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Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the 13th Annual Educational Conference of The Food and Drug Law Institute, Inc., and The Food and Drug Administration

Papers Presented at the 1970 Annual Meeting of the New York State Bar Association Section on Food, Drug and Cosmetic Law

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

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REPORTS

TO THE READER

1969 FDLI-FDA Conference.—The following are the concluding papers presented at the 13th Annual Joint Educational Conference of the Food and Drug Law Institute, Inc. and FDA.

The FDA should publish criteria of good manufacturing practices through policy statements, not through a rule of law approach. This regulatory policy is urged for FDA by *William F. Cody* in his article, "GMP Regulations," beginning on page 116. Mr. Cody is an attorney for CPC International, Inc.

Alfred Barnard, Acting Associate Director of FDA's Bureau of Compliance, discusses recent seafood regulations and raises several questions as to the status of model ordinances and codes in respect to the federal-state relationship, in his article "Food GMPs" beginning on page 123.

"Self-Certification of Foods: A Progress Report," by *Nathaniel L. Geary,* presents a second progress report on the Self-Certification Program, beginning on page 127. Mr. Geary is associated with FDA's Bureau of Compliance.

H. A. Frediani discusses the "FDA's Intensified Drug Inspection Program" in his article beginning on page 131. Mr. Frediani, who is associated with Bristol Laboratories in Syracuse, New York, makes recommendations for increasing the efficiency of the program.

"The National Center for Drug Analysis," by *Daniel Banes,* describes the development of large-scale monitoring of the nation's drug supply. Dr. Banes, whose article begins on page 135, is Director of the Division of Pharmaceutical Sciences, FDA.

Mechanisms for Setting Food Standards in Canada.—Past and present Canadian legislation and procedures for amending these standards are outlined by *Dr. J. A. Campbell* beginning on page 140. Dr. Campbell, who is Assistant Director of General Foods of the Department of National Health and Welfare, Ontario, Canada, presented his paper to the Meeting of the Food Protection Committee and Liaison Panel of the NAS-NRC in Washington, D. C. on December 9, 1969.

Twenty-Fifth Annual Meeting of the Food, Drug and Cosmetic Law Section of the New York State Bar Association.—The following three papers were presented at this meeting, which was held on January 27, 1970, at the New York Hilton Hotel. Additional papers will be published in a later issue.

Franklin M. Depew, Chairman of the Food, Drug and Cosmetic Law Section of the New York State Bar Association and President of the Food and Drug Law Institute, offers an "Introductory Statement" in the article beginning on page 147. Mr. Depew makes recommendations to the Bar section and reports on food law legislation abroad.

In "The Function of Guaranties," *Merrill Thompson* questions whether the statutory framework providing for food and drug guaranties results in a waste of time and money. His article begins on page 150. Mr. Thompson is a member of Chadwell, Keck, Kayser & Ruggles.

In his article, "Product Liability—1969," beginning on page 158, *William J. Condon* discusses several cases of product liability and compares the decisions of the courts. The author is a member of Condon and McMurray, New York.

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GMP Regulations

By WILLIAM F. CODY

This Paper and the Four Following Were Presented at the 13th Annual FDLI-FDA Conference. Mr. Cody Is Associated with CPC International, Inc., Englewood Cliffs, N. J.

THE "UMBRELLA" GOOD MANUFACTURING PRACTICE (GMP) Regulations[1] have now been in effect for just over six months, and I think it perhaps an appropriate time to look over the progress to date and the prospects for the near future.

I cannot imagine that anyone in the food industry dissents from the proposition that food manufacturing sanitation demands a high order of priority, and that better definitions of criteria for manufacturing sanitation are advantageous to consumers, regulatory agencies and manufacturers. Food-borne diseases have received increased attention in recent years for a number of reasons. There is not necessarily any greater incidence of food-borne diseases today than, say, twenty years ago. However, several incidents have focused the attention of the Communicable Disease Center on the subject in recent years. Thereafter, improved reporting by physicians and hospitals and improved analytical methods have made us more aware of the incidence of such diseases. Responsible manufacturers have always emphasized the avoidance of microbiological contamination of foods; however, with enhanced awareness and better data, agencies such as the Food and Drug Administration (FDA) were understandably disposed to reexamine the regulatory approach to the matter.

[1] 21 CFR § 128; 34 FR 6977, April 26, 1969.

Regulatory Approaches

There are several basic regulatory approaches available to FDA under the Food, Drug and Cosmetic Act. First, a food product is deemed adulterated if it actually *contains* any harmful, deleterious or filthy substance (Sections 402(a)(1); 402(a)(3)). This is, of course, a useful regulatory tool, but is not the best approach to a basic program relating to food-borne diseases. The analysis of finished food products is physically cumbersome, and because of statistical problems related to sampling, it does not always provide a complete assurance of freedom from contamination. Analysis of of finished products is important, but one cannot count on it alone as a basic or exclusive safeguard. The second available regulatory approach is Section 402(a)(4) of the Act, whereby a food is deemed to be adulterated if it has been "prepared, packed or held under conditions *whereby it may have become* contaminated . . . or . . . injurious to health." (21 USC § 342(a)(4)). This is a kind of "early warning system." No actual contamination of the finished product need be shown, but only the "incipiency" of contamination, which is a concept related to the one so dear to the hearts of Clayton Act lawyers.[2] This prophylactic approach is probably the only really efficacious approach to the contamination problem, just as market *structure*, rather than actual market *behavior*, may well become the only effective way to enforce Section 7 of the Clayton Act. FDA has correctly chosen, I think, this approach as the main front for its food contamination program as far as selection of the best-suited legal regulatory machinery.[3]

We are all familiar with the regulatory steps FDA has taken under § 402(a)(4): the "umbrella" GMPs effective May 26, 1969 (21 CFR § 128a; 34 FR 6977, April 26, 1969) and the two specific industry GMPs which have recently been proposed for the frozen shrimp and smoked fish industries (21 CFR § 128a.401 et seq.; 34 FR 14476, Sept. 17, 1969; 21 CFR 128a.1 et seq.; 34 FR 17176, Oct. 23, 1969).

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[2] In *Berger v. U.S.*, 200 F2 818, 821 (8th Cir., 1952), the court used the term "incipiency," and drew an analogy to the antitrust area in its characterization of the operation of § 402(a)(4).

[3] There are other statutory provisions whereby FDA may probably impose sanitary requirements, such as standards of identity under § 401 and Food Additive Orders under § 409. Safety was held to be an appropriate consideration in a food standard in *Atlas Powder Co. v. Ewing*, 201 F2 347 (3rd Cir., 1952); in spite of suggestions that the Food Additives amendment superseded the *Atlas* ruling, safety is probably still a legitimate consideration in § 401 proceedings where it relates strictly to the product's characteristics. For example, the standard of identity for egg products (21 CFR 42) was recently amended to require pasteur-

(Continued on next page.)

An Unanswered Question

Although the initial give-and-take over the "umbrella" GMPs has long since subsided, and although the regulations themselves are now reasonably non-controversial as far as their substance is concerned, some troublesome questions remain. I do not intend to rehearse at length the arguments concerning the legal status and effect of the GMPs, but I do wish to discuss one question which still remains unanswered and to point out that this question retains considerable significance, which will doubtless escalate with the coming of the specific industry GMPs.

The problem, briefly stated, is whether the GMPs comprise only FDA's expert interpretation of the general statutory language, which serve to guide industry in voluntary compliance by making clear when FDA will be disposed to initiate enforcement proceedings and to guide the courts in making their decisions in such enforcement proceedings, or whether the GMPs actually rise to the dignity of rules of law, violations of which comprise *per se* violations of the Food, Drug and Cosmetic Act. Most of those outside of FDA have taken the position that FDA lacks the statutory authority to make rules of law in this area;[4] FDA officials incline to the view that the GMPs are not interpretations, but are rules of law.[5] Moreover, the FDA people say: "You tell us that you propose to comply, so why debate the consequences of non-compliance?"

I think the question retains real significance because the consequences of non-compliance will become increasingly critical as the specific industry GMPs are issued. The umbrella GMPs, well padded with qualifiers such as the term "adequate," and conditioned upon the likelihood of "contamination," probably raise few specific rules of conduct that FDA could not enforce just as conveniently under § 402(a)(4) itself. The specific industry GMPs, however, promise to

(Footnote 3 continued.)
ization, an amendment obviously pointed at contamination. The recent Food Additive Order regarding the use of nitrites in smoked fish prescribes time and temperature requirements and clearly extends to the contamination area, since the latter is directly related to the safety of the proposed use of the additive (21 CFR 121.1230). However, neither § 401 nor § 409 is particularly versatile in this area; e.g., it would be impractical, and of dubious legality, to regulate employee sanitation practices, building maintenance, equipment cleaning, etc. under these two provisions.

[4] For example, Forte, *The GMP Regulations and the Proper Scope of FDA Rulemaking Authority*, 56 Geo. L. J. 688 (1968); Cody, *Authoritative Effect of FDA Regulations*, 24 Bus. Law 479 (1969).

[5] Goodrich, *Rule-Making as Viewed by the Commissioner, the Congress and the Court*, 22 F D & C L. J. 613, 618 (1967).

provide such detailed rules of conduct as minimum time-temperature requirements,[6] and the question of the legal consequences of noncompliance may thus be less academic. Also, I believe that the question retains significance because it involves an effort by an executive agency which does not have any statutory power to adjudicate violations in the food sanitation area, to take over the adjudicative function, and perhaps even more important, to adjudicate in advance of particular fact situations.[7]

What FDA Should Do

However, I would prefer to address myself to the question of what FDA *should* do in this area as a matter of regulatory policy, rather than what FDA *may* do in terms of its statutory power. I believe that there ought to be criteria expressed by FDA in the area of food plant sanitation. Judge Friendly states in his study of federal administrative agencies that the need for publicized administrative standards and criteria is perhaps the most critical need in our administrative law system.[8] Judge Friendly believes that consistency of treatment among the regulated parties, opportunity to predict results prior to positioning oneself, and relief of agency officers from outside pressures to influence their activities would follow from regular agency policy pronouncements in the areas that it regulates.[9] He acknowledges that policy cannot be stated in advance to the extent that one will be enabled to predict the outcome of a regulatory proceeding with a computer, but he maintains that having *some* known criteria or standards pronounced in advance is better than making subjective case-by-case dispositions of regulatory matters. I agree with this position entirely, and I believe that it may be uniquely applicable to the food sanitation question we are discussing, primarily because the statutory command is quite broad and

[6] See, for example, 21 CFR § 128a.7(d), specifying that smoked fish are to be held for at least 30 minutes at a temperature of at least 180°F.

[7] FDA has shown a tendency in other areas to use rule-making to encroach upon the adjudicative process. In *PMA v. Finch*, (D.C. Del., Civ. 3797) the question of FDA's power to declare by regulation in advance of a hearing what will or will not constitute substantial evidence of efficacy for pre-1962 drugs is in litigation. Regardless of the obvious drawbacks and the time consumed in adjudicating such matters on the record at a hearing or trial, the interests of one charged with a crime (violation of § 402 (a)(4)) or threatened with the loss of a valuable New Drug Application (NDA) more than outweigh the inconvenience to FDA.

[8] Friendly, *The Federal Administrative Agencies: The Need for a Better Definition of Standards* (1962), 5-6.

[9] *Id.*, 15-16.

general.[10] Predictability is critical. The public relations consequences of an FDA seizure being what they are, even if one should later be vindicated at trial, one needs to know in advance what conditions will cause FDA to institute an enforcement action. Consistency is also critical. With all of the Federal District Courts in the U. S. adjudicating food sanitation violations, the general statutory language permits the application of inconsistent standards. [11] Voluntary compliance is also critical, although it is in bad odor with some Federal Trade Commission aficionados, who would like to see violators required to wear the scarlet letter.[12]

Additionally, the courts have suggested that the standard of § 402(a)(4) is basically the average or norm of industry practices.[13] Obviously FDA, with its factory inspection powers and other country-wide data-collecting activities, is in the best position to make a thorough, meaningful determination of these averages or norms.[14] The situation is not unlike the determination of generally accepted accounting practices, which cannot necessarily be divined by any single accounting firm and which may only be feasibly determined and articulated by the Accounting Principles Board, with the SEC looking on.

Appropriate Form of Pronouncement

Therefore, I believe that FDA should publish standards and criteria as to what constitutes good manufacturing practice. However, I feel that there is some question as to the ideal vehicle for such criteria. Again, I am not now speaking to FDA's power to establish rules of law in this area. I am instead speaking to the question of what as a matter of regulatory policy is the appropriate form of pronouncement of such criteria. Judge Friendly points out that policy statements are the preferable approach, even in agencies which have adjudicative powers, and that a rule of law approach, even where authorized by statute, is inappropriate where the principle

[10] *Berger v. U. S.*, supra, 821.

[11] See *U. S. v. 1500 Cases... Tomato Paste*, 236 F2 208, 212 (7th Cir., 1956), where the Court observed that decisions under § 402(a)(4) are likely to be "highly subjective."

[12] See, for example, FTC News Release of November 18, 1969, relating to the motion by Students Opposing Unfair Practices (SOUP) to intervene in the consent order proceeding involving Campbell Soup Company (File No. 692 3061).

[13] *U. S. v. 1500 Cases... Tomato Paste*, footnote 11, at 212.

[14] In addition to factory inspections, FDA regulatory practices and proceedings regarding food standards, food and color additives, pesticide residues, etc., give FDA broad familiarity with technological and processing practices in the food industry.

does not lend itself to, or is not ripe for, precise articulation, or where the agency wishes to retain flexibility to change its position without going through the Administrative Procedure Act rule-making procedures.[15] Both of the points Judge Friendly raises as objections to the rule-making approach apply here. Surely, the criteria of plant sanitation are difficult to precisely articulate, and the constant changes in technology and scientific techniques indicate that the official sanitation criteria should be subject to prompt amendment by FDA as circumstances change. The policy or interpretive statement approach also avoids encroachment upon the adjudicative function, which the statutory scheme reserves to the District Court in respect of § 402(a)(4).[16]

In short, I am convinced that the pronouncement of sanitation criteria as statements of policy or interpretation would fully serve the regulatory interests that Judge Friendly emphasizes: predictability, consistency and regulatory flexibility. I am convinced that any sanitation practice which would merit criminal proceedings will be grave enough to comprise a violation of § 402(a)(4) itself. FDA also has its considerable publicity powers under § 705, for jawbone enforcement. I find that kind of flexible approach far preferable to the prospect of an executive agency, without clear congressional delegation of such power, enacting voluminous criminal laws for us. I heartily recommend this approach to FDA as the specific industry GMP regulations are being worked up.

Finally, I should say a word about the reaction of my company to the first six months of the umbrella GMPs. I put this question to our quality control people without suggesting any particular answer. The answer was that the regulations were actually welcomed, and have been most helpful. My company, and I am sure most other food manufacturers, have been voluntarily applying virtually all of the criteria set forth in the GMPs for many years.[17] However, they

[15] Friendly, *op cit*, pp. 146-7. The Administrative Procedure Act, 5 USC § 553 (b), provides that "statements of policy or interpretation" are exempt from the notice and hearing requirements for rule-making.

[16] When the Justice Department announced its criteria for initiation of proceedings under Section 7 of the Clayton Act, in the spirit of Judge Friendly's recommendations, that agency declared only what circumstances would elicit a complaint (US Dept. of Justice, release of May 30, 1968). It did not purport to declare how the District Courts would find in each case.

[17] It should be noted that the manufacturing plant is not the only area which requires definition of sanitation criteria. Food-borne diseases may also be caused by improper practices in distribution and handling by persons other than the manufacturer. See, for example, Recommendations of Panel III-4, White House Con-

(Continued on next page.)

find that the GMPs, based upon the wealth of data that FDA has gathered through inspections and Plant Evaluator Systems in thousands of food plants, provide a kind of systematic, thorough check-list approach which is far more complete than any one manufacturer might have assembled. Our people also have no trepidation about the specific industry GMP program; although neither of the two specific regulations published to date affects our operations, we understand that FDA intends to develop such regulations in cooperation with the affected industries.

Conclusion

I suppose the question of what legal vestments the GMP regulations should wear ultimately rests, apart from legal niceties, on whether one believes that there is anything to the concept of voluntary compliance with the Food, Drug and Cosmetic Act. If there is, and I am convinced that there is and *must be* if there is to be any effective compliance at all, then FDA can do its job best by publishing specific, detailed statements of policy regarding GMP, looking to industry cooperation and publicity to secure compliance with this policy, and looking only as a last resort to criminal sanctions under the Food, Drug and Cosmetic Act itself. **[The End]**

FACTORY INSPECTION

Certiorari has been denied by the Supreme Court in a case in which the U. S. Court of Appeals for the Fifth Circuit held that FDA inspectors were not required to inform a food processor of his right to refuse a factory inspection without a search warrant. At the time the inspectors obtained permission to perform the inspection, the processor had neither been charged with a crime, nor had the investigation reached the accusatory stage. Since the Supreme Court refused to review the case, the decision of the lower court stands.

(*U. S. v. Hammond Milling Co.*, U. S. Supreme Court Dkt. No. 648.)

(Footnote 17 continued.)
ference on Food & Nutrition (December, 1969). § 402(a)(4) clearly extends to holding or storage by others in the distribution chain; it is not limited to manufacturers. Yet, the GMP regulations are ambiguous as to their coverage of non-manufacturer distributors.

Food GMPs

By ALFRED BARNARD

Mr. Barnard Is Acting Associate Director of the Bureau of Compliance, FDA.

THE SUBJECT OF FOOD GMPs was my original subject for this paper, but I have expanded this to include significant federal-state relations. So in the limited space available, I will try to cover both of these. First, I will briefly bring us up to date on food Good Manufacturing Practices (GMPs), and second, I will open up a subject area in which few key decisions have been made, but which should provoke some very interesting questions and discussion.

Since I last had the opportunity to meet with this group, we have published, in final form, the so-called "umbrella" food GMP regulations. Despite dire forecasts to the contrary, this regulation became effective without a hearing, and so far without any direct court challenge. This can be attributed, I think, to the fact that we fully took into consideration all the views expressed by the food industry. As our final order, we issued a document which was reasonable and made good sense.

Proposed Regulations

Following our announced plan, we have since proceeded with the development of appendices spelling out GMPs for specific so-called high risk food products. Two of these have been published in proposed form.

The appendix for frozen breaded shrimp is in final form and is expected to appear very shortly in the *Federal Register*. It represents, in my opinion, an outstanding example of effective government-industry effort in the interests of both industry and the consumer.

In this particular situation, we were fortunate in being able to deal with a single organization which represented a large percentage

of the total industry. The organization provided us with technical know-how and guidance to be used in the development of the appendix, and it was possible to meet with the technical people from the industry to solve most of the problems before the appendix was published as a proposal.

When it was published, every effort was made to encourage comment from all interested parties. Because most of the technical problems had been solved in advance, the comments received were very limited and focused primarily on one specific problem. After consultation with our microbiological advisors and a further review of industry practices, it was decided that the issue was well taken and the proposed regulation was revised along the lines urged in the comments.

The process of sitting down with the best technical brains from industry and carrying out a frank discussion of industry problems, and at the same time, developing an understanding of what the regulatory agency is seeking to accomplish, is, in my opinion, the best method for the development of this type of regulation.

The hot smoked fish regulations are more complex, involving difficult technical problems. We are presently evaluating more than twenty comments we have received from six or more individual firms and a number of other interested parties. The comments reflect direct or indirect response by just about everyone in this relatively small industry. Even though the comments are not 100% favorable, we welcome this kind of extensive industry participation in the regulation-making process. It appears, however, that there will be some delay in getting the technical problems resolved and a final order published.

The other area I would like to bring to your attention involves certain functions previously carried on by the Public Health Service, which have been re-assigned to the Food and Drug Administration (FDA) during the past year and a half. Specifically, I refer to the Food, Milk, and Interstate Carrier Sanitation functions, and to a lesser extent, to the National Shellfish Sanitation Program.

Non-Federal Codes and Ordinances

The Milk and Food Sanitation services have developed several model ordinances and codes which are presented to state and local governments for enactment and enforcement. These recommended ordinances and codes now constitute statements of what the FDA

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thinks state and local governments should require of industry under local jurisdiction.

They have an additional major impact. The Milk Sanitation Service is responsible for the maintenance of the Interstate Milk Shippers List, and has primary responsibility for setting standards by which firms seeking to get on the list are judged. While the list really has no federal legal status, in that there is no federal bar to the shipment of milk in interstate commerce, by firms not on the list, in a practical sense you just are not in the Grade A fluid milk market in interstate commerce—you cannot supply military contracts for Veteran's Administration hospitals unless you are on the list. The Grade A Pasteurized Milk Ordinance, which is one of the recommended ordinances and codes issued by the Milk Sanitation Service, establishes the requirements for including a firm on the Interstate Milk Shippers List. In addition, we require, through the Interstate Quarantine Regulations, which appear in Title 42, that firms not on the list will not be classed as acceptable sources for fluid milk products purchased for consumption on interstate conveyances.

Through similar mechanisms, the National Shellfish Sanitation Program sets standards for the inclusion of specific plants on the National Certified Shellfish Shippers List. The interstate quarantine regulations already prohibit the purchase, for serving on any interstate conveyance, of any raw or frozen, fresh or partially cooked shellfish from any source other than a certified shellfish shipper. In view of the potential for the spread of communicable diseases inherent in fresh or frozen raw shellfish, we are currently exploring the legality of forbidding the interstate shipment of any raw or frozen, fresh or partially cooked shellfish from other than certified sources.

I think you can readily see that these advisory or state cooperative programs have substantial impact on industry. I think you can also see that it is imperative that the position they express not be different from the position expressed by FDA in Food Additive Regulations, GMP Regulations, food standards or other official positions set forth in Title 21 of the *Code of Federal Regulations*.

FDA's Two Voices

This raises at least one or two basic issues. Can FDA afford to speak with two voices? In other words, is it appropriate for FDA to issue recommended ordinances and codes, such as the Pasteurized Milk Ordinance, the Vending Machine Ordinance, and the Food

Manufacturing Ordinance currently proposed, or must FDA limit its issuances in these areas to a single document?

It has been argued that FDA cannot say the same thing in two different sets of language, because to do so implies some difference in meaning. If we provide the more detailed specifications and interpretations which are presently an integral part of the recommended ordinance and code system, are we then obligated to incorporate the same detail in GMP Regulations?

Can FDA appropriately recommend to its state and local counterparts that they impose specific requirements on industries which FDA either is unwilling or unable to impose on the same commodities in interstate commerce? Are we thereby limited to publishing recommended ordinances only in those areas where we choose not to develop GMP regulations?

I opened this subject for discussion in a provocative vein. Decisions have not been made at the top level on some of these questions. I have recommended to the Commissioner, however, that we not go the one document, one voice restrictive route delineated in the foregoing comments. I have recommended that instead we should realize that recommended ordinances and codes serve a different purpose from regulations promulgated under specific authorities granted in the Food, Drug, and Cosmetic Act; that the broad grant of authority under the Public Health Service Act to protect the public health frees us to become involved more broadly. It is patently obvious that there must be no conflict between expressions set forth in GMP regulations and positions taken in recommended ordinances and codes. I suggest, however, that we can effectively enhance total consumer protection by FDA if we regard the Milk, Food and Shellfish Sanitation Services as additional tools to be employed, rather than as something to be brought into, and rendered indistinguishable from, the traditional Food, Drug and Cosmetic Act compliance approach.

Conclusion

I leave for your consideration questions concerning the status of model ordinances and codes in FDA—they clearly have the force and effect of law in those jurisdictions where they are enacted by an appropriate body, but what is their status, if any, at the federal level —and how do they relate legally, if at all, to the GMP regulations? Can we in FDA continue the past practice of making changes in recommended ordinances and codes and their interpretation without prior notification to affected parties? **[The End]**

Self-Certification of Foods: A Progress Report

By NATHANIEL L. GEARY

Mr. Geary Is Special Assistant for Quality Assurance, Bureau of Compliance, Food and Drug Administration, Consumer Protection and Environmental Health Service, Public Health Service, Department of Health, Education and Welfare.

LAST YEAR I told you about the Food and Drug Administration (FDA) and industry cooperating in a voluntary Self-Certification Program. The Program, designed to see if industry and FDA could achieve quality assurance (i.e., consumer protection) in foods more efficiently, was being tested at General Foods' Dover, Delaware plant and Green Giant's Blue Earth, Minnesota plant. We wanted to: (1) see if workable specifications could be developed for the quality of ingredients, processes, environment and finished products in the pilot plants; (2) test the mechanics of the plan; (3) determine the minimum control specifications needed to extend the plan to other products and other plants; and (4) maintain good communications between the participants. Today I'd like to answer three questions in my second progress report to you on the Self-Certification Program: What have we done since our last report? Where are we now? And where are we going?

What Have We Done?

Expanded Pilot Studies.—FDA expanded its pilot studies to include five additional plants each in a different industry. They are non-fat dry milk and milk products, eggs and egg products, fish and fishery products, nuts and nut products, and convenience foods. Thus far we have two plants, a shelled pecan producer and a producer of frozen eggs, which have agreed to participate in pilot studies. In addition, Green Giant's Glencoe, Minnesota plant, a processor of canned and frozen vegetables, joined the pilot program.

Evaluated General Foods' Pilot Program.—General Foods and FDA successfully completed their pilot study at the Dover, Delaware plant. Information gained from this pioneering effort has been used to:

(1) improve the technical and administrative aspects of operating subsequent pilot studies;

(2) focus upon problems which may be examined in pilot studies or administratively; and

(3) provide a basis for expanding the program from the pilot to a modest operational program by July 1, 1970.

We concluded that the General Foods Study met the four objectives outlined in my opening remarks. In addition, General Foods evaluated their experience as follows:

1. They improved their quality assurance program without increasing operating costs. For example, appropriate emphasis on ingredient sampling has prevented unfit ingredients from being used.

2. They have a greater appreciation for the requirements imposed by government upon industry. Knowing these requirements enabled them to operate with confidence that they were doing a good job.

3. They plan to incorporate the Self-Certification approach throughout their Corporate quality assurance programs.

4. They want to participate in the Self-Certification program when it becomes operational, and when our priorities permit.

5. They have volunteered continued cooperation with FDA citing the value of good communications and excellent rapport developed during the pilot study.

What Are We Doing?

We are developing the administrative and technical procedures for an operational program by July 1, 1970. Examples include the following:

Improved Communications Reduce Delays.—By developing "model draft specifications" for use in negotiating specifications for a plant, FDA has reduced the time to reach agreement with the plant from six months to three months. We can expect further improvement as we gain additional experience from the pilot studies.

Staggered Acceptance of Plants to Enhance Progress.—To better use the unique experience with each plant in developing operating procedures, we are accepting only one plant at a time. We are analyzing the acceptance procedure from start to finish. The results of analysis are incorporated into the next plan. When we have accepted the five additional plants planned for this fiscal year, we should have greatly improved our procedure. For example, unnecessary delays may be minimized or excessive, costly control procedures may be excluded from specifications.

We are also evaluating the Green Giant studies to see: if the specifications are realistic, if our operating procedures are satisfactory, and the potential for state involvement in this program.

Where Are We Going?

We are moving toward our goal of 25 plants in an operational program in Fiscal Year 1970. To realize this goal we are developing instructional and informational materials for industry, our District Offices, and the states. We are also concerned with developing information for the public about this Program which affects them directly. The public and participants will be interested in, e.g., an

Evaluation of Effectiveness of the Program.—Programs, like products or stocks, no matter how good, are worthless unless and until accepted in the marketplace. Self-Certification is new, virtually untested and unevaluated. To show the merits of this approach to compliance, we plan to use three criteria:

(1) Attributes of Finished Products

(2) Costs to Industry and FDA

(3) Changes in Processes or Control which result in improved quality. Through such evaluations, FDA hopes to show how the consumer benefits. Such evaluations could also show benefits for industry, and FDA investment in the Program. We are testing these criteria in the Green Giant studies.

Why the Expanded Pilot Program in Fiscal Year 1970.—From a management viewpoint we need additional information upon which to evaluate Self-Certification. We need to know if we can expect

comparable results from plants of various sizes, with diverse processes and products. Having tested the Program with only two major food producers, we believe that our studies should also provide experience in smaller plants and with a variety of products and processes. We hope to develop a better knowledge of the specifications for the quality of various products, processes, ingredients and environmental controls. Such knowledge will help us to apply controls more efficiently in other plants producing similar products or using similar processes.

We hope to improve the overall effectiveness of our cooperative voluntary efforts to assure the quality of your products.

Program Priorities May Change.—Our approach to Self-Certification is this: To bring into the Program plants making foods which are subject to microbial contamination. We have identified industries which meet this criterion. However, there are some recent developments which may change our approach, e.g., the joint decision of the Departments of Agriculture and Health, Education, and Welfare to place non-fat dry milk under United States Department of Agriculture (USDA) administration. With such a change, FDA would not need a Self-Certification Program for non-fat dry milk. If a similar decision is made for eggs and egg products, FDA may have to eliminate them from consideration for Self-Certification. Industry and government participants in the Self-Certification Program practice the theme of this conference, "The Obligation of Excellence". Both have the duty, responsibility, authority, and indeed the obligation to produce or assure production of safe, wholesome, properly labeled foods. The Program approaches its mission, Quality Assurance, with this philosophy, plants participating in this program must do everything possible to achieve their goals for product quality. Goals are reached when plants do the best job possible with available resources, and if resources are insufficient, with additional resources to meet objectives of quality. They strive for excellence not for mediocrity.

Next April we will begin contacting such plants and receiving their applications for participation in the Self-Certification Program. We hope that all food manufacturers who want to participate will be able to join us in this Program within the next few years. **[The End]**

FDA's Intensified Drug Inspection Program

By H. A. FREDIANI

Mr. Frediani Is Associated With Bristol Laboratories, Syracuse, New York.

THE HARRIS-KEFAUVER AMENDMENTS to the Food and Drug Administration (FDA) required that each drug firm in the United States be inspected at least once every two years. To the larger companies in the prescription drug business, this two-year inspection basis seemed rather ludicrous since it had been our experience that FDA inspections were made in our plants at least half a dozen times a year.

In order to implement this two-year inspection basis, Dr. James Goddard, then the Commissioner of the FDA, announced the Intensified Drug Inspection Program (IDIP) Plan. The Intensified Drug Inspection Program was designed to put a team of specially trained FDA inspectors into a prescription drug manufacturing plant in order to carry out an intensified in-depth inspection to assure adherence to the current good manufacturing practice regulations.

The avowed purposes of this inspection was to bring weaknesses to the foreground and to assure maximum consumer protection in the field of prescription drugs. The program was to start on July 1, 1969 and to have all 700 or 800 prescription drug manufacturers in the United States inspected at least once during the following two years. In initiating the program, the regional FDA director wrote a letter to top management of the drug firms to be inspected and invited them and their representatives to a conference at which the program of the inspections and the ground rules to be followed were to be discussed.

Preparation for Inspection

In general, the manufacturer was informed that a team of at least two FDA inspectors would be assigned to the job of the intensified inspection and would be kept in the plant for whatever time it was necessary to

carry out such inspections in extreme depth. The inspection was to familiarize the inspectors with the background of the manufacturer and with every detail of his operation including his plant, receipt and handling of raw materials, storage of raw materials, finished products and intermediates, the adequacy of equipment used in manufacturing and testing raw materials and finished products, the existence and adequacy of written specifications and detailed manufacturing instructions. Also included in this inspection was to be a careful perusal of the record and sample-keeping policies of the company with selected batches of important finished products being traced backwards to assure that adequate records had been kept of every step in the production of the dosage form.

This included such details as checking the analytical lab records involved not only for the finished product but for the raw materials that went into it and solvents that may have been used in the processing operation. Included was a checking of weights used, calculations carried out, neatness and clarity, other records kept and proper initialing of all processing steps.

The entire inspection was to be carried out in three or four stages depending on the complexity. After each stage the inspectors would summarize their findings and bring to the attention of the firm's management any weaknesses and shortcomings that had been found up to then.

A further final meeting was to be held with the expected attendance of the top executive officer, the head of the Control Division, regional director of the FDA, the inspectors involved in the operation and the appropriate manufacturer's representatives who had spent their time with the FDA Inspectors as guides and interpretors.

At this meeting, a review was to have been made of shortcomings that had been evident and pointed out in order that there was a clear-cut understanding between the FDA representatives and the manufacturer as to what steps had been taken, were proposed to be taken in the future, and/or reasons why the manufacturer did not believe that shortcomings pointed out by the FDA inspectors to be valid.

Having recently completed just such an inspection at Bristol Laboratories, we have found that the program essentially worked out as indicated. The time involved by the FDA Inspectors, by company officials in the Control Division and by supervisors in the manufacturing and storage was long but not exceedingly so considering the depth of inspection. The calendar time occupied by the inspectors was overly prolonged primarily due to the necessity of the FDA pulling out their special inspectors for emergency work from time to time.

How do we feel about such an inspection?

The Bristol Labs Inspection

The inspection was set up as programmed at the original briefing session. Two men from Bristol Control were assigned, as alternates, to guide the FDA inspectors, answer questions or get answers from other Bristol employees. The Control men were chosen because of their overall knowledge of our plant operations. Thus, at each of the inspections we had the two FDA men, one Control man and a key man for the area to be inspected, i. e., warehouse, tablet production supervisor in the granulating and tabulating area, fermentation manager in the fermentation area, chief chemist in the chemical laboratory, etc. The inspectors were asked to limit their questions to operators to their immediate duties and to pose questions concerning theory or reasoning behind various operating steps to the area supervisor. Although operators may be chosen with care they usually have limited technical backgrounds and often, in a spirit of co-operation, tend to think they know more than they really do.

There is no doubt in our minds that this inspection served a very useful purpose. In spite of the large amounts of money we spend for Quality Control, it is very advisable to have some some outsider come in and take a look at what we have been doing. Although no major weaknesses were found in our system, some minor points that could have led to problems were pointed out and thus corrected. In our case, for example, incoming raw materials are assigned raw material numbers involving a letter followed by four digits. These letters started with A and proceeded through the alphabet. At the time of inspection, we had arrived at the letter T. Our in-plant traffic department, too, had a move order system which operates on a written move order basis. These move orders are sequentially numbered by T and four digits. Thus, at this stage of our operation, we could have confused a move order with a raw material number because of the similarity.

Since the inspection of our plant took almost a year in elapsed time, it is difficult for many to believe that the FDA can inspect all 700 prescription drug manufacturers to this extent in the first two-year period of the program. Obviously, it is to our interest, since we have gone through this program, to feel that every other manufacturer in the industry should have the same close scrutiny. It is both my feeling and that of our management that the inspection, although it has cost us some money, has done much towards confirming the fact that our operations were good and that we are and were adhering to the current good manufacturing practices regulation.

The cooperation received from both the regional FDA Inspector and his inspectors was outstanding. The high quality of the inspectors assigned

to the job leads us to feel that none of our special manufacturing know-how and processes are in danger of being peddled to our competitors. This is a real risk and the manufacturer is protected only by the quality of FDA inspectors assigned to his plant.

Industry Recommendations

I have discussed the IDIP Program with three or four Pharmaceutical Manufacturers Association (PMA) member companies who have either had their inspections completed or who are in the process now. Their experience has been very comparable to our own. They felt that the actual in-plant time was not excessive, but the overall elapsed time was too long.

An interesting comment from one Control Director was that the program is essentially un-American. When asked to explain this comment, he pointed out that Americans are given laws and willing to abide by them if the laws are enforced equally to all people. This is not being done with respect to the IDIP and the larger manufacturers are being subjected to inspections to a greater extent than the smaller fly-by-night operations.

It may be well to point ont here that the time spent in the single Bristol inspection could have resulted in the completion of 15-20 inspections of small companies, primarily involved in dosage formulation production, usually limited in physical size and numbers of products and not involved in bulk drug production. As indicated by published records of prescription drug lot recalls these 15-20 inspections would have resulted in the upgrading of companies who need it more than Bristol.

With respect to the failings that have been proven as indicated by drug recalls, about a year ago we went through all the published records and evaluated the number of recalls, tabulating them with respect to whether the manufacturer was a PMA member or not. There were a total of 190 lots recalled by 50 member companies. During the same period there were 390 lots recalled by 110 nonmembers. Thus, despite the fact that approximately 90% of the drugs now on the market are manufactured by PMA members, this group only constitutes 20-25% of the total number of manufacturers of ethical drugs. There are more than twice as many non-PMA member companies involved in recalls and twice as many lots recalled in spite of the fact that they were only responsible for the distribution of 10-20% of the present drugs on the market. Ten were required to recall between 10 and 30 different lots during this period.

Since up to the present time, only 80 companies have had their inspections completed, it would be of great interest to know how many of these ten severely delinquent companies had been inspected and found to be adhering to good manufacturing practices. **[The End]**

The National Center for Drug Analysis

By DANIEL BANES

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THE INCREASING INCIDENCE OF RECALLS in recent years, as well as several other regulatory indicators, have indicated the need for a new approach to the control of drugs in the United States. As a consequence of these findings, the Food and Drug Administration (FDA) concluded that the most important groups of drugs should be sampled and tested in large volume according to a program design capable of yielding statistically reliable data on the character of the nation's drug supply.

A major scientific stimulus for the creation of a new facility in FDA was that drug analysis on a large volume basis requires complex instrumentation and capabilities in terms of both personnel and physical support that were not readily available in the existing district laboratories. It seemed logical to develop an automated facility which could expeditiously examine huge numbers of samples to monitor the quality of drug products in the marketplace.

On February 20, 1967, a pilot study was initiated in the St. Louis District laboratories to determine whether such large scale analytical operations were feasible. Upon successful completion of this pilot study, the National Center for Drug Analysis (NCDA) was officially established in July 1967 as a field installation of the Division of Pharmaceutical Sciences in the Bureau of Science. During Fiscal Year 1968 the Center examined a total of 7,227 samples. In Fiscal Year 1969 the Center examined 9,395 samples with a staff of 43, of whom 29 were professional scientists, and 14 administrative and laboratory supports. As the staff gains experience, and additional manpower and instruments are obtained, the sample workload is increased. It is estimated that approximately 12,000 samples will be examined in Fiscal Year 1970.

Analysis of Data

The drug monitoring projects completed and in progress as of October 1, 1969, are listed in Table 2, together with data on the numbers of samples analyzed, the numbers of violative samples, and the percentages of violative samples. Table 1 lists the dosage forms of all the drug products examined in these survey projects.

Let us first consider the more reassuring aspects of the data in Table 2. It should be noted that in Studies 002, 004, 704, 008, 009, 014, 016, and 017, the violative rate (the percentage of lots that failed to meet the legal requirements) was below 1%. In a few additional instances, the violative rate was between 1% and 1.5%.

However, several projects such as studies 001 on Anticoagulants and 013 on Ergot alkaloids disclose cause for concern. In study 001 on the vitally important Anticoagulants, the bulk of the violations were concentrated in one type of preparation, so that the proportion of defectives in this sub-group was even greater than 4%. An in-depth analysis of the difficulties revealed several interesting facts about deficiencies in the manufacturing process and about inadequacies in the official monograph which had been composed and recommended by the manufacturer.

The two surveys on Reserpine Tablets, Studies X07 and 799, are also noteworthy. In the earlier study, the violative rate was close to 10%. Several of the samples were significantly superpotent, others were decomposed, and there was evidence that adulterated reserpine had been used in formulating some batches. As a result of these findings, several recalls and other appropriate regulatory actions were consummated.

The violative rate in the follow-up survey, Study 799, was 3.6% and the deficiencies, although still disquieting, were far less serious than those encountered earlier.

None of the batches was superpotent or decomposed, nor was there any evidence of adulterated reserpine in use. Most of the violations involved sub-potent lots whose assay values were within 5% of the lower acceptable limit. We have plans for instituting similar repeat studies with other drug preparations.

In the reserpine surveys, samples were collected at the formulator level, in manufacturing plants and warehouses. The sampling pattern in all of the other studies depended upon collections at hospital and retail pharmacies. We are considering various procedures in an attempt to devise optimal sampling operations. We are also

experimenting with new approaches to more efficient sample preparation prior to analysis, and streamlined data report and paper handling.

The invention and use of analytical methods in automated systems for large-scale operations has been an exciting stimulus to our ingenuity for scientific improvisation. Furthermore, NCDA investigations have afforded valuable information about the dependability of many official assay procedures—information which will form the basis of interesting future researches. But, most important, the drug monitoring activities have already provided, and should continue to provide with ever greater effectiveness, reliable current data about the quality of pharmaceutical preparations in the marketplace. It thus serves as a proficient instrument for furthering the chief objectives of our regulatory program for drugs: to remove defective articles from commerce and to help in improving the quality of the products consumed by the public.

TABLE 1.

Dosage Forms and Drug Products Examined in NCDA Monitoring Studies

Study Number	*Products Examined*
001	Acenocoumarol Tablets
	Anisindione Tablets
	Bishydroxycoumarin Tablets
	Diphenadione Tablets
	Phenindione Tablets
	Phenprocoumon Tablets
	Potassium Warfarin Tablets
	Sodium Warfarin Tablets
002	Benactyzine HCl Tablets
	Buclizine HCl Tablets
	Chloridazepoxide HCl Tablets
	Chlormezanone Tablets
	Diazepam Tablets
	Emylcamate Tablets
	Hydroxyphenamate Tablets
	Hydroxyzine Tablets
	Mephenoxalone Tablets
	Meprobamate Tablets
	Oxazepam Tablets
	Phenaglycodol Tablets
	Tybamate Tablets
003	Dexamethasone Tablets
	Hydrocortisone Tablets
	Prednisone Tablets
	Prednisolone Tablets
	Betamethasone Tablets
	Cortisone Acetate Tablets
	Desoxycorticosterone Tablets
	Fludrocortisone Acetate Tablets
	Fluprednisolone Tablets
	Methylprednisolone Tablets
	Paramethasone Acetate Tablets
	Triamcinolone Tablets

TABLE 1—Continued

Study Number	*Products Examined*
004	Phenformin Tablets
704	Chlorpropamide Tablets Acetohexamide Tablets Tolbutamide Tablets Tolazamide Tablets
005	Acetyldigitoxin Tablets Digitoxin Tablets Digoxin Tablets Lanatoside C Tablets
006	Sulfacetamide Tablets Sulfadiazine Tablets Sulfamerazine Tablets Sulfaguanidine Tablets Sulfapyridine Tablets Sulfathiazole Tablets
007	Amphetamine Sulfate Tablets Dextroamphetamine Sulfate Tablets Methamphetamine Hydrochloride Tablets
008	Butabarbital Tablets Sodium Pentobarbital Capsules Phenobarbital Tablets Secobarbital Capsules Amobarbital Capsules
009	Diphenhydramine Hydrochloride Capsules Chlorpheniramine Maleate Tablets Tripelennamine Hydrochloride Tablets
010	Nitroglycerin Tablets
X07	Reserpine Tablets
799	Reserpine Tablets
013	Ergonovine Maleate Tablets Methylergonovine Maleate Tablets
014	Diethylstilbestrol Tablets Dienestrol Tablets
015	Chlorothiazide Tablets Hydrochlorothiazide Tablets
016	Sodium Diphenylhydantoin Capsules Methsuximide Capsules Phensuximide Capsules
017	Quinidine Sulfate Tablets and Capsules Procainamide Hydrochloride Capsules
018	Carisoprodol Tablets Chlorphenesin Carbamate Tablets Orphenadrine HCl Tablets Orphenadrine Citrate Tablets
019	Chlormezanone Tablets Methocarbamol Tablets Metaxalone Tablets Mephenesin Tablets and Capsules

TABLE 2. Drug Monitoring Studies Conducted in NCDA

Study	*No. of Samples*	*No. of Violative Samples*	*% Violative Samples*	*Date Initiated*	*Date Terminated*	*Identification*
001	1454	57	3.9	03-01-67	11-30-67	Anticoagulants
002	1411	5	0.4	03-01-67	11-02-67	Tranquilizers
003	2009	42	2.1	07-17-67	08-02-68	Adrenocortical Steroids
004	997	1	0.1	12-01-67	05-24-68	Oral Hypoglycemics
704	167	0	0.0	02-12-68	04-05-68	Pilot Study for Oral Hypoglycemics
005	1677	23	1.4	01-15-68	10-29-68	Cardiac Glycosides
006	1146	14	1.2	05-02-68	01-23-69	Sulphonamides
007	1030	14	1.4	05-02-68	12-26-68	Amphetamines
008	1192	7	0.6	07-26-68	02-03-69	Barbiturates
009	926	4	0.4	08-01-68	01-31-69	Antihistaminics
X07	245	23	9.4	09-25-67	10-13-67	Reserpine
010	1343	45	3.4	08-01-68	03-11-69	Nitroglycerin
799	968	35	3.6	01-24-69	04-15-69	Reserpine
013	175	9	5.1	03-01-69	04-18-69	Ergot Alkaloids
014	679	7	0.9	05-19-69		Nonsteroid Estrogens
015	1137	12	1.1	03-01-69	09-03-69	Thiazide Diuretics
016	726	4	0.6	04-15-69		Anticonvulsants
017	917	3	0.3	04-01-69	09-03-69	Cardiac Anti-arrhythmics
018	96	0	0.0	08-01-69		Skeletal Muscle Relaxants
019	75	0	0.0	08-01-69		Skeletal Muscle Relaxants

[The End]

Mechanisms for Setting Food Standards in Canada

By DR. J. A. CAMPBELL

This Paper Was Presented Before the Meeting of the Food Protection Committee and Liaison Panel of the NAS-NRC. Dr. Campbell Is Assistant Director of General Foods of the Department of National Health and Welfare, Ottawa, Ontario, Canada.

IT IS A GREAT PLEASURE and honor for me to be invited to discuss with you the way in which food standards are developed in Canada. I feel that we in the Food and Drug Directorate in Canada are very fortunate in being able to raise questions and seek answers to our problems with many of you in the Food and Drug Administration (FDA), in universities and industry here in the United States on essentially the same basis as we would in Canada. These discussions are of great value to us. I am very happy, therefore, to have this opportunity of describing to you mechanisms for setting food standards in Canada. I trust that this will be of value and of interest to you.

Early Legislation

The first act pertaining to the control of foods and drugs in Canada was passed in 1875—94 years ago. It is thus the oldest national law relating to food in the western hemisphere. The history of its development makes interesting reading and I believe aids in an understanding of our present legislation.

It is recorded[1] that in the early days of confederation there was excessive drinking in some areas. Not only was there too much liquor, but a great deal of it was immature fiery spirit. In the House of Commons in 1873, it was claimed that 60% of the cases of insanity and 80% of the cases of crime were caused by intemperance.

[1] Davidson, A. L., *The Genesis and Growth of the Food and Drug Administration in Canada*, King's Printer, Ottawa, Canada, 1949.

Public opinion was deeply aroused and petitions poured into Ottawa asking the Parliament to do something about the situation. Although there were many who favoured prohibition of the use of liquor, as was tried here, many legislators felt that it was not liquor but bad liquor which ought to be banned. Thus it was that Sir Richard Cartwright[2] in the House of Commons in 1874, moved that the House consider a resolution that all persons carrying on business as compounders and mixers of wine, brandy or other alcoholic liquors be required to take out a license to do so.

Within two weeks of Sir Richard's motion, an act was passed entitled "An Act to Impose License Duties on Compounders of Spirits and to amend the 'Act Respecting Inland Revenue' and to prevent the Adulteration of Food, Drink and Drugs." It was operative as of January 1, 1875 and was cited as "The Inland Revenue Act of 1875." It was patterned after the English Adulteration of Food and Drugs Act of 1872.

The act provided for the bonding and licensing of compounders of liquors. Persons possessing "competent medical, chemical or microscopical knowledge as analysts of food, drink and drugs" were to be appointed to analyze samples collected by Inland Revenue officers and other inspectors. Liquor was adulterated if it contained certain specified substances such as common salt, copperas, opium, Indian hemp, tobacco, or salts of zinc or lead. Adulterated food was defined as "all articles of food with which was included any deleterious ingredients or any material of less value than is understood by name." Thus, in 1875, the principle of protection of the public against health hazards and fraud had been established and procedures set up to enforce it.

The early act suffered from two chief weaknesses. In the first place, it did not provide a clear understanding of what constituted adulteration which at that time was rampant. In fact, it is reported that one of the early administrators indicated that adulteration was so widespread that he believed it must be practiced according to some general formula. For example, the adulterant for mustard was flour colored with turmeric, for pepper, slightly roasted flour, for coffee, chicory, for chocolate, starch and flour, to mention only a few. The second weakness lay in the lack of authority to prescribe

[2] Curran, R. E., CANADA'S FOOD AND DRUG LAWS, Commerce Clearing House, Inc., Chicago, 1953.

standards. The time-honored jokes of the pump being close to the milking shed were not without foundation. In May 1887, as a result of an investigation of various factors influencing the composition of milk, a standard was suggested with the composition of 3.5% of butterfat and 8.5% of solids-not-fat. Although this proposal did not become law for some years, the need for and importance of setting standards was recognized and in 1890 an amendment[3] to the earlier act was passed in which adulteration was defined more closely and the Governor-in-Council was given authority to make standards.

These amendments had two important functions. They placed on a firm basis the fixing of legal standards by order-in-Council and they represented the beginning of a distinctive aspect of Canadian food and drug legislation namely "delegated legislation."

Another major advance in Canadian food legislation occurred in 1920[4] when the Parliament of Canada passed the first "Food and Drugs Act." One of the most important provisions of this act was the enlarging and formalization of "delegated legislation" or legislation by regulation. Relevant sections of the act gave the Governor-in-Council, which in practice is the Cabinet, the authority to make regulations covering all phases of the manufacture, sale and distribution of foods, drugs, cosmetics and therapeutic devices. Although the act was subsequently rewritten and expanded in 1953[5] to accommodate changes in technology, this authority was retained. Delegated legislation is in the nature of a delegation by Parliament to the Governor-in-Council of one of its law-making functions. It has the advantage that amendments do not have to await the passage of other legislative matters. Furthermore, a regulation or standard made under authority of the act, has the same force and effect as the act itself.

The pertinent sections of the 1953 Food and Drugs Act read as follows:

24. (1) The Governor-in-Council may make regulations for carrying the purposes and provisions of this Act into effect, and, in particular, but not so as to restrict the generality of the foregoing, may make regulations

(a) declaring that any food or drug or class of food or drugs is adulterated if any prescribed substance or class of substance is present therein or has been added thereto or extracted or omitted therefrom;

(b) respecting

(i) the labeling and packaging and the offering, exposing and advertising for sale of food, drugs, cosmetics and devices.

[3] See footnote 2.

[4] See footnote 2.

[5] Canada, Department of National Health and Welfare Office, Consolidation of the Food and Drugs Act 1954.

(ii) the size, dimensions, fill and other specifications of packages of food, drugs, cosmetics and devices,

(iii) the sale or the condition of sale of any food, drug, cosmetic or device, and

(iv) the use of any substance as an ingredient in any food, drug, cosmetic or device,

to prevent the consumer or purchaser thereof from being deceived or misled as to its quantity, character, value, composition, merit or safety or to prevent injury to the health of the consumer or purchaser;

(c) prescribing standards of composition, strength, potency, purity, quality or other property of any article of food, drug, cosmetic or device.

There is no provision in our law requiring a public or other form of inquiry before a regulation is promulgated. As a matter of practical policy, however, we have developed a procedure which involves discussion with the trade, either in general or in particular, before a regulation is made. Furthermore, although the Governor-in-Council is not under restrictive procedures, there are effective checks on what may be done in this connection. A regulation may be challenged in court if it exceeds the authority so delegated. It may be exposed to debate in Parliament and thus subjected to the test of approval by the appointed representatives of the people. Finally, there is possibly a third check in that the minister is open to direct access by industry and a regulation which is impractical, unworkable or which does not command the respect of those required to observe it, is impossible to enforce. Thus, the support of the trade becomes an important factor.

It should also be noted that in Canada, the Food and Drugs Act, since it involves injury to health of the individual and fraud, and not pure regulatory control of a trade, is considered criminal law. As such, it is a federal responsibility and interprovincial trade does not have to be proven.

Philosophy

Our philosophy in the formulation and promulgation of regulations (including standards) may be summarized in six points:

1. Standards should be based primarily on a need to protect the consumer in the broad areas of health hazard and fraud.
2. Standards may also be of benefit to industry through the establishment of uniform rules.
3. Standards should not be developed unnecessarily.
4. Standards should not be unnecessarily restrictive.
5. Standards (and regulations generally) can and should be changed when a need for change becomes evident.

6. Suggestions from industry and other non-governmental organizations are welcomed.

We realize that these are broad statements subject to considerable differences in interpretation. Limitations in staff and other resources often slow down relatively simple amendments to standards which otherwise, might be processed in a minimum of time. Thus, it may seem at times that our philosophy is somewhat different from what I have described. Nevertheless, from the point of view of industry, it must be stressed that if you, individually or collectively, are concerned about a regulation, do not hesitate to register your concern. This is a first step, if we cannot agree with you we will try to tell you why. If we can, we will try to remedy the situation and amend the regulation.

Present Procedures

Now, what are our present standard-making procedures? Requests for amendments to existing standards or the formulation of new ones may come from several sources. They may arise from research findings, from problems encountered in the field or from a review of a particular problem within the Directorate. They may come from other departments including the Department of Consumer and Corporate Affairs which is now responsible for labeling, advertising and packaging of foods. They may also come as a result of a submission by an individual company or an industrial association.

All submissions concerning foods are directed to the Food Advisory Bureau, whose responsibility is to review the request and ensure that sufficient information is available to make a decision. If necessary, they will go back to the sponsor of the submission to supply more information. One way to save time is to ensure that the original submission is as complete as possible. In this connection, it should be noted regarding food additives that Section B.16.002 of the regulations requires that requests for additions to the lists of food additives should include:

1. A description of the food additive,
2. A statement of the amount of the food additive proposed for use, and the purpose for which it is proposed,
3. Where necessary, an acceptable method of analysis,
4. Data establishing that the food additive will have the intended physical or other technical effect,
5. Detailed reports of tests made to establish the safety of the food additive,

6. Data to indicate the residues that may remain in or upon the finished food, and

7. A proposed maximum limit for residues of the food additive in or upon the finished food.

In reviewing a submission, the whole expertise of the Directorate is brought to bear on the problem. If necessary, outside consultants may be sought on a particular aspect. If the matter is of an appropriate nature, the views of experts in the field, in universities and institutions in Canada, the United States and elsewhere may be sought. Our recent proposals on substitute milks is an example of this broad type of approach.

As a result of this discussion, a standard or an amendment to a standard is proposed and brought before the Food Advisory Committee chaired by the Director of the Food Advisory Bureau. At this meeting representatives of all other bureaus are present along with experts in the fields involved. In general, the proposals before this group may be classed into two types. On the one hand, there are requests for relatively minor changes in standards, the inclusion of an additional additive, the lowering of a pesticide tolerance or a modification of a label statement. On the other hand, there are broader items requiring a policy decision of the Directorate on matters such as the development of standards in new areas, the modification of standards which may affect the economics of an industry, or the reversal of a previous policy decision in the light of new information.

In the first and simpler case, an amendment to the regulation is written with the assistance of, or by, our Legal Division and checked by the Department of Justice. The trade is then usually advised of the proposed action via a Trade Information Letter (TIL). In the second and more complex case, the matter is referred to the Operations Committee for a policy decision. This committee is chaired by the Director-General and its membership consists of the Assistant Directors-General and the directors of the various bureaus. This committee decides the course of action to be taken including the issuance of a TIL, the effect on Directorate resources, the possible effect on industry, the possible disadvantages of the proposal, the organizations likely to be affected, and the people and organizations to be contacted. If cleared, the item usually goes back to Food Advisory Bureau for checking with the Legal Division and with the Department of Justice prior to the issuance of a TIL.

If it is decided that the standard is of sufficient significance that the views of the trade or outside organizations should be sought, it

is the responsibility of the appropriate Assistant Director-General for foods or drugs to receive and review comments obtained. These are again considered and possible amendments made in the original proposal. If the matter is sufficiently difficult or complex, or the impact on industry sufficiently serious, it may be necessary to hold discussions with technical representatives of the particular industry involved. These discussions are of an informal nature aimed at coming to a reasoned conclusion.

When essential agreement has been reached, or the Directorate has decided that within its responsibility a course of action is indicated, or the matter under review is a relatively minor one, the trade is then advised by TIL that the Director-General, Food and Drug Directorate, plans to recommend to the Minister of National Health and Welfare that certain standards be adopted. This is the final action of the Directorate on a standard and it should be noted that this is a notice of intent not an indication that the change is, or even will be effective.

The proposed regulation or standard is now considered by the Minister, who, if he agrees, submits it for approval by the Governor-in-Council which in practice, is a committee of Cabinet. When this occurs the standard is then published in the Canada Gazette Part II and becomes law as of the date of publication unless some other date is stipulated in the Gazette. This corresponds to publication in your Federal Register. It is usually required that regulations involving substantial manufacturing, packaging or labeling changes have a future effective date to give industry an opportunity to conform without undue economic stress.

In summary, it is our feeling that standards should be formulated for the protection of the consumer. They must not be static but should be amended when they have ceased to serve their purpose and should probably be subject to periodic review. Amendments should be based on the best scientific information available. In seeking this, it is important to have the benefit of broad discussion among scientists both inside and outside the Directorate. Although some amendments may require more time than seems necessary, it is our intention to try to expedite these changes by any possible means.

Finally, may I say to those of you who may be interested in having food standards in Canada amended, if you feel there is a need for change do not hesitate to contact us. We may not agree with you but we are willing at any time to listen to your point of view.

[The End]

Introductory Statement

By FRANKLIN M. DEPEW

Mr. Depew Is Chairman of the Food, Drug and Cosmetic Law Section of the New York State Bar Association, and President of the Food and Drug Law Institute. His Article and the Ones Following Were Presented at the Annual Meeting of the Food, Drug and Cosmetic Law Section of the New York State Bar Association.

THE TWENTY-FIFTH ANNUAL MEETING of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association denotes a quarter of a century of service to the legal profession and to the general public in the furthering of a better understanding of our food, drug and cosmetic laws. This section was the first Bar Association group to be organized by lawyers practicing in this field and our membership is not restricted to New York State but is a nationwide one.

Our program consists of eleven valuable papers which I'm sure you will find of interest. Regretfully, neither former Commissioner of Food and Drugs, Dr. Herbert L. Ley, Jr., nor the present Commissioner, Dr. Charles C. Edwards, was able to accept our invitation to speak here. Fortunately, however, Bradshaw Mintener, former Assistant Secretary of Health, Education and Welfare has agreed to address the meeting on "Developments at FDA."

Before proceeding with the formal part of our program, I would like to make some brief observations about some of the recent developments at the Food and Drug Administration (FDA). The recent changes topside at FDA are of concern to all of us. Not only have Commissioner Ley, and Associate Commissioner J. Kenneth Kirk retired, Deputy Commissioner Winton Rankin been re-assigned outside of the FDA, but many other key personnel of the FDA have retired as of the end of 1969. The appointment of Dr. Charles C. Edwards as Commissioner has met with general approval, and I know you all join me in wishing Dr. Edwards an outstanding success in his new and responsible assignment. The re-establishment of the

FDA as an independent agency has met with universal acclaim and this should prove helpful to Dr. Edwards in carrying out his responsibilities.

We sincerely hope that the recent losses of key personnel in the FDA will not unduly handicap the new administration of Commissioner Edwards and trust that he will soon be able to improve the morale of those who are making a career of working in the agency and also be able to build a highly qualified staff of competent and devoted career people. I am confident that you, as lawyers, will work with Commissioner Edwards to this end that our great National Food and Drug Law may be effectively administered in the public interest. The strength of our FDA is one of our country's greatest assets.

Recommended Actions

This section and our American Bar Association (ABA) counterpart have always advocated adequate budgets for FDA. However, many of the problems encountered by FDA have been the result of insufficient funds, staff, and facilities for the amount of work involved. Thus, we should all urge Congress to provide adequately for the needs of this important consumer protection agency.

This section has always strongly endorsed the adoption of uniform State food, drug and cosmetic laws as being in the public interest, and we have passed a number of resolutions to that effect. During the past year, there has been an increase in some states in the introduction of proposed legislation that, if passed, would not be uniform with the federal law nor with laws in their surrounding states or in other states. Accordingly, I recommend that this section adopt a resolution reaffirming its endorsement of uniformity in this field.

Several months ago an application was made by the National Canner's Association to the Committee on Rules of Practice and Procedure to amend Rule C(4) of the Supplemental Rules for Certain Admiralty and Maritime Claims of the Federal Rules of Civil Procedure to provide that in cases of seizures made pursuant to the Food, Drug, and Cosmetic Acts, the Meat Inspection Act and the Poultry Inspection Act that would require service, which could be by mail, upon the manufacturer, packer, or distributor identified on the label. If adopted, this amendment to the Supplemental Rules would potentially benefit all manufacturers and distributors of foods, drugs, cosmetics and other consumer commodities. Although the manufacturer usually receives notice of seizures in some informal way in time to

take appropriate action, there have been enough incidences of the receipt of notice after destruction of the goods to merit general interest in a corrective amendment. The proposal seems to be of enough importance to merit a Resolution by the section endorsing the change.

International Food Laws

I would like to make a brief reference to international matters. A meeting of the Food and Drug Law Committee of the Inter-American Bar Association was held in Macuto, Venezuela on November 4, 1969 where problems of food law harmonization in Latin America were discussed. Dr. A. E. Olszyna-Marzys of the Pan American Health Organization (PAHO) Institute of Nutrition of Central America and Panama, reported on the assistance given by PAHO toward the harmonization of food legislation in the Central American isthmus. A code of 380 food standards recommended for inclusion in the laws of the six countries has been adopted by Honduras and Guatemala. The Honduran law, however, does not adopt the PAHO recommendation that Central American products registered in their country of origin should be sold freely throughout the isthmus. The speakers from Argentina, Dr. Julio C. E. Alfaro, and from Brazil, Dr. Julio Fleishmann, stressed the fact that uniformization of legislation between the states or provinces was the first urgent step before their harmonization at the international level. Brazilian Decree Law No. 209 of February 27, 1967 was the first food law applicable to that nation as a whole and the first national food law of Argentina has only just been introduced, Law No. 18284 of July 18, 1969. The meeting was attended not only by lawyers but by enforcement officials who expressed their appreciation of the efforts being made by the association to further harmonization of food laws. The Committee adopted a resolution recommending continued studies and promulgation of standards which would serve as the basis for effective harmonization of the food laws of Latin America.

The Joint Food and Agriculture Organization and World Health Organization (FAO/WHO) Codex Alimentarius Commission will meet on April 7-17 next, at which time a report will be made on the state of acceptance of recommended Codex standards and pending standard proposals will be considered at various steps. The actions taken by this Commission are important to the American food industry. A report of the meeting will be published in the Food, Drug and Cosmetic Law Journal and I recommend it for your appropriate consideration. **[The End]**

The Function of Guaranties

By MERRILL S. THOMPSON

Mr. Thompson Is a Partner in the Firm of Chadwell, Keck, Kayser & Ruggles, Chicago, Illinois.

TO THOSE OF YOU who expect a review of the kind of product guaranty which is of interest to the Federal Trade Commission (FTC), I owe an apology for not being more specific. I will not be talking about money-back or lifetime or unconditional guaranties. My topic relates instead to what is commonly referred to as the Section 303(c)(2) food and drug guaranty.[1]

As a matter of fact, the guaranty which I will discuss would not, in most cases, comply with the FTC's guaranty rule,[2] since in its usual form, the guarantor does not disclose what he will do if his guaranty proves to be false. Section 303 of the Federal Food, Drug, and Cosmetic Act[3] does that for him. Because of that statute, the guarantor may be agreeing to go to jail or pay a fine, or both.

The subject of food and drug guaranties is simply not as viable or controversial as other more popular subjects of discussion. There are no current developments to report; no hearings in progress; no recent landmark decisions. Since I cannot report any action which would be of interest to you, I decided instead to stir up a bit of controversy, and let you take it from there.

Before stating my question, however, I think it might help even this expert audience to review briefly the portions of the Federal Food, Drug, and Cosmetic Act[4] which most directly relate to guaranties. They are very few.

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[1] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 303(c)(2). Section 303(c)(3) guaranties are not discussed though very analogous in most respects. 21 U. S. C. § 303(c)(3).

[2] 17 C. F. R. Part 239, Guides against deceptive advertising of guaranties.

[3] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 303.

[4] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 301 and following.

You will recall that Section 301[5] of the act lists the things which you must not do. Among the acts prohibited is the introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded. This is covered by Section 301(a).[6]

Section 303[7] is what might be described as the penalty and pardon section of the act. Loosely speaking, 303 says, among other things, that if you violate Section 301(a),[8] that is, if you introduce adulterated or misbranded articles in interstate commerce, you will be subject to criminal penalties unless you can produce a written guaranty adequately identifying the person from whom you received the article in good faith. If your supplier gave you a false guaranty, he can be liable for having violated Section 301(h)[9] prohibiting false guaranties unless he too relied upon a guaranty from his supplier.

Now for my question. Is it possible that this statutory framework providing for food and drug guaranties results in an unjustifiable waste of time and money? I think it might. In my opinion the bar should take a careful look at the function of such guaranties and and give consideration to suitable amendment of the Federal Food, Drug, and Cosmetic Act.

Those of you who may never have seen a guaranty during your professional career might ask whether there is a practical problem worthy of a solution.

Disadvantage of Guaranties

To those I say that food and drug guaranties are a truly miserable fact of life for many. They are regularly solicited and granted by numerous if not all companies within the regulated industry. Some companies have adopted rigid formal policies to the effect that a pure food and drug guaranty must be obtained from every supplier of articles subject to the Federal Food, Drug, and Cosmetic Act.

The most direct and continuing disadvantage of such a policy is the unavoidable cost of its administration. In some cases we are talking about literally thousands of guaranties given and obtained necessitating a mammoth internal control system. The effort to

[5] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 301.

[6] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 301(a).

[7] See footnote 2.

[8] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 301(a); § 301(d).

[9] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 301(h).

make certain that a currently effective, acceptable guaranty is on file from each potential supplier can involve numerous battles over forms such as you ordinarly see only in connection with purchase orders. Everyone has a "standard" form, but no two standard forms are alike.

I am sure that many of you have been involved in extended correspondence relating to the terms of a guaranty requested of or by your client. Questions arise concerning the authority of the persons signing guaranties on behalf of their companies. Sometimes the guaranty is used as a vehicle for an inappropriate attempt to limit liability. Occasionally the guarantor insists on rights to assume the defense of actions involving the guaranteed article which are unreasonable under the circumstances. Objectionable indemnification provisions have been included in some standard forms. And strange as it may seem, I have even known companies to include provisions to the effect that their guaranties are void if their articles are adulterated. It goes without saying that many of these problems would never arise were it not for the need to request the guaranty.

Your client will quickly tell you that the practice is not only expensive to administer but on occasion severely strains relationships with suppliers. The request for a guaranty in certain situations undoubtedly discourages a supplier who is not familiar with the practice or, if he is under the impression that he is taking on an added commercial burden, the request may result in a higher price. The policy may even totally disqualify a desirable source of supply inasmuch as certain suppliers may persist in their refusal to provide the guaranty requested.

All of these problems are accentuated by the fact that so many laymen dealing even regularly with food and drug guaranties do not fully understand them. They do not really comprehend the very specialized legal function of the guaranty. They cannot distinguish it from a type of rigorous contractual provision which they would like to overlook or modify to accomplish some unrelated purpose.

In view of these disadvantages which are very real in terms of dollars and cents, we should ask ourselves, how real are the advantages? Do guaranties function as intended? Is there a sufficient public interest to warrant their continuance? Or should we be considering an amendment to the act making such guaranties unnecessary or perhaps optional?

Advantages of Guaranties

Before reviewing the special legal purpose of the guaranty which warranted its incorporation as a part of the regulatory scheme under the Food, Drug, and Cosmetic Act, I should mention briefly that there are business purposes or advantages which merit some consideration. For example, the previously mentioned indemnities are willingly signed by hundreds of suppliers when they are a part of a food and drug guaranty. Though I have made no effort to determine the extent to which these indemnities have in fact been relied upon or proven to be of practical value, it seems likely that they have been helpful from time to time.

More speculatively, the existence of a guaranty could conceivably be relied upon for contractual warranty purposes or as evidence of good manufacturing practices, or the lack of fault in the defense of product liability claims.

A further advantage is that the purchaser's act of requesting a guaranty impresses upon the supplier his responsibilities under the Federal Food, Drug, and Cosmetic Act and communicates forcefully one's determination to obtain products which comply with the spirit and the letter of the law.

Still another intangible advantage is the legitimate assumption that the practice of demanding guaranties makes a favorable impression on the Food and Drug Administration (FDA), since the practice is consistent with FDA's previously expressed opinion that food and drug guaranties have utility. Such cooperation with FDA is, of course, an important practical factor to be taken into account since we are discussing exemptions from criminal prosecution under the act which is, in most instances, a matter of administrative discretion.

But after all is said and done, were it not for Section 303[10] of the act and the public interest which persuaded Congress to enact that section of the law, I suggest that the practice of exchanging food and drug guaranties would become a past and forgotten practice. This, in turn, makes it all the more right that we, who regularly work with the law, evaluate its implementation from time to time to see whether it still accomplishes a worthwhile public purpose.

History of Food and Drug Guaranties

The food and drug guaranty as we know it today has existed for more than sixty years. The Federal Food and Drug Act of 1906[11]

[10] See footnote 2.

[11] Federal Food, and Drug Act 9, 34 Stat. 768 (1906).

(more often called the Wiley Act) contained a provision for guaranties very similar in effect to that[12] contained in our present law which was enacted in 1938.

At the time Congress was considering the adoption of the 1934 version of the act finally adopted in 1938, the function of the food and drug guaranty was reevaluated as a part of the consideration given to the following exemption which was being proposed:

> No dealer shall be prosecuted . . . because of commerce in any article he has purchased or received in good faith if he furnishes on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article . . . .[13]

In effect it was proposed that if you are innocent of any wrongdoing and if you give FDA the information it requests, you should not be subject to criminal penalties.

In his statement to the Senate, then FDA Commissioner Walter G. Campbell objected strongly to the proposed language. He said:

> This creates a loophole for extensive traffic in adulterated or misbranded foods, drugs, and cosmetics. Any dealer purchasing from a manufacturer in the same State, against whom we could not proceed because of lack of Federal jurisdiction, could distribute throughout the country such products upon the mere compliance with this requirement to furnish us the name and address of the person through whom he bought them. The difficulty of showing bad faith on the part of the dealer would, in many instances, be insurmountable until extensive damage to the public had occurred. It would be quite easy for a manufacturer of illicit goods to set up within the same State a sales agency and effectively conceal the true relationship that existed between himself and the agency.[14]

While still objecting to the more broad exemption proposed, the Commissioner alluded further to the most basic function of the food and drug guaranty when he said:

> Under the present act the dealer is protected simply by the guaranty provision . . . . This provision, which states that no dealer shall be prosecuted if he establishes a guaranty from the person from whom he received the article, has been of untold value in fixing responsibility for infractions of the law where they belong, and has not led to unwarranted prosecutions of dealers.[15]

Several years later Justice Jackson in his dissent in the *Walsh*[16] case described this same public interest in guaranties well when he said

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[12] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 303(c)(2).

[13] Dunn, Charles W., *Federal Food, Drug, and Cosmetic Act, A Statement of Its Legislative Record*, 1938, pp. 1208-9.

[14] Statement of Walter G. Campbell, Chief, Food and Drug Administration, Department of Agriculture, March 1 and 3, 1934, on Senate Bill 2800, 73rd Congress, cited at footnote 13, p. 1209.

[15] See footnote 14.

[16] *United States v. Walsh*, 331 U. S. 432 (1947).

that "the whole plan was to have a substituted liability in case the violator of the Act became such in good faith."[17]

Some might argue with the basic premise that a criminally accountable person *must* be available to the FDA whenever the Food, Drug, and Cosmetic Act is violated. But I think this concept of the public welfare offense is too well establish by statute and by case law to warrant challenge at this time.[18] Who can argue with these often-quoted views in support of consumerism expressed as long ago as 1943 by Justice Frankfurter in the *Dotterweich*[19] case:

> The prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. * * * The offense is committed, *unless the enterprise which they are serving enjoys the immunity of a guaranty,* by all who . . . have . . . a responsible share in the furtherance of the transaction which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs. Hardship there doubtless may be under a statute which thus penalizes the transaction though consciousness of wrongdoing be totally wanting. Balancing relative hardships, Congress has preferred to place it upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are wholly helpless.[20]

I am sure that these words of Justice Frankfurter are just as true today as they were twenty-seven years ago. Thus we should assume, at least for the sake of argument, that liability for each violation of the Food, Drug, and Cosmetic Act must be placed upon someone. But do we need guaranties for this purpose?

Expanding Federal Jurisdiction

Since our current law was enacted in 1938 there have been a number of decisions which are anything but comforting to those who

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[17] See footnote 16 on page 439.

[18] See the opinion of the court in *United States v. Mayfield* where it is stated: "The purpose of Congress was to place liability for the violation of the law upon some one in each instance. Primarily the liability is on the dealer who introduces the article into interstate commerce. The liability can be shifted from the dealer only by imposing the same liability upon the manufacturer. This can be done only by virtue of the manufacturer's guaranty to the dealer. If, for any reason, the guaranty is insufficient to impose liability upon the manufacturer, it remains where it primarily rested—upon the dealer. To have the effect of releasing the dealer from liability for the violation of the act, complained of in this prosecution, the guaranty must be of a character to impose liability for the same violation upon the manufacturer, if he were substituted for these defendants in this case; otherwise, both parties would escape liability, and the purpose expressed by Congress would be defeated." 177 F. 765, 768-69 (D. C. Ala. 1910).

[19] *United States v. Dotterweich,* 320 U. S. 277, 64 S. Ct. 134; U. S. Sup. Ct. 1943, rev'g CA-2.

[20] See footnote 19, 320 U. S. 280-81.284-85 (emphasis added).

might rely upon the intrastate nature of their contact with adulterated or misbranded articles to escape prosecution by the FDA. They clearly extend federal jurisdiction beyond the boundaries assumed by Commissioner Campbell when he opposed the broader exemption which might have eliminated the need for guaranties.

The cases I am talking about include the previously mentioned *Dotterweich* case.[21] You will recall that Justice Frankfurther asserted that the offense is committed by all who have a responsible share in the furtherance of the prohibited transaction.[22] This declaration could be applied to any manufacturer whose goods find their way into interstate commerce.

In the 1949 *Tannuzzo*[23] case, the circuit court held that a defendant who delivered stolen goods to another person for sale caused them to be shipped in interstate commerce though he had nothing to do with the shipment and did not know that they were going to be shipped in interstate commerce. A court might well impose this same risk upon an intrastate food, drug or cosmetic manufacturer whose products end up in interstate commerce.

The *Sanders*[24] and the *Drown*[25] cases in 1952 confirmed the proposition that a person has violated Section 301(a) of the act when he delivers adulterated or misbranded articles to customers with knowledge of their intended or likely interstate transportation. No guaranty was required in either case to fix responsibility or create jurisdiction.

The *Pinocchio Brand Oil*[26] case in 1961 and the *Korleen*[27] case in 1964 established the theory that a product fabricated from ingredients received in interstate commerce remains a part of interstate commerce. This theory further restricts the possibility that a person is able to manufacture, process or label a product which later enters the stream of interstate commerce without thereby becoming subject to the jurisdiction of federal authorities.

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[21] See footnote 19.

[22] See footnote 19, 320 U. S. 284.

[23] *United States v. Tannuzzo*, 174 F. 2d 177 (2nd Cir. 1949).

[24] *United States v. Sanders*, 196 F. 2d 895 (10th Cir. 1952).

[25] *Drown v. United States*, 198 F. 2d 999 (U. S. Sup. Ct. 1953) cert. denied (CA-9 1952).

[26] *United States v. Forty Cases . . . Pinocchio Brand 75% Corn*, 289 F. 2d 343 (U. S. Sup. Ct. 1961) cert. denied (CA-2 1961, rev'g D. C. N. Y.).

[27] *United States v. Detroit Vital Foods, Inc.*, 330 F. 2d 78 (CA-6 1964, aff'g D. C. Mich.).

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Current Function of Guaranties

But it was not the existence of these cases expanding federal jurisdiction which led me to question whether we need food and drug guaranties. It was the fact that although I have counseled companies maintaining thousands of guaranties, I have *never* observed one being used for its intended purpose. I know of no instance during the last thirteen years of a guaranty in the files of any of my firm's clients being used as the basis for substituted liability or a criminal prosecution. If such disuse is representative, perhaps we have created a mountain which is now being inhabited by a mere mole which can be trapped a new and better way.

I wonder how different would be the result of FDA enforcement efforts if we now adopted the proposal which Commissioner Campbell rejected in 1934.[28] Would the elimination of guaranties really insulate guilty processors from federal jurisdiction? If there were a serious risk in that regard, could we not add a new section to the act making it a federal crime to adulterate or misbrand an article later shipped in interstate commerce? Perhaps we should review this question with FDA and then give serious thought to the possible amendment of the Federal Food, Drug, and Cosmetic Act to assure criminal responsibility where it is desirable, but without the artifice of a pure food and drug guaranty. In this age of hypertechnical regulation I am certain that a breath of simplicity would be appreciated by all. **[The End]**

[28] The abolition of food and drug guaranties might be a boon for FDA since it must sometimes convince a court that a guaranty is not properly raised as a defense. See *United States v. Crown Rubber Sundries Co.*, 67 F. Supp. 92 (D. C. Ohio 1946). An end to the distinction between Sections 303(c)(1) and 303(c)(2) of the Food, Drug, and Cosmetic Act would certainly be of assistance to the courts which thus far have experienced difficulty in efforts to apply those sections in a consistent manner, for example; *United States v. American Stores Co.*, 183 F. Supp. 852 (D. C. Md. 1960); *United States v. H. L. Moore Drug Exchange, Inc.*, 239 F. Supp. 256 (D. C. Conn. 1965); *United States v. Bess J. Levine* (D. C. Pa. No. 14528, 1948); and *United States v. Parfait Powder Puff Co.*, 163 F. 2d 1008 (CA-7 1947), 332 U. S. 851 (U. S. Sup. Ct. 1948) cert. denied.

Product Liability—1969

By WILLIAM J. CONDON

Mr. Condon Is an Attorney with Condon and McMurray, New York City, New York.

TO SELECT SIGNIFICANT DEVELOPMENTS in product liability in each passing year becomes increasingly difficult. 1969 produced so many significant and controversial cases that the selection of cases for treatment in this report may appear more arbitrary than logical.

Statute of Limitation Cases

Since this is a section of the New York State Bar Association, it is perhaps appropriate to begin with a most significant decision by our Court of Appeals. *Mendel v. Pittsburgh Plate Glass Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 6283, is significant for two very important reasons. The case arose out of injuries sustained by plaintiff when she was struck by glass doors in a commercial building some seven years after they had been delivered and installed by defendant. Plaintiff claims that the doors were defective and seeks recovery in both negligence and breach of warranty. The issue before the Court of Appeals was whether or not the warranty cause of action was time-barred by the then applicable six-year statute of limitations in warranty cases. Plaintiff argued that, in *Goldberg v. Kollsman Instrument Corp.,* 12 N. Y. 2d 432, the New York Court had adopted, at least in favor of third-party strangers to the contract, the doctrine of strict liability in tort. Therefore, she concluded that the applicable statute of limitations should be three years from the time of injury.

In a four to three decision, the New York Court held, first, that *Goldberg,* while it did contain language approving of the strict tort concept, merely extended the cause of action for breach of implied warranty to those not in privity with the seller; and, second, that the applicable statute of limitations was the six-year-from-the-time-of-sale provision. Accordingly, plaintiff's cause of action for breach of im-

plied warranty had already been extinguished prior to the time of her injury.

Thus, to the surprise of many, including this commentator, New York may not at this time be included among the jurisdictions which have adopted the strict tort theory of liability.

The second aspect of *Mendel,* namely the time when the statute of limitations begins to run, received a surprising amount of attention around the country. A Michigan Court found no difficulty in sustaining a complaint for negligent design of a press where the injury occurred some 42 years after the sale of the press. (*Hoeppner v. E. W. Bliss Company, et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 6105.) On the other hand, the Tennessee Supreme Court held that the plaintiff had no cause of action in either negligence or breach of warranty where the injury occurred some 2½ years after the sale of the allegedly defective automobile, since the two-year personal injury statute of limitations had already run. Obviously, the effect of this holding is that plaintiff's cause of action was time-barred before any injury ever occurred. The Court's reasoning is somewhat interesting, being based upon the proposition that the cause of action was not the injury which plaintiff sustained, but rather was either the breach of warranty or the breach of a duty owed by defendant to plaintiff. In either case, the breach occurred, and thus the cause of action accrued, at the time of the sale and the statute of limitations began to run at that moment. The Court went on to point out that adopting a rule which would allow the statute to commence to run only at the time of the injury would create an intolerable situation, inasmuch as under such a rule, there would never be a time that a suit could not be brought.

Conversely, plaintiff was held to have stated a good cause of action in both negligence and strict tort liability for the wrongful death of her husband as a result of an allegedly defective 10-year-old grinding wheel. The Wisconsin Supreme Court held that both the personal injury and wrongful death causes of action accrued at the time of the injury. Although it had obviously indulged in considerable construction in order to reach this result, the Court said that, if there were to be a separate period of limitations for product liability cases, this was proper for the legislature and not for the courts. (*Holifield v. Setco Industries, Inc., et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 6181.)

Not to be outdone, Virginia's highest court held that the personal injury statute of limitations does not commence to run in a breach

of warranty action until plaintiff is injured. In reaching this result, the Court used the following language:

"Obviously, since the plaintiff had not been injured at the time she purchased the car, she could not then maintain an action for her injuries. To say, then, that her right of action accrued before her injuries were received is to say that she was without remedy to recover damages for her alleged injuries. Such an unjust and inequitable result is not the purpose of statutes of limitation. They are designed to compel the prompt assertion of an accrued right of action; not to bar such a right before it has accrued."

(*Caudill v. Wise Rambler, Inc., et al.,* CCH PRODUCTS LIABILITY REPORTS ¶ 6196.)

A somewhat different element was introduced into this raging controversy by the Florida Supreme Court (*Creviston v. General Motors Corporation*, CCH PRODUCTS LIABILITY REPORTS ¶ 6218). Plaintiff was injured when a hinge broke and the door fell off a refrigerator almost 5 years after sale. The Court held that the three-year statute of limitations for unwritten contracts did not begin to run until the defect was discovered by the plaintiff or reasonably should have been discovered. The question of when plaintiff learned or should have learned of the defect was for the jury.

Still another aspect was introduced in the statute of limitations area by the California Court of Appeals in the case of *Warrington v. Charles Pfizer & Co., Inc.* Plaintiff claims to have suffered bodily ailments as a result of injesting defendant's drug product prescribed for her during a period of pregnancy. The applicable statute of limitations for personal injuries is one year. Plaintiff's injuries and ailments occurred more than one year prior to the commencement of her action. It appeared that during a consultation with one of her attorneys concerning another matter, she happened to mention that she had suffered certain symptoms during and after her pregnancy. The attorney inquired what medications she had been taking at the time. When she mentioned defendant's drug, the attorney suggested that that may have been the cause of her illness. The action was instituted within one year from the date of that consultation. The Court held that the statute of limitations began to run at that time and therefore plaintiff's action was timely. You will note that this is the first case we have discussed wherein the physical injuries manifested themselves at a time longer than the statutory prescribed period prior to the institution of suit. Here we have a holding that the statute of limitations does not begin to run until plaintiff discovers the cause of her injury. In reaching this conclusion, the Court said this:

"Analysis of the cited cases indicates to us that when a personal injury is suffered without perceptible trauma and by silent and insidious impregnation as a consequence of the act or omission of another, who knows, or is charged with the responsibility of knowing that such act or omission may result in personal injury, and the injured person is unaware of the cause of his injury, and as a reasonably prudent and intelligent person could not, without specialized knowledge, have been made aware of such cause, no action for tort resulting from such cause begins to accrue until the injured person knows or by the exercise of reasonable diligence should have discovered the cause of such injury."

Aside from the fact that this has to be one of the longest sentences in recent judicial history, it seems to me that it opens a veritable Pandora's box for claims against drug manufacturers. Presumably, in the course of trial, plaintiff would be charged with the burden of proving that she could not have discovered the cause of her ailment within the statutory period by consulting a competent physician. Nevertheless, it appears to be extremely unwise to create this type of open-end liability.

From all of the foregoing cases, it should be clear that problems involving the commencement of the limitation period are becoming acutely important in product cases and promise to be with us for some time to come.

Duty to Warn

Another still-developing area in product liability involves the duty to warn. We had in 1969 three cases which are of some significance in this regard. The first of these, *Sterling Drug, Inc. v. Yarrow*, was decided in the United States Court of Appeals for the 8th Circuit. It involved the claim of negligent failure to warn that continued use of defendant's drug over a prolonged period of time could have the effect of causing irreversible eye damage in the user. There was considerable evidence concerning the history and development of medical suspicion and literature concerning this potential side effect. Eventually, defendant sent out a "Dear Doctor" letter to some 248,000 physicians and hospital personnel comprising essentially the whole medical population of the United States. The District Court found, and the Court of Appeals affirmed the finding, that defendant had failed adequately to warn of this potential side effect because it had not conveyed the message to physicians through its detail men. This, according to the Court, constituted failure to make reasonable efforts to warn the prescribing physicians. The Court of Appeals said "Under the circumstances of this case, when the dangers of the prolonged use of this drug, mass produced and sold in large quantities, became reasonably apparent, it was not unreasonable to find that the

appellant should have employed all its usual means of communication, including detail men, to warn the prescribing physicians of these dangers. In this connection it is noted that no extraordinary means of giving a warning of high intensity was employed."

There were strong issues of fact in this case concerning the timeliness of defendant's action, as well as the attention inviting qualities of the language used in the "Dear Doctor" letter. In view of these conflicts, which received considerable emphasis in the opinion, it is not entirely clear whether what follows is holding or dictum. Nonetheless, there is a rather strong indication that the defendant in a case such as this will be held liable if he does not employ the "most effective method," elsewhere in the opinion called "the best method" of communicating the warning to prescribing physicians. In this instance, the trial court had found that the most effective method would have been through the use of defendant's force of detail men. Of course, underlying all this, is the evidence from which the trial court found that this particular prescribing physician was not aware of the potential side effect involved.

The second of our three cases, *Johnston v. The Upjohn Company,* came out somewhat more propitiously for the drug industry. Plaintiff had suffered an allergic reaction following the injection by her physician of defendant's drug. A jury below had awarded a substantial verdict for plaintiff. On appeal, the issue before the Kansas City Court of Appeals was whether plaintiff had made a submissible case. It appeared that plaintiff's reaction was the first of its kind to have come to the attention of defendant. All other adverse reactions and contraindications had been fairly and clearly included in the package insert distributed with the product. Under these circumstances, the Appellate Court reversed the judgment below and directed that judgment be entered for the defendant. In so doing, it held that, in the absence of knowledge of the dangerous propensity of its product, defendant had no duty to warn thereof.

The final case in this trilogy, *Alberto-Culver Company v. Morgan,* involved the wonderful world of cosmetic allergy. Plaintiff suffered a condition diagnosed as allergic contact dermatitis caused by the use of a hair tint manufactured by defendant. Applying the doctrine of strict liability, the Texas Court of Civil Appeals nevertheless found that plaintiff had failed to make out a case against defendant. The Court reasoned that in a case such as this, plaintiff must either negate any allergy or hypersensitivity on her own part, or, in the alternative,

show that she was part of an appreciable class or number of persons who would have been reasonably foreseen to be harmed by the product. Since her own doctor characterized her injury as allergic in nature, and since she was unable to show that others had been similarly affected, she failed to sustain that burden. While it was not necessary to the disposition of the case, the Court concluded its discussion with what might be a very significant statement. It said "Mrs. Morgan was not aware of any allergy or hypersensitivity prior to her use of New Dawn and there is no evidence that any warning to her in advertisements would have been in any wise effective." Apparently, the Court is suggesting that any failure to warn could not be the cause of injury to a plaintiff in any case where there is no evidence that a warning would have affected plaintiff's conduct. Since there is frequently testimony in allergy cases that plaintiff never suffered any allergic or hypersensitive reaction before, this suggestion, if given wide acceptance, could be of substantial significance.

Food Cases

Two food cases in this year's report raise serious questions about the standard of proof which will be applied in establishing plaintiff's case. *Martel v. Duffy-Mott Corporation* involved two young boys who were given applesauce by their mother as part of a meal. The 8-year-old boy mixed his with the rest of his food and ate a substantial amount without comment. The 10-year-old ate his separately and told his mother that the applesauce tasted funny. The mother tasted and smelled the applesauce, and both she and the 10-year-old testified that it both tasted and smelled bad. She called the local poison control center and was advised to take the remaining applesauce and the children to the nearest hospital. When they arrived at the hospital, the applesauce was examined by hospital personnel who decided to and did pump the children's stomachs. No evidence was introduced as to the nature of the examination made at the hospital and, apparently, no laboratory tests of any kind were conducted. The applesauce was not available at the trial. The children were apprehensive on the way to the hospital, but suffered no other symptoms before or after the pumping. The trial court ruled that the plaintiffs had failed to establish a prima facie case on the ground that there was no evidence from which the jury could properly infer that the applesauce contained a deleterious matter. The Michigan Court of Appeals reversed and remanded for a new trial. The Court pointed out that there was testimony from persons well experienced in eating apple-

sauce that the applesauce tasted and smelled bad. From this testimony, the jury would be justified in concluding that the applesauce was inedible. That being so, the defendant's warranty of merchantability was breached and plaintiffs were entitled to recover damages for all the harmful consequences which followed. These consequences included the pumping of the stomach, and, incidentally, as a proper element of damage, the loss of enjoyment of eating applesauce which had previously been one of the boys' favorite foods.

The second of the food cases, *Franks v. National Dairy Products Corporation,* was even more bizarre than the applesauce case. It involved the "explosion" of shortening manufactured by defendant. Plaintiff was the operator of a drive-in restaurant and had used defendant's shortening in his deep-fry cooker for many years. On the day in question, plaintiff decided to drain the oil which had been in the cooker for three days and replace it with fresh oil. He turned off the fryer and let it cool for about three or four minutes. He then drained the shortening into an empty container which he had washed out several days earlier. A few minutes later he walked over to the container, and as he reached over it to see if all the grease had been drained, the hot grease splattered with a loud noise, covering his hands, arms, face and shoulders. In a strict liability case, tried to a judge sitting without a jury, this was held to be sufficient evidence of a defect in defendant's shortening and to justify the imposition of liability. The United States Court of Appeals for the 5th Circuit affirmed. Inasmuch as the trial court had found that plaintiff's proof negatived any improper handling or use on plaintiff's part, by his testimony that there were no food particles in the grease and that there was no moisture in the can when he started to drain it, the Court held that an inference of a defect in the shortening was a reasonable and proper one. In view of the fact that this shortening had been used at substantially higher temperatures for three full days prior to this occurrence, without incident, this strikes me as a totally incredible position. If ever there was a case where plaintiff was allowed to recover on the basis of the mere happening of an accident without proof of defect, this would seem to be it.

Breach of Warranty and Misrepresentation

Two years ago we discussed the case of *Rooney v. S. A. Healy Co.,* 20 N. Y. 2d 42, wherein recovery in warranty was allowed a City worker who was asphyxiated in a sewer as a result of a defective

gas mask which had been purchased second hand by the City. This year, we have a sequel to that case in the case of *Guarino v. Mine Safety Appliances Company,* CCH PRODUCTS LIABILITY REPORTS ¶ 6113. This was an action for the deaths of two would-be rescuers and the injuries to four others, who went into the sewer in response to Rooney's cries for help. All of these plaintiffs brought their actions in breach of warranty based upon the defective mask that Rooney was wearing. The jury found for all the plaintiffs and the New York Appellate Division affirmed the judgment entered on those verdicts with modification as to the amount of damage. In reaching its decision that judgment below was correct, the Court applied the doctrine known as "danger invites rescue." When defendant breached its warranty, and thus committed a wrong against Rooney, it also committed a wrong against his would-be rescuers. Plaintiffs' causes of action are derived from Rooney's. Therefore, they are equally entitled to recovery in breach of warranty for the damage done to them. This case could have fairly far-reaching implications if it is allowed to stand.

Another decision which raises interesting possibilities was handed down by the California Court of Appeal in the case of *Hanberry v. Hearst Corporation,* CCH PRODUCTS LIABILITY REPORTS ¶ 6267. Plaintiff purchased a new pair of shoes and suffered personal injuries when she slipped and fell on the vinyl-tiled floor of her kitchen. The decision in this case is concerned with the sufficiency of a complaint in an action against the publisher of *Good Housekeeping Magazine,* wherein plaintiff alleged that she relied upon the *Good Housekeeping* consumer guaranty seal, the product was defectively designed, the representations of Good Housekeeping that it had examined and tested the product were untrue, or that such testing was negligently performed, and that she was injured as a result thereof. The Court held that this was sufficient to state a cause of action against the publisher of Good Housekeeping for negligent misrepresentation and, if proved, would render defendant liable for plaintiff's injuries. The Court specifically rejected plaintiff's contention that she might also proceed in warranty or strict liability. In reaching its conclusion that there could be liability in this situation for negligent misrepresentation, the Court used some interesting language. It said:

"The basic question presented on this appeal is whether one who endorses a product for his own economic gain, and for the purpose of encouraging and inducing the public to buy it, may be liable to purchaser who, relying on the endorsement, buys the product and is injured because it is defective and not as represented in the endorsement. We conclude such liability may exist and a cause of action has been pleaded in the instant case. In arriving at this con-

clusion, we are influenced more by public policy than by whether such cause of action can be comfortably fitted into one of the law's traditional categories of liability."

Other publications and agencies which issue endorsements, seals of approval, and seals of quality, must of necessity pay particular heed to the potential implications of this case.

Conclusion

In order to prove that there are still some reservoirs of sanity extant in the country, I am pleased to report that privity of contract is still required in order to bring an action for breach of implied warranty in the Commonwealth of Massachusetts. (*Young v. Land O'Lakes Creameries, Inc.*)

Some of you may remember an old song which characterized the feelings of a lot of people. The first line, as I recall, went something like this: "I like bananas because they have no bones." Mrs. Barbara Molloy was one of the people who felt this way. You can, therefore, sympathize with her for bringing an action after biting into a banana and encountering a fruit thermometer. No bones? How about thermometers? She recovered. (*Di Gregorio v. Champlain Valley Fruit Co., Inc.*). After this lengthy and rather dry dissertation, I hope you will too.

PRODUCT LIABILITY CASES FOR 1969

The list of cases for 1969, grouped according to classification, is as follows:

FOREIGN SUBSTANCE AND CONTAMINATED FOOD CASES

Young v. Land O'Lakes Creameries, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6139 (Mass. App. Div.).

Long v. Penn Fruit Company, CCH PRODUCTS LIABILITY REPORTS ¶ 6140 (USDC, E. D., Pa.).

Martel v. Duffy-Mott Corp., CCH PRODUCTS LIABILITY REPORTS ¶ 6154 (Mich. Ct. App.).

Franks v. National Dairy Products Corp., CCH PRODUCTS LIABILITY REPORTS ¶ 6220 (CA-5).

DiGregorio v. Champlain Valley Fruit Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6222 (Vt.).

Doherty v. Servend, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6282 (Mass. App. Div.).

FOREIGN SUBSTANCE BEVERAGE CASES

Chapman v. Coca-Cola Bottling Co. of Lake Charles, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6130 (La. Ct. App.).

Hyatt v. Pepsi-Cola Albany Bottling Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6149 (N. Y. App. Div. 3rd Dept.).

Fowler v. Coastal Coca-Cola Bottling Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6204 (S. C.).

Ford v. Roddy Mfg. Co., CCH PRODUCTS LIABILITY REPORTS ¶ 6242 (Ct. App., Tenn.).

BURSTING BEVERAGE BOTTLE CASES

Royal Crown Bottling Co., Inc. v. Terry, CCH PRODUCTS LIABILITY REPORTS ¶ 6159 (Ark.).

Davis v. Safeway Stores, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6172 (Cal. Ct. App., 2nd Dist.).

Pittsburg Coca-Cola Bottling Works v. Ponder, CCH PRODUCTS LIABILITY REPORTS ¶ 6180 (Tex.).

DRUG CASES

Sterling Drug, Inc. v. Yarrow, CCH PRODUCTS LIABILITY REPORTS ¶ 6125 (CA-8).

Johnston v. The Upjohn Company, CCH PRODUCTS LIABILITY REPORTS ¶ 6155, (Kansas City Ct. App., Mo.).

Tinnerholm v. Parke-Davis & Co., CCH PRODUCTS LIABILITY REPORTS ¶ 6178 (CA-2).

Parke-Davis & Co. v. Stromsodt, CCH PRODUCTS LIABILITY REPORTS ¶ 6179 (CA-8).

C. A. Hoover & Son v. O. M. Franklin Serum Co., CCH PRODUCTS LIABILITY REPORTS ¶ 6217 (Tex.).

Warrington v. Chas. Pfizer & Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6226 (Cal. Ct. App.).

Hoffman v. Misericordia Hospital of Philadelphia, CCH PRODUCTS LIABILITY REPORTS ¶ 6228 (Pa. Ct. Common Pleas).

Grinnell v. Charles Pfizer & Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6233 (Cal. Ct. App.).

Kershan v. Sterling Drug, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6237 (CA-5).

Schrib v. Seidenberg, et al., CCH PRODUCTS LIABILITY REPORTS ¶ 6252 (N. M.).

Carter v. Inter-Faith Hospital of Queens et al., CCH PRODUCTS LIABILITY REPORTS ¶ 6254 (N. Y. Sup. Ct.).

Basko v. Sterling Drug, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6259 (CA-2).

Cunningham v. MacNeal Memorial Hospital, CCH PRODUCTS LIABILITY REPORTS ¶ 6271 (Ill. App. Ct.).

COSMETIC CASES

Eck v. Helene Curtis Industries, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6210 (Ariz. Ct. App.).

Elliot v. Lachance, CCH PRODUCTS LIABILITY REPORTS ¶ 6234 (N. H.).

Alberto-Culver Co. v. Morgan, CCH PRODUCTS LIABILITY REPORTS ¶ 6249 (Tex. Ct. Civ. App.).

Newmark v. Gimbel's Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6277 (N. J.).

TOBACCO CANCER CASES

Green v. American Tobacco Company, CCH PRODUCTS LIABILITY REPORTS ¶ 6142 (CA-5); rev'd ¶ 6143 (CA-5 en banc).

DEVICE CASES

Picker X-Ray Corp. v. Frerker, CCH PRODUCTS LIABILITY REPORTS ¶ 6122 (CA-8).

[The End]

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