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

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Food and Drug Administration, Federal Trade Commission and the Deceptive Packaging of Foods

By WESLEY E. FORTE

This Article Is Reprinted from the New York University Law Review (Vol. 40, No. 5, November, 1965) with the Permission of New York University and of the Author. The First Part of This Article Was Reprinted in the April Issue. Mr. Forte Is a Member of the Pennsylvania Bar.

II

The FTC and the Deceptive Packaging of Foods

A. Rulemaking

1. Trade Practice Rules

JUST AS THE FOOD AND DRUG ADMINISTRATION (FDA) HAS THE POWER to promulgate standards of fill for containers of foods, the Federal Trade Commission (FTC) has the power to promulgate trade practice rules regulating the packaging of foods, and has promulgated some such rules.[94] Unlike the FDA's standards

[94] Although there is no express statutory warrant for trade practice rules (except the general rulemaking power of the FTC under § 6(g) of the act, 38 Stat. 722 (1914), 15 U. S. C. § 46(g) (1964)), the FTC has used the trade practice rule procedure since at least 1919. See Kittelle & Mostow, "A Review of the Trade Practice Conferences of the Federal Trade Commission," 8 *Geo. Wash. L. Rev.* 427-29 (1940). Trade practice rules can take the form of either direct restrictions prohibiting deceptive packaging or indirect restrictions prohibiting the advertising of deceptively packaged foods. Compare the trade practice rules prohibiting the sale of slack-filled sardine and tuna products, 16 C. F. R. § 144.8 (1960); 16 C. F. R. § 146.9 (1960); with the trade practice rules prohibiting the advertising of slack-filled candy, 16 C. F. R. § 186.18 (1960). The trade prac-

(Continued on next page.)

of fill, the FTC's trade practice rules do not have the effect of law,[95] and when taking legal action, the FTC charges not a violation of the trade practice rules but a violation of the underlying statute.[96] For this and other reasons, the FTC has been reluctant to use trade practice rules to fix specific percentages of fill of containers for individual foods.

The trade practice rules procedure consists of an application for a conference of the industry with the FTC,[97] at which the proposed rules are developed;[98] a public hearing on the proposed rules;[99] and the promulgation of the final trade practice rules by the FTC.[100] The FDA's concurrent jurisdiction is no barrier to the FTC's promulgation of trade practice rules regulating the packaging of foods and, indeed, the FTC has already promulgated some trade practice rules banning slack-fill in containers of foods in particular and misrepresentations concerning the quantities of foods in general.[101] Trade practice rules are designed to interpret the legal requirements applicable to a particular industry and to provide the basis for members of the industry to voluntarily and simultaneously abandon unlawful practices.[102] The practical value of the present trade practice rules governing slack-fill in foods is dubious because the rules do not fix a minimum percentage of fill

(Footnote 94 continued.)
tice rules governing sardines and tuna also prohibit the sale of these foods in odd-sized containers simulating containers which are known to the public as standard containers of definite capacity. Other trade practice rules prohibiting deception generally relating to the quantity of foods include the following: Cocoa and Chocolate Industry, 16 C. F. R. § 194.1 (1960); Ice Cream Industry, 16 C. F. R. § 89.8 (1960); Macaroni and Noodle Products Industry, 16 C. F. R. § 132.2 (1960); Oleomargarine Manufacturing Industry, 16 C. F. R. § 134.1 (1960); Ripe Olive Industry, 16 C. F. R. § 148.3 (1960); and Tomato Paste Manufacturing Industry, 16 C. F. R. § 133.1 (1960). While these rules typically prohibit all misrepresentations in regard to quantity, for example, the Ripe Olive Industry Rules, a few rules have been specifically limited to advertising, see, for example, the Macaroni and Noodle Products Industry Rules, while a few rules have also been broadened to specifically include packaging of foods in a manner which would mislead prospective purchasers with respect to quantity. See, for example, the Tomato Paste Manufactuirng Industry Rules.

[95] 4 Trade Reg. Rep. ¶ 40020 (1963).

[96] Id. at ¶ 40070; FTC Procedures and Rules, 16 C. F. R. § 1.62 (Supp. 1965).

[97] 4 Trade Reg. Rep. ¶ 40100 (1963); FTC Procedures and Rules, 16 C. F. R. § 1.66 (Supp. 1965).

[98] 4 Trade Reg. Rep. ¶ 40110 (1963); FTC Procedures and Rules, 16 C. F. R. § 1.67(a), (b) (Supp. 1965).

[99] 4 Trade Reg. Rep. ¶ 40120 (1963); FTC Procedures and Rules, 16 C. F. R. § 1.67(c) (Supp. 1965).

[100] 4 Trade Reg. Rep. ¶ 40130 (1963); FTC Procedures and Rules, 16 C. F. R. § 1.67(d), (e) (Supp. 1965).

[101] See footnote 94 above. Some of the rules listed therein merely prohibit misrepresentations in advertising and would be beyond FDA jurisdiction while others prohibit misrepresentations in labeling or by packing and would be within FDA jurisdiction.

[102] FTC Procedures and Rules, 16 C. F. R. § 1.62 (Supp. 1965).

but state generally that excessive slack-fill is an unfair trade practice.[103] Thus the rules fail to do precisely what trade practice rules are intended to do—interpret the legal requirements applicable to an industry in a manner which gives guidance to the members of that industry.[104] The FTC, with some inconsistency, has given three reasons why trade practice rules fixing minimum percentages of fill for individual foods are not an appropriate method of regulating deceptive packaging. These are: (1) the FTC has no power to call a trade practice conference and tell manufacturers how to package their products; (2) trade practice rules are broad ethical principles and do not normally deal with specific details such as percentage of fill; and (3) trade practice rules on deceptive packaging would be voluntary and unpersuasive.[105] Each of these contentions is analyzed here:

[103] The trade practice rules do not define how much slack-fill is necessary to violate § 5 of the FTC Act. Apparently the test is whether the slack-fill is sufficient to deceive the public—certainly a nebulous standard. The trade practice rules governing canned sardines (which are as specific as any on this point) provide:

> It is an unfair trade practice to sell . . . canned sardines or canned sardine products packed in slack-filled or short-weight containers, or packed in odd-sized containers simulating in size or shape standard sized or shaped containers which are known to the public as standard containers of definite capacity, with the tendency of or effect of misleading or deceiving the purchasing or consuming public . . . or which are packed in containers so made, formed, or filled as to be otherwise misleading.

16 C. F. R. § 144.8 (1960). See Tuna Industry Rules, 16 C. F. R. § 146.9 (1960). Cf. the Candy Manufacturing Industry Rules, 16 C. F. R. § 186.18 (1960).

[104] Cf. FTC Procedures and Rules, 16 C. F. R. § 1.62 (Supp. 1965).

[105] At the 1963 Hearing on S. 387, the following colloquy took place between Chairman Dixon and Mr. Raitt, counsel for the minority:

> Mr. Dixon. Let's take napkins. We have no power to call the napkin manufacturers into an announced hearing and listen to them and talk about what would be a desirable way to market or package these products. We have not that power today. Unless it would come by our finding that there was some slack filling or something that was really deceptive, we could sue someone. . . .
>
> Mr. Raitt. Yes. But could you, using the napkin illustration, bring these people in and say, Mr. Manufacturer, the Commission feels that the evidence shows that you are engaging, the whole industry is engaging in a particular practice. It is the Commission's view that this is a deceptive trade practice within section 5 or section 12. And if you went ahead and promulgated a regulation that said, we view this particular practice as deceptive, or to put it in the affirmative, we think to not be deceptive you have to do it in this way, you go ahead and issue that interpretation.
>
> Mr. Dixon. We can. But do you know how persuasive it would be?
>
> Mr. Raitt. That is the next question I want to get to. Then what in your estimation would be the reaction of the napkin manufacturers?
>
> Mr. Dixon. The same reaction apparently that you are getting here.
>
> Mr. Raitt. What is that?
>
> Mr. Dixon. I think that they would frown upon anyone telling them how to run their business. They would say, if I am wrong, you prove it.

(Continued on next page.)

(1) *FTC's Alleged Lack of Power to Call a Trade Practice Conference:* The FTC Rules expressly provide that rule making proceedings may be commenced by the FTC upon its own initiative or pursuant to petition filed by an interested person or group.[106] This procedure governs the promulgation of trade practice rules.[107] Therefore, according to the FTC's own Rules, it could initiate trade practice rule proceedings although the more normal procedure is for industry to initiate the proceedings.[108]

Since the FTC has the power to initiate trade practice rules proceedings, the next question is whether the FTC could compel industry members to attend a trade practice conference. This question, while intriguing, is largely academic.[109] Practically, industry would not boycott a trade practice conference since such a boycott would inevitably be followed by FTC investigations of individual companies for possible violations of section 5 through deceptive packaging. These investigations are certainly within the FTC's power.[110] Those boycotting the conference would gain nothing by that action since the FTC could be expected to handle any deceptive packaging violations uncovered by the investigations through cease and desist orders against individual companies, and might do so with a vengeance.

(2) *The Alleged Distinction Between Trade Practice Rules and Specific Detailed Standards:* Trade practice rules *are* frequently broad

(Footnote 105 continued.)

Mr. Raitt. Well, you are at least putting them on notice that you think they are wrong and if they want to avoid the problem of litigation before the Federal Trade Commission—

Mr. Dixon. We have 166 some odd—how many? 163? One hundred sixty-six trade practice conference rules that have been issued at the Federal Trade Commission during its history. These rules were sought by the industry itself. It wasn't an idea the Commission had. The industry came in as a whole and these largely were ethical rules but they never reached anything like what you are talking about here. They were ethical rules in broad language.

No sir. Those rules were for guidance, but to enforce them, if someone would violate whatever was in that rule, we would go back, and we don't charge violating that rule. 1963 Hearings 284, 293-94.

[106] FTC Procedures and Rules, 16 C. F. R. § 1.66 (Supp. 1965).

[107] FTC Procedures and Rules, 16 C. F. R. § 1.61 (Supp. 1965).

[108] 4 Trade Reg. Rep. ¶ 40100 (1963).

[109] The FTC Rules provide that in connection with any rule-making proceeding, the Commission can conduct such investigations, make such studies and hold such conferences as it may deem necessary. FTC Procedures and Rules, 16 C. F. R. § 1.67 (Supp. 1965). If the FTC considered the conference an essential part of a § 5 investigation, it could probably compel attendance of industry representatives as witnesses in connection with the investigation. See Federal Trade Commission Act § 9, 38 Stat. 722 (1914), 15 U. S. C. § 49 (1964).

[110] See Federal Trade Commission Act § 9, 38 Stat. 722 (1914), 15 U. S. C. § 49 (1964).

ethical rules for fair competition.[111] All of the present trade practice rules governing the packaging of foods fit within this category. However, the FTC has also promulgated trade practice rules setting specific detailed standards, when this is necessary to safeguard the public from deception.[112] For example, trade practice rules now require that jewelry marked "Gold Electroplate" be covered with a gold alloy of at least ten karat fineness, at least 7/1,000,000ths of an inch thick;[113] jewelry marked "Sterling Silver" must be at least 925/1000ths silver;[114] jam must consist of at least forty-five pounds of fruit to fifty-five pounds of sugar;[115] radios marked "Limited World-Wave" must receive frequencies from 540 kilocycles to 18,000 kilocycles;[116] tuna marked "standard" must contain at least seventy-five per cent large pieces of solid meat;[117] and razor blades must be tempered to a hardness of at least 90 to 92 on a Rockwell 15 N Scale, Superficial Hardness Tester, unless the blades are marked "substandard" or "seconds."[118] A trade practice rule setting a specific minimum percentage of fill for containers carrying a certain food could hardly be any more specific or detailed than these rules which have already been promulgated by the FTC.[119]

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[111] See 1962 Hearings 830, wherein Chairman Dixon refers to trade practice rules as "ethical rules of conduct."

[112] Cf. Nelson, "Trade Practice Conference Rules and the Consumer," 8 *Geo. Wash. L. Rev.* 452, 453 (1940):

> Moreover, while provisions dealing with the . . . purely competitive relationship are usually general in character and amount to little more than restatements of accepted law, those dealing with the sales transaction from the point of view of the buyer often lay down specific rules of conduct going far beyond the obvious implications of law and probably yield a very real benefit to the consumer.

Since the problem of deceptive packaging is a problem of consumer protection as well as fair competitive relations, specific rules would be acceptable under this analysis. See also 1963 Hearings 294.

[113] Jewelry Industry Rules, 16 C. F. R. § 23.22(c)(3) (1960).

[114] Jewelry Industry Rules, 16 C. F. R. § 23.23(b) (1960). See Metallic Watch Band Industry Rules, 16 C. F. R. § 60.2 (Supp. 1965).

[115] Preserve Manufacturing Industry Rules, 16 C. F. R. § 114.1(a) (1960). Cf. Tomato Paste Manufacturing Industry Rules, 16 C. F. R. § 133.2 (1960).

[116] Radio and Television Industry Rules, 16 C. F. R. § 142.2(b) (1960).

[117] Tuna Industry Rules, 16 C. F. R. § 146.1(b)(1) (1960).

[118] Razor and Razor Blade Industry Rules, 16 C. F. R. § 161.14 (1960).

[119] Cf. the testimony of Frederick M. Rowe in 1963 Hearings 716-17 in which Mr. Rowe stated that if specific rules are needed, they should be promulgated through the trade practice conference procedure.

Trade practice rules prescribing truthful labeling have been praised as "a very real step forward for the consumer by making it possible for him to base his purchases upon adequate knowledge rather than upon misinformation or half information." Nelson, cited at footnote 112, at 468. Rules prescribing minimum percentages of fill for foods would be supported by the same rationale.

(3) *The Alleged Ineffectiveness of Trade Practice Rules Governing Deceptive Packaging, Due to Their Voluntary Nature:* Trade practice rules are *always* voluntary rather than compulsory. Therefore this is no reason not to use these rules to set specific standards of fill in deceptive packaging situations. The FTC's reasoning is that since industry protested that the proposed new legislation concerning deceptive packaging would be an unjustified interference with management, industry would also be uncooperative if the FTC promulgated specific trade practice rules governing packaging of foods.[120] This reasoning will not withstand analysis. While protests were made that some provisions of the proposed new legislation would be unjustified interference with management,[121] both proponents and opponents of the new legislation agree that industry also voluntarily reviewed its packaging to eliminate the causes of consumer confusion.[122] If industry took the same attitude toward FTC trade practice rules as it did toward the Senate hearings, the FTC would be assured of considerable cooperation.

It should also be recognized that the amount of voluntary cooperation required may not be very great, depending upon what trade practice rules are promulgated. In many product lines competition has stabilized the percentage of fill of containers at roughly the same level, with a few companies using containers filled substantially below this informal standard. If the FTC issued a trade practice rule fixing a percentage of fill slightly below the industry average, the FTC would, in effect, be asking the minority to increase its fill. Part of that minority would probably comply with the new rule. The remaining companies would be forced to litigate against the FTC in a situation in which they were packing below the industry average and below the FTC's recommendation. Some litigation is not unusual after trade practice rules have been promulgated, and the enforcement of the type of trade practice rules described above would require no more voluntary cooperation from industry or litigation by the FTC than is usually required in connection with trade practice rules.[123]

[120] See 1963 Hearings 294. The FTC also reasons that regulations governing deceptive packaging should have the force and effect of law since otherwise a competitor can get an advantage by not complying with the rules. See 1962 Hearings 830. Again, this objection is common to most trade practice rules. For example, in the Feather and Down Products Industry Rules, 16 C. F. R. § 200.3(c)(1) (1960), a producer could get a competitive advantage by violating the 15% tolerance and yet the FTC used trade practice rules in that situation.

[121] See 1963 Hearings 69, 83-88, 259-64, 306-09, 333-42, 400-03, 424-30, 552-56, 596-601, 645-58.

[122] Id. at 13, 124, 136-44, 230-31, 488-92.

[123] Although trade practice rules are "voluntary," this does not mean that every company in the industry necessarily concurs with each rule promul-

(Continued on next page.)

Because of possible antitrust problems, industry could not voluntarily agree on specific minimum percentages of fill of container for foods in the absence of trade practice rules.[124]

2. *Trade Regulation Rules*

The FTC could probably also promulgate trade regulation rules setting specific minimum percentages of fill for containers of food.[125]

(Footnote 123 continued.)
gated for that industry. For example, the Feather and Down Products Industry Rules, 16 C. F. R. § 200.3(c)(1) (1960), provided in part, that the industry must label the type of feather product or down used in pillows and like products and that such labeling must be accurate except that up to 15% of the filling can be material other than that indicated on the label. The tolerance was necessary because practically no manufacturer can be sure that any filling is all one type of feather. The litigation following the promulgation of the Feather and Down Products Industry Rules is proof that not all of the industry agreed that a 15% tolerance was sufficient. See *Barclay Home Prods. v. FTC,* 241 F. 2d 451 (D. C. Cir.), cert. denied, 354 U. S. 942 (1957); *Lazar v. FTC,* 240 F. 2d 176 (7th Cir. 1957); *Burton-Dixie Corp. v. FTC,* 240 F. 2d 166 (7th Cir. 1957); *Buchwalter v. FTC,* 235 F. 2d 344 (2d Cir. 1956); *Northern Feather Works v. FTC,* 234 F. 2d 335 (3d Cir. 1956). The FTC brought eleven cease and desist proceedings in connection with the Feather and Down Industry Rules and these eleven proceedings involved practically all pillow production in the industry. *Burton-Dixie Corp. v. FTC,* cited at footnote 168. It is difficult to understand how the disputes concerning tolerances fixed in connection with minimum percentages of fill for foods would be any greater than the disputes which occurred in connection with the tolerance fixed in the Feather and Down Products Industry Rules. See also Chairman Dixon's statement in 1963 Hearings 294-95 that the FTC was still suing companies which refused to comply with trade practice rules regulating the use of the term "shockproof" on watches. *Cf. Kittelle & Mostow,* cited at footnote 94, at 441-42, in which the authors describe an early trade practice rule proceeding which was "voluntary" only in the sense that retailers and consumers had forced industry into participation in the procedure.

[124] See Statement of Paul Rand Dixon, Chairman, FTC, 1965 Hearings 79, in which he states, "And if the producers themselves, without Government supervision, attempt to achieve standardization or uniformity of product, they may run afoul of the antitrust laws."

[125] It should be noted that "there is still considerable uncertainty about the precise dimensions of the authority of the FTC . . . to issue regulations determinative of legal status." Shapiro, "The Choice of Rulemaking or Adjudication in the Development of Administrative Policy," 78 *Harv. L. Rev.* 921, 960-61 (1965). At an earlier time, it was suggested that a general grant of rulemaking authority to a federal agency was limited to matters of internal procedure and organization. Att'y Gen. Comm. on Administrative Procedure, Final Report 98 n. 18 (1941); Hart, "The Exercise of Rule-Making Power, in President's Comm. on Administrative Management," Report 309, 332 (1937). Similar objections were again raised during the hearings on the recent FTC trade regulation rule on cigarette advertising. "Transcript of Hearings, In the Matter of Proposed Trade Regulation Rules for the Advertising and Labeling of Cigarettes" 50-54, 83-E to -P, 180-91, 273 (1964) (cited in *Shapiro,* cited at 965 n. 165).

In spite of such objections, there is good reason to believe that the FTC presently has the basic authority neces-

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These rules would be based on Section 6(g) of the FTC Act.[126] The procedure of promulgating trade regulation rules is to publish a proposed rule, asking interested persons to present their views in writing concerning it.[127] The FTC may then hold a public hearing and thereafter issue the trade regulation rule in its final form. Trade regulation rules, unlike trade practice rules, have the effect of law and the FTC charges a violation of the rule, rather than the statute, when legal action is necessary.[128]

The FTC has now issued trade regulation rules for the following products: sleeping bags,[129] binoculars,[130] dry cell batteries,[131] tablecloths,[132] leather belts[133] and used lubricating oil.[134] These rules prohibit generally deception concerning the labeling, advertising and

(Footnote 125 continued.)
sary for the specific rulemaking activities suggested in this article. The FTC has summarized some of the arguments leading to this conclusion in 29 Fed. Reg. 8325, 8366-68 (1964), but the most authoritative source is the Supreme Court's decision in *FPC v. Texaco*, 377 U. S. 33 (1964), upholding the power of the FPC to promulgate a regulation concerning pricing provisions in gas producers' contracts and to enforce the regulation without individual adjudication. The general rulemaking authority given the FPC by § 16 of the Natural Gas Act, 52 Stat. 830 (1938), 15 U. S. C. § 717*o* (1964), is nearly identical to that of the FTC under § 6(g) of the Federal Trade Commission Act, 38 Stat. 722 (1914), 15 U. S. C. § 46(g) (1964). It seems, therefore, that the only value of the specific delegation of rulemaking authority proposed in S. 985 is that suggested by Chairman Dixon: it would be more "orderly" for Congress to make the grant express in regard to deceptive packaging. 1962 Hearings 836. In the 1963 Hearings Chairman Dixon testified that the FTC does not have the power under § 6(g) of the FTCA to issue "legislative regulations." 1963 Hearings 293. Rules setting minimum percentages of fill of containers for specific foods would not seem as "legislative" in nature as the trade regulations relating to cigarette advertising and labeling. See "Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking," 16 C. F. R. § 408 (Supp. 1965).

[126] 38 Stat. 722 (1914), 15 U. S. C. § 46(g) (1964); Remarks by Commissioner MacIntyre, Winter Conference of the American Marketing Association, New York City, Dec. 27, 1961, pp. 21-22. (Copy on file in New York University Law Review Office.)

[127] See FTC Procedures and Rules, 16 C. F. R. § 1.67 (Supp. 1965); Address by Chairman Dixon Before the American Association of Advertising Agencies, White Sulphur Springs, W. Va., April 28, 1962, p. 10. (Copy on file in New York University Law Review Office.)

[128] See Remarks by Commissioner MacIntyre, cited at footnote 126 at 22, 28-29. See also Speech by Commissioner Anderson Before the Charlotte-Piedmont Better Business Bureau, Charlotte, N. C., Nov. 16, 1962, pp. 20-21. (Copy on file in New York University Law Review Office.) Trade regulation rules, unlike the trade practice rules, need not be limited to any particular industry. FTC Procedures and Rules, 16 C. F. R. §§ 1.62-.63 (Supp. 1965).

[129] 16 C. F. R. § 400.1 (Supp. 1965).

[130] 16 C. F. R. § 402 (Supp. 1965).

[131] 16 C. F. R. § 403 (Supp. 1965).

[132] 16 C. F. R. § 404 (Supp. 1965).

[133] 16 C. F. R. § 405 (Supp. 1965).

[134] 16 C. F. R. § 406 (Supp. 1965).

appearance of these products. A trade regulation rule has been issued requiring warnings of dangers to health on cigarette packages and in cigarette advertising.[135] Trade regulation rules have also been proposed preventing deception concerning the size of television screens.[136]

All trade regulation rules exist for the purpose of preventing the deception of the consumer. Trade regulation rules prohibiting unnecessary slack-fill in containers of foods would be consistent in purpose with the trade regulation rules already issued by the FTC.[137] These rules would be the ultimate answer to the objection that trade practice rules are voluntary and cannot be used to fix specific standards of fill.

B. Individual Actions: Cease and Desist Orders

The FTC has the power to issue orders under Section 5 of the FTC Act requiring persons and corporations to cease and desist from using unfair methods of competition and unfair or deceptive acts or practices in commerce.[138] Deceptive packaging deceives actual and prospective purchasers and shifts sales from honest competitors to those engaged in this unethical conduct.[139] Deceptive packaging is therefore considered both a deceptive practice and an unfair method of competition under section 5.[140]

The general procedure is for the FTC to file a complaint, giving respondent an opportunity to answer the complaint in a hearing before an FTC examiner.[141] The examiner may issue a cease and desist

[135] 16 C. F. R. § 408 (Supp. 1965). Since the promulgation of this rule, Congress has passed legislation requiring that such a warning be placed on each cigarette package, but preventing the requiring of a warning in advertising. Federal Cigarette Labeling and Advertising Act, 79 Stat. 282 (1965). The FTC's trade regulation rules relating to cigarette advertising and labeling were discussed at 113 *U. Pa. L. Rev.* 303 (1964).

[136] 29 Fed. Reg. 12088 (1964).

[137] Prevention of deception of the consumer is the basis for the trade practice rules which already in general terms prohibit slack-fill in some products.

[138] 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(a), (b) (1964).

[139] See *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964). In that action, the FTC held that deceptive packaging through slack-filling was an unfair method of competition (in addition to a deceptive practice) because: (1) such packaging takes sales from competitors selling the same quantity of product without slack-fill because such packaging appears to offer a greater quantity of goods for the same price; and (2) such packaging takes sales from competitors selling a greater quantity of product without slack-fill because such packaging appears to offer an equal quantity of goods for a lower price. Id. at 21653.

[140] Id. at 21652-53.

[141] 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(b) (1964); FTC Procedures and Rules, 16 C. F. R. §§ 3.4, .5 (Supp. 1965). The FTC's jurisdiction is limited to proceedings which are "to the interest of the public." 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(b) (1964), but this has presented no problem in the deceptive packaging

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order and respondent may appeal that order to the full Commission.[142] If the FTC affirms the order, it becomes final unless respondent appeals to the court of appeals.[143] A cease and desist order forbids respondent from violating its terms forever and each separate violation (or each day in which a violation is continued) is a separate offense which may result in a civil penalty of not more than $5000.[144] The FDA's concurrent jurisdiction over deceptive packaging of foods is no barrier to the FTC's exercise of jurisdiction and, indeed, the FTC in some instances has already issued cease and desist orders prohibiting the deceptive packaging of foods.[145] The more important deceptive packaging cases of the FTC are summarized below.

In *Mountain Grove Creamery, Ice and Elec. Co.*,[146] an early FTC deceptive packaging case, respondent manufactured and sold in interstate commerce the customary one pound packages of butter, containing two individual half pounds or four individual quarter pounds in each package. Respondent then reduced the net weight of the butter in its packages from one pound to roughly 14 or 15 ounces, with a reduction in the net weight of the former half pounds to approximately 7 and 7½ ounces and of the former quarter pounds to approximately 3½ to 3¾ ounces. The correct net weight was marked on the outer label of the package but the individual subdivisions inside the package had unprinted wrappers with no net weight statements. Both the outer package used by respondent and the individual subdivisions were similar in size, shape and appearance to the standard one pound packages and standard half and quarter pounds formerly sold by respondent and still sold by respondent's competitors. The reduction in the net weight of respondent's butter occurred after the butter manufacturers had agreed among themselves and with the FTC in a "Trade Practice Submittal" that it was unfair competition to sell

(Footnote 141 continued.)
cases. The limitation might have relevance if a deceptive packaging case involved a "passing-off" dispute between competitors, cf. *FTC v. Klesner*, 280 U. S. 19 (1929), although most recent cases seem to suggest the FTC should have jurisdiction even then. See, for example, *Pep Boys—Manny, Moe & Jack, Inc. v. FTC*, 122 F. 2d 158 (3d Cir. 1941) (the FTC has jurisdiction over a dispute involving deceptive use of the trademark "Remington"); *Marlborough Labs., Inc.*, 32 F. T. C. 1014, 1020 (1941).

[142] 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(b) (1964); FTC Procedures and Rules, 16 C. F. R. §§ 3.21, .22 (Supp. 1965).

[143] 38 Stat. 720 (1914), as amended, 15 U. S. C. § 45(c) (1964).

[144] 52 Stat. 114 (1938), as amended, 15 U. S. C. § 45(*l*) (1964).

[145] See, for example, *Harry Greenberg*, 39 F. T. C. 188 (1944); *Burry Biscuit Corp.*, 33 F. T. C. 89 (1941).

[146] 6 F. T. C. 426 (1923). See also *Ozark Creamery Co.*, 8 F. T. C. 377 (1925); *Wichita Creamery Co.*, 6 F. T. C. 435 (1923); and *Meriden Creamery Co.*, 6 F. T. C. 444 (1923), which involved like practices and resulted in like holdings.

butter in weights other than the standard weights of 16 ounces, 8 ounces or 4 ounces, or to sell butter without the correct net weight marked thereon.

The FTC held that respondent's acts had deceived and misled purchasers, and had placed an instrument into the hands of retailers by which they could deceive and mislead purchasers into the false belief that they were purchasing the standard weights. Respondent was ordered to cease and desist from selling butter

in shapes, sizes and dress in imitation of, or resembling the standard or recognized shapes and sizes generally known to the purchasing public to contain four ounces, eight ounces and one pound of butter, respectively, when such shapes and sizes contain less than said standard respective weights.[147]

Respondent in *Burry Biscuit Corp.* manufactured and sold packaged crackers in interstate commerce.[148] The cardboard containers used by respondent were of a capacity and size in excess of that "reasonably required" for the quantity of crackers placed therein, and the quantity of crackers was "substantially less" than the capacity of the containers.[149] The FTC held that respondent had misled and deceived a "substantial portion of the buying public" into the false belief that the packages were filled to capacity and contained the quantity of crackers indicated by the capacity of the containers, and had placed in the hands of retail sellers the means by which the retailers could similarly mislead and deceive members of the buying public.[150] Respondent was ordered to cease and desist from offering for sale or selling any of its bakery products in a container or package "which is substantially larger in size or capacity than that required for packaging the quantity of product contained therein."[151]

In *Harry Greenberg,*[152] respondent manufactured and sold packaged candy. The packages, in addition to the candy, contained toys or novelties of little value. All of the respondent's packages were substantially larger than was necessary to contain the candy and some of the packages were substantially larger than necessary to contain both the candy and the toy or novelty packed therein. The FTC held that respondent had misled and deceived a "substantial portion of the purchasers and prospective purchasers" into the false belief that the packages were filled to capacity and contained the quantity of candy indicated by the capacity of the containers, and had placed in the

[147] 6 F. T. C. at 434.
[148] 33 F. T. C. 89 (1941).
[149] Id. at 93.
[150] Ibid.
[151] Id. at 94. Respondent had also stated on the label of its package "Average 90 Crackers" which was false, and was therefore ordered to cease and desist from misrepresenting the quantity of product in its containers. Id. at 93-94.
[152] 39 F. T. C. 188 (1944).

hands of retail sellers the means by which the retailers could similarly mislead and deceive members of the purchasing public.[153] Respondent was ordered to cease and desist from offering for sale or selling any of his candy products or other merchandise in a container or package "which is substantially larger in size or capacity than that required for packaging the quantity of product contained or placed therein."[154]

A recent case, *The Papercraft Corp.*,[155] involved a respondent who manufactured and sold gift-wrapping paper. The rolls of gift-wrapping paper were 20 inches long and were contained in a box which was 24 inches long with 2 inches of empty space at each end. There was a transparent "window" 19 inches long in the box but the discrepancy between the length of the rolls and the length of the box was not apparent by looking through the window. The FTC held that respondent had violated Section 5 of the FTC Act, stating: "'Slack-filling'—broadly any use of oversized containers to create a false and misleading impression of the quantities contained in them—is an unlawful trade practice."[156] An accurate label statement of the actual length of the rolls of paper did not cure the misleading impression created by the box, the FTC also holding that: "[A] person deceived in this fashion is not one of the 'foolish or feeble-minded' who are not entitled to the Commission's protection."[157]

Finally, the FTC made it plain that it was not laying down a per se rule against slack-fill. Technical factors (*e.g.*, fragility) might require the use of oversized containers, though the seller must take "all responsible precautions" to prevent deception.[158]

Commissioner MacIntyre dissented, stating that the FTC's opinion could be construed as a retreat from the FTC's long-held position that the public as a whole was entitled to the FTC's protection.[159]

These decisions and a few other FTC deceptive packaging decisions,[160] although admittedly a limited amount of authority, do set forth fundamental principles by which containers should be judged under Section 5 of the FTC Act. These principles are:

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[153] Id. at 190.

[154] Id. at 191.

[155] Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964).

[156] Id. at 21652.

[157] Id. at 21653.

[158] Ibid.

[159] Id. at 21657.

[160] See *U. S. Packaging Corp.*, 53 F. T. C. 1174 (1957) (consent order); *United Drug Co.*, 35 F. T. C. 643 (1942); *Marlborough Labs., Inc.*, 32 F. T. C. 1014 (1941); *Trade Labs., Inc.*, 25 F. T. C. 937 (1937); *Export Petroleum Co.*, 17 F. T. C. 119 (1932); *Baltimore Paint & Color Works, Inc.*, 9 F. T. C. 242 (1925), aff'd, 41 F. 2d 474 (4th Cir. 1930).

(1) As with FDA cases under section 403(d), even if the net weight is correctly stated, the container will probably be considered deceptive, if misleading representations were made as to the volume of its contents.[161] In deciding whether the container is deceptive, the FTC first determines what representation was made concerning the volume of the contents and then considers whether that representation was deceptive.[162]

(2) "A substantial portion of the buying public" is the standard by which the FTC will determine (a) the representations made by the container and (b) whether those representations were deceptive.[163] This is probably closer to the FDA standard of the ordinary pur-

[161] See *Ozark Creamery Co.*, 8 F. T. C. 377 (1925); *Mountain Grove Creamery, Ice and Elec. Co.*, 6 F. T. C. 426 (1923); *Wichita Creamery Co.*, 6 F. T. C. 435 (1923); *Meriden Creamery Co.*, 6 F. T. C. 444 (1923), in which the FTC held the outer packages for butter deceptive although the correct net weights were stated plainly on the labels. See also *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964), in which the FTC held a container of rolls of wrapping paper deceptive although the size of the rolls was plainly stated on the label of the package.

[162] The FTC's reasoning on this point is implicit rather than explicit and therefore it would be difficult to quote language of the Commission supporting this proposition. It is not difficult at all, however, to demonstrate that the FTC follows this approach.

There are two basic lines of deceptive packaging cases which have been decided by the FTC. One line of cases involves deception through the use of standard containers for less than standard quantities. See *Marlborough Labs., Inc.*, 32 F. T. C. 1014, 1029 (1941); *Export Petroleum Co.*, 17 F. T. C. 119 (1932); *Baltimore Paint & Color Works, Inc.*, 9 F. T. C. 242 (1925), aff'd, 41 F. 2d 474 (4th Cir. 1930); *Ozark Creamery Co.*, 8 F. T. C. 377 (1925); *Mountain Grove Creamery, Ice and Elec. Co.*, 6 F. T. C. 426 (1923); *Wichita Creamery Co.*, 6 F. T. C. 435 (1923); *Meriden Creamery Co.*, 6 F. T. C. 444 (1923). The other line of cases involves deception through substantial slack-filling of nonstandard containers. See *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964); *U. S. Packaging Corp.*, 53 F. T. C. 1174 (1957) (consent order); *Harry Greenberg*, 39 F. T. C. 188 (1944); *United Drug Co.*, 35 F. T. C. 643 (1942); *Burry Biscuit Corp.*, 33 F. T. C. 89 (1941); *Trade Labs., Inc.*, 25 F. T. C. 937 (1937). The FTC distinguishes clearly between the theories involved in the two lines of cases and therefore must determine which representation was made by the container.

[163] The FTC has consistently proved deception which would meet this type of test in its later packaging cases. See *Harry Greenberg*, 39 F. T. C. 188, 190 (1944) ("substantial portion of the purchasers and prospective purchasers, members of the buying public"); *United Drug Co.*, 35 F. T. C. 643, 647 (1942) ("substantial portion of the purchasing public"); *Burry Biscuit Corp.*, 33 F. T. C. 89, 93 (1941) ("substantial portion of the buying public"). *Cf. Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964); *Trade Labs., Inc.*, 25 F. T. C. 937, 946 (1937). In the earlier cases listed in footnote 162 above, the FTC seemed to prove only deception of the public, members of the public, or purchasers, rather than deception of a substantial portion of the public. It could be argued that the FTC is simply "overproving" its cases now and that there is no necessity for the FTC to prove

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chaser than to the more liberal standard frequently applied in FTC actions against deceptive advertising.[164] Both elements—"a substantial portion" and "the buying public"—are significant. "A substantial portion" means more than the foolish and feeble-minded.[165] Thus while FTC protection may extend below the level of the average purchaser, the FTC will not push to an "absurd extreme."[166] The buying public probably means "purchasers" and "prospective purchasers."[167] A purchaser or prospective purchaser is likely to have a greater interest in the container and more experience with similar products than an ordinary member of the public and may be charged with a knowledge of those facts which seem apparent from a reasonable inspection of the container.

(3) In general, representations concerning volume will fall within the following categories:

First, a nonstandard nontransparent container for a finished food probably represents that it is reasonably full of the finished food considering settling after packing and other limitations on fill which would be known to purchasers and prospective purchasers.[168] As with

(Footnote 163 continued.)
deception of a substantial portion of the buying public rather than deception of the most credulous members of the public, the foolish and feeble-minded. The validity of this argument was undermined, however, by the majority of the FTC when they clung to Commissioner Elman's language in the Papercraft decision in the face of Commissioner MacIntyre's dissent which explicitly advocated the adoption of the latter test. *Papercraft Corp.*, cited at 21657.

[164] See footnotes 47-53 (21 Food Drug Cosmetic Law Journal 214-216) and accompanying text.

[165] See *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721, at 21653 (FTC 1964).

[166] In *Papercraft*, the FTC relied upon *Heinz W. Kirchner*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16664 (FTC 1964). Kirchner accepted the principle that the FTC should protect the gullible and credulous but not the foolish and feeble-minded. Kirchner also suggested that the FTC will not push to an "absurd extreme." Id. at 21539. See also Millstein, "The Federal Trade Commission and False Advertising," 64 *Colum. L. Rev.* 439, 461 n. 97 (1964).

[167] *Cf. Harry Greenberg*, 39 F. T. C. 188, 190 (1944), in which the terms appear to be used interchangeably.

[168] All of the FTC's cases have involved finished foods rather than mixes for foods. Cf. text accompanying footnote 54 (21 Food Drug Cosmetic Law Journal 216) for the definition of a finished food, and footnotes 57-59 (21 Food Drug Cosmetic Law Journal 217-218) for a discussion of mixes for foods and deceptive packaging under the Federal Food, Drug, and Cosmetic Act.

The FTC does not usually identify the deceptive representation which was made by the container in slack-fill cases. The FTC usually holds merely that the container was not filled to capacity and that the quantity of food therein was substantially less than the capacity of the container. See *Harry Greenberg*, 39 F. T. C. 188 (1944); *Burry Biscuit Corp.*, 33 F. T. C. 89 (1941). See also *United Drug Co.*, 35 F. T. C. 643 (1942); *Trade Labs., Inc.*, 25 F. T. C. 937 (1937). However, the representation made by the container

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FDA cases under section 403(d), the container is not expected to be 100 per cent full, but it may be considered deceptive if it is "substantially larger" than is necessary to contain the food.[169]

Premiums packed in the container with the food may give rise to special problems. In *Harry Greenberg,* the FTC held that a package which contained candy and a premium of negligible value was deceptive because it was not reasonably filled with candy. While the FTC did not elucidate its reasoning, it seemed to hold that the premium was to be disregarded in considering whether the container was "slack-filled."[170] This probably means simply that a candy container represents that it is reasonably full of candy in the absence of notice that there is some other item inside the package. A different result might have been reached if the presence of the premium together with some indication of its size were prominently disclosed on the label or if the container were transparent.[171] The facts would have also been more favorable to respondent had the premium been of greater value.[172]

Second, as with FDA rulings under section 403(d), a standard nontransparent container probably represents that it contains the standard quantity of food.[173] In such a situation, the container has

(Footnote 168 continued.)
depends upon the expectations of substantial portions of the purchasing public, see *Trade Labs., Inc.*, cited at 940, and it is submitted that in the absence of special circumstances (e.g., adequate and effective disclosure of the contrary) those expectations are that the container of finished food will be "reasonably full." *Cf.* the consent order in *U. S. Packaging Corp.*, 53 F. T. C. 1174, 1176 (1957), barring containers of a size or capacity in excess of that "reasonably required" for packaging the quantity of product actually contained therein.

[169] See the cease and desist orders in *Harry Greenberg,* cited at footnote 168, at 191; *United Drug Co.*, cited at footnote 168, at 648; *Burry Biscuit Corp.*, cited at footnote 168, at 94; *Trade Labs., Inc.*, cited at footnote 168, at 947.

[170] One of the respondent's said packages of candy . . . is packed in a cardboard carton 1" × 3" × 5", said carton containing five or six small pieces of candy taffy and a toy of infinitesimal value. The carton in which said candy is packed is substantially larger than necessary to contain the amount of *candy* therein packed. Others of respondent's packages . . . consist of a few pieces of candy . . . and a toy or novelty of no appreciable value, which are packed in a carton 1½" × 2" × 3" in dimension, said cartons being of substantially greater size than is necessary to contain the *candy and novelty.* 39 F. T. C. at 190. (Emphasis added.) All of the containers were held deceptive.

[171] In either case respondent could then argue that he made full disclosure to actual and prospective purchasers.

[172] The FTC's reference to the "infinitesimal value" of the toy, 39 F. T. C. at 190, suggests that perhaps the FTC thought the presence of the toy was merely an excuse to cheat purchasers by putting less candy in the container. The suspicion would have been allayed had the premium been of greater value than a corresponding volume of candy.

[173] See *Ozark Creamery Co.*, 8 F. T. C. 377 (1925); *Mountain Grove Creamery,*
(Continued on next page.)

acquired a secondary meaning in regard to volume of fill which has displaced the ordinary representation made by the container.[174] Even a minor reduction in fill below the standard may be considered deceptive in such circumstances (*e.g.*, 15 ounces of butter in a standard one pound package). The FTC has been successful in a number of cases based on this theory.[175] Conversely, a substantial amount of slack-fill may not be deceptive if the container contains the standard fill which is expected by purchasers.[176]

Third, corresponding to the FDA deceptive packaging principles, a transparent container makes no implied representation concerning the volume of its contents and a nontransparent container usually makes no implied representation concerning its volume which is inconsistent with a reasonable inspection of the container.[177] The FTC

(Footnote 173 continued.)
Ice and Elec. Co., 6 F. T. C. 426 (1923); *Wichita Creamery Co.*, 6 F. T. C. 435 (1923); *Meriden Creamery Co.*, 6 F. T. C. 444 (1923) and text accompanying footnotes 146-47 above. *Cf. Marlborough Labs., Inc.*, 32 F. T. C. 1014 (1941) (regular size tooth pastes and shaving creams in giant size cartons); *Export Petroleum Co.*, 17 F. T. C. 119 (1932) (9.6 gallons of gasoline in standard 10 gallon cases); *Baltimore Paint & Color Works, Inc.*, 9 F. T. C. 242 (1925), aff'd, 41 F. 2d 474 (4th Cir. 1930) (less than ½ gallon and 1 gallon of shellac in standard ½ gallon and 1 gallon cans); and the trade practice rules for the sardine and tuna industries discussed in footnote 103 above. *Cf. Royal Baking Powder Co. v. FTC*, 281 Fed. 744 (2d Cir. 1922), and *FTC v. American Snuff Co.*, 38 F. 2d 547 (3d Cir. 1930), in which the FTC alleged that respondents' packages were associated with products composed of certain ingredients and that it was deceptive for respondents to continue to use the same style packages after changes were made in the ingredients. The FTC secured a judgment in the *Royal Baking Powder Co.* case but lost in the *American Snuff Co.* case because the FTC could not convince the court that the public was deceived. For the definition of a standard nontransparent container, see text accompanying footnote 60 (21 FOOD DRUG COSMETIC LAW JOURNAL 218).

[174] The ordinary representation is probably either that the container is reasonably full considering settling after packing and other limitations on fill which would be known to purchasers and prospective purchasers, or, perhaps in the case of a mix for food, that the container contains sufficient fill to make a specified volume of food.

[175] See cases cited in footnote 173 above.

[176] *Cf. United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding*, 71 F. Supp. 279 (D. Ariz. 1946) discussed in text accompanying footnotes 35-36 (21 FOOD DRUG COSMETIC LAW JOURNAL 211). However, analogous cases involving false and misleading advertising and labeling suggest that it will not be easy to convince the FTC or the courts that a secondary meaning exists which negates the charge of deception. See *C. Howard Hunt Pen Co. v. FTC*, 197 F. 2d 273 (3d Cir. 1952); *Jacob Siegel Co. v. FTC*, 150 F. 2d 751 (3d Cir. 1945), rev'd on other grounds, 327 U. S. 608 (1946); *FTC v. Hires Turner Glass Co.*, 81 F. 2d 362 (3d Cir. 1935).

[177] See, e.g., *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964); *United Drug Co.*, 35 F. T. C. 643, 647 (1942). But see *National Silver Co. v. FTC*, 88 F. 2d 425 (2d Cir. 1937).

has on at least two occasions commented on respondents' failure to use a container with an opening which would permit prospective purchasers to determine the extent of the slack-fill, suggesting that such disclosure might have cured the deception.[178] A reasonable inspection does not, of course, require prospective purchasers to open outer cartons to inspect the size of tubes or other containers inside.[179]

Fourth, in deciding what representations were made by the container and whether those representations were deceptive, the FTC may simply inspect the containers and base its finding upon its "independent, first-hand examination of these boxes."[180] Other evidence which has been considered by the FTC includes the size and capacity of the exterior of the container compared with the volume of the food therein,[181] the presence of any cardboard fillers and other nonfood materials hidden inside the container,[182] and aesthetical factors, at least in regard to containers where aesthetics are of traditional importance.[183] The relative paucity of evidence considered by the FTC compared with the greater evidence which has been considered in FDA packaging cases[184] probably reflects the FTC's tendency to rely upon its "expertise" in determining what representations were made by the

[178] See *Papercraft Corp.*, cited at footnote 177; *United Drug Co.*, cited at footnote 177, at 647.

[179] *Cf. Marlborough Labs., Inc.*, 32 F. T. C. 1014, 1027 (1941).

[180] *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721, at 21652 (FTC 1964). The FTC is not required to sample public opinion to determine what representations were made by an advertisement and whether they were misleading. *Carter Prods., Inc. v. FTC*, 268 F. 2d 461, 495 (9th Cir.), cert. denied, 361 U. S. 884 (1959); *E. F. Drew & Co. v. FTC*, 235 F. 2d 735 (2d Cir. 1956), cert. denied, 352 U. S. 969 (1957); *Zenith Radio Corp. v. FTC*, 143 F. 2d 29 (7th Cir. 1944). The FTC may rely upon its own expertise even in the face of a preponderance of adverse testimony. See Millstein, cited at footnote 166, at 471-75.

[181] See *Harry Greenberg*, 39 F. T. C. 188 (1944); *United Drug Co.*, 35 F. T. C. 643 (1942); *Burry Biscuit Corp.*, 33 F. T. C. 89 (1941); *Trade Labs., Inc.*, 25 F. T. C. 937 (1937).

[182] *United Drug Co.*, 35 F. T. C. 643 (1942). *Cf. Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721, at 21653 n. 6 (FTC 1964).

[183] In *United Drug Co.*, cited at footnote 182, at 647, the FTC made due allowance for the custom and practice of the trade to package cosmetics in attractive containers which were larger than functionally required for the product but held that this particular container was deceptive. The complaint charged the container was only 50 to 70% full, and the FTC found an inner container, a powder pouch, and cardboard all inside the package, reducing the volume therein allowed for the face powder itself. Thus while the FTC accepted respondent's legal theory, the FTC held on the facts that the container was deceptive. The decision may be helpful in defending containers of foods designed for the more affluent members of society (for example, decorative containers of candy) or special holiday packs of food (for example, Christmas fruit cakes).

[184] See text accompanying footnotes 63-69 (21 FOOD DRUG COSMETIC LAW JOURNAL 219-220) for a description of the evidence considered in FDA packaging cases.

container and whether these representations are deceptive.[185] It may also be an indication that the respondents in FTC proceedings have not fought as hard as the claimants in FDA packaging cases.[186] Analogies from FTC false and misleading advertising cases suggest that consumer testimony, expert testimony, and consumer surveys are relevant.[187] Analogies from the FDA's packaging cases support this conclusion and suggest that respondent's intent in adopting the container, as well as complaints or absence of complaints about the container, may also be relevant.[188] However, it is likely that the FTC will rely primarily upon its own judgment in determining the representations made by the container and whether those representations were misleading. The courts can be expected to affirm the FTC's conclusions.

Fifth, even if the representations made by the container are deceptive in regard to volume, the FTC may dismiss the action if the requirements of effective, legitimate packaging are in irreconcilable conflict with the needs of consumer protection. This question was

[185] See Brennan, "Affirmative Disclosure in Advertising and Control of Packaging Design Under The Federal Trade Commission Act," 20 *Bus. Law*, 133, 141 (1964). Cf. Millstein, cited at footnote 166, at 470-75, for a discussion of the FTC's tendency to rely upon its expertise in false and misleading advertising cases.

[186] See text accompanying footnotes 35-43 (21 FOOD DRUG COSMETIC LAW JOURNAL 211-212) for a review of the FDA deceptive packaging cases. The FTC does not seem to have faced either the technological justification defenses that were present in the *Arden's Candy Drops* and *Delson's Mints* cases or the complications in regard to the representations made by the package which were present in the *Jiffy-Lou Vanilla Pudding* case.

[187] See Millstein, cited at footnote 166, at 475-81 (1964). Consumer testimony, expert testimony and consumer surveys are regularly admitted in FTC advertising cases. See, for example, *Gulf Oil Corp. v. FTC*, 150 F. 2d 106 (5th Cir. 1945) (consumer testimony); *Korber Hats, Inc. v. FTC*, 311 F. 2d 358 (1st Cir. 1962) (expert testimony); *Rhodes Pharmacal Co. v. FTC*, 208 F. 2d 382 (7th Cir. 1953), rev'd on other grounds, 348 U. S. 940 (1955) (consumer survey). The expert testimony could be given by pyschologists and sociologists or by trade experts. Cf. Millstein, cited at 477. If the FTC relies upon any of this evidence, it is unlikely to be reversed. Id. at 475. However, the evidence will probably not carry the same weight with reviewing courts if it is relied upon by respondents. In such situations, the court may determine that FTC's expertise outweights respondent's evidence.

Respondent may also find that his expert testimony or consumer survey has undercut his own defense. Even if the expert testifies or the consumer survey indicates that most purchasers are not deceived, the evidence will probably backfire if it also supports the conclusion that any substantial portion of the buying public may be misled. Cf. id. at 478. Unanimous consumer testimony that the package is not deceptive, while relevant, may be disregarded on the theory that the existence of satisfied customers is not a defense to a § 5 proceeding. See *Erickson v. FTC*, 272 F. 2d 318 (7th Cir. 1959), cert. denied, 362 U. S. 940 (1960).

[188] See text accompanying footnotes 63-69 (21 FOOD DRUG COSMETIC LAW JOURNAL 219-220).

expressly reserved by the FTC in the *Papercraft* decision.[189] The FTC may be somewhat more demanding than the courts have been in concluding that such an irreconcilable conflict exists. If the respondent succeeds in establishing a technological justification for the container itself, the FTC is likely to seek alternative means of preventing deception. In *Papercraft,* the FTC indicated that if technical factors required the use of a container which could create a misleading impression, the seller would have to take "all reasonable precautions" to prevent deception.[190] This sounds as if affirmative disclosure of slack-fill may be required when the container would otherwise be deceptive and one commentator has already suggested this, indicating that the disclosure could either take the form of a statement such as "80% full" or a "filled up to here" line on the package.[191] There is certainly ample analogous authority available to encourage the FTC to take such an approach.[192] Thus the technological justification defense may be successful in FTC proceedings insofar as respondent's goal is to continue to use the same container in the future, but may not be successful insofar as respondent's goal is to avoid a cease and desist order entirely.

If the FTC decides that a cease and desist order must be entered and respondent acquiesces in that decision, the controversy may still be far from finished. The FTC and respondent will still have to agree on the scope of the cease and desist order. The two issues on which

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[189] *Papercraft Corp.,* Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721.

[190] Ibid.

[191] See Brennan, cited at footnote 185, at 142-44.

[192] There are several broad lines of authority which support the conclusion that when purchasers would otherwise be deceived, the FTC can compel affirmative disclosure of the facts to prevent such deception. For example, purchasers would ordinarily assume that paperback books contained the full text of the original edition, see *Bantam Books, Inc. v. FTC,* 275 F. 2d 680 (2d Cir.), cert. denied, 364 U. S. 819 (1960); see also *New Am. Library of World Literature, Inc. v. FTC,* 227 F. 2d 384 (2d Cir. 1955) and 213 F. 2d 143 (2d Cir. 1954); that motor oil was made from new oil, see *Kerran v. FTC,* 265 F. 2d 246 (10th Cir.), cert. denied sub nom. *Double Eagle Ref. Co. v. FTC,* 361 U. S. 818 (1959); *Mohawk Ref. Corp. v. FTC,* 263 F. 2d 818 (3d Cir. 1958), cert. denied, 361 U. S. 814 (1959); *Royal Oil Corp. v. FTC,* 262 F. 2d 741 (4th Cir. 1959), and that preparations or devices advertised as remedies for baldness or bed-wetting would aid in most cases involving these problems, see *Feil v. FTC,* 285 F. 2d 879 (9th Cir. 1960); *Ward Labs., Inc. v. FTC,* 276 F. 2d 952 (2d Cir.), cert. denied, 364 U. S. 827 (1960); *Keele Hair & Scalp Specialists, Inc. v. FTC,* 275 F. 2d 18 (5th Cir. 1960), and the FTC has therefore compelled affirmative disclosure of the facts when the contrary is true. See also Millstein, cited at footnote 166, at 489 n. 247. From the above cases and like authorities, the FTC could reason that purchasers would ordinarily assume that nonstandard nontransparent containers of finished foods would be reasonably full, and that when the contrary is true a disclosure of the extent of the slack-fill is necessary to avoid deception.

the FTC and respondent may have conflicting positions are (a) whether the order should be limited to the product involved in the original proceeding and (b) whether the order should be limited to the deceptive practice involved in the original proceeding. Because a cease and desist order is perpetual,[193] because the law of deceptive packaging consists of vague and expanding restrictions,[194] and because the penalties for violating a cease and desist order are so severe,[195] respondent may stand fast on these issues. The FTC's converse and perhaps equally steadfast position will probably be that respondent has already violated the law once and the FTC cannot be expected to litigate in multiple proceedings at public expense the legality of every conceivable deceptive packaging practice on every conceivable product when one proceeding could accomplish the same objective.[196] Additionally, the FTC will probably point out that the broad cease and desist order imposes no hardship on respondent so long as it complies with the law in the future.

The cease and desist orders entered by the FTC in deceptive packaging cases to date can be divided into two broad classes.

The first of these classes deals with product limitations. Prior to 1932, the FTC's cease and desist orders relating to deceptive packag-

[193] The FTC may at any time modify or set aside a cease and desist order issued by it if the FTC believes that the facts or the law has so changed as to require such action or if the public interest requires such action. See Federal Trade Commission Act § 5, 38 Stat. 719 (1914), as amended, 15 U. S. C. § 45(b) (1964). On occasion the FTC has even joined with respondent in asking the circuit court to vacate its final decree enforcing an FTC order. See *Rosenblum v. FTC*, 214 F. 2d 338 (2d Cir. 1954). However, these extraordinary proceedings should not be permitted to obscure the fact that for most respondents a cease and desist order operates as a perpetual restraint on the respondent's business.

[194] Compliance with an FTC order to cease and desist using over-sized containers and other methods of packaging whereby the quantity of the contents may be made to appear bigger than it is may be difficult. There are no definitions or rules describing what is an oversized container. The general prohibition against packaging whereby the quantity of contents may be made to appear bigger than it is seems vague enough to embrace new restrictions on packaging which may be promulgated in the future. Because the FTC's enforcement of § 5 has been sporadic at best, respondent is likely to be laboring under a handicap which is not shared by its competitors.

[195] See Federal Trade Commission Act § 5(*l*), 52 Stat. 114 (1938), as amended, 15 U. S. C. § 45(*l*) (1964) (penalty of not more than $5000 for each violation or each day in which a violation is continued).

[196] *Cf. FTC v. Ruberoid Co.*, 343 U. S. 470, 473 (1952) (price discrimination case):

> [T]he Commission is not limited to prohibiting the illegal practice in the precise form in which it is found to have existed in the past. If the Commission is to attain the objectives Congress envisioned, it cannot be required to confine its road block to the narrow lane the transgressor has traveled; it must be allowed effectively to close all roads to the prohibited goal, so that its order may not be by-passed with impunity.

ing were limited strictly to the particular product involved, *e.g.*, "gasoline,"[197] "paint,"[198] or "butter."[199]

From 1932 until 1953, the FTC's cease and desist orders relating to deceptive packaging were extended to include the generic type of product involved, *e.g.*, "face powder and other cosmetic products";[200] "bakery products, inclusive of crackers";[201] "cosmetics, tooth pastes, and shaving creams, or other toilet articles";[202] or "shaving cream, dental cream, shoe polish, sun tan cream, similar commercial preparations and toilet articles."[203]

The FTC's latest order and a 1957 consent order relating to deceptive packaging were limited strictly to the particular product involved: "gift-wrapping paper,"[204] and "materials or preparations for use in making artificial snow."[205] Whether the FTC has reverted to its pre-1932 policy or whether there were special circumstances involved in these cases (perhaps, for example, the respondents only produced the one product mentioned in the order) is difficult to determine from this limited authority.

The FTC's consistent reluctance to order respondents to cease and desist from using deceptive practices in connection with all of their products[206] is particularly important to corporations which have diverse product lines.[207]

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[197] *Export Petroleum Co.*, 17 F. T. C. 119 (1932).

[198] *Baltimore Paint & Color Works, Inc.*, 9 F. T. C. 242 (1925), aff'd, 41 F. 2d 474 (4th Cir. 1930).

[199] *Ozark Creamery Co.*, 8 F. T. C. 377 (1925); *Mountain Grove Creamery, Ice & Elec. Co.*, 6 F. T. C. 426 (1923); *Wichita Creamery Co.*, 6 F. T. C. 435 (1923); *Meriden Creamery Co.*, 6 F. T. C. 444 (1923).

[200] *United Drug Co.*, 35 F. T. C. 643 (1942).

[201] *Burry Biscuit Corp.*, 33 F. T. C. 89 (1941).

[202] *Marlborough Labs., Inc.*, 32 F. T. C. 1014 (1941).

[203] *Trade Labs., Inc.*, 25 F. T. C. 937 (1937).

[204] *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964). The portion of the order relating to deceptive packaging is reprinted in Brennan, cited at footnote 185, at 140.

[205] *U. S. Packaging Corp.*, 53 F. T. C. 1174 (1957).

[206] In *Harry Greenberg*, 39 F. T. C. 188 (1944), the FTC issued an order governing "candy products or any other merchandise." This probably resulted from the fact that toys were being included with the candy, rather than from any conscious intent by the FTC to broaden the order beyond candy products.

The FTC's practice of not extending its cease and desist orders to all of the respondent's products may be merely a matter of policy. The FTC has wide discretion in its choice of remedy, see *Jacob Siegel Co. v. FTC*, 327 U. S. 608 (1946), and in deceptive advertising cases which also fall under § 5 of the FTC Act, the courts frequently affirm cease and desist orders covering all the respondents' products. See, for example, *FTC v. Colgate-Palmolive Co.*, 380 U. S. 374, 394 (1965); *Carter Prod., Inc. v. FTC*, 323 F. 2d 523, 532-33 (5th Cir. 1963); *Niresk Indus., Inc. v. FTC*, 278 F. 2d 337, 342-43 (7th Cir.), cert. denied, 364 U. S. 883 (1960).

[207] *For footnote [207] see next page.*

The second category of deceptive packaging cases concerns the FTC's cease and desist orders relating to deceptive practice limitations. The orders have generally been limited to the particular deceptive practices involved, forbidding either the use of containers which are substantially larger in size or capacity than is required for packaging the quantity of product therein[208] or the use of specified standard containers for less than the standard quantities of product.[209]

In two instances, the FTC's cease and desist orders relating to deceptive packaging were broadened in scope to include not only the use of over-sized or standard containers but also any other method of packaging whereby the quantity of the contents is made to appear greater than it actually is.[210] In both of these instances the FTC was dealing with phony medical endorsements, fictitious prices, and a number of unrelated sins of the respondent in addition to the deceptive packaging issue. This may indicate simply that if the FTC is convinced that the respondent is given to fraud, it will draft its orders broadly enough to curb such fraudulent tendencies.

C. Summary

The FTC's power to prohibit unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce would appear to be the broadest possible power over deceptive packaging.[211]

[207] The position of such corporations could be intolerable if they were subject to cease and desist orders governing all their products while the FTC's enforcement of § 5 against competitors was limited to competitors in a single product line. There is probably no legal remedy in such a situation. *Cf. Moog Indus., Inc. v. FTC*, 355 U. S. 411 (1958); *Regina Corp. v. FTC*, 322 F. 2d 765, 769 (3d Cir. 1963).

[208] See *U. S. Packaging Corp.*, 53 F. T. C. 1174 (1957); *Harry Greenberg*, 39 F. T. C. 188 (1944); *United Drug Co.*, 35 F. T. C. 643 (1942); *Burry Biscuit Corp.*, 33 F. T. C. 89 (1941). See also *Papercraft Corp.*, Trade Reg. Rep. (Transfer Binder, 1963-1965) ¶ 16721 (FTC 1964).

[209] *Export Petroleum Co.*, 17 F. T. C. 119 (1932); *Baltimore Paint & Color Works, Inc.*, 9 F. T. C. 242 (1925), aff'd, 41 F. 2d 474 (4th Cir. 1930); *Ozark Creamery Co.*, 8 F. T. C. 377 (1925); *Mountain Grove Creamery, Ice & Elec. Co.*, 6 F. T. C. 426 (1923); *Wichita Creamery Co.*, 6 F. T. C. 435 (1923); *Meriden Creamery Co.*, 6 F. T. C. 444 (1923).

[210] *Marlborough Labs., Inc.*, 32 F. T. C. 1014 (1941); *Trade Labs., Inc.*, 25 F. T. C. 937 (1937).

[211] Once jurisdictional questions are resolved, deceptive packaging almost by definition violates § 5 of the FTC Act. The only way to increase the FTC's powers over packaging is to give the FTC authority to regulate nondeceptive packaging. This could be done, for example, by giving the FTC the authority by regulation to establish reasonable weights or quantities in which consumer commodities could be distributed for retail sale when such regulations appear necessary to enable consumers to make rational comparisons with respect to price. Cf. S. 985, 89th Cong., 1st Sess. (1965). This would increase the FTC's powers in an area which is not usually

(Continued on next page.)

Even proof of deceptiveness is made easy since the Commission can rely upon its own expertise in the absence of proof that would be required by the courts in non-FTC proceedings. When the FTC determines that commodities are being packaged deceptively, it can attack the problem either through its rulemaking power or by bringing individual actions against offenders. If the FTC decides to use its rulemaking power, it can promulgate either voluntary trade practice rules or compulsory trade regulation rules. The present trade practice rules governing deceptively packaged foods are so vague that they are ineffective, and there are no trade regulation rules dealing with packaging at all. It is probable that either trade practice rules or trade regulation rules setting a minimum percentage of fill by product line would be an effective means of dealing with slack-filled containers of foods.[212]

If the FTC decides to handle packaging violations individually, it has adequate authority to do so effectively. Since 1914, the FTC has tried 13 deceptive packaging cases involving over-sized containers and standard containers with less than the standard quantity, and has been successful in all of them.[213] The FTC has issued one consent order involving packaging which was deceptive through its color and appearance[214] and one consent order involving an over-sized con-

(Footnote 211 continued.)
considered within the definition of deceptive packaging. But see text accompanying footnotes 146-47 above for an example of a situation in which the FTC accomplished a like result because the weights in which butter was sold were deceptive.

[212] In Note, "Federal Regulation of Deceptive Packaging: The Relevance of Technological Justifications," 72 *Yale L. J.* 788 (1963), the practical problems involved in setting a minimum percentage of fill for various products were reviewed. The author concluded that percentages of fill could be fixed for some items with relatively little difficulty and that percentages of fill could not be fixed for other products without greater problems. Id. at 800. The distinction suggested was between those items in which the slack-fill remains constant (for example, a candy bar on a cardboard tray) in contrast to those items in which the slack-fill varies because of settling from vibration or breakage (for example, boxes of cereal). Probably the solution is to allow a greater tolerance for slack-fill in products in which fill may vary from breakage or settling than is permitted in products in which the fill remains constant. In all product lines there must be some minimum percentage of fill which can be packed consistently and the FDA or the FTC, acting in cooperation with the reputable manufacturers in industries in which deceptive packaging is allegedly most flagrant, ought to be able to discover that percentage and enforce it by regulation if necessary. The problem is not unlike that which the FTC faced and resolved successfully in setting the tolerance in the Feather and Down Products Industry Rules. See footnote 123 above.

[213] See cases discussed in footnote 162 above.

[214] See *Superior Insulating Tape Co., No.* C-206, FTC, August 15, 1962. Chairman Dixon summarized this order as follows:

(Continued on next page.)

tainer.[215] In several instances, the FTC has also ordered respondents to cease and desist from using containers which make deceptive representations concerning the quality of their contents.[216]

The FTC's limited enforcement of section 5 against deceptively packaged foods, drugs, devices and cosmetics appears to be due to its working agreement with the FDA rather than to any deficiencies in its powers.

III

Conclusion

The law of deceptive packaging is part of that broader segment of our law which prohibits commercial misrepresentations which are materially misleading.[217] Once the law of deceptive packaging is

(Footnote 214 continued.)

The Commission also prohibited the use of a method of packaging insulating tape which gave a visually deceptive image of the amount of tape on the spool. The tape was rolled around a spool, part of which was of the same color and appearance as the tape, while the balance of the center of the spool was of a contrasting color

. . . .

1965 Hearings 80.

[215] *U. S. Packaging Corp.*, 53 F. T. C. 1174 (1957).

[216] *Royal Baking Powder Co. v. FTC*, 281 Fed. 744 (2d Cir. 1922). See also *FTC v. American Snuff Co.*, 38 F. 2d 547 (3d Cir. 1930).

[217] Neither § 403(d) of the Food, Drug and Cosmetic Act nor § 5 of the Federal Trade Commission Act states that the misrepresentation must be *materially* misleading. However, this is probably implied.

The deceptive advertising cases decided under § 5 of the FTC Act require that the advertisement be materially misleading. See, for example, *FTC v. Colgate-Palmolive Co.*, 380 U. S. 374, 386-87 (1965) in which the Supreme Court held that § 5 prohibits misrepresentation of any fact which materially induces a purchaser's decision to buy. The injunction remedies and criminal penalties for false advertisements of foods, drugs, devices and cosmetics under the Wheeler-Lea Act also require that the advertisement be misleading in a material respect. See Federal Trade Commission Act § 15(a), 52 Stat. 116 (1938), as amended, 15 U. S. C. § 55(a) (1964). It seems certain that the courts will reach the same conclusion in regard to deceptive packaging. The FTC cases have already held that the purchasers relied upon the apparent capacity of the deceptive containers in making their purchases, thus touching upon this issue indirectly. See for example, *Harry Greenberg*, 39 F. T. C. 188 (1944); *Burry Biscuit Corp.*, 33 F. T. C. 89 (1941).

The FDA cases under § 403(d) have all involved deception in regard to the quantity of fill in the container. Thus the materiality of the alleged representation was apparent. But see *United States v. 738 Cases of Jiffy-Lou Vanilla Flavor Pudding*, 71 F. Supp. 279, 280 (D. Ariz. 1946), holding that there was no relationship between the size of the container used and the reasons causing the public to purchase the commodity, and *United States v. 174 Cases of Delson Thin Mints*, 195 F. Supp. 326, 327 (D. N. J. 1961), aff'd per curiam, 302 F. 2d 724 (3d Cir. 1962), reviewing evidence which tended to show that purchasers were motivated in their choice of packages by size rather than price. This search to find a relationship between the deception and the purchase can be viewed as an effort to prove the materiality of the misrepresentation. While no FDA case

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viewed from this perspective, it becomes apparent that the proper approach to a deceptive packaging problem is to first identify the representations made by the container and second, determine whether any representation is misleading. If any representation made by the container is materially misleading to a substantial number of purchasers, regulatory action may be indicated. This action may take the form of individual lawsuits or of regulations applicable to the entire industry. Either approach lies within the powers already granted to the FDA and the FTC.

Much of the furor in connection with deceptive packaging involves containers of foods which are allegedly misleading with respect to the volume of their contents. The cases suggest that a nonstandard container for a finished food represents that it is reasonably full; that a nonstandard container for a mix for food represents either that it is reasonably full or that it contains sufficient mix to make a specified volume of food; and that a standard container represents that it contains the standard quantity of the food. All of these representations can be regulated effectively under existing law through percentages of fill of container set by the FDA's standards of fill or the FTC's trade practice or trade regulation rules,[218] or by individual FDA

(Footnote 217 continued.)
has held this directly, it must be remembered that the law of deceptive packaging is in its infancy and that technological justification (which also is not mentioned in the statute) was not recognized as a defense until 1961. See *United States v. 174 Cases of Delson Thin Mints*, 287 F. 2d 246 (3d Cir. 1961).

Additional support for the materiality concept can be gleaned from § 201 of the Food, Drug, and Cosmetic Act, 52 Stat. 1041 (1938), 21 U. S. C. § 321(n) (1964). While express misrepresentations on the label are probihited if they are misleading in any particular, see Federal Food, Drug, and Cosmetic Act § 403(a), 52 Stat. 1047 (1938), 21 U. S. C. § 343(a) (1964); Federal Food, Drug, and Cosmetic Act § 502(a), 52 Stat. 1050 (1938), 21 U. S. C. § 352(a) (1964); Federal Food, Drug, and Cosmetic Act § 602(a), 52 Stat. 1054 (1938), 21 U. S. C. § 362(a) (1964), it is the failure to reveal *material* facts which is prohibited. See 52 Stat. 1041 (1938), 21 U. S. C. § 321(n) (1964). Analogously, deception in packaging usually occurs because of a failure to fully disclose the quantity or quality of the contents under circumstances which would mislead the ordinary purchaser. See cases discussed in text accompanying footnotes 35-43 (21 FOOD DRUG COSMETIC LAW JOURNAL 212) and in footnote 60 (21 FOOD DRUG COSMETIC LAW JOURNAL 218). The Food, Drug, and Cosmetic Act is a criminal statute, and it seems unlikely that Congress intended to impose criminal penalties when the failure to disclose facts was de minimis or did not affect the purchaser's decision to buy.

[218] The proposed bill would also subject to the rulemaking power of the FDA and the FTC a number of specific items other than standard of fill, such as pictures or words qualifying the statement of net quantity. See S. 985, 89th Cong., 1st Sess. §§ 3(a)(1)-(6), (c)(1)-(6). However, the agencies' present power to prescribe regulations governing standards of fill is of much greater importance to the elimination of deception in packaging than those which would be added by S. 985.

seizures or FTC cease and desist proceedings, or by the FTC or possibly the FDA compelling affirmative disclosure in the unlikely event that it is necessary.[219]

The FDA and the FTC may, with their greater expertise, discover additional representations which are made by some containers, but it seems certain that the misrepresentations which can be made by a container are limited when constrasted with the infinite and subtle varieties of misrepresentations which can be made through the artful use of false and misleading advertising. Yet misrepresentations made through advertising can be effectively regulated by present provisions of the FTC Act[220] and misrepresentations made by containers of foods are already regulated by *both* the FTC Act and the Federal Food, Drug and Cosmetic Act.[221] In spite of this, the pressure to enact new legislation dealing with the regulation of deceptive

[219] Affirmative disclosure is necessary only when there is a conflict between the representation made by the package and the technological justification defense; i.e., when it is impossible to pack a fill equal to purchasers' expectations. In all other situations, the proper remedy is to issue regulations fixing as a minimum that percentage of fill which is expected by purchasers. In general the contention that purchasers expect a greater fill than can be packed in the container should be approached with skepticism. While such situations may exist, the more obvious examples (For example, boxes of cereal and bags of potato chips) probably involve products in which the purchasers expect some slack-fill and are not misled so long as the package is filled as much as is reasonably possible.

Those who regard affirmative disclosure as a panacea for all packaging problems probably have not considered the matter fully. For example, suggestions that packages state "80% full" or bear a "filled-to-here line," see Brennan, cited at footnote 185, at 144, will probably have to be modified to allow a tolerance for over-fill and under-fill and for settling and breakage of some products during shipment, or these suggestions may lead manufacturers into false and misleading labeling. Thus "80% full" may have to become "average fill: 80%" or "minimum fill: 80%" or "75 to 85% full." Similar adjustments may have to be made in the "filled-to-here line." The value of the disclosure to prospective purchasers will be correspondingly reduced as it becomes less exact. If economic benefits to the consumer are the test, it would seem more fruitful for the FDA and the FTC to establish percentages of fill which eliminate unnecessary slack-fill than to require affirmative disclosure of slack-fill which cannot be eliminated.

[220] The FTC is by far the most important agency exercising control over advertising. Note, The Regulation of Advertising, 56 *Colum. L. Rev.* 1018, 1021 (1956). Other federal agencies—principally the Post Office Department, Federal Communications Commission, Alcohol and Tobacco Tax Division of the Internal Revenue Service and the Securities and Exchange Commission—and the states control some aspects of advertising. Id. at 1020-53, 1057-78.

[221] The FTC and the FDA are by far the most important agencies exercising control over packaging. Other federal agencies—principally the Department of Agriculture, Bureau of Standards, Internal Revenue Service and Bureau of Customs—and the states control some aspects of packaging. See Appendix to 1963 Hearings at 847-60.

packaging practices continues. This paradox is difficult to understand. If the answer is simply that the FDA has not been given adequate appropriations and that the FTC has shown undue deference to the FDA,[222] then perhaps the solution is merely to increase the FDA's appropriations with the understanding that the increase is intended for packaging regulation. The FDA could then undertake the full utilization of its powers. In the absence of appropriations permitting such action, the problem may still be resolved under existing law. The FTC has again begun to move against deceptive packaging and it is inconceivable that the agency which now regulates the more complex problems of false and misleading advertising will fail when it turns the same powers against the more limited deception which is created by the occasional use of over-sized and otherwise misleading packages. **[The End]**

THE NAS—NRC AGREES TO STUDY THE EFFICACY OF DRUGS

At the request of the Food and Drug Administration, the National Academy of Sciences—National Research Council has agreed to undertake, beginning this summer, a review of the medical effectiveness of drugs marketed from 1938 to 1962. This review of drugs, called for under the Kefauver-Harris Amendments of 1962, will guide the FDA in its final determination of the effectiveness of the drugs involved. The NAS-NRC was asked to assist in this study because of its capability of employing the help of the top medical and scientific talent of the nation.

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[222] All indications are that the failure to enforce existing laws has caused the current furor over packaging. At the 1963 Hearings, both Commissioner Larrick and Chairman Dixon testified clearly that the existing laws had not been vigorously enforced. Their testimony was:

> Mr. Raitt. As I get the impression from reading the testimony given last year, would you say that the law relating to misbranding has been vigorously enforced? Have you had personnel and time vigorously to enforce the existing law? I realize it is a judgment, but there seems to me to be a flavor in last year's testimony that you felt maybe you hadn't had the time, or the money, or the personnel really to attend to this particular area of law, and you have had responsibilities in other areas, such as health and safety matters, which required your personal attention.
>
> Is that a fair estimate of your testimony last year?
>
> Mr. Larrick. It certainly is. . . .

1963 Hearings 366-67.

> Mr. Dixon. I think that both Food and Drug and the Federal Trade Commission had responsibility in this area and I don't think the record is very good by either agency on what we have done in this area.

1963 Hearings 286.

The Law Governing FDA Factory Inspection

By ANDREW J. GRAHAM

The Following Article Was Presented Before a Joint Session of the Proprietary Associaton and the Food and Drug Administration, the First Manufacturing Controls Seminar, in Tarrytown, New York, on October 27-28, 1965. Mr. Graham Is a Partner of Graham & McGuire, New York, N. Y.

THE SUBJECT OF FACTORY INSPECTION raises political, technical, scientific, policy making and legal questions. I am going to talk about the *legal* questions which may arise when the inspector knocks at the door of the *proprietary drug* manufacturer.

The limited right of factory inspection—and it is a *limited* right—is granted to the Food and Drug Administration (FDA) specifically for "purposes of enforcement" of the law. It is, therefore, part of the law enforcement procedure and generally it is the first step taken in preparation of a civil case or criminal prosecution.

FDA's Right of Inspection

Before discussing the rights and obligations of the administration and those of the party whose establishment is to be inspected, I want to define the term "factory inspection" and to review briefly the development of the law in this area.

Section 704 of the Federal Food, Drug and Cosmetic Act of 1938 (Copeland Act) (21 U. S. C. 374), created the basic right of FDA inspectors to enter and inspect, at reasonable times, and within reasonable limits and in a reasonable manner, any factory, warehouse, establishment or vehicle in which food, drugs, devices or cosmetics are manufactured, processed, packed or held before or after shipment in interstate commerce.

In the case of nonprescription drugs, foods and cosmetics, the FDA's basic right of inspection encompasses *only:*

1. All pertinent equipment;
2. Finished and unfinished materials;
3. Containers; and finally,
4. Labeling.

But where prescription drugs are involved, section 704, as amended in 1962, confers a much broader right of inspection. With respect to these drugs, it extends to "all things" bearing on adulteration, misbranding or other violations of the act. Specifically, in the case of prescription drugs, it includes the right to examine: records, files, papers, processes, controls, facilities.

But this does not include (a) financial data; (b) sales data, other than shipment data; (c) pricing data; (d) certain personnel data, and (e) certain research data except as it relates to new and antibiotic drugs.

Although the FDA's basic right of factory inspection is now much broader in the case of prescription drugs, the scope of inspection has not changed since 1938 so far as nonprescription drugs are concerned.

I have intentionally referred to the right of factory inspection under section 704 of the Act as the FDA's "basic" right of inspection. As a practical matter, FDA has other rights of inspection relating to nonprescription drugs which may be exercised in the course of inspection under section 704.

Thus, in defining factory inspection in a broader sense, it is desirable to include reference to other matters which may arise. Accordingly, we ought to consider section 703 of the act which deals with records of interstate shipment. Sections 703 and 704 are not interdependent, but there is nothing to prevent an inspector from proceeding under both on the same occasion.

Section 703 provides that, for purposes of enforcement of the act, carriers and persons receiving or holding food, drugs, devices and cosmetics (where interstate commerce is involved) shall, upon the request of authorized FDA personnel, permit, at reasonable times, access to and copying of all records showing the movement in interstate commerce of such products and records concerning the holding of them during or after such movement, and pertaining to the quantity, shipper and consignee thereof. Accordingly, where manufacturer, distributor or packer of over-the-counter drugs has *received* drugs which have been shipped to him in interstate commerce the statute specifies that he must accord access to and the right to copy shipping and holding records. Possibly, though this is not spelled

out, records showing *reshipment* of drugs which have been moved in interstate commerce are included, but clearly a shipper's records showing initial interstate shipments are not covered, as this section speaks only of carriers engaged in interstate commerce and of persons who have *received* or who *hold* goods after shipment in interstate commerce.

Continuing with our broader definition of factory inspection, we must not overlook the fact that, if a nonprescription drug also happens to fall within the new drug category, it is subject to an extensive record-keeping and reporting procedure. The FDA has the right, at all reasonable times, to have access to and the right to copy and verify, all of the records which must be maintained respecting new drugs (Sec. 505(j)(2)). An inspector making a routine inspection under section 704 might, and probably would, also review any new drug records which were in the premises being inspected. The records of a new drug which is subject to an investigational exemption are also subject to inspection.

At this point, I think it desirable to limit our discussion of factory inspection to the items I have mentioned. If we do not do so, the next logical step would be to inquire as to what would be involved if we were to consider what rights of inspection FDA would have if both prescription and nonprescription drugs were produced or held in the plant to be inspected. I believe this goes beyond the scope of this Seminar, so I shall put this and similar peripheral matters, such as new drug records, aside and talk only about section 704—the section which deals with the basic right of inspection.

Section 704 of the Act

Historically, section 704 is relatively new. Indeed, compulsory factory inspection has been in existence only for 12 years. Under the Wiley Act—the Food and Drug Act of 1906—there was no provision whatsoever for factory inspection. The administration secured cooperation in the food and drug industries, and inspection of many plants proceeded on a purely voluntary basis. Of course, some manufacturers—apparently a minority—refused to permit inspection of their plants. This led to the inclusion of section 704 among the comprehensive provisions of the Federal Food, Drug and Cosmetic Act of 1938.

In this original enactment, factory inspection was authorized only after the inspector had made a request and obtained permission of the owner, operator or custodian.

According to its terms, section 704 provided only for voluntary inspection. The fact the permission was required certainly suggested that inspection was to be upon a voluntary basis, but lawmakers do strange things. Section 301(f) of the 1938 enactment made it a crime to refuse to permit the entry and inspection authorized by section 704. Of course, under section 704, no entry or inspection *was authorized until* permission had been granted. The crime did not consist of refusing permission to enter and inspect, but, rather, in refusing to permit entry and inspection after permission had been given and the inspector had thus been authorized to enter and inspect. In 1952, the Supreme Court in *U. S. v. Cardiff*, 334 U. S. 174, held that section 301(f) was void as being too vague to create a crime. One of the judges of the Court of Appeals had remarked in the *Cardiff* case that section 301(f), when read with section 704, was "just plain nonsense." It was only the penalty section—section 301(f)—which was affected by the decision. Section 704 itself was not affected but, under it, factory inspection could be made only with permission, and that might be withheld.

It took 14 years to discover that there were no teeth in the factory inspection law of 1938. In 1953, section 704 was amended to eliminate the requirement of consent.

As enacted in 1938, and as amended in 1953, section 704 authorized only the inspection of "all pertinent equipment, finished and unfinished materials, containers and labeling." No distinction was made as to scope of inspection among foods, drugs, devices and cosmetics.

The Kefauver-Harris Amendments of 1962 made a significant change by amending section 704 to provide far broader powers of inspection over prescription drugs and, for the first time, to provide in the case of such drugs, for inspection of records other than shipping records, as provided for in section 703. The scope of basic factory inspection as it relates to nonprescription drugs, foods and cosmetics has not changed since 1938.

Now, in a context of reality, what are the rights of the parties and how are they to be enforced?

Rights of the Inspector

An inspector arrives at a plant where nonprescription drugs are made. In order to have the right to enter and inspect, he must first present appropriate credentials showing that he has been duly designated by the Secretary of Health, Education and Welfare (HEW). Second, he must present a written Notice of Inspection. His creden-

tials and the Notice of Inspection must be presented to the owner, operator, or agent in charge of the premises. Only when the inspector has presented his credentials and Notice of Inspection is he authorized to enter at a reasonable time, and to inspect at a reasonable time, and in a reasonable manner.

His right to inspect does not extend beyond "all pertinent equipment, finished and unfinished materials, containers and labeling." It is a crime to refuse him this, but there is no requirement that questions must be answered or that inspection must be permitted outside the statutory scope. To acquiesce in any inspection beyond that compelled by the statute would constitute a waiver of rights under the Fourth Amendment of the Constitution, which is our safeguard against unreasonable search and seizure. If the administration wishes to extend the scope of its inspection beyond that authorized by statute, it must first procure a search warrant.

No appellate court case has yet been decided that holds that evidence developed as a result of inspection under section 704 may be used in a criminal prosecution against the inspected party who stands on his rights under the Fourth Amendment. True, in a number of cases, attempts have been made to bar prosecution or exclude evidence on the grounds that the inspection provided for in section 704 offends against the Fourth Amendment. In each of these cases, however, it was found as a fact that the defendant had expressly or impliedly waived his rights by failing to assert them. In short, where a party has permitted an inspector to go beyond his statutory rights of inspection, the Constitutional safeguards are no longer available to him.

Whether or not evidence developed by an inspector acting within his statutory authorization and, in the absence of any consent other than mere compliance with the mandate of section 704, may be used against the inspected party in a criminal case, is an open question in the federal courts.

That there is a very real problem here of Constitutional law, however, appears from some state court decisions. For example, in *People v. Laverne,* 14 N. Y. 2d 304 (1964), the Court of Appeals of New York recognized the distinction between an inspection made for purposes of enforcement by civil or administrative proceedings, and one made for purposes of criminal proceedings. In that case, the court reversed a conviction for violation of zoning laws on the grounds that the evidence obtained by a building inspector should have been suppressed as having been obtained by an illegal search and seizure.

The court concluded, however, that an entry into private premises by a public officer without a search warrant, against the resistance of the occupant in pursuance of the authority of law to eliminate a hazard to public health or safety, is probably Constitutionally valid if made for the purpose of summary or other administrative correction, or as a foundation for civil or other administrative proceedings.

In enacting section 703 to provide for the inspection and copying of shipping records, Congress appears to have been aware of the Constitutional problem it ignored in providing for compulsory factory inspections under section 704.

Section 703 provides: "that evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained."

It is to be remembered, though, that if shipping records were volunteered, the granted immunity could be lost. Thus, to preserve the immunity provided by the statute in this case, it is essential that the inspected party insist upon strict compliance and refuse to permit inspection and copying, unless the inspector's request is accompanied by a statement in writing, which he is required to give under section 703, "specifying the nature or kind of food, drug, device, or cosmetics to which such request relates."

In some quarters, there is a constant cry that further legislation is needed to regulate the drug industry. I am a lawyer, not a legislator, and I shall not debate this question. I would feel a bit more secure in my own home, however, if I heard more voices raised in support of the Constitutional rights of all the people—including people engaged in the drug industry. Section 704 of the Food, Drug and Cosmetic Act should be amended to provide in terms similar to those used in section 703 that no evidence developed during a compulsory factory inspection may be used in any criminal prosecution of the inspected party.

But to get back to the inspection of our hypothetical factory, when the inspection has been properly commenced by notice it may continue, and each entry of the inspector during the period of the inspection does not require a new notice.

Upon completion of inspection and before leaving the premises, the officer making the inspection is required to give the owner, operator or agent in charge a written report setting forth any conditions or practices observed by him which, in his judgment, indicate that any drug in the establishment:

1. Consists in whole or in part of any filthy, putrid or decomposed substances, or;

2. Has been prepared, packed or held under unsanitary conditions, whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

The inspection made under section 704 is for "purposes of enforcement" of the act, but the report which the inspector is required to make upon completion of his inspection does not encompass all of the things he has noted which might involve a violation of the act. Accordingly, while he must report his observations respecting conditions which may constitute one sort of adulteration, he is not required, for example, to report his observations concerning deviations from purity or quality nor is he required to report his observations respecting misbranding.

If, in the course of factory inspection, the officer making it obtains any sample, he is required to leave with the owner, operator or agent in charge a receipt describing the samples obtained.

Section 501 of the Act

Section 501 deals with adulteration. The section, as amended in 1962, now provides that a drug shall be deemed to be adulterated if the methods used in, or the facilities or controls for its manufacture, processing, packing or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice. The regulations promulgated under this section (21 CFR Pt. 133) do not define current good manufacturing practice, but specify criteria for buildings, equipment, personnel, components, master-formula and batch production records, production and control procedures, packing and labeling, laboratory control, distribution records, stability and compliant files.

Under the broader scope of factory inspection which applies to prescription drugs, the records kept to establish current good manufacturing practices are undoubtedly subject to inspection. However, the amendment to section 501, that requires that good manufacturing practice be followed, does not increase the scope of factory inspection in a plant in which prescription drugs *are not* produced. Thus, although the law requires proprietary drug manufacturers to keep records required to establish current good manufacturing practice, it does not render those records subject to inspection under the factory inspection provisions of section 704.

Section 510, as amended in 1962, of the act deals with the registration of producers of drugs but does not increase the scope of factory inspection, even though it makes provision for frequency of inspection. Subdivision (h) of section 510 prescribes that every registered producer of drugs shall be subject to inspection pursuant to section 704 and that his establishment shall be inspected at least once in the two-year period following registration and at least once in every successive two-year period thereafter.

In the past, factory inspection has generally taken place only at longer intervals. Henceforth, it will occur more frequently and undoubtedly many questions will arise which have not, as yet, had the benefit of a judicial answer.

Conclusion

The foregoing is intended to deal with "factory inspection" as that term is generally used and understood by management personnel and lawyers in the drug industry. It is implicit that no attempt has been made to deal with all the inquisitional, investigational and prosecuting powers or potential possessed by the FDA. The inspection of certain objects, data or documents may not be subject to "factory inspection," but would, of course, be available if the FDA inspector had procured a search warrant. This suggests that the FDA may procure such a warrant where it is disposed to do so and can make the necessary showing. Its powers, however, do not end here. It may enlist the aid of the Department of Justice and, by doing so, avail itself of the virtually unlimited powers of a Grand Jury. It also may seek the cooperation of other government agencies such as the Federal Trade Commission (FTC), and thus indirectly avail itself of more sweeping investigational powers. Section 702 of the Federal Food, Drug and Cosmetic Act of 1938 (21 U. S. C. § 372) specifically authorizes FDA to conduct examinations and investigations for the purposes of the act through its own employees *or* through any health, food or drug officer or employee of any state, territory or political subdivision thereof. To effect this purpose, the Secretary of HEW has authority to commission any such person as an FDA officer. Moreover, it is not uncommon for FDA inspectors to work in cooperation with state health officials. Obviously, the full scope of the investigational powers of FDA should be considered when evaluating the wisdom of taking a technical approach to the requests made by an inspector during the course of "factory inspection" under section 704 of the act. **[The End]**

Food Safety in Canada

By R. A. CHAPMAN

The Following Article Was Presented at the Dedication of the Food and Drug Administration Building, Washington, D. C., on November 23, 1965. Mr. Chapman Is Director-General, Food and Drugs, Ottawa, Canada.

IN DISCUSSING THE TOPIC OF FOOD SAFETY, I felt it might be of interest to discuss briefly the history of food and drug legislation in our country. The first act pertaining to the control of foods and drugs in Canada was enacted in 1875. I do not think I can do better than to quote from a paper written by A. Linton Davidson, entitled "The Genesis and Growth of the Food and Drug Administration in Canada", which was published in 1950 on the occasion of the 75th anniversary of the first Food and Drugs Act. A section of this paper reads as follows:

> Unquestionably there was too much drinking in Canada in the early days of Confederation. The saloon, with its attendant evils, was an unqualified curse. Men working in out-of-the-way places on great national projects, such as the building of the railways, came back to the fringe of civilization after a lengthy absence, their pockets bulging with money; and lo, there stood the saloon, . . . ready to relieve them of the fruit of their toil and sweat!
>
> Not only was there too much liquor but a great deal of it was immature fiery spirit. In the House of Commons in 1873, it was claimed that three-fifths of the cases of insanity and four-fifths of the cases of crime and pauperism were caused by intemperance. Gaols were overcrowded and lunatic asylums were bursting at the seams owing to overcrowding by alcoholics.
>
> No wonder public opinion was deeply aroused over these stains on the fair escutcheon of a noble people seeking a foothold among the nations of the earth! Our neighbours to the South had experienced the same situation and had met it by banning the manufacture and sale of strong drink. . . . Parliament had to do something about it. A Committee was appointed to consider the enactment of a prohibitory liquor law. Although it meant a loss—substantial in those days—of nearly $5,000,000 in revenue—the Committee was prepared to sacrifice this in order to exterminate vice, so they thought, and recommend prohibition. However, prohibition had its opponents then as now and the opposition came from French parishes in Quebec whose opinion demanded consideration. But such opposition did not arise from pure sentiment: it was no secret that much of the liquor sold was grossly adulterated; and the legislators held the view that it was not liquor but bad liquor that ought to be banned. So Sir Richard Cartwright in the House of Commons in 1874 moved that the

House consider a resolution that all carrying on business as compounders and mixers of wine, brandy or other alcoholic liquors be required to take out a license to do so.

What a strange introduction to a history of food control! Here is the sequel. Within two weeks of Sir Richard's motion, an Act was assented to entitled "An Act to Impose License Duties on Compounders of Spirits and to Amend the 'Act Respecting Inland Revenue' and to Prevent the Adulteration of Food, Drink and Drugs." It was operative as from 1st January, 1875, and was to be cited as "The Inland Revenue Act of 1875."

As anticipated, the Act provided for the bonding and licensing of compounders of liquor. Persons possessing "competent medical, chemical or microscopical knowledge as analysts of food, drink and drugs" were to be appointed in each Inland Revenue division to analyse samples collected by Inland Revenue Officers, inspectors of weights and measures and inspectors of staple commodities. Liquor was adulterated if it contained certain specified substances, such as common salt, copperas, opium, Indian hemp, tobacco or salts of zinc or lead. Adulterated food was defined as 'all articles of food with which was included any deleterious ingredients or any material of less value than is understood by the name'.

Organization of the Food and Drug Directorate

The Order-in-Council which brought into effect the original Act of 1875 also appointed four analysts and this was the entire staff of what was then the Food and Drug Directorate. These analysts were granted an allowance of $300 for the first year for apparatus and material used in the laboratory, an annual retaining fee of $200 and an allowance of $100 per year for rent and payment for work done on a fee basis up to a maximum of $2000 per year. How times have changed! Our staff now numbers 718 persons and our annual budget for 1965-66 is $5,182,600.

In the intervening years the Directorate has undergone many organizational changes, the latest of which was introduced only in June of this year. Under this latest arrangement there are three major operating units of the Directorate at the Ottawa headquarters. These are (1) Bureau of Operations, (2) Bureau of Scientific Advisory Services, and (3) Research Laboratories.

The Bureau of Operations is responsible for all enforcement activities including the field programme. In regard to field activities, Canada has been divided into five regions for administrative purposes with headquarters located in Halifax, Montreal, Toronto, Winnipeg and Vancouver. District offices have also been established in 24 additional localities where there is a significant amount of regulatory work. This Bureau also is responsible for the labelling and advertising of food and drugs and for all legal actions. Advertising of all foods, drugs, cosmetics and medical devices comes within the authority

of the Food and Drugs Act. As far as advertising on radio and television is concerned, we are in a position to exercise effective control since all such advertising comes under the authority of the Canadian Broadcasting Act. The Board of Broadcast Governors who are responsible for its enforcement has delegated authority to clear all radio and television advertising of food and drugs through the Directorate. Thus all such continuities are reviewed by officers of the Directorate before going on the air. Our control over magazine and newspaper advertising is not as effective inasmuch as there is no requirement for prior clearance.

The Bureau of Scientific Advisory Services which was only established in June of this year, has responsibility for evaluating submissions on all new drugs, requests for the use of new food additives and the establishment of tolerances for pesticide residues. This Bureau consists of the Divisions of Medicine, Veterinary Medicine, Pharmacological Evaluation and Standards and Additives. Thus all review and advisory aspects of our responsibilities are under the direction of one senior officer who reports to the Director-General.

The third major area of activity at headquarters involves the Research Laboratories. These consist of Divisions of Food, Nutrition, Microbiology, Pharmaceutical Chemistry and Pharmacology and Endocrinology. This organizational structure has not been implemented in full at the present time. We also have a section of Pathology and Toxicology and a Research Services which includes Biometrics, Instrumentation and Experimental Animal Sections. The Research Laboratories provide the scientific and technical information on which valid decisions can be based. From its inception in 1875, the Food and Drug Directorate has been strongly oriented in the direction of the scientific approach to problems and we do our best to ensure that our decisions are based on the application of the scientific method. I believe this scientific attitude is best summed up in a story told by the late E. W. R. Steacie, former President of the National Research Council, Ottawa, Canada. The story concerns the man who said to his friend who was a scientist, "Look at the brown cow." The scientist pondered for a moment and then replied, "Well it's brown on this side." We believe that such an attitude is essential for sound decisions in our area of responsibility. We want to see both sides of the cow.

The Headquarters organization also includes a Consumer Division, Narcotic Control Division and Administrative Services. The proportion of our staff devoted to each of these areas is as follows:

	1965-66 Establishment	
	No.	Percent
Senior Management	10	1.4
Research Laboratories	159	22.2
Bureau of Scientific Advisory Services	59	8.2
Bureau of Operations		
Headquarters (39)		
Field (313)	352	49.0
Narcotic Control Division	59	8.2
Consumer Division	12	1.7
Administrative Services	67	9.3

Food and Drugs Act

Well, so much for the organization. I should now like to return to the legislation under which we operate. The present Food and Drugs Act was passed in 1953. The most significant difference between this latest act and those of its predecessors was the fact that it prohibited the sale of foods, drugs, or cosmetics manufactured under unsanitary conditions, and the prohibition of the manufacture, preservation, packaging and storage of foods, drugs or cosmetics under such conditions.

Under the present act, food includes any article manufactured, sold or represented for use as food or drink for man, chewing gum and any ingredient that may be mixed with food for any purpose whatever. The general provisions of the act, as they pertain to food, require that no person shall sell a food that presents a hazard to health or is deceptive in any manner. The act also provides authority for the Governor-in-Council to make regulations for carrying the purposes and provisions of the Act into effect including the establishment of standards for foods. Approximately 270 standards have been established for the more important products. In general these standards are less detailed than those adopted under United States legislation. For example, the Canadian standard for ice cream reads as follows:

B.08.062. Ice Cream

(a) shall be the frozen food made from ice cream mix by freezing;
(b) may contain cocoa or chocolate syrup, fruit, nuts or confections;
(c) shall contain not less than
(i) 36 per cent solids,
(ii) 10 per cent milk fat, and
(iii) 1.8 pounds of solids per gallon of which amount not less than 0.50 pound shall be milk fat; and
(d) shall contain not more than 100,000 bacteria per gram as determined by the official method.

Judging from the inquiries we receive, it would appear that consumers are particularly concerned in regard to the possible excessive use of food additives and the presence of pesticide residues in our food supply. I should, therefore, like to discuss these two subjects in some detail to indicate the requirements and procedures which we employ to prevent any possible hazard to health.

Food Additives

Until recently, food additives were controlled under the general section of the act which requires that "No person shall sell an article of food . . . that has in or upon it any poisonous or harmful substance." There were no specific regulations which dealt with food additives other than the permitted lists of food colours and preservatives. We believed, however, that we would be in a better position to prevent any possibility of harmful effects if we had specific requirements laid down in the regulations under the Food and Drugs Act which must be met before a substance is introduced into the food supply. Therefore, new regulations relating to food additives were developed and promulgated in September, 1964. These regulations represented almost three years of discussions with trade associations, consumer groups and other interested parties, as well as the accumulation of the vast amount of data on which to base decisions on the acceptability of each compound. The definition of a food additive under these regulations reads as follows:

> Food additive means any substance, including any source of radiation, the use of which results, or may reasonably be expected to result in it or its by-products becoming a part of or affecting the characteristics of a food, but does not include
>
> (i) any nutritive material that is used, recognized, or commonly sold as an article or ingredient of food,
>
> (ii) vitamins, mineral nutrients and amino acids,
>
> (iii) spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives,
>
> (iv) pesticides,
>
> (v) food packaging materials and components thereof, and
>
> (vi) drugs recommended for administration to animals that may be consumed as food.

You will note that this definition includes any substance the use of which may reasonably be expected to result in residues in the final food or which may affect the characteristics of a food. Furthermore, it includes any source of radiation. This latter section provides us with control over the use of irradiation as a means of preserving foods. In subparagraph (i) any nutritive material that is used, recognized or commonly sold as an article of food is ex-

cluded from the definition of a food additive. We did not wish to include in the table of food additives such foods as sugar, starch, glucose, corn syrup, salt and other materials which are generally recognized as foods.

We already have regulations governing the use of vitamins in foods and we may wish to modify these to cover mineral nutrients and amino acids. Therefore, we did not want to include them under our food additive regulations.

In the case of spices, seasonings, flavouring preparations, essential oils, oleoresins and natural extractives, we feel that the possibility of hazard to health from the use of these compounds is remote. The amounts used will be small and because of their nature will be self-limiting. If any compounds which fall into this category are found to be more toxic than presently believed, it will be possible to handle them in the same manner as we have handled coumarin and safrole, that is, to specifically prohibit their use in foods. Pesticides are already covered in Division 15 of the regulations.

It is the opinion of our scientists that present components of food packaging materials do not present serious hazards to health. Such materials, therefore, have been excluded from the definition of a food additive. In the case of veterinary drugs, we consider that possible residues in meat, milk and eggs can be adequately controlled by requiring that the manufacturer provide details of tests carried out to demonstrate that no residue remains in the food. Such information must be supplied when requested by the Food and Drug Directorate.

It was necessary in drawing up the regulations to make provision for the addition or deletion of compounds from the permitted list. A request for the introduction of a new food additive must include the following information:

(a) a description of the food additive;

(b) a statement of the amount of the food additive proposed for use;

(c) an acceptable method of analysis suitable for regulatory purposes;

(d) data establishing that the food additive will have the intended physical or other technical effect;

(e) detailed reports of tests made to establish the safety of the food additive under the conditions of use recommended;

(f) data to indicate the residues that may remain in or upon the finished food;

(g) a proposed maximum limit for residues of the food additive in or upon the finished food;

(h) specimens of the labelling proposed for the food additive; and

(i) a sample of the food additive in the form in which it is proposed to be used in foods, a sample of the active ingredient and, on request, a sample of food containing the food additive.

Finally, fourteen tables are given listing the food additives in each category. These cover all compounds from "anticaking agents" to "yeast foods."

The purpose for which the chemical additive is intended is given in the heading of the table. The additives are listed in the left-hand column. In the center column are given the foods in which the additives are permitted and in the third column a maximum level of use is indicated. The following example is taken from:

Table I

Food Additives That May Be Used As Anticaking Agents

Item No.	Column I Additive	Column II Permitted in or Upon	Column III Maximum Level of Use
C.1	Calcium Aluminum Silicate	(1) Salt (free-running) (2) Flour salt; Garlic salt; Onion salt (3) Unstandardized dry mixes	(1) 1.0% (2) 2.0% (3) Good Manufacturing Practice
C.2	Calcium Phosphate, Tribasic	(1) Salt (free-running) (2) Flour salt; Garlic salt; Onion salt (3) Dry cure (4) Unstandardized dry mixes (5) Oil soluble annatto	(1) 1.0% (2) 2.0% (3) Good Manufacturing Practice (4) Good Manufacturing Practice (5) Good Manufacturing Practice

Pesticide Residues

The possibility of pesticide residues remaining in our foods is also of concern to quite a number of Canadians. As you are aware, a considerable number of agricultural chemicals are required in the production of agricultural crops and, in some instances, trace amounts remain on the food when it is ready for marketing.

Tolerances or limits have been established in the Food and Drug Regulations for approximately 70 pesticide chemicals on a wide

variety of food products. You might also be interested in a brief outline of the procedures which we employ in establishing tolerances for these pesticide chemicals.

Our major concern is with the long-term or chronic effects of pesticide residues. It would be most unlikely that a food would contain sufficient residues of a pesticide to make one acutely ill. However, these pesticides are, in general, highly toxic substances and if our food were to contain even small amounts of pesticides, these small amounts, if ingested over many years, might have detrimental effects. Therefore, we must be on guard against any possibility of chronic poisoning and any tolerance which is established, is at a level which would permit man to ingest this amount over an entire lifetime without suffering any ill effects.

You might well ask how do we establish such levels? It is obvious that the best criterion for evaluating the toxicity of pesticides would be a long history of safe use on humans. However, as you can well appreciate, it is difficult to obtain such data. In order to determine a safe level, it is necessary to know at what level toxic effects occur and the type of damage which results. Therefore, in general, it is necessary to use experimental animals. The chronic or long-term tests are carried out with at least two species of animals, usually on rats, for their lifetime of about two years and in another species for about a year. From these studies it is possible to establish an acceptable daily intake of the pesticide for man. I might point out that this acceptable intake includes a safety factor, in most cases of 100, which is intended to provide for differences between the test animals and man, individual sensitivity, unusual eating habits and the possible synergistic effects of the pesticide in combination with other chemicals which may be present in food. From the acceptable daily intake, a permissible level or a tolerance can be established taking into account the proportion of the diet constituted by the group of foods for which a tolerance is to be established. On the basis of the foregoing it is possible to establish a level which would be without appreciable risk to man even if he ingested this amount throughout his entire lifetime.

Two Examples of Directorate Action

I should like to outline briefly, as an example, a situation which has developed in Canada within the past few years and the action taken. Early in 1964, trace amounts of heptachlor and heptachlor

epoxide were detected in market milk in British Columbia. The levels did not represent any immediate hazard to health but did warrant further investigation. Subsequent analyses of the rations of dairy cattle pin-pointed sugar beet pulp as a likely source of the contamination. It developed that sugar beets in Alberta were being grown in soil treated with fertilizer containing one percent heptachlor to control wire worms and root maggots. The original data submitted when this pesticide was registered for such use did not indicate that any significant residues would result from this treatment. However, we do know that the stability of the chlorinated hydrocarbons varies with a number of factors, including soil types and climatic conditions. To prevent a recurrence of this situation the Canada Department of Agriculture did not register heptachlor in 1965 for soil application in sugar beet production and limitations have been established under The Feeds Act on the maximum levels that may be recommended for beet pulp and feeds containing beet pulp.

Another example of the manner in which the Food and Drug Directorate has acted to protect the Canadian public from possible illness involves the microbiological contamination with Salmonella organisms of foods containing egg products. The records for salmonellosis in Canada showed an abrupt increase in the incidence of this condition over the three-year period from 1959 to 1962. During this same period the frequency of isolation of *Salmonella thompson* increased from 0.5 percent of total isolations to 25 percent. As soon as this trend was noted, the laboratories of the Directorate began a systematic examination of food products to determine the source of this particular organism. This investigation soon directed attention to foods containing dried egg products and in particular to cake mixes and meringue powders. It was found that 51.2 percent of the initial group of cake mixes examined contained salmonellae and 70 percent of those found positive, contained *Salmonella thompson*. Egg products have, of course, been known for years to be a frequent source of salmonellae. Since cake mixes had not been directly involved as a causative factor in human cases of salmonellosis and because all salmonellae present in selected mixes were shown to be destroyed when the product was prepared and cooked in accordance with manufacturers' recommendations, the significance of our findings remained uncertain. Accordingly, all provincial health departments were asked for assistance in securing epidemiological evidence linking cases of salmonellosis with cake mixes. It was not long until the circumstantial evidence began to accumulate. For example, three cases of

young children, investigated in 1962, revealed that in each of the homes involved cakes had been prepared, within a few days before the infections developed, from packaged cake mixes bearing the same lot numbers as those later shown to contain *Salmonella thompson*. In another incident, a hospitalized child was reported by its mother to have licked the bowl in which a cake mix had been prepared a day or two before the child became acutely ill.

Such reports did not constitute absolute proof of involvement of cake mixes, but the circumstantial evidence was considered sufficient to warrant recall from the market of all lots of cake mixes found to contain salmonellae and to recommend promulgation of a regulation under the authority of the Food and Drugs Act which required that "No person shall sell any egg product for use as food unless it is free from the genus *Salmonella*." This regulation came into effect in June, 1962.

Following promulgation, there was a steady decrease in the proportion of egg products contaminated with salmonellae. During the year immediately preceding the introduction of the regulation, 23.9 percent of all types of egg products were found to be contaminated. Within six months after promulgation an abrupt decline to 5.2 percent was noted. Within a further twelve-month period, the rate was reduced to 3.4 percent despite a bias due to intensified sampling of brands known to be more prone to contamination. The ultimate question, of course, is: has this action had any effect on the incidence of salmonellosis in Canada? Well, there is one encouraging statistic. The incidence of salmonellosis in man in Canada as reported by the Provincial Public Health Laboratories to our National Salmonella, Shigella and Escherichia Coli Reference and Typing Center, decreased slightly in 1964. The total of 2,796 salmonella isolations for that year represents a reduction of 7.5 percent from the 3,021 isolations reported in 1963. This is the first time in seven years that a reduction in salmonellosis in man has been noted. Time alone will tell whether or not we have actually reversed the upward trend.

I have attempted in this paper to provide an outline of the Food and Drugs Act and regulations as they apply to food safety. I have also given a few examples of action taken by the Directorate to reduce the hazard to health from food sources. I believe we have been reasonably successful in making available to the Canadian housewife foods which she can buy with confidence. **[The End]**

A Hatband and a Tube of Lipstick: The New Jersey Minority Rule on Allergic Responses

By WARREN FREEDMAN

Mr. Freedman Is a New York Attorney.

DESPITE THE EVER-MOUNTING SCIENTIFIC AND MEDICAL EVIDENCE that an allergic response is not due to a defect in the product[1] but rather to a defect in the person,[2] in the sense that the overwhelming majority of users do not react adversely to the product, the sovereign State of New Jersey persists in giving homage to a distinctly minority position epitomized by the hatband and the tube of lipstick. Two cases, *Zirpola*,[3] decided in 1939, and *Reynolds*,[4] decided in 1947, by the New Jersey Court of Errors and Appeals (on which bench were seven judges[5] who sat on both cases and ruled

[1] See Freedman, "Allergy and Products Liability Today," 24 *Ohio State Law Journal* 479, 480 (1963).

[2] Dr. Frederick Reiss, internationally known dermatologist, speaking before the Society of Medical Jurisprudence, New York Academy of Medicine, in February 1959, had expressed his personal incredulity about some allergy decisions in these words: "Certain individuals are far more responsible for an allergic reaction than is the causative agent. Who is responsible for the hives that may follow the eating of a bowl of strawberries? Is it the grocer who sold the strawberries? The farmer who grew them? If the lobster eaten at a good restaurant causes a reaction, does the fault lie with the restaurant, the lobster fisherman or even with the U. S. Government from whose waters the lobsters were taken?

It is my view that if the responsibility is to be placed, then the greatest fault is that of the parents whose chromosome pattern caused the predisposition of an individual's allergy traits. The fault cannot lie with the manufacturer or distributor. Moreover, since the dermatitis following an allergic response is usually self-limiting—naturally when the use of such a cosmetic is eliminated—claims for injury are, it seems to me, not in proportion to the proper responsibility of the manufacturer." Dr. Reiss thereupon called for— ". . . a recasting of the attitudes of lawyers and the courts. The responsibility of the manufacturer for the quality of his product is a continuing factor, but must he be held responsible for the altered from the normal, differing reaction of the user? Allergic responses are of course due to the sensitizing natures of substances themselves, but also to individualistic responses by the complex human being." (*Drug and Cosmetic Industry*, April 1959, p. 435.)

[3] *Zirpola v. Adam Hat Co.*, 122 N. J. L. 21, 4 A. 2d 73 (1939).

[4] *Reynolds v. Sun Ray Drug Co.*, 135 N. J. L. 475, 52 A. 2d 666 (1947).

[5] Judges Parker, Bodine, Donges, Heher, Wells, Rafferty, and Case.

similarly), still plague allergists, dermatologists, and lawyers today. Indeed, a quarter of a century has passed without a necessary change in the outmoded New Jersey position on the liability of a manufacturer and vendor for an allergic response sustained by an allergic user of the product.[6]

The term "allergy" is derived from two Greek words, "allos" or altered, and "ergia" meaning reactivity. Hence, allergy is an altered reactivity of an organism, the environmental modification of an organism unable to defend itself against antigen. If the particular antigen meets the antibody, and if the defense mechanism of the body is incapable of doing its normal job, the body equilibrium is upset, the antigen prevails, and there is an allergic response. Thus, the basic human fallibility, the idiosyncrasy or peculiar susceptibility of the consumer,[7] and not the product itself,[8] delineates the allergic response.

The *Zirpola* Case

The *Zirpola* case involved the claim of an allergic contact dermatitis allegedly caused by the particular dye found in a hat or in a hatband that the plaintiff had purchased in March 1936 directly from the manufacturer-vendor in Jersey City. After the plaintiff had worn the hat for a few weeks, he had it cleaned by a process of immersing the hat in a 10-gallon pail of naphtha, together with other hats, and of scrubbing the hat with the same brush. He continued to wear the hat for a short time thereafter, when he observed that his black hair had turned a reddish-orange color on each side of his head, and that he had a skin eruption on his forehead and the frontal region of his scalp. The court in 1939 thereupon concluded that both the hair discoloration and the skin eruption were due to the paraphenylenediamine in the hat.[9] The fact of the matter is that this aniline dye deriva-

[6] Both the *Zirpola* and *Reynolds* cases have strangely been infrequently cited by New Jersey courts: See *Vormack v. Farmers' Coop. Assn.*, 11 N. J. Super. 416 (App. Div., 1951); and *Locks Laboratories v. Bloomfield Molding Co.*, 35 N. J. Super. 422 (App. Div., 1955).

[7] In *Magee v. Wyeth Laboratories Inc.*, 214 A. C. A. 361 (1963), Judge Ashburn, at p. 372, opined: "There is evidence from which it may be inferred that Mr. Magee was possessed of a physical idiosyncrasy that made him allergic to Sparine, and there is no showing to the contrary."

[8] In *Kinkead v. Lysol Inc.*, 250 A. D. 832, 296 N. Y. S. 461 (1937), the New York Appellate Division ruled that the manufacturer, *as a matter of law*, did not have to anticipate an injury produced solely because of allergy. The Court pegged the defect in the unusual plaintiff rather than in the product!

[9] Note that only the *undyed* leather sweatband of the hat could conceivably, under normal use, come into contact with the skin. Since the plaintiff had a "skin eruption on his forehead and the frontal region of the scalp", it would appear that the sweatband alone was at fault! Thus, the dye (paraphenylenediamine) cannot be incriminated!

tive could not have impregnated, as opined by the court, (a) "the outside ribbon", nor (b) "the sweatband." Coal tar dyes were not in 1939 and are not today put into outside hat ribbons[10] nor sweatbands;[11] at most, the *felt* itself could have been dyed with the particular chemical. Furthermore, if there was paraphenylenediamine in the felt, it was in pigment form and chemically inert: it was not active, nor toxic, and could not diffuse into the skin, much less change the color of the plaintiff's hair.[12] The probabilities are greater that the naphtha solution, although fast-drying, initiated the hair discoloration and perhaps the allergic response in the particular plaintiff. To have placed the blame upon the dyed hat and not upon the naphtha was indeed a serious error on the part of the court. This mistake of fact was then compounded by the court's admission that "there was expert testimony offered by the defendant to show that tests made of the hat were negative as to the poison complained of." Indeed, since the court accepted this "expert testimony" that there was no paraphenylenediamine in the hat, Judge Hetfield's conclusion that "the poisonous dye was contained in the hat" was unwarranted. The burden of proof that this dye was used in making this hat rested squarely upon the plaintiff.

Judge Hetfield's opinion that the renovation of the hat (by immersion in naphtha) "contributed to the running or loosening of the dye" was also unsupported by scientific evidence. Such hats are customarily processed through several operations of hot to boiling water after dyeing to remove excess dye. In addition, a slight acid solution is added to the rinse to further set the dye. The only explanation for "bleeding" of the color is the wearer's fault, that is, subjecting the hat to excessive rain or to extra-heavy perspiration with which the sweatband is unable to cope.[13] However, the naphtha renovation of the hat was more likely the independent, efficient cause of the alleged injury, and it is unfortunate that the issue was not squarely raised by the defendant on his motion for a nonsuit. Furthermore, it should be pointed out that the trial judge's charge to the jury on "proximate cause" did not elaborate nor attempt to clarify the complicated issue

[10] A hat ribbon dye is usually a rayon acetate dye.

[11] The sweatband was genuine leather, ordinarily made from sheep or goatskin. Normal tanning and leather finishing without dyeing is generally followed.

[12] The black hair of the plaintiff allegedly became "reddish—orange". It is submitted that no dye can "lighten" natural hair color, and that the court was confused. A dye can only darken the natural color of the hair.

[13] There are no other known agents that might cause running or bleeding of color. If the rayon acetate dye in the hat *ribbon* ran—being above the brim —it would be difficult for it to touch the skin.

of "intervening cause", which is an act of independent agency destroying the causal relation between the defendant's act and the alleged injury.

The trial court in the *Zirpola* case had, in its prejudicial charge to the jury (which returned a $200 verdict), labeled this dye ingredient as "apparently a poison if used in certain quantities." The New Jersey Court of Errors and Appeals thereupon found a breach of the implied warranty of fitness for particular purpose[14] under N. J. R. S. 46:30-21(1) [Section 15(1) of the Uniform Sales Act] without ever applying the necessary standard of reasonableness. The court initially argued that the dye in the hatband was of a "poisonous nature",[15] and that its use was "forbidden in New York and several other states;" evidently, the court also incorrectly believed that the same "poison" was also "contained in the outside ribbon" as well as the sweatband of the hat. Indeed, neither paraphenylenediamine nor any other similar dye is a poison (although it is a known sensitizer); paraphenylenediamine is thoroughly oxidized by admixture with the air. This ingredient is certainly not a poison to the overwhelming number of normal purchasers and normal wearers of men's hats. And yet, the court accepted the illogical consequences of the argument that merely 4 or 5 per cent of all persons would react adversely to this particular dye. Indeed, if 95 or 96 per cent of *all* users of the product (using the court's own figures) did not sustain an allergic response, then it is submitted the dye ingredient could not possibly have been either "a poison" or of a 'poisonous nature", because *all* persons would necessarily have to react adversely (and perhaps even fatally) to a poison.

There can be little doubt that the New Jersey Court of Errors and Appeals in the *Zirpola* case misunderstood the technical nature of the chemical and the medical nature of the allergic response. Judge Hetfield used the irrelevant simile of immunity of certain people to contagious and infectious diseases, and declared that such fact does not make a vendor immune from legal liability for selling an article teeming with germs. Judge Hetfield put the cart before the horse! A vendor of a disease-bearing product cannot escape liability for contagious and infectious diseases proximately caused by the use of the product. But a vendor of a product which is innocuous to the normal user cannot be held liable to that rare individual whose peculiar predisposition or idiosyncrasy to the product was wholly unknown to

[14] It would appear that there was also an *express* warranty since inside the hat was printed the following: "Certificate of Guarantee. . . . We guarantee this hat to give proper wear. . . ." Neither the parties nor the court apparently raised this issue.

[15] Yet the court held that the plaintiff was "abnormally sensitive" to paraphenylenediamine.

the vendor. The point of the matter is that although infection may cause or be caused by an allergy, either or both infection and allergy may cause or be caused by "the psyche", or the emotional imbalance of the individual at the particular time.[16] Thus, except for infection, [which may or may not be caused by the product], it is not the product but the individual himself, his peculiar constitutional make-up which caused the allergy or the emotional imbalance.

The *Reynolds* Case

Eight years later in 1947, in the *Reynolds* case, Chancellor Oliphant, construing the *same* statute on *implied* warranty, relied entirely upon the *Zirpola* case in predicating liability against the retailer of a lipstick which allegedly caused an allergic response in the user.[17] (The trial court had ordered a nonsuit on the cause of action for breach of express warranty, and the plaintiff had suffered a voluntary nonsuit on the negligence count.) There was little or no discussion of what ingredient or substance in the product caused the allergic response, as the court simply cited an apt quotation from the *Zirpola* case. It was intimated, however, that there was a sharp cleavage in the expert testimony of the doctor and chemists.[18] The court based its determination of liability against the retailer upon the unwarranted premise that it preferred not to make an exception exculpating the retailer simply because the lipstick had been sold in a sealed package and was not open to inspection by the retailer. However, the majority rule in the United States does exculpate the retailer where the product was sold in a closed or sealed container and the retailer had no opportunity to inspect or examine the product before sale.[19]

Chancellor Oliphant also justified his decision against the product manufacturer upon the basis that, *otherwise*, in an action for breach of implied warranty, it would be necessary for the plaintiff to show the article sold was injurious to *all* users.[20] This is a *non sequitur*, for the number of users who could be adversely affected by use of the product is at most a relevant factor and not an ultimate fact giving use to such a conclusion of law. The plaintiff, in his burden of proof, need only establish that the product manufacturer or vendor had the knowl-

[16] *Freedman On Allergy & Products Liability* (1961), p. 41, and following.

[17] The word "allergy" is not mentioned in the Court's opinion—only "skin infection."

[18] The incidence of sensitivity to lipsticks is very low, perhaps one out of five million. See Masters, "Allergies to Cosmetic Products," *New York State Journal of Medicine*, June 15, 1960.

[19] Above, cited at footnote 16 at page 7 Cf. *John A. Brown Co. v. Shelton*, 391 P. 2d 259 (Okla. 1964).

[20] See generally *41 Texas Law Review* 866 (1963).

edge or should have known that a *substantial* portion of users would, and in fact did, react adversely to the product; in which event the product manufacturer then must demonstrate the adequacy of notice or warning of a possible allergic response upon the use of the product. The court apparently entertained no discussion on this relevant issue.

Despite the 1939 hatband decision in the *Zirpola* case, courts throughout the United States have almost uniformly applied the rule of nonliability in warranty for allergic responses to such fabrics as dyed dresses[21] and dyed dress shields,[22] brown kid gloves,[23] a blouse,[24] a black rayon dress,[25] and a Harris tweed coat.[26] In 1959 the Tenth U. S. Court of Appeal,[27] in a claim of allergy from a pair of gloves, approved the trial judge's charge to the jury:

> You are instructed that warranties do not extend to injuries caused by peculiar idiosyncrasies or physical conditions of a user which are not reasonably foreseeable.

And, even before the 1947 lipstick decision in the *Reynolds* case, the Florida Supreme Court[28] as well as the Connecticut courts[29] had applied the rule of nonliability in warranty in a lipstick-allergy situation.

The Rule of Reason and Warranty

It is also unfortunate that the New Jersey Court of Errors and Appeals in the *Reynolds* case did not apply a standard of reasonableness[30] which is inherent in the statutory implied warranty of fitness for particular purpose. No implied warranty is breached by an allergic response, because warranty means only *reasonable* merchantability and *reasonably* fit for the particular purpose.[31] As Dean Prosser stated in 1960:

> It is clear that the seller may expect within reasonable limits that the product will be used by normal persons and that he will not be held responsible when some idiosyncrasy peculiar to the plaintiff makes him abnormally sensitive to the product quite harmless to ordinary people.[32]

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[21] *Barrett v. S. S. Kresge Co.*, 144 Pa. Super. 516, 19 A. 2d 502 (1941), and *Payne v. R. H. White Co.*, 314 Mass. 63, 49 N. E. 2d 425 (1943).

[22] *Ross v. Porteous, Mitchell & Braun Co.*, 136 Me. 118, 3 A. 2d 650 (1939).

[23] *Longo v. Touraine Stores*, 319 Mass. 727, 66 N. E. 2d 792 (1946).

[24] *Marra v. Jones Store Co.*, 170 S. W. 2d 441 (Mo. App. 1943).

[25] *Stanton v. Sears Roebuck & Co.*, 312 Ill. App. 496, 38 N. E. 2d 801 (1942).

[26] *Griffiths v. Peter Conway, Ltd.*, 1 All. Eng. 685 (1939).

[27] *Ray v. Penney Co.*, 274 F. 2d 519 (1959).

[28] See *Smith v. Burdine's Inc.*, 144 Fla. 500, 198 So. 223 (1940).

[29] See *Cicarelli v. Lipshitz*, 8 Conn. Super. 526 (1940).

[30] Note *Deffebach v. Lansburgh & Bro.* 150 F. 2d 591 (District of Columbia, 1945), construing the *identical* implied warranty statute: "The only question in the case was whether or not the robe was reasonably fit for use as a robe".

[31] See *Jacquot v. Wm. Filene's Sons Co.*, 337 Mass. 312, 149 N. E. 2d 635 (1958); *Graham v. Jordan Marsh Co.*, 319 Mass. 690, 67 N. E. 2d 404 (1946).

[32] Prosser, "Strict Liability to the Consumer," 69 *Yale L. J.* 1099, 1144 (1960).

The Rule of Reason finds credence in the "natural expectations" test (as delineated in *Mix v. Ingersoll Candy Co.*)[33], which similarly precludes liability for an allergic reaction, since there can be no product under the sun to which some person at some time is not hypersensitive! The consumer may therefore "naturally expect" an allergic response from a product if he is constitutionally susceptible or peculiarly predisposed to it. The consumer cannot demand *perfection,* nor can he "naturally expect" an absolute guarantee that no person will react adversely to the product.[34] The most that the consumer can expect is that the product will be *reasonably* merchantable and *reasonably* fit for the particular purpose.[35] In the *Casagrande*[36] case the Massachusetts Supreme Judicial Court declared:

> Fitness for use by a *normal* person is a test often stated . . . The general knowledge of allergies, of which we take notice, and which is reflected in the testimony, makes it *unreasonable* to infer from any part or parts, of the evidence that a significant number of other persons would have been hurt by the deodorant. An inference of fact that the product would have hurt normal persons may not be drawn from the evidence of an allergic reaction in one person who has not previously shown sensitivity. (italics added)

The Ohio Court of Appeals has recently ruled that a product manufacturer, in the sale of a product which evinces an allergic response in a susceptible person, has only the duty to see that the product sold would not be dangerous to a *normal* person if and when used as directed.[37] And the Iowa Supreme Court has summarized:

> The overwhelming majority opinion as established in many states, and in the Federal court, is that under the above circumstances (an allergic response to a given product), neither the dealer nor the manufacturer is liable [38]

The Fifth U. S. Court of Appeals in 1963 examined a stannous fluoride toothpaste which allegedly caused an allergic response in a susceptible person, and affirmed directed verdict for the manufacturer:

> There was no evidence that the allergy from which the plaintiff suffered is one common to any substantial number of possible users.[39]

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[33] 6 Cal. 2d 674, 59 P. 2d 144 (1936).

[34] *Prosser On Torts (2nd Ed.),* p. 503: "The maker may also assume a normal user; and he is not liable where the injury is due to some allergy or other personal idiosyncrasy of the consumer . . ."

[35] See *Briggs v. National Industries,* 92 Cal. App. 2d 542, 207 P. 2d 110 (1949).

[36] *Casagrande v. F. W. Woolworth Co.,* 340 Mass. 552, 165 N. E. 2d 109 (1960).

[37] *Kennedy v. General Beauty Products, Inc.* 112 Ohio App. 505, 167 N. E. 2d 116 (1960), aff. — N. E. 2d — (1961).

[38] *Bonowski v. Revlon Incorporated,* 251 Iowa 141, 100 N. W. 2d 5, (1959). See also *Stanton v. Sears Roebuck & Co.,* 312 Ill. App. 496, 38 N. E. 2d 801 (1942) which involved an allergic response from the wearing of a rayon dress: "It can hardly be said that a vendor thereof would be liable for a breach of an implied warranty solely because of the harmful effect due to the buyer's individual idiosyncrasy."

[39] *Grau v. Procter & Gamble Co.,* 324 F. 2d 309 (1963).

Again, the Rule of Reason finds application in the doctrine of non-liability in warranty for an allergic response.

No "Defect" in the Product

It would seem that New Jersey courts must now wake up to the fact that (a) an allergic response in a susceptible, given individual is not foreseeable on the part of the product manufacturer;[40] and (b) liability can only be predicated upon proof that the product was defective, in that it contained an inherently dangerous or deleterious ingredient or substance. In the *Esborg* case[41] the Washington Supreme Court in 1963 declared that the plaintiff must prove that the allegedly harmful ingredient was in fact harmful to a reasonably foreseeable and appreciable class or number of potential users of the product. And in the *Kaspirowitz*[42] case in 1961 the New Jersey Superior Court explicitly held that there can be no breach of warranty *without proof* of a defective product;[43] a product to which a susceptible given person is allergic is not defective. If the product is properly manufactured and is not unreasonably dangerous to the normal user,[44] the product is indeed not defective. An allergic response due to the user's idiosyncrasy does not make a product defective—to the overwhelming majority of normal users, the product is merchantable and fit for the particular purpose.

The *Restatement of Torts, Second*[45] though imposing strict liability upon the product manufacturer (which "restatement" finds little if any justification in decisional law) defines "defective condition" as—

> in a . . . condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him

Under *Comment (g)* "unreasonably dangerous" is defined as—

> dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases the product with the ordinary knowledge common to the community as to its characteristics

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[40] *Bonowski v. Revlon, Inc.*, above, cited at footnote 38.

[41] *Esborg v. Bailey Drug Co.*, 61 Wash. 2d 347, 378 P. 2d 298 (1963).

[42] *Kaspirowitz v. Schering Corp.*, 70 N. J. Super. 397, 175 A. 2d 658 (1961).

[43] "Moreover, in the instant case we are not dealing with a defective product on the sale of which a claim of breach of an implied warranty of merchantability must necessarily rest." See also *Collins v. Seligman & Latz*, 38 So. 2d 132 (Fla., 1948).

[44] See *Sanders v. Clairol, Inc.* — A. D. 2d —, [NYLJ, October 2, 1956, p. 9, col. 2], denying recovery for an allergic response allegedly due to a hair dye application in a beauty salon. The New York Appellate Division expressly held that there was no evidence in the record that the product involved was inherently dangerous and poisonous. The product was deemed to be safe when applied in accordance with the precautions and instructions recommended by the manufacturer.

[45] Section 402A of Tentative Draft No. 10, adopted by the American Law Institute on May 23, 1964.

And under *Comment (k)* there is the striking statement that "the seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given where the situation calls for it, is not to be held to strict liability for the unfortunate consequences attending their use . . ." It is therefore submitted that a product which merely evinces an allergic response in a susceptible individual is an "unfortunate consequence". Such a product is *not* "defective", and *not* "unreasonably dangerous" to the overwhelming majority of normal users of the product.[46] In *Magee v. Wyeth Laboratories, Inc.*,[47] the California Supreme Court in 1963 declared:

> In the ordinary case the maker may also assume a normal user; and is not liable where the injury is due to some allergy or other personal idiosyncrasy of the consumer, found only in an insignificant percentage of the population.

Judge Ashburn tersely concluded:

> The manufacturer's duty is to reasonably guard against probabilities, not possibilities.

Requisite Knowledge on Part of Product Manufacturer

To predicate liability upon the product manufacturer it is essential that he is or should be aware of the allergenic effect of the product upon a *substantial* portion of users.[48] The product manufacturer cannot be held liable to that rare individual who perchances to be susceptible to a product which is innocuous to the vast majority of users. The prudent manufacturer in the exercise of reasonable care will, however, warn even the average, normal user of the product that contains a known sensitizer. By statute,[49] hair dyes or tints with known sensitizers carry caution statements requiring the user to make a preliminary patch or skin test for hypersensitivity 24 hours in advance of each and every application of the hair dye or tint, in accord

[46] See *Grau v. Procter & Gamble Co.*, above, cited at footnote 39, wherein the Fifth U. S. Court of Appeals opined: "There was no evidence that the allergy from which plaintiff suffered is one common to any substantial number of possible users."

[47] 214 ACA 361 (1963).

[48] However, four complaints out of 600,000 bottles of a spray deodorant prompted the N. Y. Supreme Court in *Kaempfe v. Lehn & Fink, Inc.*, 249 N. Y. S. 2d 840 (1964) to remark: "We have not yet reached the point . . . . where the manufacturer is to be held under an absolute duty of giving special warning against a remote possibility of harm due to an unusual allergic reaction from use by a miniscule percentage of the potential customers."

The Court distinguished *Wright v. Carter Products Co.* (244 F. 2d 53 CA 2, 1957) which case "specifically purports to apply the decisional law as developed in Massachusetts, and the Court concluded: "In any event we believe that the views expressed are not only supported by the weight of evidence but also by a common sense application of general negligence doctrine."

[49] Section 601 (a) of the Federal Food, Drug and Cosmetic Act.

with detailed, printed instructions accompanying the product.[50] Failure to comply with the statute obviously subjects the product manufacturer to liability; failure of the user to make the required patch test constitutes contributory negligence or assumption of the risk, and precludes recovery in a warranty action.[51]

Requisite Knowledge on Part of the Consumer

One writer[52] has opined that "the physical nature of the plaintiff should be just another factor to be considered in issues of duty to warn, duty to know, and duty to test." Indeed, if this plaintiff's advocate is serious, the only conclusion that can be drawn is that the plaintiff consumer has a reciprocal duty to warn the product manufacturer, or a reciprocal duty to know his own "physical nature" and idiosyncracies.[53] Failure of the user to warn the product manufacturer becomes contributory negligence or assumption of the risk, which are defenses to the warranty action.[54] The fact that the user may not be aware of his own idiosyncrasies is accordingly no defense.[55]

[50] Failure of the consumer to make the test was held to be contributory negligence in *Pinto v. Clairol Incorporated,* 324 F. 2d 608 (1963).

[51] *Taylor v. Jacobson,* 336 Mass. 709, 147 N. E. 2d 770 (1957), and *Pinto v. Clairol Incorporated,* above, cited at footnote 50.

[52] Rheingold, "The Drug Manufacturer's Liability," 18 *Rutgers Law Review 947,* 1005 (Summer 1964).

[53] See *Crotty v. Shartenberg's-New Haven, Inc.,* 147 Conn. 460, 467; 162 A. 2d 513, 517 (1960): "If a buyer has either actual or constructive knowledge that he is allergic to a particular substance, and knows or should know that he is allergic to that substance, he cannot recover."

[54] A majority of states, including Colorado, Illinois, Minnesota, Missouri, Mississippi, New York, North Carolina, Oregon and Texas, have all ruled that "contributory negligence" may be interposed as a defense against a claim for breach of warranty. In particular, see *Williston on Sales, Rev. Ed.,* Vol. 3, p. 379, Sec. 614b: "If the buyer's own fault or negligence contributed to the injury, as by using the goods with knowledge of their defects, he cannot recover consequential damages, since such damages were under the circumstances not proximately due to the breach of warranty."

Also, note *Sutherland on Damages 4th Ed.,* Vol. 1, p. 317, Sec. 89: "Where property is sold with a warranty of fitness for a particular purpose, if it be of such a nature that its defects can be readily, and in fact are, ascertained, yet the purchaser persists in using it, whereby losses and expenses are incurred, they come of his own wrong and he cannot recover damages for them as consequences of the breach of warranty."

[55] See *Westinghouse Electric & Mfg. Co. v. Deakins,* 305 Ky. 385, 204 S. W. 2d 434, on the question of assumed risk where a female employee with acne continued to immerse her hands in a solution which aggravated her condition: "We conclude, therefore, that the defendant violated no duty which it owed to the plaintiff, and while there might have been a recurrence of the malady, aggravated by the dangers of the work, the knowledge of her sensitive skin and pre-existing condition, coupled with her knowledge of the effect on the skin of other employees, places the responsibility upon her and not upon the Westinghouse Company. The defendant's motion for a peremptory instruction should have been sustained."

Allergy and Negligence

A tort action against the product manufacturer for injuries in the nature of an allergic response[56] must surmount these obstacles: (a) *unforeseeability of harm,* that is, whether a reasonable product manufacturer should have prudently anticipated or foreseen an allergic response in the normal user of the product;[57] (b) *adequacy of notice,* that is, whether the label or printed instructions accompanying the product warn or caution about a potential allergic response (if, indeed, a substantial portion of users are expected to react adversely to the product);[58] (c) *lack of proximate cause,* that is, whether the allergic response was proximately caused by the particular product, or was precipitated by some other food, drug, chemical, cosmetic, or other consumer product;[59] and (d) *assumption of the risk,* that is, whether the user was aware of his own idiosyncrasy, or his prior sensitization to some similar allergens.[60] Furthermore, to succeed in a negligence action, there must be proof that the product itself contained "inherently dangerous or poisonous ingredients."[61]

In a recent noteworthy decision, *Howard v. Avon Products, Inc.*[62] the Colorado Supreme Court citing *Freedman on Allergy and Products Liability,* chapters 7 and 8), ruled that an allergic reaction sustained by a purchaser and user of a skin cream was *not* compensable against the product manufacturer in an action based upon negligence[63] and

[56] See *Ravo v. Lido,* 17 A. D. 2d 476, 236 N. Y. S. 2d 135 (1963), wherein the New York Appellate Division recognized non-liability in negligence in the manufacture and distribution of a hair-waving preparation, which allegedly caused an allergic response.

[57] See *Bennett v. Pilot Products Co.,* 120 Utah 474, 235 P. 2d 525 (1951). In *Lehner v. Procter & Gamble Distr. Co.,* 208 N. Y. Misc. 186, 143 N. Y. S. 2d 172 (1955), the New York Court held that mere redness of hands acquired by a small percentage of persons tested by defendant manufacturer, unassociated with any form of dermatitis, was not sufficient by itself to put defendant on notice of possible danger to users of its product. Accord: *Antowill v. Friedmann,* 197 A. D. 230, 188 N. Y. S. 777 (1921).

[58] See *Taylor v. Jacobson and Pinto v. Clairol Incorporated,* above, cited at footnote 50.

[59] See *Karr v. Inecto, Inc.,* 247 N. Y. 360, 160 N. E. 398 (1928); *Fein v. Bonetti,* 307 N. Y. 682, 120 N. E. 2d 854 (1954), and *Hanrahan v. Walgreen Co.,* 243 N. C. 268, 90 S. E. 2d 392 (1955).

[60] See *Bennett v. Pilot Products Co.,* above, cited at footnote 57.

[61] The New York Court of Appeals in the *Fein* case, above, cited at footnote 59, accordingly reversed judgment for a beauty salon against the product manufacturer. Also, *McGuiness v. Roux Distr. Co.,* 19 N. Y. Misc. 2d 956 (1960) where plaintiff failed to establish that the product she purchased contained any deleterious substance.

[62] Colorado Supreme Court, September 14, 1964.

[63] On the negligence issue the Colorado Supreme Court held that there was no duty to warn users about possible hypersensitivity to the product because: — (a) the product manufacturer

(Continued on next page.)

upon breach of implied warranty of fitness because (a) plaintiff did not prove that product would or did harmfully affect a *substantial* number of users; plaintiff had the burden of proof of establishing that the product is injurious to a significant number of the population; (b) plaintiff was not a member of a *substantial, identifiable* class of persons allergic to the product; and (c) the product manufacturer was entitled to assume that the product would be used by a *normal* buyer, and that the alleged injury would not be "rare and truly peculiar to the particular plaintiff." It should be noted that the trial court had entered judgement for the product manufacturer, and the Colorado Supreme Court affirmed. Based upon the facts, this 1964 decision represents an important victory for the product manufacturer, not only because the court declined to impose the liability of an insurer, or the liability without fault doctrine, but especially since there was no label or caution statement on the skin cream warning about the possibility of an allergic response in a susceptible individual, other than a simple statement that a prospective purchaser *may* give herself a patch test "if she so desires." Also, on the favorable side were the following conclusions: (a) plaintiff's *chemical* expert admitted that, in test applications of the product upon subjects, he could not produce any "irritation of any kind;" (b) plaintiff's *medical* expert admitted that until 1959 (one year AFTER plaintiff used the product) he was unaware that the particular ingredient (methyl paraben) could cause an allergic reaction; (c) the product manufacturer had sold 1,652,000 jars and had received only *one* complaint up to the time plaintiff had applied the product to her skin; and (d) the first indication in the medical literature that methyl paraben could cause an allergic reaction was in 1961, three years after plaintiff used the product.

Conclusion

In view of the foregoing, it is respectfully recommended to the courts of New Jersey that the "lipstick" stain be promptly removed from the "hatband", so that New Jersey can take its rightful place as a jurisdiction where the rule of law continues to reign supreme. **[The End]**

(Footnote 63 continued.)
had no actual knowledge that the particular ingredient (methyl paraben) was an irritant; (b) the product manufacturer could not even be charged with constructive knowledge of the possibility of injury from the use of the product; (c) the product manufacturer cannot be expected to anticipate harmful consequences due to the allergy or personal idiosyncrasy of the buyer; (d) "the occurrence of injury following use of a product raises no presumption of negligence in the manufacture or sale thereof"; and (e) the doctrine of Res Ipsa Loquitur was not applicable.

More on "Zero Tolerance"

Comments by BERNARD L. OSER on the Statement made by the Department of Agriculture and the Food and Drug Administration

Dr. Oser, This Magazine's Scientific Editor, Comments Upon the Government's Statement Implementing the National Academy of Sciences-National Research Council Pesticide Residues Committee's "Report on 'No Residue' and 'Zero Tolerance.'"

As a consequence of the June 1965 report of the Pesticide Residues Committee of the National Academy of Sciences-National Research Council (NAS-NRC), on the "zero tolerance" problem (discussed in a previous issue of this JOURNAL[1]), the Departments of Agriculture and the Food and Drug Administration (FDA) of the Department of Health, Education, and Welfare (HEW) have jointly issued the following statement. The major recommendations of the NAS-NRC Committee have in effect been adopted, including the setting of a time period for the transition from "no residue" to finite but negligible tolerances, geared to published analytical methods. The NRC suggestion that the concepts of "no residue" or "zero tolerance" be abandoned was rejected on the ground that this would require legislative action, inasmuch as these terms are used in the statute. However the plan agreed upon by the two agencies actually recognizes that these concepts are literally untenable.

Statement for Implementation of Report on No Residue and Zero Tolerance [2]

Upon recommendation of the President's Science Advisory Committee and based on difficulties arising from zero tolerance and no residue registration, the Agricultural Research Service of the U. S. Department of Agriculture and the Food and Drug Administration of the Department of Health, Education, and Welfare requested that a committee be appointed by the National Academy of Sciences, National Research Council, to evaluate the present system of registering pesticides for use on food crops on a zero tolerance or no residue basis. The committee completed its study in June 1965 and submitted a report with the following eleven recommendations:

1. The concepts of "no residue" and "zero tolerance" as employed in the registration and regulation of pesticides are scientifically and administratively untenable and should be abandoned.

[1] Bernard L. Oser, "The Mathematical, Legal and Chemical Concepts of Zero." 20 FOOD DRUG COSMETIC LAW JOURNAL, 597 (October 1965).

[2] As approved by Orville L. Freeman, Secretary, Department of Agriculture, April 1, 1966, and John W. Gardner, Secretary, Department of Health, Education and Welfare, March 11, 1966. 31 *Federal Register* 5723.

2. A pesticide should be registered on the basis of either "negligible residue" or "permissible residue," depending on whether its use results in the intake of a negligible or permissible fraction of the maximum acceptable daily intake as determined by appropriate safety studies.

3. Where the use of a pesticide may reasonably be expected to result in a residue in or on food, registration by the U. S. Department of Agriculture should not be granted unless (a) it is established that the residue is a negligible residue or (b) such residue is not more than a permissible residue established by the Food and Drug Administration.

4. When a pesticide is registered on a negligible-residue basis, the negligible-residue figure should be published, as well as an analytical method for determining whether or not a food contains a residue in excess of the negligible residue. Both the amount and the analytical method should have the concurrence of the Food and Drug Administration and be controlling for its enforcement purposes.

5. The Food and Drug Administration's regulations on permissible residues should include a published description of the analytical methods used for enforcement purposes and should not be changed without notice and opportunity for comment by interested parties.

6. If a pesticide is known to be too hazardous for a particular use, registration for such use should be refused.

7. Because of the importance that pesticides play in the production of our food supply and the many nonfood uses necessary for protecting the health and economy of the nation, it would seem appropriate that the registration of pesticides should continue to be the responsibility of the U. S. Department of Agriculture.

8. The publication of a reasonable schedule for an orderly transition from the present procedure is necessary, and its duration should be decided by mutual agreement between the Department of Agriculture and the Department of Health, Education, and Welfare.

9. Programs should be developed for continuing centralized leadership, free and prompt exchange of information, training activities, and interlaboratory evaluation. A manual of operating instructions for residue methods should be produced by the U. S. Department of Agriculture and the Department of Health, Education, and Welfare and continuously revised according to changing usage, food habits, and new pesticides and mixtures.

10. A formal program for education in residue analysis is urgently needed and the Departments of Agriculture and Health, Education, and Welfare, and any other agencies concerned should cooperatively sponsor this program with suitable training centers.

11. There should be an expanded research program on the persistence of pesticides in the total environment, and on the toxicology, pharmacology, and biochemistry of pesticides that would improve the reliability and precision of animal studies and their relevance to man.

After extensive consideration of the report and conferring together, the Agricultural Research Service and the Food and Drug Administration have agreed on certain general principles and procedures to be followed in implementation of the recommendations.

The Federal Food, Drug, and Cosmetic Act specifies that any pesticide chemical in or on food shall be deemed unsafe unless a "tolerance" [3] for such pesticide chemical has been prescribed and the quantity is within the limits of the tolerance so prescribed. The act also provides for setting a "tolerance" at "zero" level if the scientific data do not justify the establishment of a greater tolerance. Thus, these terms cannot be abandoned as recom-

[3] As used in this statement, the term "tolerance" also includes exemption from the requirement of a tolerance.

mended without a change in the law. Also, misuse of pesticides on crops for which there is no tolerance and no registered use requires the zero tolerance concept to handle the illegal unsafe residues resulting from such misuse.

While the committee uses the terms "permissible residue" and "negligible residue," both of these are included within the concept of "tolerance" as used in the act. Authority exists under the law for establishing by regulation "tolerances" to cover "permissible residues" and "negligible residues."

Both agencies agree that the concept of "no residue" as employed in registration of pesticides for uses that may leave residues—even very small ones—on food should be abandoned in favor of a concept of finite tolerances for residues at the negligible level.

Both agencies accept the principle that new uses of pesticides on food crops which may reasonably be expected to result in small residues in or on food should not be registered under the Federal Insecticide, Fungicide, and Rodenticide Act unless a finite residue level is formally provided for by tolerances promulgated under the Federal Food, Drug, and Cosmetic Act. Such tolerances should be established on the basis of data in petitions presented by proponents to establish that such uses will be safe.

It is reasonable to expect that uses of persistent pesticides on crops or in soil in which crops are to be grown may result in residues on the crop at harvest. Agricultural uses of pesticides for which it can be concluded there is no reasonable expectation of any residues on the food will be considered as nonfood uses and can continue to be registered in the absence of a finite tolerance. These pesticide uses include applications highly remote from food crops. If a pesticide use considered under this paragraph is found to result in a finite residue by newly developed tests, and it is clear that this residue on the crop presents no hazard to the public health, the facts will be reported to the Agricultural Research Service looking toward reappraisal of the registered use, with continuance only if a finite tolerance can be established.

While chronic feeding studies in two species of animals and reproduction studies conducted in accord with recognized protocols are generally required for tolerance purposes, if only negligible levels are involved 90-day feeding studies on two species of test animals may be sufficient to provide a provisional or tentative basis for such tolerance. The negligible level for a pesticide chemical will be determined by the nature and degree of toxicity demonstrated. No procedure or formula is to be employed which will serve to override scientific judgment based on adequate safety data.

If the available data do not establish the safety of a pesticide for a particular use, such use will be deemed to be hazardous and USDA would not register the pesticide for such use.

It is agreed that pesticide use patterns registered on a no-residue or zero tolerance basis which have resulted in regulatory actions because of the finding of residues in food should be immediately discontinued. Such registrations would not be restored until tolerances are established. Prompt action will be taken on petitions for tolerances for negligible residues of such pesticides.

All petitions should supply an analytical method which has been demonstrated to work satisfactorily on field samples and which is suitable for regulatory purposes. This method should be published in a scientific journal or be presented in a form suitable for publication in a compendium of methods or in the pesticide regulations. The Food and Drug Administration proposes to continue to expand its Pesticide Analytical Manual to include new enforcement procedures as they are developed for new pesticides and to keep it up to date with new improved methodology. The U. S. De-

partment of Agriculture will make available for inclusion, methodology data developed under its programs. The manual will be made generally available to all interested parties. As methods are ultimately adopted by the Association of Official Analytical Chemists their location in the book of methods of that association can be conveniently referenced in the pesticide regulations.

Both agencies agree that current registrations of all uses involving reasonable expectation of small residues on the food at harvest in the face of a zero tolerance or no tolerance should be discontinued as of December 31, 1967, unless evidence is presented to support a finite tolerance or to show that enough progress has been made in the investigation to warrant the conclusion that the registration can be continued without undue hazard to the public health. Such registration will be replaced with registrations based on finite tolerances for negligible residues where data are submitted in petitions to support the establishment of such tolerances. The changeover, including processing of petitions, should be effected as soon as possible, but in no event should such no-residue or zero tolerance registrations be continued later than December 31, 1970.

Both agencies are ready to receive and process such petitions under the Food, Drug, and Cosmetic Act.

The procedures set forth in this statement will be applied in processing all pending applications for registration or reregistration and to all such future applications.

These procedures are to be applied to purposeful uses of pesticide chemicals. There is a comparable problem involving inadvertent and unavoidable residues in our food supply, such as meat, milk and eggs, which needs resolution.

While the principles of the Pesticide Residues Committee dealing with the zero problem will in many instances apply to this kind of residue problem, no definitive steps are contemplated in this area until the recommendations of the new committee being established by the Commissioner of Food and Drugs are reviewed in connection with the petition for tolerances for residues of certain pesticides in milk, as submitted by the California Departments of Agriculture and Public Health.

That committee, in addition to reviewing the California petition, will also be charged to look into this matter of unavoidable residues in milk and other foods.

Both agencies agree that under existing statutes the registration of pesticides is the responsibility of the U. S. Department of Agriculture.

Although close relationships have been maintained, the Departments of Agriculture and Health, Education, and Welfare will do everything possible to improve liaison and coordination in the registration of pesticides and regulation of residues on food. Under the present interdepartmental agreement regarding pesticides, the Public Health Service of the Department of Health, Education, and Welfare is participating in the review of proposed pesticide uses from the human health standpoint.

As budget authorizations permit, both departments will increase research on the chemistry and toxicology of pesticide residues entering food supplies, participation in a program to provide exchange of information, training activities in pesticide methodology, and interlaboratory evaluation among all Federal and State governmental units having responsibility relating to pesticides. The Public Health Service of the Department of Health, Education, and Welfare has basic health responsibilities and laboratory and clinical research programs. The competencies of the Service are available for consultation and correlating human experience with animal experience and the studies of pharmacological actions of classes of pesticides.

[The End]

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