first meeting had accepted various work assignments and the results of this work would be examined at the next meeting of the Committee. The Commission approved the proposed outline of work of the Committee and emphasized the need for international referee methods of analysis. The Commission confirmed in accordance with the general principles of the Codex Alimentarius that the Codex Committee on Methods of Analysis should include within its scope of work sampling and draw upon the collaboration of ISO in this field. The Commission confirmed that the chairmanship of the Codex Committee should continue to be the responsibility of the Government of the Federal Republic of Germany, but that in the future it should be known as the Committee on Methods of Analysis and Sampling.

Food Labelling

The Codex Committee on Food Labelling, chaired by Canada, presented its report. The Committee had formulated and agreed upon general principles for the labelling of food. Attention was called to the requirement for listing the ingredients on labels, but it was pointed out there were certain foods where such labelling is not normally required. The Committee requested the names of such foods along with supporting reasons for not listing ingredients. Views were also requested on the use of class names instead of actual ingredients, i.e.,

emulsifiers; artificial (or natural) color added. At the request of the Commission, the Committee's report of its first meeting is to be sent to Member Governments in addition to those who had participated in this session to secure their comments and the specific information sought by the Committee.

Food Additives

The Commission, having further considered the membership and main responsibilities of the Codex Committee on Food Additives and the Joint FAO/WHO Expert Committee on Food Additives decided to modify the prior procedure and to adopt the following in its place:

(a) The Codex Committee on Food Additives should carry out a general review of the whole field of Food Additives and plan the work required to be done. Taking into account the lists prepared by Codex Committees and other international bodies of additives used in specific foods, the Codex Committee on Food Additives should evaluate the technological need for the use of the additives and prepare priority lists. Priority should be given to those food additives which are used in foods entering international trade in substantial amounts. Any government which wishes to suggest the inclusion of any particular additive belonging to the group of additives under consideration by the Codex Committee on Food Additives in a Codex list of permitted additives should submit full information about the additive, including evidence of need and suggested level of use, to the Chairman of the Codex Committee on Food Additives, Ministry of Agriculture and Fisheries, The Hague, Netherlands. At the same time data on (i) specifications of identity and purity should be sent to the Science Branch, Nutrition Division, FAO, Rome, and (ii) data on the biological properties to Nutrition Unit, WHO, Geneva. If the Codex Committee considers that a case has been established on the basis of need and that the additive concerned is not unsuitable for inclusion in a permitted list, the Codex Committee will ask the Joint FAO/WHO Expert Committee on Food Additives to consider the additive concerned.

(b) The Joint FAO/WHO Expert Committee on Food Additives should, as expeditiously as possible, establish acceptable daily intakes and specifications of identity and purity for all additives so submitted. This data would be communicated to the Codex Committee on Food Additives.

(c) The Codex Committee on Food Additives would then recommend levels of use for the food additive in specific foods and submit such levels of use to the Codex Alimentarius Commission.

(d) The Codex Alimentarius Commission would invite government comments on these levels of use in the usual manner.

In addition, the Commission decided that the general principles for the use of food additives as prepared by the Codex Committee on Food Additives should be sent, amended in the light of the discussions, to governments for comments in accordance with Step 3.

The Commission also expressed the desire that feed additives, as they leave residues in food and those that make a change in the food, should be considered by the Codex Committee on Food Additives.

Pesticide Chemicals

The Commission received a brief oral report on arrangements being made for the first session of the Codex Committee on Pesticide Residues which is scheduled to be held in The Hague in January 1966.

The Commission, having been informed that in future the WHO Expert Committee on Pesticide Residues will meet jointly with the FAO Working Party on Pesticide Residues (hereinafter referred to as the Joint Meeting on Pesticide Residues) and having considered the membership and main functions of the FAO and WHO Committee working towards the establishment of tolerances for pesticide residues on an international basis, decided to modify the prior procedure and the following revised procedure was adopted:

(a) The Codex Committee on Pesticide Residues should plan the work required to be done, taking into account the work already done by the various expert committees of the FAO and WHO, should prepare priority lists and transmit data to the Joint Meeting on Pesticide Residues. Priority should be given to those pesticides which are used in substantial amounts on food entering international trade. Any government which wishes to suggest that an international tolerance be established for a particular pesticide on specific food products should submit full information regarding technological justification, levels of residues resulting from their use, tolerances, consumption of food concerned, methods of analysis for residues to the Codex Committee on Pesticide Residues, Ministry of Health, The Hague, Netherlands, with copies to the Plant Production and Protection Division, FAO, Rome. At the same time, two copies of all toxicological and related data should be sent to Nutrition/Food Additives, WHO, Geneva. If the Codex Committee considers that a case has been established on the basis of need, that the pesticide concerned is not unsuitable for inclusion in an authorized list and that adequate data have been pro-

vided, they will transmit the data to the Joint Meeting on Pesticide Residues for consideration.

(b) The Joint Meeting on Pesticide Residues should, as expeditiously as possible, establish acceptable daily intakes, tolerances on specific foods based on good agriculture practice checked against the acceptable daily intake and methods of analysis. They should transmit their report to the Codex Committee on Pesticide Residues.

(c) The Codex Committee on Pesticide Residues would then recommend, where necessary, tolerances for acceptance by governments for the pesticide in specific foods and submit such tolerances to the Codex Alimentarius Commission.

(d) The Codex Alimentarius Commission would invite government comments on these tolerances in the usual manner.

Standards for Sugars and Honey

The Commission had for consideration at Step 5 of its Procedure the following draft provisional standards as prepared by the Codex Committee on Sugars: white sugar, powdered sugar (icing sugar), soft sugars and brown sugars, glucose syrup, dried glucose syrup, dextrose monohydrate and dextrose anhydrous. The Commission decided that all the above sugars should be sent to Governments for comment in accordance with Step 6 of its Procedure with the exception of the standard for white sugar which was referred back to the Codex Committee on Sugars for further consideration. The Codex Committee was requested to reconsider the elaboration of standards for white sugar in the light of the general principles as adopted by the Commission. In connection with the standards for these sugars the Commission recommended that the requirements in respect of intentional and unintentional additives should be referred to the Codex Committee on Food Additives. The Secretariat was requested to make it clear to all Governments when the standards at Step 6 were sent for comments that the requirements in respect of intentional and unintentional additives were subject to examination by the Codex Committee on Food Additives.

At the Second Session the Government of Austria agreed to complete the work it had begun on a honey standard for the European region. This draft standard as revised by the United Kingdom was submitted to the Commission. After discussion, the Commission decided to consider the draft revised by the United Kingdom as being at Step 5 of the Commission's procedure for the elaboration of re-

gional standards and recommended that the draft standard be sent for comment to Member Governments in accordance with Step 6.

Progress on Other Standards

Progress reports were submitted on Cocoa Products and Chocolate; Fats and Oils; Fruit Juices; Milk and Milk Products; Processed Fruit and Vegetables; Meat and Meat Products; Fresh Vegetables and Frozen Foods. Nine draft standards for cocoa products and eleven draft standards for canned fruits and vegetables were reported as ready for submission to governments in accordance with Step 3. The Commission approved a proposal of the government of France to assume leadership from January 1, 1966 for the preparation of draft standards for jams, jellies and marmalades in the work of the Codex Committee on Processed Fruits.

The Commission accepted the offer of the Government of Norway to undertake responsibility and chairmanship of a Codex Committee on Fish and Fishery Products to elaborate world-wide standards for fresh, frozen (including deep- and quick-frozen) or otherwise processed fish, crustaceans and mollusks. The Commission, after further consideration of the subject of Poultry Meat, decided that the time was opportune to establish a Codex Committee on Poultry Meat and accepted with appreciation an offer of the Government of the United States to assume responsibility for chairmanship of this Committee.

The Committee for Meat and Meat Products at its first meeting had established six subcommittees dealing respectively with carcasses and cuts; transportation and storage of carcasses and cuts; classification and evaluation of carcasses and cuts of lamb and sheep; meat products; meat hygiene; and additives used in the production of meat products.

Co-ordinating Committee for Europe

The Commission received reports of the first and second meetings of the Co-ordinating Committee for Europe. The Commission approved a proposal to establish a European Codex Committee to elaborate standards for natural mineral waters (excluding mineral waters for therapeutic use) and designated the government of Switzerland as Chairman. The Commission also approved the proposal of the Co-ordinating Committee to establish a European Codex Committee on Dietic Foods under the chairmanship of the Federal Republic of Germany. The Commission, after emphasizing that the

work of the Committee would be to elaborate regional standards as a first step towards world-wide standards, approved the following terms of reference:

Dietetic foods are those foods which, by reason of their composition, meet a particular nutritive need of a person whose normal power of assimilation is restricted or for whom a particular effect is to be obtained by a controlled diet. They are foods and not medicines. They may be divided into the following main groups:

(a) Foods which meet a particular physiological need of healthy people. These needs may result from a particular age (babies, infants, the aged) or, for example, as a consequence of pregnancy or breast-feeding.

(b) Foods, the use of which is connected with morbid conditions of the human body (diabetes, obesity, abnormal emaciation, poor utilization of sodium, etc.).

(c) Supplementary nutrients, required by reason of unusual physical strain or as a result of particular external conditions or to improve or complete a normal diet.

Proposal Made by African Countries

The following six African countries attending the Third Session of the Commission, Burundi, the Democratic Republic of the Congo (Leopoldville), Ghana, Senegal, Sudan and Tunisia, proposed that in view of the particular dietary situation of the peoples of emerging countries it would be desirable to have a Co-ordinating Committee for Africa established as soon as possible in order to study and present standards appropriate to the background, social life and purchasing power of such peoples of Africa. The Commission recommended as a first step that the Secretariat be requested to bring to the attention of the Directors-General the proposal of the African countries.

Finance

The Commission took note of the decisions by FAO and WHO which will lead to financing the work of the Codex Alimentarius Commission out of the regular budgets of the two organizations beginning January 1, 1966. The United States Delegate stated that his country believes the program is important and has a great potential in solving many problems in international trade, breaking down trade barriers, protecting consumers, promoting fair trade practices, and facilitating trade. The Delegate pointed out that as in previous years the United

States met its 1965 doubled contribution to the Trust Fund—not with U. S. Government funds but by the generous contributions from members of the country's food and allied industries who also felt that the program was important. The Delegate paid tribute to these contributors in industry and expressed thanks and appreciation for the financial assistance provided.

Valediction for Mr. John L. Harvey

On behalf of FAO and WHO, Dr. B. R. Sen, Director General of FAO complimented Mr. John L. Harvey, United States Deputy Commissioner of Food and Drugs, for his interest, efforts and effective leadership in serving as Commission Chairman. Professor Dr. Dols, Mr. Harvey's successor as Commission Chairman, on behalf of the Codex Alimentarius Commission, expressed the appreciation of the Commission and all the members thereof to the retiring Chairman, Dr. J. L. Harvey. The Commission gave Dr. Harvey a standing ovation for his inspiring leadership of the Commission in its formative years.

Progress Made at Third Session

As indicated by the foregoing, the Third Session of the Codex Alimentarius Commission made significant progress toward the successful establishment of food standards. Those wishing a more detailed report on this program may secure it by writing to U. S. FAO Interagency Subcommittee on Codex Alimentarius, Agricultural Marketing Service, U. S. Department of Agriculture, Washington, D. C. 20204, for the Official Report of the United States Delegation. The food standards program was greatly strengthened at the Third Session, and it can be confidently stated that we are on the threshold of the time when many standards will be approved which are sound and in the interest of facilitating international trade.

The United States Delegation from the start has supported the policy now incorporated in the General Principles which the Commission adopted at its Third Session. The Delegation has provided strong leadership and support to bring into being and maintain a policy that food standards generally should safeguard the consumer and facilitate trade. American industry again owes a deep debt of gratitude to the government and industry representatives on the United States Delegation, and particularly to Messrs. John L. Harvey and Nathan Koenig. Also not to be forgotten is the part played by those in private industry who made it possible for the United States Government to contribute to the Trust Fund. **[The End]**

The President's Message on Consumer Interests

The Following Are Excerpts from President Johnson's Message to Congress on Consumer Interests. These Excerpts Relate to the President's Recommendations Concerning Food and Drugs. The Message Was Delivered on March 21, 1966.

Protection From Dangerous Substances

The consumer must not only be informed. He must also be protected from dangerous drugs, foods, and other substances.

Our ability to conquer pain and disease has increased dramatically. But we must not allow the development of new drugs and nutrients to outstrip our capacity to test and certify them for safety and effectiveness.

I recommend three related items of legislation to reinforce consumer protection.

The Child Safety Act

Children must be our first concern. They are our hope and our future.

Too many children now become seriously ill—too many die—because of accidents that could be avoided by adequate labeling and packaging of dangerous substances. This is senseless and needless tragedy.

Most drug manufacturers have taken responsible action in providing appropriate warnings on drug labels. The Food and Drug Administration has accomplished much in reducing the incidence of these private tragedies. But both have been greatly handicapped by gaps in the laws dealing with hazardous substances and materials.

It is still true, for example, that present law nowhere provides for inspection of unpackaged toys and novelties that may be poisonous to children.

To extend legal protection for the safety of all our citizens, especially our children, I recommend legislation to—

Bring all hazardous substances, regardless of their wrapping, under the safeguards of the Federal Hazardous Substances Labeling Act;

Ban from commerce those household substances that are so hazardous that warning labels are not adequate safeguards;

Ban the sale of toys and other children's articles containing hazardous substances, regardless of their packaging;

Require labels to warn consumers against possible injury from drugs and cosmetics, and from food in pressurized containers;

Limit the amount of children's aspirin available in retail packages;

Require certain potent drugs attractive to children to have safety closure caps.

Drug Safety Act

Each year the Food and Drug Administration receives over 4,000 requests for study and approval of new drugs. Each new product is carefully analyzed and tested. This process is a basic consumer protection in which the United States leads the world.

But it is just as basic that the law require more accurate and detailed labeling of dangerous drugs—and that it deal specifically with drugs whose period of potency and purity is limited.

To make these improvements, and to protect the lives of all of our citizens, I recommend legislation to—

Authorize the Government to require records and reports of experience and to require labeling changes on any drug, whether old or new;

Require certification of all drugs whose potency and purity can mean life or death to a patient, thus extending the law which now applies to insulin and antibiotics; and

Control the unsolicited distribution of drug samples.

Professional Training and Cooperation Amendments

The task of protecting the consumer cannot and should not be left solely to the Federal Government. The Government can and should provide creative Federal leadership to help States and local communities in their own constructive and determined efforts.

As a step forward, Federal assistance is needed to strengthen and enlarge State and local professional staffs in the food and drug areas.

To begin to meet our Federal responsibility, I recommend legislation authorizing expansion of the Food and Drug Administration's training programs for non-Federal officials. This will be the first in a series of measures to broaden Federal-State-local cooperation in this vital field.

Revitalizing the Food and Drug Administration

In addition to these legislative proposals, I pledge continued efforts to revitalize the Food and Drug Administration. This process is already well under way.

This agency has performed notably in the past. Yet the scope of its responsibility has been considerably broadened in recent years. The public interest demands that it receive the additional support it needs to perform its many new functions.

I recently appointed a new Commissioner of Food and Drugs to give the agency new leadership and new direction. I have directed him to conduct a thorough review of the agency's roles and missions and to move purposefully toward a new structure fitted to the demands of the times. I have also asked him to recruit personnel with the most outstanding backgrounds in science and public service.

The responsibilities of the Food and Drug Administration are heavy. But they will be met.

To strengthen the Food and Drug Administration, I have proposed, in the fiscal year 1967 budget, the largest single increase ever requested for this agency.

I believe that the interests of the Nation fully support this request. I urge the Congress to provide the necessary funds and enact the recommended legislation to enable this important agency to fulfill the needs of our people.

Cosmetics and Medical Devices

Assurance of the safety and effectiveness of the drugs we buy has the highest priority. But further action may be necessary to protect the consumer against harmful cosmetics and against medical devices that are neither safe nor effective.

I have asked the Secretary of Health, Education, and Welfare to begin a thorough analysis of the legislative authority now available and to recommend new steps that may be needed to close the gaps in the laws dealing with cosmetics and medical devices.

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