VOL. 25, NO. 6 JUNE 1970

Food Drug Cosmetic Law JOURNAL

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

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

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

June, 1970
Volume 25 • Number 6

Second-class postage paid at Chicago, Illinois and at additional mailing offices

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TO THE READER

Consumer Protection Aspects of the Federal Food, Drug, and Cosmetic Act.—*George M. Burditt* prepared this paper for delivery as the Charles Wesley Dunn Memorial Lecture, held at the University of Southern California Law Center, Los Angeles, California, on February 18, 1970. Mr. Burditt discusses the various types of protection afforded the consumer by the Act, and mentions the areas that need to be reviewed or revised in light of modern technology. Mr. Burditt, whose article begins on page 268, is a Partner in the firm of Burditt, Calkins & Wiley, and a member of the Illinois House of Representatives.

Current GMP Regulations Applicable to the Human Food Industry.—This paper, which begins on page 279, was presented at the Food Update Seminar of the Food and Drug Law Institute, Inc., held in Chicago, Illinois, on March 23, 1970. *Merrill S. Thompson* discusses the development and scope of Current Good Manufacturing Practice regulations, emphasizing that several problems relating to these regulations remain unsolved. The author also questions whether the regulations are to reflect average conditions, or whether they are to reflect desired levels not currently achieved within the industry. Mr. Thompson is a Partner in the law firm of Chadwell, Keck, Kayser & Ruggles.

Report of the Seventh Session of the Joint FAO/WHO Codex Alimentarius Commission.—This report, which begins on page 284, was written by *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, Inc. Mr. Depew reviews the discussions, activities and progress of the Seventh Session of the Commission, and also gives reasons why some of the proposals were not adopted. In evaluating the work of the Seventh Session, Mr. Depew says that progress is moving forward, but at a slow pace, and urges acceptance of the Commission's proposals as far as practical or desirable for the United States.

The Freedom of Information Act and the FDA.—This article, written by *James M. Johnstone,* is a revision of a talk given to the Food and Drug Committee of the Federal Bar Association on March 12, 1970. Mr. Johnstone examines the Freedom of Information Act and its applicability to FDA activities in order to contribute to the understanding of the complex and contradictory statute, and offers some tentative suggestions as to the future significance of the Act for FDA and its industry and public constituency. The article begins on page 296. The author, who is a member of the Washington, D. C. Bar, acknowledges the valuable assistance of Bruce L. McDonald, of the Washington, D. C. Bar, and Bartley M. O'Hara, Catholic University School of Law.

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Consumer Protection Aspects of the Federal Food, Drug, and Cosmetic Act

By GEORGE M. BURDITT

This Paper Was Prepared for Delivery as the Charles Wesley Dunn Memorial Lecture, Held at The University of Southern California Law Center, Los Angeles, California, on February 18, 1970. Mr. Burditt Is a Partner in the Firm of Burditt, Calkins & Wiley, and a Member of the Illinois House of Representatives.

CHARLES WESLEY DUNN. Those of us who had the privilege of knowing Mr. Dunn will always remember him as a tower of strength in the legal community. His physical stature, his intellect, his vigor, his voice, his unique style were all equally imposing. Bradshaw Mintener, in the Charles Wesley Dunn Memorial Lecture in 1966, said that Mr. Dunn "epitomized, exemplified and personified the Lawyer-Statesman."[1] Mr. Dunn was the founder and chief organizer of the Food Law Institute (now the Food and Drug Law Institute), which sponsors this series of lectures. He was also the chief organizer of the American Bar Association's Division of Food, Drug and Cosmetic Law; the New York State Bar Association's Section of Food, Drug & Cosmetic Law; the FOOD, DRUG, COSMETIC LAW JOURNAL; the joint FDLI-FDA annual conference; and the Nutrition Foundation. He was a Professor of Law at New York

[1] Mintener, Bradshaw, "Wanted — Lawyer-Statesmen," 22 FOOD DRUG COSMETIC LAW JOURNAL 242 (April, 1966).

University School of Law, and he also worked for a living as General Counsel of the Grocery Manufacturers of America. Of course, he ran, and I do mean ran, the Institute, the Committees, the Journal, the Conferences—virtually everything with which he was associated. And I should add that Mr. Depew is currently performing most of Mr. Dunn's jobs!

I really haven't much more than touched the surface of Mr. Dunn's activities, and the interesting thing is that if this were an antitrust law lecture rather than a food and drug law lecture, a good many of the same things could be said about his accomplishments in that field. He was truly an amazing Lawyer-Statesman, and it is a great honor for me to deliver a lecture in his memory.

Consumer Protection Aspects

Mr. Dunn was a chief advocate and supporter of the Federal Food, Drug, and Cosmetic Act of 1938.[2] And since the Act is probably the most extensive and effective consumer protection legislation ever devised by man, it is highly appropriate that in this era of consumer protection we should honor Mr. Dunn by discussing the Consumer Protection Aspects of the Act.

This Act is an amazingly efficient consumer protection device. It is thorough; it is authoritarian where it should be; it delegates power where it should be delegated; and it is adaptable to change and indeed has been adapted many times, including several very significant amendments.

The closer the consumer is to the source of supply of his food and drugs and cosmetics, the less protection he needs. The Pilgrims who grew their own corn didn't need to be concerned about additives and fill of container and labeling and price per ounce. But when the consumer is removed from the producer by hundreds of miles, by scores of pesticides and preservatives and colors and flavors, and by all kinds of middlemen and holding conditions and laboratory and production techniques, he very simply needs more protection. This protection is the first and foremost function of the Act, and of the dedicated public servants who are charged with the responsibility of enforcing it.

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[2] 21 U. S. C. 301, and following.

Consumer protection is also the primary purpose of the food, drug and cosmetic industries. When the profit motive of an individual or a company is allowed to take precedence over consumer protection, the Act and the administrators and the consuming public step in to correct the situation. Too often we lose sight of this fact: Consumer protection, however it is dressed up or by whatever name it is called, is necessarily the joint responsibility and goal of the government and industry.

The guidelines in the accomplishment of this goal are set by the Food, Drug, and Cosmetic Act. It isn't the final word; it has been amended regularly and substantially since 1938, and, of course, will continue to be amended. And it isn't perfect; few statutes are, even in Illinois! It seems to me, however, that it does meet the requirements of those words used in § 501(a)(2)(B)[3] in another context, "current" and "good." It is the responsibility of Congress to make certain that the Act is perpetually "current" and "good," and it is the responsibility of all of us who deal with this Act on a daily basis to help Congress in its duties. 1215[4] was the starting point in another field of consumer protection, and it has been followed by a few amendments and clarifications like 1776[5] and 1787.[6] And if we do our job properly, I trust that 500 years after 1938, some lawyer from around Chicago will be giving the Charles Wesley Dunn Memorial Lecture in a sterile atmosphere, in sunny southern California "free from smoke and smog, fumes and even fog."

So let me discuss with you today some of the ways in which the Act, as it has been amended over the years, affords protection to us consumers. Necessarily, I'm going to do a little *ex*plaining and *com*plaining, and a little *storming* and *brain*storming.

Protection of Food

Let's start with food. The concept of the Act is to define adulterated food[7] and misbranded food,[8] and, with some refinements, to prohibit their introduction or delivery for introduction into interstate commerce.[9] The penalties for a violation are extremely severe: forfeiture of the goods in a seizure action,[10] injunction against further violations,[11] and criminal prosecution which can result in fine and

[3] 21 U. S. C. 351(a)(2)(B).
[4] At Runnymede.
[5] At Philadelphia.
[6] See footnote 5, above.
[7] 21 U. S. C. 342.
[8] 21 U. S. C. 343.
[9] 21 U. S. C. 331.
[10] 21 U. S. C. 334.
[11] 21 U. S. C. 332.

imprisonment,[12] even though the defendant had no knowledge of or intent to commit a violation of the Act.[13] Those of us who deal with the Act daily tend to shrug our shoulders at this criminal responsibility without knowledge or intent, but this is one of the very few instances in Anglo-American jurisprudence in which the defendant can go to jail without even having known that a statute was being violated. This is about as extreme consumer protection as I can imagine.

The broad definition of adulteration and misbranding are also tremendous protection for the consumer. For example, a food is adulterated if it contains any "poisonous or deleterious substance,"[14] or any "filthy, putrid or decomposed substance."[15] or if it has been "prepared, packed, or held under insanitary conditions,"[16] or "if its container is composed . . . of any poisonous or deleterious substance."[17]

Then there is a paragraph on *economic* adulteration.[18] A food is adulterated "if any valuable constituent has been in whole or in part omitted,"[19] or "if any substance has been substituted wholly or in part therefor,"[20] or if damage or inferiority has been concealed,[21] or if anything is added to it "to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is."[22] This is very effective consumer protection, and gives the enforcement authorities the tools they need to ensure a safe food supply.

There was one very basic change in the Act which was necessitated by the rapid development of technology in the twenty years after the Act was passed. Up until 1958, a manufacturer was not required to obtain approval from the government before using an ingredient in food. But this concept was completely reversed by the Food Additives Amendment of 1958.[23] Henceforth, no ingredient could be used without prior approval. Actually, the amendment goes far beyond what we customarily think of as an ingredient, since it defines food additive as:

> any *substance* the intended use of which results or *may reasonably be expected to result*, directly or *indirectly*, in its becoming a component or otherwise affecting the characteristics of any food. . . .[24] (Emphasis added.)

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[12] 21 U. S. C. 333.
[13] *U. S. v. Dotterweich*, 320 U. S. 277 64 S. Ct. 134 (1943).
[14] 21 U. S. C. 342(a)(1) and (2).
[15] 21 U. S. C. 342(a)(3).
[16] 21 U. S. C. 342(a)(4).
[17] 21 U. S. C. 342(a)(6).
[18] 21 U. S. C. 342(b).
[19] 21 U. S. C. 342(b)(1).
[20] 21 U. S. C. 342(b)(2).
[21] 21 U. S. C. 342(b)(3).
[22] 21 U. S. C. 342(b)(4).
[23] 72 Stat. 1784.
[24] 21 U. S. C. 321(s).

If any such substance was not "generally recognized, among experts qualified by scientific training and experience to evaluate its safety"[25] to be safe, it could not be used in food unless authorized by a regulation promulgated by FDA. Since this broad definition applied to packaging materials and all of the chemicals and other substances used in packaging materials, and to inks which might migrate through packaging materials, and to anything which might wear off a rubber hose or gasket or a metal or wood tank or line used in processing, obviously an entire new era of consumer protection was opened.

But as is sometimes the case, the recent cyclamate episode may show that we have over-protected ourselves. The Delaney clause,[26] which was added to the Food Additives Amendment over the objection of some administrators, legislators and others, absolutely prohibits any food additive which may induce cancer in animals, even though there may be no scientifically demonstrable connection between implanting a large amount of the substance in the bladder of a particular strain of rats, and human ingestion of an infinitesimal amount of the substance. We know more in 1970 than we did in 1958, and perhaps other aspects of consumer protection, like protecting us from obesity, may, and probably should, result in a Congressional modification of this absolute prohibition.

Let's look at some other ways our food is protected by the Act. A food is misbranded "if its labeling is false or misleading in any particular,"[27] or "if it is offered for sale under the name of another food,"[28] or "if it is an imitation"[29] unless its label says so—in the same size and prominence of type as the name of the food imitated, or "if its container . . . is misleading,"[30] or if it doesn't bear certain specified labeling,[31] or if the labeling isn't sufficiently prominent,[32] or if it purports to be a standardized food but doesn't conform to the standard,[33] or a dietary food but doesn't conform to the dietary regulations.[34]

How thorough Senator Wiley and his colleagues were in drafting this great monument of consumer protection! Every once in a while I ache to debate some demagogue who cries about the lack of consumer protection in food and drugs. It's all right there in the Act. All we need to do is enforce it.

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[25] See footnote 24, above.
[26] 21 U. S. C. 348(c)(3)(A).
[27] 21 U. S. C. 343(a).
[28] 21 U. S. C. 343(b).
[29] 21 U. S. C. 343(c).
[30] 21 U. S. C. 343(d).
[31] 21 U. S. C. 343(e) and (i).
[32] 21 U. S. C. 343(f).
[33] 21 U. S. C. 343(g) and (h).
[34] 21 U. S. C. 343(j).

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Reconsideration Needed

Let me mention two areas in which we may have taken too narrow a view of consumer protection. One is imitations and the other is standards of identity. When § 403(c) was originally adopted in 1938, Congress was very properly concerned about the possibility of lower-quality foods being palmed off as the real thing. But as in other facets of our lives, technology has moved faster than legislation. Congress didn't contemplate a food which was nutritionally better and economically cheaper than one of the old standbys. And the Food and Drug Administration (FDA) and the courts have insisted that an enriched food is still an imitation,[35] and a vegetable-fat frozen dessert is still imitation ice cream.[36] It seems to me that these are *not* consumer protection decisions. The food industry should be *en*couraged, not *dis*couraged, in the production of more nutritious or less expensive foods, or foods designed to meet specific dietary needs.

President Nixon's White House Conference on Food, Nutrition and Health last December brought some of these problems into sharp focus. How do we bring better nutrition to the ghetto, to Appalachia, to the candy and soft drink teenager, to the pregnant and nursing mother or the mother who doesn't have the time or inclination to eat after feeding all the kids, to the father who may tend to be a little paunchy? Certainly not by adhering fastidiously to 1938 norms. Rather, by adopting new foods which retain their nutrition even under adverse holding conditions, by adapting the food to the user, because the user doesn't adapt to the food. We've come a long way in this regard, with instant breakfast, 900 calorie meals, and nutritious research and education. But we have a long way to go, as was perfectly obvious from President Nixon's Conference. The apparently imminent appointment of one of the key leaders of the Conference to be Deputy Commissioner—second in command—of FDA indicates the President's and Secretary Finch's concern in this area. One of the corollaries of this program is that informative and concise labeling is the path of the future, not an ambiguous word like "imitation" which can mean low fat or vegetable fat, or low calorie or vitamins added, or low sodium or any one of an infinite number of nutritional variations.

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[35] *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218 (1943), 63 S. Ct. 589.

[36] *United States v. 651 * * * Chocolate Chil-Zert*, 114 F. Supp. 430 (D. C. N. Y. 1953).

Another food section of the Act which merits reconsideration, at least in its implementation, is § 401,[37] authorizing the promulgation of standards of identity, quality and fill of container, whenever "honesty and fair dealing" in the interest of the consumer dictates. § 401 is a very important consumer protection section because it establishes quality floors—for example, the minimum amount of fruit in jam—when properly implemented. And § 401 can, and sometimes should, be used to build quality walls on the floors—for example, a labeling wall or an optional ingredient wall.[38] But the section should not be used to build a ceiling on quality. And this may mean that those labeling and optional ingredient sidewalls should be loosened up a little. For example, if a particular standardized food is a regularly-used staple commodity in the ghetto, we ought to encourage, and possibly even require, the addition of basic nutrients to that food. This business of proper nutrition is extremely important, and we simply must pay more attention to it. I am sure you are aware of the studies which show that the nutrition of pregnant and nursing mothers, and of children during the first few years, has a direct bearing on the intelligence of that child as he matures. Incidentally, one step along this path to more informative standards has recently been taken by FDA in the promulgation of a standard for "low sodium cheese,"[39] which, in the absence of a standard, would have to be called "imitation."

Of course, no lecture on food law these days is complete without at least a passing reference to the dietary regulations[40] and dietary hearings, although it is getting more difficult to say anything new and exciting. The hearings have been in progress full-time for well over a year and have at least three or four more months to go, even if Commissioner Edwards' fiat is followed. I sincerely hope, although I must admit I am a little cynical, that the degree of consumer protection achieved will be directly proportional to the time spent. If that is too optimistic, perhaps we should hope for a formula: consumer protection improvements, plus experience gained in conducting hearings, plus nutritional facts established, equals the square root of the time spent on the hearings. And maybe we should throw legal fees and expert witness fees onto the left side of that equation!

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[37] 21 U. S. C. 341.
[38] See 21 C. F. R. Part 27.
[39] 21 C. F. R. Part 19.503.
[40] 21 C. F. R. Part 80 and Part 125.

Protection of Drugs

So much for food. Let's examine the capabilities of the Act for consumer protection in the field of drugs. Here's where the emphasis has been in the last few years. Not too long ago, approximately 70% of FDA's budget was devoted to food, and 30% to drugs; now the figures are reversed and the budget is substantially increased.

The drug and device adulteration[41] and misbranding[42] sections are constructed along the same general lines as the food adulteration and misbranding sections, but four special consumer protection points deserve emphasis:

1. § 501(a)(2)(B)[43] requires that drugs be manufactured in accordance with "current good manufacturing practice." The Act doesn't define these words, but interpretive[44] regulations which are very comprehensive do so.[45] Furthermore, since manufacturing practices must be "current," FDA is proposing extensive revisions to the Good Manufacturing Practice (GMP) regulations.[46] The proposal goes beyond what is really "current," but for our purposes today the important point is the flexibility of the Act in affording continuously-improved consumer protection. I should also say that GMPs have also been promulgated for the food industry,[47] but they haven't, at least as yet, had nearly the impact of the drug GMPs. And they are on somewhat more tenuous legal ground, since the food section of the Act[48] does not use the words "current good manufacturing practice."

2. The second drug paragraph which merits mention is the paragraph which refers to official compendia such as the U. S. Pharmacopoeia and National Formulary.[49] The Act requires that drugs meet the identity, strength, quality and purity as set forth in these Compendia, and since they are regularly updated, here is another example of how consumer protection is continually improved to keep pace with modern technology.

3. Another requirement for drugs is that they bear "adequate directions for use."[50] The regulations[51] say, and the legislative

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[41] 21 U. S. C. 351.
[42] 21 U. S. C. 352.
[43] 21 U. S. C. 351(a)(2)(B).
[44] *U. S. v. Bel Mar Laboratories*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,315, 284 F. Supp. 875 (D. C. N. Y. 1968).
[45] 21 C. F. R. Part 133.
[46] 34 C. F. R. 13553, 17338.
[47] 21 C. F. R. Part 128.
[48] See footnote 16, above.
[49] 21 U. S. C. 352(b) and 377.
[50] 21 U. S. C. 352(f)(1).
[51] 21 C. F. R. 1.106(a).

history bears this out, that this means "adequate directions for use by a layman."[52] But how can you give a layman adequate directions on how to use a prescription drug? Obviously you can't. So FDA has devised a unique consumer protection subterfuge: prescription drugs are exempted from this requirement.[53] But the conditions on which the exemption is granted are something else again. They occupy a good many paragraphs of fine print, and by the time the prescription drug manufacturer has complied with the regulation, you can't imagine how much protection the consumer, and indeed the physician, has.

4. Fourth, I should mention the provision in § 502(n)[54] which governs prescription drug advertising. This section has also been implemented by an extensive regulation[55] covering such matters as "brief summary" and "fair balance" and what kinds of descriptive information are labeling and what are advertising. It is impossible to read these regulations without realizing how extensive is the consumer protection afforded by the drug provisions of the Act.

New Drugs

Let's also spend a minute on "new drugs," which the Act defines as:

> Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective . . . .[56]

The 1938 Act merely required safety. In 1962 the requirement of efficacy was added.[57] And FDA has implemented this provision with real zeal. The result is that the number of new drugs coming on the market has been very substantially reduced, presumably to the benefit of the consumer, although I must admit that in this regard I'm not sure the consumer might not be better protected in the long run if it were a little easier to obtain approval of a new drug, to the end that physicians might in the future continue to have a substantial number of drugs in their armamentarium.

To compound the problem, FDA has interpreted a 1962 amendment to require a review for efficacy of all drugs first marketed be-

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[52] Dunn, Charles Wesley, *Federal Food, Drug, and Cosmetic Act of 1938*, G. E. Stechert & Co., New York, 1938.
[53] 21 C. F. R. 1.106(b).
[54] 21 U. S. C. 352(n).
[55] 21 U. S. C. 1.105.
[56] 21 U. S. C. 321(p).
[57] 76 Stat. 780 (1962).

tween 1938 and 1962.[58] To undertake this monumental task, FDA contracted with the National Academy of Science-National Research Council (NAS-NRC) which created a Drug Efficacy Study Group to carry out the job of studying something like 4,000 drugs. The NAS-NRC is classifying the drugs as effective, probably effective, possibly effective, or not effective. FDA has chosen to follow the course of removing from the market without a hearing, drugs found to be not effective, regardless of the clinical experience with the drug. The result has been a number of lawsuits against FDA, at least two of which have resulted in injunctions against FDA.[59] Query, how consumer protection fits into this situation. Of course, consumers should be protected against ineffective drugs, just as they should be protected against unsafe drugs, as the Act says. But when the determination of efficacy is being made, it seems to me that the firm which has developed the drug and is convinced of its efficacy, is at the very least entitled to a hearing. I have a personal interest in this subject since I have clients who are faced with this problem, but at least two courts have held that the Act does require a hearing, and I submit that consumer protection also requires it. For an important part of consumer protection is the variety of drugs available to physicians, who after all are the best qualified to judge the efficacy of a drug in a particular situation. Consumer protection does *not* require depriving physicians and patients of drugs which they have both deemed to be effective for many years. As a lawyer who spends a fairly substantial part of his life trying to help make function the democracy in which I believe so strongly, I very sincerely object to FDA's denial of hearings in the drug efficacy cases.

Other Consumer Protection Aspects

The consumer protection aspects of this Act are so extensive that I really haven't any more than scratched the surface. Let me just mention, without any detail, a few of the others:

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[58] Gifford D. Hampshire, "The NAS-NRC Drug Efficiency Study: A Peer Review," *FDA Papers*, 3:4, November, 1969.

[59] *The Upjohn Company v. . . . Finch . . . and . . . Ley*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,363, 303 F. Supp. 241 (D. C. Mich., 1969) [Author's note: This case has been completely nullified by a Sixth Circuit case decided subsequent to this lecture. *The Upjohn Company v. . . . Finch . . . and . . . Ley*— F. 2d—(No. 19926, C. A. 6, 2-27-70)].

American Home Products Corporation v. . . . Finch . . . and . . . Ley, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,364, 303 F. Supp. 448 (D. C. Del., 1969).

1. *Devices* are covered by most of the drug provisions[60] and we are going to see some updating in this area in the next few years, possibly along the line of new drug applications.

2. *Cosmetics*[61] are covered by an entire chapter of the Act, with provisions defining adulterated and misbranded cosmetics, along the same lines as food and drugs.

3. The *Fair Packaging and Labeling Act* of 1966[62] amended the Act in several important ways, and indeed required the redesigning of virtually every food label subject to the Act.

4. Tolerances for pesticides are covered in § 408,[63] and here, too, is a field in which new discoveries are requiring additional consumer protection both within and without the Act.

5. The provisions of the Act relating to *depressant, stimulant and hallucinogenic* drugs[64] have been updated by the Drug Abuse Control Amendments of 1965[65] and by administrative changes, and are in for more updating as society continues to wrestle with this very difficult problem.

6. Insulin,[66] antibiotics,[67] color additives[68] and seafood[69] are all covered in special and detailed sections which give particular protection to consumers.

7. And finally the *factory inspection*[70] provision of the Act which appeared to be adequate in 1938 was substantially amended in 1953[71] and will undoubtedly be reconsidered again by Congress in the near future.

So we really have consumer protection. Charles Wesley Dunn stands tall among the lawyer-statesmen of our country who ushered in the era of consumer protection and who gave us a statute fully capable of assuring us the continually safest and best supply of food and drugs in the history of man. I am proud to salute Mr. Dunn.

[The End]

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[60] 21 U. S. C. 321(h); 351-353.
[61] 21 U. S. C. 361-363.
[62] 80 Stat. 1296.
[63] 21 U. S. C. 348.
[64] 21 U. S. C. 352(d).
[65] 79 Stat. 226 (1965).
[66] 21 U. S. C. 356.
[67] 21 U. S. C. 357.
[68] 21 U. S. C. 342(c), 351(a)(4), 361(e), and 376.
[69] 21 U. S. C. 372a.
[70] 21 U. S. C. 374.
[71] 67 Stat. 476 (1953).

Current GMP Regulations Applicable to the Human Food Industry

By MERRILL S. THOMPSON

The Following Paper Was Presented at the Food Update Seminar of the Food and Drug Law Institute, Inc., Held in Chicago, Illinois, on March 23, 1970. Mr. Thompson Is a Partner in the Law Firm of Chadwell, Keck, Kayser & Ruggles.

CURRENT GOOD MANUFACTURING PRACTICE (GMP) regulations are of immediate interest to everyone connected with the food industry. Interest in GMPs started, I believe, in 1956 when the FDA seized a shipment of allegedly adulterated canned tomato paste.[1] One of the charges was that the paste violated Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act,[2] under which a product is deemed to be adulterated if it is prepared under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health. FDA was able to prove that conditions in and around the plant were certainly not the best. However, the canning company was able to impress the judge with the fact that the manufacturing practices and conditions existing in their plant were equivalent to average conditions found in canneries throughout the country. The lower court held that the tomato paste was not adulterated, and the Court of Appeals confirmed the lower court's holding with the following advice to FDA:

> If the Federal Food and Drug Administration desires to improve [the industry] average, it would be more likely to receive the support of the courts if it promulgated regulations which provided detailed standards as to cleaning procedures, screens, hygiene facilities, etc., publishing them to food packers as the requi-

[1] *United States v. 1500 Cases More or Less, Tomato Paste, et al.*, 236 F. 2d 208 (CA-7 1956).

[2] Federal Food, Drug, and Cosmetic Act, 21 U. S. C. § 343(a)(4).

sites for complying with [Sec. 402(a)(4)], and *then* seizing food packed in plants not meeting the specific standards set.[3]

I have no doubt that this advice made an impression upon FDA and, at least in part, prompted the promulgation of Current Good Manufacturing Practice regulations.

Further support for the legal concept of GMPs developed in 1962 when Congress enacted the Kefauver-Harris Amendment applicable to drugs.[4] For the first time, compliance with current good manufacturing practices was specifically required by federal statute. However, the new statute did not define what was meant by "Current Good Manufacturing Practice," so FDA filled that vacuum by promulgating regulations spelling out GMPs relating to pharmaceuticals and medicated feeds.

Development of GMPs

About five years after the Kefauver-Harris Amendment, FDA was faced with a serious recurrence of manufacturing practices in the seafood industry which threatened fatal outbreaks of botulism food poisoning. One result was that the Director of what was then the Bureau of Regulatory Compliance recommended the application of the drug GMP philosophy to foods. Commissioner Goddard gave him the green light and work on a draft of umbrella food GMP regulations began.

FDA's two-step approach to GMPs has been, first, to promulgate so-called umbrella regulations applicable to the entire food industry, which are to be followed by a series of separate appendices for individual foods. The umbrella regulations are necessarily very broad in nature. After prolonged consideration and debate, they became effective about a year ago, on May 26, 1969.

FDA is now making commendable progress in its effort to develop a GMP appendix for each basic category of food. FDA is tackling the various foods according to priorities directly related to the potential health hazards associated with their production and distribution.

The first appendix promulgated is applicable to the frozen raw breaded shrimp industry. That appendix became effective on February 12, 1970. I understand that it reflects a great deal of cooperation among representatives of the government and of the affected industry.

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[3] *United States v. 1500 Cases More or Less, Tomato Paste, et al.*, at 212.

[4] 21 U. S. C. § 351(a)(2)(b).

A proposed appendix for smoked fish has already been published for comment. It is likely that the next proposal will relate to eggs and egg products. Also high on the list will be soft-filled baked goods, ready-to-eat frozen foods, and nonfat dry milk. These apparently are the foods most susceptible to microbiological contamination if poor practices are followed in their production and storage.

In case you wish to make a note of where the GMPs may be found, I will refer you first to the Code of Federal Regulations, where they can be found in Part 128 of Title 21.[5] If you generally use the Commerce Clearing House Food, Drug, Cosmetic Law Reporter, you can find the GMPs beginning with paragraph 58,001. Pamphlet copies of the GMP regulations are available from FDA.

The GMP regulations need to be distinguished from the Plant Evaluator System (PEV) and from the Good Manufacturing Practice *Guidelines* currently utilized by the FDA in its inspectional activities. The PEVs are plant evaluator forms filled out by FDA inspectors during their inspections. FDA, by use of the PEV, is attempting to collect data with respect to each of several industries at calculated intervals in order to isolate and identify industry trends and practices. FDA hopes to be able to relate those trends and practices to its enforcement activities in order to evaluate the effectiveness of its efforts.

The so-called Good Manufacturing Practice *Guidelines* are generally less detailed than GMPs. They currently serve to guide an FDA inspector as he makes his inspection. There are such guidelines for dry milk, dried yeast, and animal, fish and poultry by-product processors. It is clear that each of these guidelines, though they now serve merely to educate FDA inspectors, will become the initial draft of a future GMP appendix.

Scope of the GMPs

Because the GMP regulations for foods are relatively new, it may be worthwhile to briefly outline their scope. The umbrella regulations, of course, pertain to every factor which you would suppose has a bearing on the quality of the finished product, and maybe a few more for good measure. The regulations consist of very general provisions, specifying practices relating to plant construction and design, the surrounding grounds, equipment and utensils, water supply, sewage, plumbing, toilet facilities, maintenance, animal and vermin control, storage and handling of equipment, the condition and handling

[5] 21 C. F. R. Part 128.

of raw materials and ingredients, record retention, testing procedures, and packaging, as well as the education, training, supervision and cleanliness of personnel.

The breaded shrimp appendix currently in effect covers most of the same subjects, but in much briefer fashion. As you would assume, it emphasizes factors which have created particular concern in the breaded shrimp industry. For example, since the food covered is a frozen product, the appendix has provisions specifically relating to freezer compartments designed to assure constant and adequate temperatures, and alarm systems designed to indicate significant temperature variations.

One aspect of the GMP regulations frequently discussed is their legal effect. Many competent lawyers would say that the regulations are merely advisory in that they advise the affected industry and the courts of FDA's expert opinion concerning legally adequate plant practices. Other competent lawyers are convinced that these regulations have the force and effect of law. If the latter be so, then evidence of a violation of a GMP is equivalent to evidence of a violation of the Food, Drug, and Cosmetic Act itself. I personally believe any difference is largely theoretical since, subject to possible exceptions, the GMPs will be based upon such a foundation of expertise and general acceptance that the courts will consider them equivalent to law. The exceptions to this general rule will make interesting lawsuits, however.

I might add that those within FDA who will develop and administer the GMPs may not be particularly enthralled with the GMPs exalted legal status, since this status carries with it a truly awesome degree of responsibility for the detailed dictation of conditions within the food industry. They also realize that the GMPs will eventually become incorporated in nearly all of our state food and drug laws and regulations, and the GMPs will often be incorporated by reference in the specifications included in most purchase contracts, whether with the government or with private purchasers. I predict that the GMPs will also find their way eventually into the laws and regulations administered by the United States Department of Agriculture, as well as those administered by any other agency with jurisdiction over foods.

Unanswered Questions

Despite the fact that we now have final umbrella regulations and the first of the numerous appendices which are to be expected, there remain several problems and unanswered questions.

Note that the regulations are entitled "*Current* Good Manufacturing Practices." Will it be possible for FDA to keep these regulations current? This will be a tremendous task, but it will also be an *essential* task.

By what means will these approved practices be improved? If innovations or departures constitute criminal violations, how will these differing practices ever become so current that they can be incorporated in the regulations?

Is there any leeway permitting the use of *equivalent* practices? If you are able to prove equivalency, must you first seek a change in the regulation before using the procedure?

Should the Food and Drug Administration attempt to reach and educate union officials so that the adoption of the GMP regulations relating, for example, to personnel will not result in labor troubles?

Do the GMPs purport to give FDA the right to inspect records or facilities not otherwise subject to inspection under Section 704 of the Act?

Is there anything which can be done to encourage the *uniform* interpretation and enforcement of vague requirements stated in terms such as "adequate," "sufficient," "unobstructed," "excessively," "good repair," "effective," and other like terms so susceptible to subjective interpretation? Perhaps the use of these terms in the regulations suggests that the GMPs do not really add anything to the statutory test, since FDA's burden of proof as to the violation of the extremely vague regulation may be as great as the burden involved in proving the existence of the insanitary conditions proscribed in the statute.

The major philosophical question which I believe faces FDA is whether these regulations are to reflect *average* conditions, or whether they are to reflect desired levels not currently achieved within the industry. The latter objective, that is, *improving* the average, would seem to be consistent with the advice of the Court of Appeals in 1956 which originally prompted the food GMP concept. However, that objective is not compatible with the idea that each violation of the regulations constitutes a crime and subjects to seizure all foods produced in plants not meeting the idealistic targets. A law making criminals of us all would be a bad law, whether or not it is invoked only by a well-intentioned and honorable group of administrators. In such a case we become an industry governed by the whims of men, rather than by law. The courts will ultimately answer this question, but in the meantime the responsibility for making the right choice rests with FDA. **[The End]**

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

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, Inc.

THE SEVENTH SESSION of the Food and Agriculture Organization/World Health Organization (FAO/WHO) Codex Alimentarius Commission was held at the FAO Headquarters, Rome, Italy, from April 7 to 17, 1970. The session was attended by about 250 registrants made up of delegates and observers from some 60 countries—23 from the European region, 2 from North America, 13 from Latin America, 11 from Africa, 2 from the Southwest Pacific and 9 from Asia—and from 22 international organizations. This was a substantial increase in the representation of countries outside the European region over that of the Sixth Session, when there were 10 from Latin America, 5 from Africa and 3 from Asia. The total membership of the Commission at the opening of this meeting was 74 countries. This is a substantial increase since the close of the Sixth Session, when the total membership was 65. At the close of the Fifth Session it was only 52. Of the present total membership of 74, it was pointed out that 44 members were developing countries located in Africa, Asia and Latin America.

The session was opened in behalf of the Directors-General of FAO and WHO by Mr. P. Terver, Assistant Director-General of FAO. In his welcoming remarks, Mr. Terver reported that FAO was most encouraged at the progress the Commission was making. He

said both FAO and WHO felt that every effort must be made to encourage international trade, and stressed the importance of the work of the Commission in connection with the removal of non-economic obstacles to international trade. He continued by saying that FAO receives more and more requests for advice about food laws which will harmonize with food laws throughout the world.

Mr. Terver further reported that during the course of the session, four recommended Codex standards and three recommended Codes of Hygienic Practice adopted by the Commission at prior meetings would be issued to governments for acceptance. The recommended standards were the General Standard for the Labeling of Pre-packaged Foods, the Standard for Canned Pacific Salmon, the European Regional Standard for Honey, and a number of Tolerances for Pesticide Residues. The recommended Codes of Practice were the General Principles of Food Hygiene, the Code of Hygienic Practice for Canned Fruit and Vegetable Products, and the Code of Hygienic Practice for Dried Fruits.

He also noted that the Commission hoped to send the adopted recommended standards for fats and oils, margarine, sugars and processed fruits and vegetables to governments for acceptance shortly after the current session. As the first of these standards were originally approved to go to member countries at the end of the Fifth Session of the Commission, two years ago, it is apparent that there has been considerable delay on the part of the Secretariat in proceeding with these matters. Mr. Terver apologized for this and pointed out that the tremendous burden of work placed on the Secretariat was responsible. As a result of this burden of work, it was proposed that the next session of the Commission should not be held until the summer of 1971, and that thereafter it might be desirable to schedule the sessions for every 18 months instead of every year.

Composition of the Seventh Session

Mr. John H. V. Davies of the United Kingdom presided throughout the session. He was assisted by the Secretariat made up of representatives from FAO and WHO, the Joint Secretaries being Dr. C. Agthe, Senior Scientist, Food Additives, WHO, and Mr. Graham O. Kermode, Chief, Joint FAO/WHO Food Standards Program, FAO.

The United States Delegation consisted of 16 representatives—Mr. George R. Grange, Deputy Administrator, Consumer and Marketing Service, United States Department of Agriculture, its Chairman; and Mr. Sam D. Fine, Associate Commissioner for Compliance, Food and Drug Administration, his alternate. Mr. Grange and Mr. Fine were assisted by Mr. E. F. Kimbrell, Assistant Codex Coordinator, Consumer and Marketing Service, USDA, and Mr. J. W. Slavin of the U. S. Bureau of Commercial Fisheries, and by the following industry representatives: Dr. C. M. B. Gooding, American Oil Chemists' Society, Mr. M. M. Hoover, Manufacturing Chemists Association, Mr. J. Russel Ives, American Meat Institute, Mr. Paul M. Karl, CPC International, Inc., Mr. Robert C. Liebenow, Corn Refiners Association, Inc., Mr. Leonard K. Lobred, National Canners Association, Michael F. Markel, Esq., Mr. Jan J. Mertens, National Canners Association, Mr. Donald M. Mounce, Campbell Soup Company, Mr. Albert H. Nagel, General Foods Corporation, Dr. Howard C. Spencer, The Dow Chemical Company, and Dr. J. Bryan Stine, Kraft Foods Division of Kraftco Corporation.

During the session the Commission elected Mr. G. Weill of France to serve as Chairman from the end of the Seventh Session until the end of the Eighth Session. The Commission also elected Dr. N. A. de Heer of Ghana, Mr. George R. Grange of the United States of America, and Mr. A. Miklovicz of Hungary as Vice Chairmen for the same period. In accepting these offices, the Vice Chairmen all pledged to work diligently for harmonization. Mr. Weill compared the program of the Commission with the flight of an airplane, and said that up to now the Chairman had guided the Commission during the turmoil of takeoff, and he felt that during his chairmanship it would proceed at cruising speed.

The Commission also elected representatives for the same period for the following geographic locations on the Executive Committee of the Commission: Africa—Tunisia, Asia—Japan, Europe—Federal Republic of Germany, Latin America—Argentina, North America—Canada, Southwest Pacific—Australia.

Important Progress

The most valuable work accomplished by this Session was the approval at Step 9 of the Codex procedure of commodity standards

for canned pineapple, olive oils, edible mustardseed oil, quick-frozen gutted Pacific salmon, canned shrimp, or shrimps or prawns, and quick-frozen peas, as well as edible fungi and fungus products and the European regional standard for fresh fungus Charterelle, and the approval at Step 9 of certain residue tolerances and temporary tolerances for diphenyl, heptachlor, hydrogen phosphide, inorganic bromide, piperonyl butoxide and pyrethrins.

Approval at Step 9 leaves only the acceptance by an appropriate number of governments to entitle the Commission to take the final step of publishing them as Codex standards.

In approving the standard for canned shrimp at Step 9, the Commission placed a restriction on the ingredients of the packing medium; namely, that the packing medium may consist of water, salt, lemon juice and sugars only. The Codex Committee on Fish and Fishery Products had proposed that the packing medium consist of water and salt, and that other ingredients such as lemon juice and sugar may also be added.

The restriction on the packing medium prompted me to make the following statement:

I would like to make a brief comment but one which I believe is important. When the Commission was organized it was agreed, as I understand it, that the standards adopted would be standards of characterization or platform standards rather than recipe standards. I see a tendency toward adoption of recipe standards in the restriction on the packing medium for shrimps. While this may be appropriate in this instance, it seems to me this medium could have been better described as "an appropriate packing medium." Restrictions in standards will stifle innovation, which is not in the public interest.

This statement received many favorable comments from members of various delegations. One member suggested that it would be desirable to make a record of it and play it at every meeting of Codex Committees, as well as at the meetings of the Commission itself.

The German Delegation proposed that canned shrimps and prawns be date-marked, and the Swedish Delegation supported this proposal, indicating that Sweden will be introducing legislation in 1971 to require such date-marking. However, the Commission did not adopt this proposal.

The Commission declined to move to Step 9 standards for apricot, peach and pear nectars, apple juice, orange juice, lemon juice and

grapefruit juice. It was pointed out that there were a number of inconsistencies in the labeling provisions, and there were differing opinions relative to the addition of sugar and to the labeling of reconstituted juices. Also denied advancement to Step 9 was a draft European Regional Standard for natural mineral waters because of disputes over allowable health claims.

The delegation of the Federal Republic of Germany was of the opinion that in the case of food packed in liquid media, the consumer would be better protected if he were informed as to the quantity of the ingoing food item in question. The delegation was therefore in favor of establishing minimum limits for ingoing food ingredients in the standards for canned pineapple, canned shrimp and prawns, and certain edible fungus products, and of declaring the quantity of ingoing food, rather than drained weight.

The Commission postponed for a year the question of standardizing soups and broths, and asked the Swiss Delegation to set up a Committee to prepare first drafts of such standards, consulting with the Secretariat and the Codex Committees on Food Hygiene, Food Additives and Food Labeling. The Commission also decided that there is no present need to proceed with a worldwide standard for edible ices. The Swedish Delegation was asked to prepare a draft standard, however, which will be considered as the basis for a possible European regional standard. On the other hand, the Commission decided that a draft standard for powdered dextrose should be undertaken.

The Commission decided to expand the jurisdiction of the Codex Committee on Food Labeling to cover advertising, by empowering it to study problems associated with the advertisement of foods with particular reference to claims and misleading descriptions.

The Secretariat indicated that it was preparing a paper for consideration by the Commission which included cereal products, tropical tubers and coffee, and was collecting material to form the basis of a paper on alcoholic beverages. The Secretariat had not been in a position to start work on a paper dealing with pulses, but would do so as soon as possible. It also indicated that it had been collecting information on soft drinks. As regards eggs and egg products, the Commission noted that the Codex Committee on Food

Hygiene was developing a code of hygienic practice for these products, and that the international trade in eggs in the shell did not appear to warrant work being commenced on this product at this time. A number of delegates strongly supported the proposal that cereal products should be the subject of future work by the Commission. The Commission recognized that it would be difficult to proceed with further work in the next two or three years in view of the present workload.

Several delegations drew attention to the importance of the harmonization of the general principles on which food legislation was established. The Commission considered that further attention might be given to this subject by the Codex Committee on General Principles at a future session.

Food Additives

The Commission rejected, by an 18 to 5 vote, with 6 abstentions, a Swiss proposal that the Codex Committee on Food Additives be instructed to cease work on flour treatment agents. At the meeting of this Committee, there had been considerable discussion concerning the technological need for the use of a number of flour treatment agents. Delegates from many European countries objected to the use of any agent except ascorbic acid. It was agreed, however, that the needs of countries with highly mechanized industry should be considered relative to the need for these additional flour treatment agents.

The United States Delegation urged deletion of language requiring that a food additive may be approved only if its use could not be avoided by changes in processing practices. The language in question was revised to provide that a food additive should not be approved "when the desired effect can be obtained by other manufacturing practices which are economically and technologically satisfactory."

The Commission confirmed its previous decision that food additives which had not been endorsed, or temporarily endorsed, by the Codex Committee on Food Additives should be deleted from standards before issuing them to governments for acceptance.

The Commission had before it a working paper containing government comments on definitions of the terms "food additive," "contaminant" and "process," but delayed consideration of it since it had not yet received a proposed definition for "pesticide residue" from the Codex Committee on Pesticide Residues.

Some delegates urged that arrangements should be made for the exchange of information on the toxicity of food additives. The Commission agreed that this would be desirable, and requested WHO to examine whether arrangements could be made to facilitate the exchange of toxicity data on an international basis.

A proposal that the Codex Committee on Food Additives should study additives in soft drinks was criticized by a number of delegations since there was no Codex commodity committee for soft drinks, and this proposal did not receive support.

The request of the Committee to elaborate specifications of purity for sodium chloride was discussed. The Commission noted that the Executive Committee had requested the Secretariat to examine in more detail the feasibility of elaborating standards for salt and to report to a future session of the Commission. The Commission agreed that the Codex Committee on Food Additives could elaborate specifications of purity for sodium chloride, but that it should not give the work a high priority.

Pesticide Residues

There were some changes in the proposed tolerances for residues of heptachlor, and not all were approved. The United States Delegation urged that the tolerance for heptachlor be changed to 0.3 p.p.m. for meat, saying that meat from 13 countries, which had been imported into the United States, was found in some cases to contain residues up to this amount on a fat basis. The Netherlands Delegation said that a similar survey showed no heptachlor residues in meat above 0.1 p.p.m. The Commission decided that this matter should be returned to Step 7 so that the Codex Committee could study the U. S. and Netherlands data.

The proposed heptachlor residue limit in whole milk was eliminated, and a 0.125 p.p.m. practical residue limit in milk and milk

products on a fat basis was advanced to Step 9. Also approved at Step 9 were heptachlor tolerances of 0.1 p.p.m., temporary tolerance for root vegetables except carrots, potatoes and sugar beets, and 0.05 p.p.m. practical residue limit for potatoes and 0.1 p.p.m. temporary tolerance for cole crops and leafy vegetables.

The Commission further approved at Step 9 a tolerance of 0.1 p.p.m. for hydrogen phosphide in raw cereals, temporary tolerances of inorganic bromide of 75 p.p.m. in avocados, 30 p.p.m. in citrus fruits and strawberries, in amounts varying from 20 p.p.m. to 250 p.p.m. for certain dried fruits and 400 p.p.m. for herbs and spices, temporary tolerances for piperonyl butoxide of 20 p.p.m. in raw cereals and 8 p.p.m. in fruit for canning, dried fruits and vegetables, oil seeds and tree nuts, and temporary tolerances for pyrethrine of 3 p.p.m. in raw cereals, and 1 p.p.m. in fruits for canning, dried fruits and vegetables, oil seeds and tree nuts.

The Commission concluded that pesticide tolerances are to be deleted from commodity standards unless the tolerance applicable to the product is adopted by the Commission at Step 8. It was noted that tolerances are set on a pesticide-by-pesticide basis, not on a food-by-food basis.

The Commission also authorized the Codex Pesticides Residue Committee to set up an ad hoc group to consider differences in national application of residue limits. The United States Delegation suggested that this group study the problem of allowing a greater tolerance for imports. In an effort to clarify the function of Codex pesticide tolerances, the Commission reaffirmed its decision:

that there was no question of Codex tolerances for pesticide residues applying only to imported produce. It was pointed out that Codex Standards applied to pesticide residues, not to the use of pesticides. A member country accepting a Codex residue tolerance was not thereby prohibited from controlling the use of a pesticide. It was certainly not compelled to encourage the use of a pesticide that was not required within its territories. If a pest was not present in a country's agriculture, it was not required to permit a pesticide to control such a pest. However, the tolerance for the pesticide residue concerned would apply to all food distributed within the territorial jurisdiction of the country accepting the standard.

Food Colors

The Commission had before it a list of food colors which were in addition to the open list of colors which were sent to govern-

ments for information after the Sixth Session. The Commission decided that this list of food colors prepared by the Food Additives Committee should be printed for informational purposes only, but that member countries could comment on the list. It was specifically stated that as the list is to be sent out for information only, formal comments will not be received. Several delegations said there was little point in receiving informal comments on the list of colors, while others said the list should not be sent out for informational purposes without being first sent to governments for comments. It was suggested that the Secretariat should make available to the Codex Committee on Food Additives information on colors that should be prohibited so that this list could be circulated to Member Governments as a working paper for that Committee.

The Idea of a General Standard

The Commission considered government comments on a paper entitled "The Idea of a General Standard" which had been prepared by the delegation of the United Kingdom for the Codex Committee on General Principles. A number of delegations said they were in the process of drafting the general provisions of their food law, and international agreement on the necessary general provisions would be helpful. It was pointed out that without such general provisions there would be a lacuna in the Codex Alimentarius, but that the differences in the legal structure in different countries would make it very difficult to accept the precise wording of any general standard. It might be better to regard the proposal as a general indication of the provisions which should appear in any food law, to which member governments should be invited to express agreement in principle. The Commission decided that further work should be done on the General Standard without taking any decision as to whether it should finally take the form of a Codex standard, code of practice, or general preamble to Codex standards. The delegation of the United Kingdom undertook to revise the draft standard in the light of the comments received, and to prepare a paper which would include this redraft, together with any government comments for revision which had been taken account of in the revised draft.

Food Standards Work in Africa, Asia and Latin America

The Commission decided that it should give consideration to a program for suggesting legislation and standards which will be in harmony with those of other countries, and that this should be done especially to aid developing countries of Africa, Asia and Latin America. These countries seem to desire a basic food law which will cover their principal needs in this respect. In the meantime, it was reported that FAO will try to assist in devising legislation which fits in with the constitutional framework of the country involved. The necessity was mentioned of grouping together countries with similar food habits and economics in order to stimulate their participation in food standards work.

Progress on Other Standards

Also sent out for comments at Step 6, that is, for a second round of comments from governments, were the commodity standards for raisins, processed tomato concentrate, canned pears, canned mandarin oranges, frozen fillets of plaice, frozen fillets of ocean perch, canned hams, canned corned beef, canned luncheon meat, quick-frozen spinach, quick-frozen raspberries and foods for special dietary uses. The Commission further sent out at Step 6, the Code of Hygienic Practice for Tree Nuts and the Descriptions of Cutting Methods of Commercial Units of Carcasses, Halves and Quarters, as well as a number of tolerances for pesticide residues. With respect to these tolerances, the Committee on Pesticide Residues was instructed to establish more precise definitions of the products in which residues were being controlled.

The Commission agreed to establish an independent Committee on Processed Meat Products, and renamed the former Committee on Meat and Processed Meat Products as the Committee on Meat.

The Secretariat of the European Economic Community (EEC) reported on the present state of work in the Community on harmonization of food legislation. The report indicated that general regulations covering packaging materials, dietetic foods, low-sodium dietetic foods, foods for infants and children, labeling, preserves

and canned foods, sampling procedures and irradiation were in the course of preparation. It also summarized the state of work on food additives (colors, preservatives, antioxidants, emulsifiers, stabilizers, thickeners, gelling agents, aromatic substances and artificial sweeteners) and on commodities or commodity groups.

From this report, it would appear that the Commission has placed some 18 propositions before the Council of the EEC for approval, and that 6 more will be submitted on or before July 1, 1970. The failure of the Council to take action on the propositions indicates that there are difficulties in securing agreement among the EEC countries on the proposals. In response to a question as to whether EEC would follow Codex standards, the EEC representative said only that EEC standards have a nature somewhat different from the Codex standards, and will serve to harmonize the existing legislation in the Common Market countries. He further said it is the intention of EEC to remove technical barriers to free movement of foods and to harmonize the laws of the various countries in this respect, resulting in a unified food market.

The representative of the International Organization for Standardization (ISO) reported on the activities of the ISO relating to testing and sampling, handling, transportation, storage and packaging of agricultural food products, as well as on problems of terminology. It was noted that some 170 recommendations were under consideration by ISO.

The Commission considered the suitability of the Sampling Plans for Prepackaged Foods proposed by the Codex Committee on Methods of Analysis and Sampling. There was considerable discussion as to whether the plans were more suitable for production quality control, rather than for enforcement purposes. The Commission decided to request the Executive Committee to consider at its next session whether or not a special session of the Committee on Methods of Analysis and Sampling should be convened to examine the whole question of the sampling plans in the light of the foregoing and of the observations of the Codex Commodity Committees.

The Commission noted that the work being carried out by the Council of Europe on natural and artificial flavors and on packaging materials was of particular interest to the Codex Committee on

Food Additives, and that the Commission looked forward to receiving the recommendations of the Council of Europe on these matters.

The Commission considered its relation to the FAO/WHO Committee of Government Experts on the Code of Principles concerning milk and milk products, and agreed that the Committee should consider acceptance of milk-product standards in the light of the General Principles of the Codex Alimentarius, and that the Committee should report on them to the Commission. The Commission agreed that it would then be a matter for the Commission to decide, in the light of these acceptances, whether the standard concerned should be published in the Codex Alimentarius as a worldwide standard.

Progress of the Seventh Session

The foregoing report discloses that while progress towards harmonization of food laws is moving forward, it will continue to move at a slow pace. There are many difficulties yet to be overcome. However, much solid progress was made at this Seventh Session. Messrs. Grange and Fine and all other members of the United States Delegation worked most diligently and effectively to protect the interests of the American consumer and the American food industry. No major points were agreed upon that United States industry could not live with if they were imposed by importing countries, and many correspond to the United States' recommendations. While some provisions may not be entirely practical or desirable for adoption by the United States, we should take a positive approach in evaluating them and accept them as far as possible. Reasons for reservations or rejections should be limited to critical factors—health, unfair restrictions, misleading requirements, etc. This is a crucial stage for the Codex Alimentarius Commission, as the reaction of governments to the standards sent out for acceptance will determine whether or not a useful function is being served.

Those desiring a more detailed report on this meeting may secure it by writing to:

U. S. FAO Inter-Agency Sub-Committee on Codex Alimentarius
Agriculture Marketing Service, U. S. Dept. of Agriculture
Washington, D. C. 20250

[The End]

The Freedom of Informaton Act and the FDA

By JAMES M. JOHNSTONE

Mr. Johnstone Is a Member of the Washington, D. C. Bar. The Article Is a Revision of a Talk Given to the Food and Drug Committee of the Federal Bar Association on March 12, 1970.

IN EXAMINING THE FREDOM OF INFORMATION ACT and its applicability to Food and Drug Administration (FDA) activities, I will try to contribute what I can to the understanding of this complex and contradictory statute, and to offer some tentative suggestions as to the future significance of the Act for the FDA and its industry and public constituency.

Now codified in 5 USC § 552, the Freedom of Information (FOI) Act is a complete and thoroughgoing amendment of original Section 3 of the Administrative Procedure Act. Old Section 3, misleadingly labelled "Public Information," expressly permitted secrecy either "in the public interest" or "for good cause found." Only "persons properly and directly concerned" with particular information were entitled to view those records not held secret or confidential.[1]

Not surprisingly, old Section 3 proved far more effective as a justification for bureaucratic secrecy than an opening for "public information." The sponsors of the Freedom of Information Act sought to end this abuse.[2]

In translating this purpose into legislative language, Congress faced continued conflicts between the polar principles of disclosure

[1] 5 U. S. C. § 1002 (1964).

[2] S. Rep. No. 813, 89th Cong., 2d Sess. (1965); H. R. Rep. No. 1497, 89th Cong., 1st Sess. (1965).

and confidentiality. President Johnson's statement on signing the bill[3] reveals the strain between the two opposites. On the one hand, he proclaimed that:

> [A] democracy works best when the people have all the information that the security of the nation permits. No one should be able to pull curtains of secrecy around decisions which can be revealed without injury to the public interest.

Yet in the next paragraph he cautioned,

> [T]he welfare of the Nation or the rights of individuals may require that some documents not he made available.[4]

These conflicting principles are imperfectly resolved in the statute, in its legislative history, and in judicial decisions to date.

Essentially, the Act sets up three classes of documents—(a) those required to be published in the *Federal Register*;[5] (b) those required to be made "available for public inspection and copying";[6] and (c) those other "identifiable records" which must be made available to "any person" on request "made in accordance with published rules."[7] All of the disclosure requirements are subject to nine exemptions from disclosure,[8] which in turn are subject to a potentially troublesome caveat that, "This section does not authorize withholding of information or limit the availability of records to the public, except as specifically stated in this section."[9]

The Act further grants jurisdiction to the United States District Courts "to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld. . . ." Such cases are to be determined *de novo* on an expedited basis, and "the burden is on the agency to sustain its action."[10]

Implementing the statute, the Department of Health, Education, and Welfare (HEW) has published regulations, codified in 45 CFR

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[3] Statement by President Johnson Upon Signing Public Law 89-487 on July 4, 1966, Reprinted in *The Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* (June, 1966).

[4] See footnote 3.

[5] 5 U. S. C. A. § 552(a)(1).

[6] 5 U. S. C. A. § 552(a)(2).

[7] 5 U. S. C. A. § 552(a)(3).

[8] 5 U. S. C. A. § 552(b)(1)-(9).

[9] 5 U. S. C. A. § 552(c). *See Grumman Aircraft Engineering Corp. v. The Renegotiation Board*, No. 22,635, Slip op. at 4 n. 5. (D. C. Cir., decided Mar. 10, 1970) (court construing this section as one which "requires that exemptions be narrowly construed").

[10] 5 U. S. C. A. § 552(a)(3).

Part 5. The FDA regulations are found in 21 CFR Part 4, but the pertinent portions only refer to the HEW regulations. In some respects, the HEW regulations as printed in C. F. R. may be one or two reorganizations behind the times, but they are still worth consulting.

Requesting Disclosure

The FDA information center, provided in accordance with HEW regulations, is located at 200 C Street, S. W., Washington, D. C. It will remain there despite the move of much of FDA to Rockville, Maryland. The center is *required* to keep the relevant portions of the *Federal Register,* final orders and opinions, administrative staff manuals and program manuals which affect members of the public, policy statements issued after July 4, 1967, and current indices of the foregoing materials issued after July 4, 1967.[11] In fact, more than this minimum is available there. Copies may be made, for a price.

To request some identifiable FDA "record," write to Miss Ruth Cockerham, Information Specialist, at the FDA Information Center.[12] Upon receipt of a written request describing the document, Miss Cockerham will usually obtain and furnish the requested information. If any problems are raised, the request is referred to Mr. J. Stewart Hunter, Associate Director of Information (Public Services), Office of the Secretary, who consults with the General Counsel's Office to determine the position to take.

Should the request for disclosure be denied, Mr. Hunter will send a formal letter of denial. The inquiring party may then appeal his ruling to the Assistant Secretary of Health and Scientific Affairs.[13] Only if and after the Assistant Secretary refuses the appeal, court action can follow.

Despite the basic simplicity of the statutory scheme, as implemented by the HEW/FDA regulations, the Freedom of Information Act presents numerous perplexing problems to the practitioner.

As just one example, exemption (4) for "trade secrets and commercial or financial information obtained from a person and privileged or confidential" is a hodge-podge of semantic confusion.[14] Read lit-

[11] 45 C. F. R. § 5.34 (1969).
[12] 45 C. F. R. § 5.51 (1969).
[13] 45 C. F. R. § 5.82 (1969).
[14] 5 U. S. C. A. § 552(b)(4).

erally, it may protect from disclosure only "commercial or financial information" obtained from a person, and then only if it is otherwise "privileged or confidential." Professor Davis has constructed an elaborate analysis demonstrating how the probable reaction of the courts to this exemption could render the disclosure portions of the Act virtually meaningless.[15]

As another example, note exemption (5) for "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." Focusing on the question of whether a *court—not the agency*—would order the documents disclosed in *court* litigation,[16] this exemption has been construed by one District Court to permit the agency to establish a prima facie case for nondisclosure by showing that "in the *normal* sort of action in which the documents might be of value, courts would not order the documents produced."[17] To another District Court, however, the question was whether the claimed intra-agency records "would not be available to *any* party in *any* litigation" with the agency; that is, "whether the records would be privileged and thus outside the scope of Rule 26(b)" of the Federal Rules.[18] The D. C. Circuit, in the recent *Grumman* case, said the exemption did not apply to documents which a court would "routinely" order produced in discovery proceedings,[19] reading into the statute language from the House Report which does not appear in the statute and which had been rejected in earlier interpretations.[20]

One reassuring thread of consistency in these cases is that disclosure was ordered in all of them.

Those of you who are interested in statutory fun and games can find many more possibilities on the face of the Act. In case you miss

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[15] Davis, "The Information Act: A Preliminary Analysis," 34 *U. Chi. L. Rev.* 761, 787-89 (1967).

[16] *Consumers Union of the United States, Inc. v. Veterans Administration*, 301 F. Supp. 796, 804 (S. D. N. Y. 1969).

[17] *Benson v. GSA*, 289 F. Supp. 590, 595 (W. D. Wash. 1968), *aff'd, GSA v. Benson*, 415 F. 2d 878 (9th Cir. 1969).

[18] *Consumers Union*, footnote 16, above, at 804.

[19] *Grumman Aircraft Engineering Corp. v. The Renegotiation Board*, No. 22,635, Slip op. at 7, n. 14 (D. C. Cir., decided March 10, 1970).

[20] *Benson v. GSA* footnote 17, above, at 595. (Court noting "the word 'routinely' does not appear in the statute, nor does it appear in the Senate Report").

any, Professor Davis' exhaustive 1967 article, "The Information Act: A Preliminary Analysis," points out most of the trouble spots, although I'm sure none of us will like all of his suggested solutions.[21]

Legislative History and Interpretation

Confounding the problems of statutory interpretation, available legislative history and interpretive aids point in contradictory directions.

Generally speaking, the Senate Report, *S. Rep. No. 813, 89th Cong. 1st Sess. (1969)*, which is the earlier one, is most favorable to disclosure. The House Report, *H. R. Rep. No. 149, 89th Cong. 2d Sess. (1966)*, contains language most favorable to confidentiality, but its authority as a source of legislative intent is at best uncertain since neither the House Committee nor the House itself changed the bill after it passed the Senate.[22]

Further complicating the picture is the Attorney General's *Memorandum on the Public Information Section of the Administrative Procedure Act* (June, 1967) which, although not binding on the courts,[23] can be presumed to guide the agencies in their operations under the Act. In interpreting the Act, this Memorandum most frequently follows the nondisclosure policies of the House Report, adding a few interpretations of its own which are supported neither by statutory language nor by legislative history.[24]

Finally, judicial interpretations of the Act to date indicate that doctrines of Executive Privilege and equity discretion remain to be

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[21] *Davis*, footnote 15, above.

[22] *Davis*, footnote 15, above, at 809-10; *Consumers Union*, footnote 16, above, at 800.

[23] *Consumers Union*, footnote 16, above, at 800; *Davis*, footnote 15, above, at 761, 778.

[24] *Davis*, footnote 15, above, at 781-83. For example, § 552(b) requires every agency to maintain a current index for "any matter . . . required to be made available."

The House Report (footnote 2, above, at 8), in explaining the requirements of this subsection, said that the subsection "requires an index of all the documents having precedential significance" but the Senate Report (see footnote 2, above, at 7) viewed this language as "requiring the agencies to keep a current index of their orders."

However, the Attorney General's Memorandum (footnote 3, above, at 21) instructed the agencies: "careful and continuing attention will be required to distinguish documents having precedential significance . . . — the only ones required to be included in the index — from the great mass of materials which have no such significance and which would only clutter the index and detract from its usefulness."

Per Professor Davis, "the *Attorney General's Memorandum* assumes without discussion that the House Committee's half-wrong remark overrides the clear statute and the Senate Committee's view." *Davis*, footnote 15, above, at 783.

reckoned with in any attempt to secure disclosure of information pursuant to the Act.[25]

Despite its shortcomings, the Freedom of Information Act shows definite signs of becoming and remaining a valuable and viable means of access to governmental information.

Effectiveness of the Statute

The effectiveness of the statute cannot really be assessed by looking at the litigated cases. More important would be the day-to-day handling of information requests, or the instances where threats of FOI action resulted in disclosure without going to court. Equally important is the pro-disclosure "atmosphere" which some say FOI has created among agency employees, whatever top-level policies may be.

Focusing on the court cases, District Courts have ordered disclosure of information ranging from hearing-aid test data to names and addresses of Draft Board members to applicants including litigants before or with agencies, consumer groups, and attorney advisors.[26] The FDA itself has been involved in two litigated cases of

[25] *See*, for example, *Consumers Union*, footnote 16, above, where the Court exercised its equity jurisdiction to deny disclosure of certain information, even though the Court's prior analysis of the act concluded that the information sought was not necessarily exempt from the act; *accord*, *GSA v. Benson*, footnote 17, above, at 880.

On executive privilege, *see GSA v. Benson*, 415 F. 2d at 879-881, citing and discussing *Carl Zeiss Stiftung v. V. E. B. Carl Zeiss, Jena*, 40 F. R. D. 318, 324 (D. D. C. 1966), *aff'd per curiam sub nom. V. E. B. Carl Zeiss, Jena v. Clark*, 384 F. 2d 979, *cert. denied*, 389 U. S. 952 (1967).

[26] District Court cases in which disclosure was required include: *Tuchinsky v. Selective Service System of the United States*, 294 F. Supp. 803 (N. D. Ill.), *aff'd*, 26 Ad. L. 2d 101 (7th Cir. 1969) (names and addresses of draft board members); *Benson v. GSA*, footnote 17, above, (agency compelled to make records of land transaction available to enable member of partnership to prove correct tax status of income received from land sale); *Consumers Union*, footnote 16, above, (hearing aid test scores); *Cooney v. Sun Shipbuilding and Drydock Co.*, 288 F. Supp. 708 (E. D. Pa. 1968) (accident reports); *Tobacco Institute v. FTC*, C. A. No. 3035-67 (D. D. C., filed April 11, 1968) (names and responses of individuals who responded to FTC survey on the effects of cigarette smoking).

For District Court cases in which disclosure was denied, *see Bristol-Myers v. FTC*, 284 F. Supp. 743 (D. D. C. 1968), *rev'd*, No. 22,277 (D. C. Cir., decided March 26, 1970) (agency records relied on in proposing rule for advertising analgesic medicines); *Barceloneta Shoe Corp. v. Compton*, 271 F. Supp. 591 (D. Puerto Rico 1967); *Clement Bros. Co. v. N. L. R. B.*, 282 F. Supp. 540 (N. D. Ga. 1968) (both rejecting requests for statements of persons interviewed by NLRB investigators); *Ep-*

(Continued on the following page.)

which I am aware. The first of these is *Ackerly v. Ley*,[27] which I will discuss in a moment. The second is *Matonis v. FDA*,[28] where the Administration was granted summary judgment because it had provided all the identifiable records which were requested.

Appellate interpretations of the Act to date have come down primarily on the side of disclosure.[29] Two District of Columbia cases wash, or at least expose, a good deal of agency dirty linen in the process.

The first Court of Appeals decision, *American Mail Line v. Gulick*, involved a request for a staff memorandum prepared in connection with a Maritime subsidy case. In deciding the case, the agency had incorporated verbatim in its letter to the affected parties five pages of the 33-page staff memo. Yet it steadfastly refused to disclose the staff memorandum, a position which was upheld by the District Court, apparently on the grounds that "[p]lainly within the terms of the statute, it is an intra-agency memorandum that is not routinely disclosed."[30]

(Footnote 26 continued.)
stein v. Resor, 296 F. Supp. 214 (N. D. Calif. 1969), *aff'd*, 38 U. S. L. W. 2473 (9th Cir., February 6, 1970) ("top secret" information on post-war repatriation of Soviet citizens); *Miller v. Smith*, 292 F. Supp. 55 (S. D. N. Y. 1968) (staff memoranda submitted to commandant of Coast Guard); *Kovic v. Gardener*, C. A. No. 2008-67 (D. D. C., Defendant's Motion to Dismiss granted Nov. 29, 1967) (petitioner purportedly had copies of social security records or access thereto); *Bandy v. Commissioner of Immigration and Naturalization*, C. A. No. 2239-67 (D. D. C., Defendant's Motion to Dismiss pending further administrative action granted Dec. 7, 1967) (request by inmate of federal penitentiary for current address of his wife. In later action agency refused to conduct search for wife's whereabouts).

[27] *Ackerly v. Ley*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 40,373 (CA D of C 1969) 420 F. 2d 1336.

[28] C. A. No. 479-68 (D. D. C., filed May 1, 1968).

[29] *Grumman Aircraft*, footnote 19, above, *American Mail Line Ltd. v. Gulick*, 411 F. 2d 696 (D. C. Cir. 1969); *Ackerly v. Ley*, footnote 27, above, *GSA v. Benson*, footnote 17, above, and *Bristol-Myers Co. v. FTC*, footnote 26, above. *But see, Epstein v. Resor*, footnote 26, above, (Army not required to disclose information to historian on post-war repatriation of Soviet citizens, because "top secret" information was: (1) within the first exemption (information required to be kept secret in interest of national defense); (2) recently updated; and (3) classified in a reasonable manner); *Cook v. Willingham*, 400 F. 2d 885 (10th Cir. 1968) (court is not an agency under Act); *Skolnick v. Parsons*, 397 F. 2d 523 (7th Cir. 1968) (government commission disbanded); *Shakespeare Co. v. United States*, 389 F. 2d 772 (Ct. Cl. 1968) (IRS letter rulings to competitors); *Tuchinsky v. Selective Service*, footnote 26, above, (names and addresses of local draft boards must be obtained from the local boards, not from the regional office).

[30] *American Mail Line Ltd. v. Gulick*, C. A. No. 1347-68 (D. D. C. 1968) (oral argument of Nathan Dodell, Counsel for Gulick, at 17).

The Court of Appeals, however, ordered disclosure, short-cutting the "intra-agency" exemption claim by holding that disclosure of part of the staff memorandum had vitiated the entire memorandum's status as an "intra-agency" document. In the process, the Court made several unflattering comments about the agency's decision-making procedures which gave rise to the case in the first place.

Closer to home before an FDA audience, the court's opinion in *Ackerly v. Ley*[31] flayed the FDA's "grudging" compliance with the Act, strongly hinting that FDA secrecy, in that case, had jeopardized the utility of the two-step rulemaking procedure required by Section 701 of the Federal Food, Drug, and Cosmetic Act.[32]

The *Ackerly* case began with a request to the FDA for access to "all of the Records" underlying a proposed hazardous substance rule banning carbon tetrachloride. Although not required by the Freedom of Information Act, Ackerly's request specifically stated that access was sought to "permit me an opportunity to examine the data and records available to the Food and Drug Administration which would justify a finding that carbon tetrachloride should be classified as a banned hazardous substance" so that "a responsive and relevant comment can be submitted. . . ." Ackerly pointed out that "eventually, all of this evidence and data must be made public if the procedures for administrative and judicial review are followed. If it is made available now, it may not be necessary to follow the very expensive and time-consuming administrative review procedures."[33]

The Court seemed to agree, scathingly commenting that the FDA's stalling of disclosure "hardly comports with the vigorous defense of the two-stage [rulemaking] device"[34] FDA had urged on the Court in *PMA v. Gardner*.[35]

Raising somewhat analogous issues to those involved in the *Ackerly* case, the pending appeal in *Bristol Myers v. FTC*[36] should still

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[31] See footnote 27, above.

[32] *Ackerly*, footnote 27, above, Slip op. at 7.

[33] Letter, dated March 7, 1968, from Robert L. Ackerly to Hon. James Goddard, attached as exhibit D to Complaint in *Ackerly v. Goddard,* CCH Food Drug Cosmetic Law Reporter ¶ 40,338 (DC D of C 1969) C. A. No. 923-68.

[34] *Ackerly*, footnote 27, above, Slip op. 6-7.

[35] *Pharmaceutical Manufacturers Association v. Gardner,* 385 F. 2d 271, 273-74 (D. C. Cir. 1967).

[36] On March 26, 1970, two weeks after this speech was delivered, the Court of Appeals for the District of Columbia Circuit rendered its decision on this appeal. The Court made clear that, contrary to the District Court, a request for materials "relied on" in promulgating a

(Continued on the following page.)

further clarify the extent to which the Freedom of Information Act requires advance disclosure of materials underlying proposed agency regulatory actions. In that case the facts sought are data on which the FTC relied in proposing a trade regulation rule regarding analgesics.

Despite the strong language and far-reaching implications of the opinions, the *American Mail* and *Ackerly* cases also underscore one of the major shortcomings of the Freedom of Information Act. In both cases, appellate resolution of the controversy was achieved too late for the requested documents to serve their purpose. Thus, administrative delay effectively frustrated the purposes of the Act. The incentives for such delay are magnified in any Freedom of Information Act litigation in which the applicant is interested in using specific documents for a particular purpose and may be inclined to abandon the case when his particular need for the documents is obviated. Yet in all FOI disputes the agency has a dual and continuing interest in protecting both specific documents and its institutional interest in nondisclosure.

The D. C. Circuit has shown an awareness of this problem and has sought to make its rulings go beyond the case at bar. In *Grumman,* after ordering the production of the specific orders and opinions which were sought in the case, the court said, "In the future, the Board can avoid the problem by deleting identifying details from each opinion or order, *and then making it available to public inspection as a matter of course.*"[37]

The possibility that agency delay and inaction can frustrate, not only the purposes of the Freedom of Information Act, but also, as in the *Ackerly* case, the purposes of other statutorily required procedures, suggests that remedies for such delay ought to be available. In this connection, the Fourth Circuit's decision in *Deering Milliken v. Johnston*[38] indicates that delay in adjudicating a case may be grounds for

(Footnote 36 continued.)
proposed FTC rule sufficiently identified the records sought. The case was remanded to the District Court for "detailed analysis" of the particular documents to determine if any of the "specific" and "narrowly construed" statutory exemptions apply. Per the Court: "Before 1967, the Administrative Procedure Act contained a Public Information section 'full of loopholes which allow[ed] agencies to deny legitimate information to the public.' When Congress acted to close those loopholes, it clearly intended to avoid creating new ones." *Bristol-Myers Co. v. FTC,* footnote 29, above, Slip op.

[37] *Grumman,* footnote 19, above, Slip op. at 5.

[38] 295 F. 2d 856, 865 (4th Cir. 1961).

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an injunction under Section 10(a) of the Administrative Procedure Act (APA).[39] Moreover, both industry and FDA counsel may find it worthwhile to consider whether in a case more controversial than the carbon tetrachloride proceeding, Freedom of Information Act questions may provide grounds for reversal of the final agency ruling.

Future Significance to FDA

To venture a few more speculations as to the future significance of the Freedom of Information Act to the FDA, I believe that the Act should end existing confusion among FDA practitioners as to whether or not the hearing examiner's "report" in an administrative proceeding is publicly available. Arguably, such a "report" is an "order" made in the adjudication of a case, which must be made available generally under § 552(a)(2)(A). Even if not, the "report" is a "record" subject to disclosure on request, as to which *American Mail* suggests a claim of confidential "intra-agency" status would be dimly viewed.

Second, I hope and expect that the Court of Appeals' views expressed in the *Ackerly* case, together with plain common sense, will lead the FDA to more complete disclosure of the documentation and data underlying its regulatory proposals. Certainly the comment stage of Section 701 rulemaking ought to work much more effectively if the basis of the agency's proposal is fully exposed *before* agency and opponents have to rush blindly into the conflict of a public hearing on objections. Moreover, if the rumors are sound that what FDA really wants is to phase out administrative hearings completely, full disclosure of all data pertinent to regulatory actions is essential.

To the extent FDA administrative litigation continues, the private FDA practitioner may find the Freedom of Information Act an increasingly important means of documentary discovery in such litigation, particularly if ways can be found to speed up FOI processes. The ease with which the statute may be invoked and the burden to justify nondisclosure it places on the agency make FOI attractive. At the same time, the very limited power granted FDA hearing examiners to compel disclosure of documents in administrative proceedings, and the limitations on interlocutory appeals, make it inevitable that counsel will move outside the hearing process to obtain the information they need to defend their clients' interests.

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[39] 5 U. S. C. 1009 (1964).

Finally, both FDA and industry counsel will undoubtedly become much more conscious in the future that the Act opens to the press, consumers, and consumer groups a wide range of information about the products FDA regulates and the way in which it makes its regulatory and enforcement decisions.

Precedents for Disclosure

Disclosure of Veterans Administration data on hearing-aid performance to the Consumers' Union provides a precedent for the disclosure of product data not expressly protected from disclosure by statute, particularly where the data has been developed by the agency or by consultants to the agency without any express or implied promises of confidentiality to the manufacturers involved.[40]

As for inquiries into the agency's decision-making process, those who think it can't be done are respectively referred, *inter alia,* to Professor Davis's discussion of the meaning of "orders made in the adjudication of cases," "interpretations which have been adopted by the agency," and "administrative staff manuals and instructions" — all of which must be made available under § 552(a)(2).[41]

Whether the regulators or the regulated will welcome these developments, I cannot predict. I submit, however, that they are clearly in line with the basic purposes of the Freedom of Information Act and that the development and expansion of the Act in this direction is inevitable in today's climate of consumerism. **[The End]**

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[40] *Consumers Union*, footnote 16, above, at 803.

[41] Davis, footnote 15, above, at 771. Professor Davis notes that both "order" and "adjudication" are broadly defined in Section 2(d) of the Administrative Procedure Act, and "under the APA definitions, every order is issued as part of the final disposition of an adjudication." As examples of orders heretofore unavailable he cites those relating to the auditing of tax returns, FCC licenses and no action letters of the SEC.

As for interpretations which have been adopted by agencies, Davis reads the act as requiring "disclosure of such minutes [for example, FCC debate to decide whether to set broadcast renewal application for hearing], unless they are an intra-agency memorandum within the meaning of the fifth exemption." At 772. According to Davis, instructions to staff members "[s]hould be subject to compulsory disclosure to the extent that they involve interpretation of law and only to that extent." He agrees [t]hat secrecy is desirable to the extent that policies about prosecuting depend upon such strategies as inducing maximum compliance with the least expenditure." At 779.

Harmonization of Food Legislation in Latin America

The Following Article Is a Summary of Remarks Made by Some of the Members of Committee XIX on Food and Drug Law. The Committee Met at the XVI Conference of the Inter-American Bar Association, Held in Caracas, Venezuela, From November 1 Through 8, 1969.

DR. A. E. OLSZYNA-MARZYS, of the Pan American Health Organization (PAHO), Institute of Nutrition of Central America and Panama (INCAP), Guatemala City, Guatemala, referred to the assistance given by PAHO towards the harmonization of food legislation in the Central American Isthmus described in his paper entitled "Food and Drug Legislation in Central America and Panama" published in the May, 1968 issue of the FOOD DRUG COSMETIC LAW JOURNAL, and specially to developments which have taken place since the article was written.

PAHO's assistance has taken the form of:

(a) elaboration, between 1963-1965, of a set of 380 Food Standards for Central America and Panama, recommended for inclusion in the legislation of the six countries by the Council of Public Health of Central America and Panama (consisting of the six Ministers of Health, meeting annually);

(b) sponsoring and financing, since 1965, of annual Seminars on Food and Drug Control for Central America and Panama, in which chiefs of those services, consultants and observers from food and drug industry, universities and other organizations meet, and after debates make recommendations in this field to the Ministers of Health;

(c) submitting, at the 1967 Seminar, draft projects of a uniform set of Food Regulations to be adopted by each of the six countries, as well as tolerances for pesticide residues; and

(d) sponsoring the establishment of reference laboratories for foods (at INCAP, Guatemala) and for drugs (at the University of Panama).

Food and drug legislation in the Isthmus has been based mainly on very antiquated Sanitary Codes of pre-World War II vintage with some scanty regulations for specific foods, except for Panama, which between 1961-1963 put its food and drug legislation and its enforcement on pretty solid foundations. The need for the reform of the legislation and its harmonization between the countries of the Central American Common Market has therefore been very great. However, owing to the slowness of the legislative processes and to the political situation in the Isthmus, progress has been rather slow. Nevertheless, on November 14, 1966, Honduras promulgated a new Sanitary Code, and on the basis of its Title V, Articles 83-103, also promulgated a new Food Ordinance (Reglamento) signed by the Minister of Health at the beginning of 1968.

The Ordinance incorporates the main provisions of the 1967 PAHO-recommended draft, and its main importance towards harmonization of Central American legislation lies in the fact that in its Title II, Chapter III, Article 13, it adopts as legally compulsory the PAHO's Food Standards for Central America and Panama, Honduras thus being the first country to put the use of these standards on a formally legal and obligatory basis. The Ordinance goes much further than the PAHO proposed regulations. For instance, it devotes a separate article to each type of food processing plant.

Nevertheless, while introducing compulsory registration of all processed foodstuffs brands, with five-year validity, as recommended in the PAHO draft, it has failed to incorporate one of the important recommendations of the 1967 Seminar —namely, that Central American products registered in their country of origin should be sold freely throughout the Isthmus without the need for re-registration in the country of final consumption. Furthermore, it makes no mention of the Reference Laboratory.

These two aspects have been taken care of in the new Guatemalan Food Ordinance, submitted for ministerial signature on October 14, 1969, at the same time as the new Sanitary Code was being submitted for parliamentary approval. The Guatemalan Ordinance follows the PAHO pattern very closely, although it makes various provisions of the pattern somewhat stricter. In addition, it:

(a) incorporates the PAHO Food Standards (Chapter X, Article 45);

(b) allows free sale of Central American products registered in their country of origin without further registration in Guatemala (Chapter III, Article 19); and

(c) establishes the Institute of Nutrition of Central America and Panama as the Reference Laboratory for purposes of analysis which cannot be carried out in the national laboratory, and for purposes of appeal, making the results obtained by INCAP in cases of dispute final and binding (Chapter III, or IV and VI, Article 30).

The speaker stressed the part played in all this work by the late Dr. Ariosto Büller-Souto, former Director of the Institute Adolfo Lutz of São Paulo, Brazil, who can be considered as a real "father" of the Central American food laws harmonization. The standards are the work of his Institute (contracted by PAHO); so are the proposed uniform regulations, closely similar to the Brazilian Food Code of February 27, 1967 (Decree No. 209).

Dr. Eladio Chaverri Benavides, Director, Department of Food Control, Ministry of Public Health of Costa Rica, stressed that even in those countries of Central America where the Central American Standards have not yet been incorporated formally in the legislation, they were being applied as a guide to chiefs of food control departments and food laboratories in cases where the existing laws left the decisions to their discretion. He said that, unfortunately, areas thus left were very large; for instance, in the case of Costa Rica, where God's guidance had been almost the only one available to the man in charge. The position of the Chiefs would be enormously eased and strengthened by the availability of detailed and uniform regulations. He referred to the Latin American Food Code and claimed that the reluctance to

accept it as a set of standards in Central America sprang from its regulatory form, whereas the Central American standards were not only more detailed, but also conformed more to the usual concept of hygienic quality standards.

Dr. Julio Fleischmann of Brazil stressed the fact that, unlike Central America with its small republics, in large Latin American countries such as his own or Argentina, uniformization of legislation between states or provinces was the first urgent step before their harmonization at international level. He quoted the fact that the Brazilian Decree Law No. 209 of February 27, 1967, was the first food law applicable to the nation as a whole, and that a revision of this law was ready for submission. Among several amendments introduced, he quoted one referring to labeling. According to the newly-introduced proposal, imported foodstuffs, through having to conform to Brazilian legislation with respect to their hygienic quality, would no longer have to bear labels compulsory for Brazilian products, but could be offered for sale with labels legal in their country of origin.

Dr. Julio C. E. Alfaro, Counsel of the Department of Health and Welfare of the Republic of Argentina, agreed with Dr. Fleischmann's remarks on the need for priority to be given to uniformization of laws at a national level first, and spoke about his own country, where the first national Food Law has just been introduced (Law No. 18284 of July 18, 1969). This law provides for the introduction of a new Argentinian Food Code which will be compulsory throughout the nation within 180 days of the signing of the law, thus putting an end to the hitherto prevailing heterogeneity of the laws and regulations between provinces.

Dr. Ernesto Aracama Zorraquin, Attorney, President of the Inter-American Association of Industrial Property, presented a paper entitled "Interrelation Between the Industrial Property Rights and Economic Integration." Dr. Aracama pointed out that in the last fifty years, the notion of industrial property has been losing its original simplicity. This was caused by three factors: (1) political—caused by the appearance of socialist forms of the industrial property law; (2) technical—created by the second industrial revolution in the age of nuclear

fission and computers; and (3) economic—originating in the desire for economic developments. This last factor requires a study of the reciprocal relationship between industrial property and economic integration.

Dr. Aracamo discussed this particular aspect from unification of Germany through the present-day Common Markets and Free Trade Areas. In the Common Markets and Free Trade Areas, problems arise due to lack of harmonization of legislation. None of the economic integration treaties tackles the industrial property problem specifically. The author quoted various opinions on how to face the problem, and pointed out that the aim should be to harmonize two fundamental requirements: that of free circulation of products in the area, and that of the industrial property, without sacrificing one or the other. He suggested that the solution would imply harmonization of legislation, which could be done in two ways: (1) introduction of a limited-effect common legislation regulating only circulation of products within the zone and its relations with the exterior, leaving internal problems of each country to its national legislation; or (2) substitution of a uniform law applying to each country separately and to their intra-zonal and external relations. These two solutions could follow each other as two stages of the harmonization process. In conclusion, the author discussed the virtues and problems connected with the introduction of each of the two stages.

Mr. Peter J. Messite, of the Washington, D. C. law firm of Zuckert, Scoutt & Rossenberger, presented a paper entitled "The American Food Broker & Latin American Export Trade," in which he discussed the potential usefulness to the prospective Latin American food exporter of the American food broker, an intermediary in the American food distribution system. **[The End]**

SALES PROMOTION REGULATIONS PROPOSED

Proposed regulations to control "cents-off," coupon, and "economy size" sales promotions on the labeling of food, drugs, cosmetics, and devices have been issued by the Food and Drug Administration. The proposed regulations are the first to be issued under the discretionary provisions of Section 5(c) of the Fair Packaging and Labeling Act. This section provides for the issuance of regulations either to prevent deception of consumers or to facilitate value comparisons. The proposed regulations have been issued to insure that price representations made on the package or label of consumer commodities, or price savings claimed by reason of the package size, reflect a true saving to the purchaser over the customary price at which the commodity is sold.

According to the proposal, a "cents-off" coupon, or other savings representation may be made by a manufacturer, packer, or distributor only if the product's ordinary and customary retail selling price has been established and is reduced by at least the savings differential represented on the package or labeling. The sponsor of the price reduction promotion and sellers at all subsequent trade levels would be required to maintain records for at least one year showing that the wholesale price was reduced enough to allow the savings to be passed on to the consumer.

In addition, the regulations:

(1) prescribe the manner in which the price reduction representation must be displayed;

(2) specify the frequency and duration of "cents-off" or other savings promotions;

(3) prohibit the use of "cents-off" or coupon savings on newly developed consumer commodities or on commodities introduced into a geographic area for the first time until an established selling price has been in effect for at least six months. Provisions for introductory offers have been included; however, the labeling of such products must include the suggested postintroductory retail price;

(4) prohibit the use of redeemable coupon offers that are contingent upon the purchase of other items offered by the sponsor of the promotion; and,

(5) control the labeling of products that are represented as being sold at a lower price per unit of weight, measure, or count because of the economy resulting from the size of the container to assure that a price reduction has actually been passed on.

Views and comments may be filed by July 20, 1970.

CCH Food Drug Cosmetic Law Reporter ¶ 40,388

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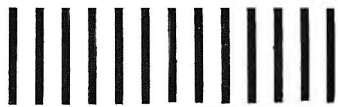

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