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Food Drug Cosmetic Law JOURNAL

Some Present Responsibilities in Labeling and Advertising (Part II) . . SIDNEY H. WILLIG

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

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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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Some Present Responsibilities in Labeling and Advertising: Part II.—The conclusion of *Sidney H. Willig's* two-part article on some of the legal considerations inherent in labeling, advertising and promotional activities begins on page 4. Professor Willig is Director of the Food, Drug and Cosmetic Law Unit, Institute for Law and the Health Services, Temple University. Part I of this article was published in the December, 1969 issue of the FOOD DRUG COSMETIC LAW JOURNAL. We sincerely regret that due to editorial error, Professor Sidney H. Willig's name was printed incorrectly in last month's publication.

Consumerism's Ultimate Challenge: Is Business Equal to the Task?—In his article beginning on page 17, *Aaron S. Yohalem* warns that Consumerism demands that business must voluntarily assume its responsibility for the welfare of the society it operates in and profits from, or its ability to make profits will be impaired. The paper was presented before a meeting of the American Management Association held in New York on November 10, 1969. Mr. Yohalem is Senior Vice President of CPC International, New York, N. Y.

1969 FDLI-FDA Conference.—The following articles were presented at the 13th Annual Joint Educational Conference of the Food and Drug Law Institute, Inc. and the Food and Drug Administration, held in Washington, D. C., on December 11 and 12, 1969. Additional articles from the Conference will be presented in the February issue of the FOOD DRUG COSMETIC LAW JOURNAL.

"Analysis and Recommendations—The Food and Drug Administration Organizational Review," by *Frederic V. Malek,* Deputy Under Secretary of the Department of Health, Education and Welfare, summarizes the findings and recommendations of the review of the organization and operating procedures of the FDA. The article begins on page 22.

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In "Nutritional Considerations in Foods," beginning on page 38, *Dale R. Lindsey* describes the methods that should be used to improve the nutritional quality of our foods, emphasizing that the effectiveness of these methods will be governed by public acceptance. Dr. Lindsey is Associate Commissioner for Science of FDA.

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Food·Drug·Cosmetic Law
Journal

Some Present Responsibilities in Labeling and Advertising Part II

By SIDNEY H. WILLIG

"Some Present Responsibilities in Labeling and Advertising: Part I" Was Published in the December, 1969 Issue of the JOURNAL, Beginning on Page 578. The Paper Was Presented at the August, 1969 Meeting of the Food, Drug and Cosmetic Division of the Corporate, Banking, and Business Law Section of the American Bar Association. Professor Willig Is Director of the Food, Drug and Cosmetic Law Unit of the Temple University Law School.

The Food and Drug Administration has expressed its post-Kefauver Amendment role as regards prescription drugs as follows:

It is a goal of FDA to assure that the labeling of a prescription drug makes effectively available to physicians "full disclosure" information, including "indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions" under which physicians can use the drug with maximum safety and effectiveness. You will recognize that some of this language is quoted from section 1.106(b)(3) of the regulations under the Federal Food, Drug, and Cosmetic Act which requires such information to appear in the drug package. This is the only way manufacturers can be required to furnish such "full disclosure" information under existing law. The advertising of drugs is not mandatory. When advertising in journals or other periodicals is employed, the law requires information in only "brief summary." It is a goal of FDA to assure that each and every form of prescription drug labeling and advertising is truthful and presents in fair balance with claims for the effectiveness of a drug, the limitations of its effectiveness, the contraindications, the side effects, needed warnings and precautions. We are concerned not only with eliminating false statements, but with assuring effective disclosure of the information needed for the physician to determine whether the potential benefits of a drug to his

patient justify the risks in its use. It is necessary that this goal apply to all forms of labeling and advertising because many of them reach the physician more directly and effectively than the package insert.[24]

The parent Section 502 of the FFDC Act applies only to drugs and devices, which are defined in Section 201 of the Act generally as any chemical or instrument or apparatus or contrivance that is used in humans or other animals for the following or related purposes: (1) The prevention, diagnosis or treatment of disease, and (2) The prevention of pregnancy.

Foods and sports equipment are excluded when they are implied in the definition of a drug or device.

Further, Section 502(n) supravenes Sections 12 through 17 of the Federal Trade Commission Act, but does not apply to any material the Secretary determines to be labeling according to 201(m).

The section then offers the basis for the charge of misbranding considering the requirements for the label, as defined in Section 201(k) of the Act, for the labeling as described in Section 201(m) and (n) of the Act and for the advertising, which remains positively undefined, but can be identified to a great extent by the requirements and prohibitions noted under Section 502(n) and 1.105 of the regulations.

If we use the product liability dictum attaching to products inherently dangerous, are we not considering certainly that group of drugs which require the judgment of a professional practitioner as an intermediary? We are talking about drugs termed "legend" or "prescription" drugs and described as such by the definitive language of the Durham-Humphrey Amendment (Sec. 503[b]) because some feature of their chemical makeup, some possibility of their pharmacological effect, nicety of administration, of dosage, make them inherently dangerous. The physician-patient relationship is one manner of minimizing the inherent danger by raising the level of knowledge and prudence that attends their use. For this reason, a legend drug dispensed or sold even by a physician, outside of the doctor-patient relationship, is misbranded[25]—its labeling technically violative.

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[24] Presented at the Food and Drug Law Institute Seminar at the School of Law, Northwestern University, Chicago, Illinois on April 14, 1967, by Julius Hauser, Assistant for Regulations, Food and Drug Administration.

[25] *Brown, Thomas Guy v. U. S.*, 250 F. 2d 745 (CA-5 1958); cert. denied, U. S. Sup. Ct., 356 U. S. 938 (1958).

Since it is turned over to a lay person without adequate labeling, the act is negligent. The intervenor distributor is liable, rather than the manufacturer. In these instances, however, vendor and vendee are frequently equally guilty, and criminal prosecution obscures the product liability implications.

The FDA holds that the manufacturer must face the real probability that in the absence of satisfactory exclusory description, every person may be reasonably expected to use his product. If his product is a prescription drug, every person so directed by a physician may be reasonably expected to use his drug.

In a sense, the FDA's interpretation of the thrust of 502(n) with regard to advertising of prescription drugs is avant garde product liability theory. Until recent years, most courts held that unless the class allergic to a product is large enough to have warranted a warning, injuries traceable to these are not compensible. The manufacturer had a right to expect his product would be used normally by normal people.

Now the product brochure and the advertising must recognize even isolated and singular reports of allergy and unusual susceptibility and thus warn all users through their physicians. In an equivalent manner, courts have adopted a response that is pitched to the plaintiff's misfortune even where it is relatively rare in proportion to the years and volume of usage.

It seems fairly obvious from the viewpoint of product liability that the labeling of similar products, whether actually identical or claimed equivalent, should have similar labeling at least substantively.

This would be especially pertinent in the case of prescription drugs where by the nature of the prescription legend, the manufacturer, the practitioner and the public understand that without the complete and full disclosure contemplated by Chapter 5 of the Federal Food, Drug and Cosmetic Act, and the effectuating regulations applicable, it has a potential for harm.

Equivalent Chemical Compounds

This shadow has arisen in the past, where drugs have come through the NDA procedures at different times, and the later submissions might conceivably carry more elaborate and comprehensive labeling as to dosage, effectiveness and warnings to achieve approval.

There have also been instances of drugs going through the NDA procedure, while some years later equivalent chemical compounds have not done so. While those marketed under the approved NDA have, through the need for supplements and record surveillance, updated their labeling, and their advertising as a consequence, until very recently the non-NDA'd equivalent chemical compounds have been comparatively ignored.

However, the manufacturer and others who place such products into use, must consider those other responsibilities apart from the Federal Food, Drug and Cosmetic Act and its regulations. A greater quantity or higher quality of disclosive information and warnings presented by his product's competitors may indicate, on his part, imprudence, negligence or willful disdain of constructive knowledge, which is where he stands as party defendant in product liability litigation.

Summarizing the impact of genericism as it is commonly understood today, while the entire question of the therapeutic equivalence of "so-called" chemical "look-alikes" is far from being resolved, manufacturers of such drugs, in the main, recognize the necessity to pattern their labeling language to that of the predecessor. If they fail to do this—and that includes keeping abreast of the predecessor drug's labeling through NDA supplements, National Academy of Sciences—National Research Council (NAS/NRC) recommendations, and following—they are most likely open to seizure on the basis of a misbranding violation, as well as the balance of FDA compliance weaponry. I do not doubt that in some cases, this may indicate changes where grandfather rights of a sort are sought to be preserved.

On the other hand, should a harmed Plaintiff show inadequate or incomplete labeling of the product based on comparison with the standard, this would go far to make out the *prima facie* case in negligence.

This is not to say that advertising or promotion of similar drugs may not address itself to different claim areas, so long as these are within the general body of labeling that serves the drugs.

From a procedural point of view, therefore, if an intervenor such as a hospital pharmacist accepts and utilizes drugs as equivalents, aside from whatever scientific responsibilities he feels required to take for satisfactory evaluation, he should assure himself that the accompanying labeling is indeed equivalent to the prime product he is replacing. His guide as to prescription drugs should be a comparison of labeling using the criteria required in 21 CFR 1.106.

Commentary on Recent Amendments to 21 CFR 1.105

Discussion of the requirement and importance of full disclosure in prescription drug labeling must lead to the "brief summary" concept further elaborated in recent revisions to 21 CFR 1.105, which applies to prescription drug advertising.

21 CFR 1.105(e) describes this as a "true statement of information in brief summary relating to side effects, contraindications, and effectiveness" required in all prescription drug advertisements except "reminder" advertisements and advertisements of bulk-sale drugs, or drugs used as prescription chemicals or compounding necessities, and in the case of these exceptions no claim is made for the therapeutic safety or effectiveness of the drug.

In 1.105(e)(1), as newly promulgated, the FDA has analogized its labeling authority to the intentional torts of slander and libel, to the extent that it has equated the qualities of labeling to those which determine that matter is libelous rather than slanderous. In short, then, wherever promotional and directive information proceeds from a written script, even though thereafter it achieves publication via electronic, mechanical, radio or televisory means, they consider that the initial preplanned writing or typing and/or printing brings it within the labeling definition of the act.

This is consistent with their earlier attempts to collect and inspect "canned" scripts provided by the manufacturer to detailmen to commit to memory and repeat to their physician contacts.

Although medical or professional detailing is a form of agent representation recognized by the courts,[26] it is neither labeling nor advertising.

It is my opinion that the host of other materials provided to detailers for their educational reinforcement by the manufacturer are not labeling by any definition, and not susceptible to collection and inspection by FDA officials.

I cannot see that the extemporaneous and gratuitous comment by persons not directly in the employ of the manufacturer could provide any basis for imposition of the 1.105(e)(1) requirements. If, however, the material was reused and presented by and for the drugs' sponsor, the argument would be dissimilar.

[26] *Wechsler v. Hoffman-La Roche, Inc.* 198 Misc. 540, 99 NYS 2d 588 (1958).

In the first instance, in relation to scientific observation or testimonials, the utterer has a constitutional privilege to make such observations or testimonials which can only be circumscribed by emergency or national hazard.

In the second instance, it is accepted that while the use of testimonials may not satisfy every element of objectivity, it is not precluded from adoption in advertising unless the testimonials are false and misleading. Once so adopted, however, they are treated as an advertising claim of the sponsor, rather than an individual opinion.[27]

In the case of "reminder" ads, the old rule of thumb was that so long as the advertisement was based solely on the prestige of the name and/or the manufacturer, and did not make a claim or direct usage, it fit the exemption. Presently, this whole area is so highly qualified as to limit the attractiveness of such ads to the sponsor. Therefore, reminder advertisements may contain only the proprietary (or "brand" or "trade" name) plus, as required, the established name and quantitative formula as they appear on the label of the drug package.

Other information which can appear would describe the dosage form, the quantitative content of the package, its price, and the name and address of the manufacturer or one placing it into interstate commerce. Any other graphic, written or printed matter appearing thereon must, as previously, contain no representation or suggestion concerning claims or directions or usage relating to the advertised drug.

Further, the privilege of such an exemption may be withdrawn on notice by the Commissioner if he finds that the drug as used has a propensity for fatalities or serious damage.[28]

This sounds like a price list minus descriptive comment on the use of the drug, as differentiated from a catalogue or product manual that could be used as a prescriptive reference. However, there is no indication in either statutory or decisional law that a price list deletion can be forced upon a manufacturer because a drug carries a high danger potential. Such a deletion would come as normal incident to measures available to the Commissioner to remove the product from the marketplace.

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[27] See *Fulton* case, footnote 12.

[28] See James Hoge: "An Appraisal of the New Drug and Cosmetic Legislation," 6 *Law and Contemporary Problems* 116, Regulatory Exemptions based on statutory precursors.

No doubt in preparing the 1.105 enlargement, the agency felt that in the interest of promulgatory tidiness, the advertising regulation should achieve a symmetry in scope with its labeling antecedent 1.106, and therefore included bulk-sale drugs. Aside from the doubtful logic, the doubtful authority is manifest. Such drugs and chemicals are advertised in the trade amongst scientifically knowledgeable people. If a manufacturer or other distributor feels that his process of comminution or solution or precipitation makes for a more efficient or efficacious product, he and his statements are measured in the marketplace by his peers and from the vantage point of their knowledge and experience. This is not the disadvantaged general consumer that legislators had in mind when Section 502(n) came into being.

Since advertising copy that is at variance with labeling so as to make it false or misleading in any particular, (and this includes rendering it inadequate), has been held by the courts to misbrand the product, paragraphs (3), (4), (5) and their subparagraphs found under the new 1.105(e) seem to be superfluous.

No doubt they would have value as internal memoranda for training personnel involved in the fabrication and screening of prescription drug advertisements. However, outside of the mechanics of identification written into the basic statute and initial regulation, the most important judgment that must be made by the ad sponsor and the ad regulator is whether in substance and design, in its totality, this prescription drug advertisement seen by an average physician of ordinary prudence would mislead him, intentionally or not, as to its prescription or administration in terms of its safety and usefulness for his patient's needs.

1.105(e)(3): Untrue or misleading information in any part of an advertisement is not considered cured by having, in another part of the advertisement, a brief statement of true information concerning side effects, contraindications and effectiveness of the product. Further, since this paragraph promotes a total view of the advertisement, inadequate qualification or information with regard to any statement or theme requires, at least, concise notice to the effect that some qualification exists, and a prominent reference on each page to the fact that the reader or viewer has available a more complete discussion of such qualification or information elsewhere in the same advertisement.

An advertisement in a medical journal, like a mailing piece of limited intent and distribution, need not include information relating

to all purposes for which the drug is directed in its full disclosure labeling. One has the option here of limiting the scope of the ad to a description of the usefulness of the drug for selected purposes to be recommended or suggested in that particular ad. In doing such, however, the sponsor must cover, in adequate fashion from his labeling, the information on effectiveness relating to specific indications for use he has set forth in the advertisement.

The same reasoning and limitation is applied to a recitation within the advertisement of side effects, warnings, precautionary advice, contraindications and similar considerations from the approved labeling for the product.

1.105(e)(4) qualifies the labeling basis for advertising where the former has evolved from the new drug approval or certification procedures. Since the possibilities of changing the labels of "old drugs" are limited by the fear of loss of status, and new drugs and antibiotics are held to the labeling particulars consonant with their approval or certification, derivatory advertising obviously follows the same base limitations.

1.105(e)(5) redundantly assails the concept of brief summary as requiring a fair balance in presentation of the "pros" and "cons" of the drug but admits that imbalance may be permissible if, by some form of measurement, the brief summarization has nonetheless achieved comparability in depth and detail between such "pros" and "cons." It also repeats the admonition from the labeling regulations that descriptions of the sort required here must relate to the particular advertisement, and not omit material facts required to be revealed.

Patterns of Violation

1.105(e)(6) describes twenty circumstances of prescription drug advertisement violation which "among other reasons" would reveal non-compliance by the sponsor. It therefore describes advertisements that are false, lacking in fair balance, or otherwise misleading or violative of Section 502(n) of the Act. These are set out in 20 patterns:

1. Representations, comparative or otherwise, that exceed prior approved representations and comparisons related to safety, effectiveness, breadth of usage;

2. Individual drug comparisons in any particular, representing greater safety and effectiveness for the sponsor's drug, without substantial back-up evidence[29] or clinical experience;

3. Contains outdated favorable opinions or information, or references and/or quotations that are over-favorable on the basis of available information and experience;

4. Give a false picture of safety by selective presentation of quotations and reference that exclude the equalizers;

5. Misrepresent a study report to make it seem a larger and more general experience than it was;

6. Misrepresenting effectiveness by non-disclosure of concomitant therapy or test conditions that gives relative indication of placebo effect in human trials;

7. Use pharmacological findings in animals or in vitro studies suggesting their clinical pertinency;

8. Failing to update authoritative opinions by eminent scientists;

9. Quoting or paraphrasing out of context so as to mislead;

10. Using irrelevant quotations or references;

11. Using literature, quotations or references for the purpose of recommending usage not included in approved labeling;

12. Broadening the spectrum of a combination drug's use by componential descriptions rather than sticking to the indications for use of that fixed combination;

13. Using studies on normal subjects without disclosing same when the drug is not intended for use on normal individuals;

14. Pooling data and statistics between unequals, and/or implying larger studies than true;

15. Downgrade, omit, deny, or conceal clinical differences;

16. Misrepresents by using "pharmacological numbers game";

17. Use data details gained at other dosage levels than indicated or approved for the drug to create favorable impression, rather than merely citing them as supplemental reports;

18. Using headlines, subheadlines, pictorial or other graphic matter in a way that is misleading;

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[29] Since the 1962 Amendments, the FDA has made considerable use of the words "substantial evidence." The courts have noted that testimonials do not provide support in the form of substantial evidence. *U. S. v. Hoxsey Cancer Clinic*, 198 F. 2d 273 (CA-5 1952, rev'g DC Tex.).

19. Improper extrapolation of claims, indications to other classes of patients and disease conditions;

20. Generalizes semantically as to side effects and contraindications rather than disclosing specific side effects, unless such general terms are in the approved labeling.

However, with regard to a specific advertisement, one may petition the FDA for a waiver on the basis that despite any incidental resemblance to the foregoing, the advertisement is nonetheless not false, imbalanced, misleading and noncompliant with 502(n).

Of course, this not new language. In *U. S. v. Ninety-Five Barrels Alleged Apple Cider Vinegar,* 265 U. S. 438, 44 S. Ct. 529 (1924), the Supreme Court said of the underlying Section 502:

> The statute is plain and direct. Its comprehensive terms condemn every statement, design or device which may mislead or deceive. Deception may result from the use of statements not technically false or which may be literally true. The aim of the statute is to prevent that resulting from indirection and ambiguity, as well as from statements which are false.

In 1.105(e)(6) the regulation purports to be definite in its proscriptive details and in equating these with certain instances of noncompliance. In 1.105(e)(7) following, the regulation describes less certain determinants: advertisements that *may* be false, lacking in fair balance, or otherwise misleading. Therefore, to the twenty positives, we must add for consideration thirteen "maybes":

1. Advertisements based on favorable information gleaned from poorly fashioned studies;

2. Use of statistical connivance or artifacts in place of true clinical significance;

3. Poor study design and improper basis for statistical evaluation, tailoring figures to desired results;

4. Use of tables and graphs with calculated disorientation to distort and misrepresent relationships, trends or other findings;

5. Incorrect, invalid or inappropriate statistical methodology;

6. Pharmacological claims knowingly insufficiently proven and not advising of such qualifications;

7. Insufficient emphasis on side effects and contraindications by repetition and other emphasis of safety and effectiveness (quantitative);

8. By printing and space techniques, etc., obscures and makes relatively non-prominent, side effects and contraindications;

9. Fails to achieve continuity of advertisement to encourage complete readership when a following page carries the cautionary information;

10. If it is for a selective class of patients it should adequately emphasize their dosage range and their likely side effects and caution any requirements;

11. Fails to have side effects and contraindications equally prominent on both pages of a two-page spread;

12. In multiple page ads, if side effects and contraindications may be bypassed, then pages not having the information should make a prominent reference to its location in that ad;

13. Using information from published or unpublished reports which are falsely or misleadingly purported to be genuine and authoritative.

1.105(1) also was amended to stake the agency's claim to authority and supervision as to advertisements for prescription drugs, (1) which appear in published journals, magazines, other periodicals, newspapers, and (2) those broadcast through media such as radio, television, or telephone communication systems.

On the other hand, the labeling provisions of Section 502 and the regulations, including those requiring and describing "full disclosure," are deemed to apply to:

1. Brochures, booklets, mailing pieces, product cards, file cards and detailing pieces;

2. Bulletins, calendars, price lists, catalogues;

3. House organs, letters;

4. Motion picture films, film strips, lantern slides;

5. Exhibits, literature and reprints;

6. Sound recording;

7. Pieces of printed, audio or visual matter descriptive of a drug;

8. References published (for example, the "Physicians Desk Reference"), physician, nurse, pharmacist product manuals;

Where: (a) these contain drug information, and (b) are supplied by the manufacturer, packer, or distributor of the drug, (c) are disseminated by or on behalf of the foregoing.

As announced in the Federal Register, this amendment became effective as of June 16, 1969.

Rigidity Versus Lucidity

With regard to the newly-amended paragraphs of 21 CFR 1.105 promulgated in accordance with Section 701(e) of the Act to effectuate Section 502(m) therein, I make these comments. I make them according to my personal beliefs, but from the vantage point of one who has enjoyed the practical and academic approach—and employed both—as a participant with FDA in a series of seminars to offer guidelines to industry.

In the *Dotterweich* language of Mr. Justice Frankfurter[30] Congress "has extended the range of its control over illicit and noxious articles and stiffened the penalties for disobedience."

Further, by the amendments to the Act of 1938, such as the Durham-Humphrey Act and the New Drug Amendment of 1962 as they affected labeling, advertising and promotion of drugs, Congress purposefully moved to where these laws could, as matters of guidance, policy and enforcement, "touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection."[31]

We need explanatory education and informational enforcement. We can no more explain by regulation than we can by statute. With these we can only create criteria for sanction and enforcement. The more these approach codification and subcodification, the more rigid, but not necessarily lucid, the structures become.

It is inadequate, false and misleading to represent that given legislative or quasi-legislative enactments and promulgations, the governmental agencies will explain and receive good advertising. To borrow from the language of Circuit Judge Mahoney in *Arner Co., Inc. v. U. S.*,[32] "Nothing is clearer than that the later [regulation] was designed to enlarge and stiffen the penal net and not to narrow and loosen it."

Assuming, then, that the categorization described in 21 CFR 1.105(1) remains unchallenged, or is judicially upheld if it is challenged, we have two areas, advertising and labeling of prescription drugs, with new indistinctions somewhat confusing to all concerned.

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[30] *U. S. v. Dotterweich*, 320 U. S. 277, 64 S. Ct. 134; U. S. Sup. Ct. (1943), rev'g CA-2.

[31] *Dotterweich*, see footnote 30.

[32] 142 F. 2d 730 (CA-1 1944, aff'g DC Mass.); cert. denied, U. S. Sup. Ct. (1944), 323 U. S. 730.

The regulations, however, are effectuators and interpreters of the legislative intent as manifest in the statutes. How much simpler these guidelines appear in the statute itself!

The agencies, both FDA and FTC, will get good advertising and good labeling by adequate staffing, internal and external education and training, and good and appropriate enforcement. As to this latter, a fifty-four-year-old penal statute needs adaptation to modern needs. A staff that has the time and resource to call in the sponsor's people, the advertising agency's people and explain to them *why* copy is unacceptable, the graphics potentially false or misleading, the brief summary inadequate or the format undesirable, will need the enforcement weapons of seizures or criminal prosecution very rarely.

Once the word gets around through such agency roundtable discussions and educations, better ads will follow. This has been true throughout every phase of the life and history of the particular agencies involved.

Within the broad guidelines of Section 502 of the Act and *stare decisis* that has evolved with it are reliable guidelines for the exercise of distinct judgment by both the regulators and the regulated.

It is unfortunate to see the competent FDA official, as well as the average, run-of-the-mill, law-abiding drug manufacturer, "straight-jacketed" within legal compartmentalization created as an answer to the "marginal" minority.

When those who label and advertise and promote, and those who regulate have gone through all their copy for the particulars and minutiae of the Fair Packaging and Labeling Act, their approved New Drug Application and its supplements if they exist, the Wheeler-Lea Act and Section 502, its subsections and the effectuating regulations pertinent thereto, they have traversed, in a time-consuming and expensive manner, a terrain best summarized in the simple, understandable and flexible language of 502(a).

There is also the horrible suspicion that, once having run this gauntlet, the drug sponsor has suffered from obscurance of some labeling and advertising factors that are essential for prevention of product liability allegations, or would provide defensive obstacles to a claimant. **[The End]**

Consumerism's Ultimate Challenge: Is Business Equal to the Task?

By AARON S. YOHALEM

This Paper Was Presented to a Meeting of the American Management Association in New York on November 10, 1969. Mr. Yohalem Is Senior Vice President of CPC International, Inc., Englewood, N. J.

LET'S CONSIDER CONSUMERISM'S IMPACT upon American business from a general, long-range point of view.

Make no mistake: Consumerism is no passing fad. It is not a sometime whim of the marketplace. No amount of invective will make it go away. Nor can its basic demands be met through current marketing techniques.

Consumerism is a distinct socio-political development of our changing and troubled times—a collection of deep-rooted and volatile questions and challenges that go far beyond the ordinary concerns of the marketplace as we have traditionally known it.

Consumerism is a concomitant phenomenon of the great unrest of our cities; of the unprecedented revolt of our youth; of the extraordinary rise of inspired, militant and articulate minorities. It is a reflection of the thoughtful search for *excellence* by our great middle class.

Its aspects are many and contrasting: from the tumult of a mass protest before the national headquarters of a giant retail corporation to the quiet of a judicial chamber where basic law is being rewritten and wholly reinterpreted.

Already the changes it has wrought are far-reaching: We are now at a time when the historic adage—"let the buyer beware"—no longer obtains. It is being replaced with "let the *seller* beware." Consumerism, in short, embodies a profound upheaval in the ancient rules of the marketplace.

In nuclear physics, there is a point at which sufficient fissionable material is present to support a violent explosion. It is called "critical mass"—and our consumer-oriented economy is at just such a point.

For there is no doubt in my mind that the period we are now going through—the end results of which cannot yet be foreseen—marks an historic change which will alter *permanently* the very character of American business itself.

Some view Consumerism as something which business should fear. Some see it as a threat. But I view the entire historical sweep with equanimity—and, indeed, keen anticipation.

I do so because, no matter what else is involved, Consumerism is a challenge to American business. Business, through its performance in meeting and even surpassing yesterday's consumer demands for better products and more choice of products, has aroused consumer expectations for newer, higher levels of satisfaction. And, like all challenges worthy of the name, it offers us a rich opportunity.

Reduced to its absolute essentials, Consumerism challenges business to do better.

Qualitative Aspects

And I do not mean "better" merely in a quantitative sense. For that matter, American business has always been the equal of any *quantitative* demand to produce more goods or services. Simply look at the major role business has played, in a quantitative sense, in fulfilling the consumer demands of the last twenty-five years.

No—I wish to imply in the words "to do better"—the *qualitative* challenge of Consumerism: to help make life itself better *qualitatively*.

We are used to talking of quality in the sense of the styling of an automobile or the texture of a cake or the feel of a synthetic textile . . . or of mechanical efficiency, or purity of ingredients or materials . . . questions of product substance. More recently, we have recognized consumer demands for quality in the forms we use to promote and present our products and services . . . reflected in American industry's capacities to meet and resolve such issues as truth in lending, truth in packaging, or the reduction of package proliferation.

These questions of substance and form have encouraged a stimulating dialogue among all parties to Consumerism: the consumer herself—individually and collectively through consumerist groups—the Government, and the businessman.

More and more individual companies are forming their own consumer advisory panels and joining industry-wide consumer councils to receive, consider and act on consumer grievances of all kinds. Business is participating actively and enthusiastically in hammering out legislative and executive programs to provide better consumer protection and redress of grievances.

Business is on the move in this regard, and examples can be cited in programs of the Chamber of Commerce and the Better Business Bureau's vital consumer involvements, such as its program in Harlem.

However, I am concerned about our ability to appreciate, and therefore, to respond fully to Consumerism's insistence upon *qualitative* change at a new, higher level.

This insistence is already upon us. Whether this striving for qualitative betterment is a trend, a movement, or even a revolution, its goals and purposes are increasingly clear. In a real sense—affecting their total lives—consumers want more value. They not only want things as such, but they want things that have healthful or nutritional or aesthetic or individual and formal *relevance* to the new, vital and wholly unprecedented life styles that we are creating in our society.

The forces that make up Consumerism are increasingly insisting that the corporation replenish the social capital which business has traditionally depended on to operate: ample, clean and healthful air, water and soil; to train and educate society's disadvantaged; and to restore and enhance the other community resources which in earlier days were assumed to be provided by the taxes that business quite simply paid for—and seemingly took for granted.

In our society, we have people with a great many views. The way America has grown and prospered has been through accommodation. Historically, as new forces arise, they insist upon broader responsibility and participation for themselves, while also insisting upon fuller accountability from business. Accommodations are insisted upon. And they usually are made. So that in the end, business activity becomes broader and includes more elements in the related processes of making a profit and serving more broadly the public welfare than had been the case before historic change.

Today the force called Consumerism is the keen cutting edge of this historic thrust of accommodation. But we must remember, it is also an independent force which—through its own machinery—is quite capable of generating change.

Customarily, forces for change have manifested themselves through voluntary, legislative, or regulatory machinery.

This is a quite proper direction.

But sometimes the demands of groups—such as consumers imbued with a socio-political force—are so intense, so immediate and so pressing that they are not quickly or entirely digested by the

normal machinery set up by our system to accommodate and bring about change.

The challenge we face, then, is to recognize and respond voluntarily to merited consumer demands, so we can assure that the thrust of Consumerism manifests itself through the normal machinery to the maximum feasible extent—so the merits can be examined carefully and thoughtfully and the issues resolved in orderly and rational legislative or regulatory change.

Consequences of Inaction

If this is not done, it is perfectly conceivable that Consumerism ultimately could pose a serious challenge to the core of private enterprise: the profit system itself.

Unless we stay ahead of the challenges of Consumerism, unless as intelligent businessmen we either initiate change or make accommodation for it, what I can easily envisage—namely, a challenge to the profit system itself—could very well receive its chief impetus from the solid, respectable citizens who constitute the mass base of Consumerism.

It is not at all inconceivable that well-educated, eloquent, and organized consumerists—composed of middle and upper-middle class housewives, professionals, church-goers, and wage earners—militantly inspired by what they view as uncontrolled inflation and an unresponsive business system, will organize nationally to a far greater extent than they already have. They would consolidate broad, large consumerist organizations. They would become major political forces.

And that is power.

It is also not inconceivable that some of the under-30 generation of executives and professionals who now make up our middle and entry-level management would insist upon—and achieve—such broad representations on corporate boards so as to revolutionize the entire concept of the board of directors in American management.

And that is impact.

The chorus of Consumerism's many voices today is building into something like a crescendo which, if the words could be clearly heard, might carry a message something like this:

> You, American business, shall not continue to make a private profit without full, public accountability and without taking a fuller share of responsibility for our lives and our environment: You shall help assure that the rivers and seas are clean; the air made pure; cities prosperous and safe; health facilities adequate; food healthful; and transport safe, swift and reliable—all in relevant, meaningful, *qualitative* abundance.

These expectations are not entirely new. Any student of American history recognizes that, as corporations have grown in size, as communications have improved—indeed have become instantaneous —the economic process of making a profit necessarily has social consequences; and further, that the profit-making process has such an impact upon man that full accountability to the individual citizen, for both social and economic consequences, *is today a business necessity.*

Today, with the new thrust of Consumerism, the pressures are more direct, the tone is more direct, the voices louder and tougher.

The Ultimate Challenge

In short, Consumerism finally demands that business shall either voluntarily take its full share of responsibility for the common weal of the society it operates in and profits from; or, its ability to make profits will be seriously impaired—even called into question altogether.

This may then well be the "ultimate challenge of Consumerism." The trial that lies ahead will be a grave, trying one, demanding our fullest resourcefulness and dedication.

One of the interesting characteristics of American business is that it often appears to be teetering along the edge of disaster. It appears too often to be too slow—even recalcitrant—in responding to needs that are very obvious to others. The critics of business should not be deceived. The system is remarkably adaptable to the needs of the people, once these needs are perceived.

The challenge for American business today is to perceive the need for intensive, systematic attention—for business as well as social purposes—to areas that have up to now been viewed merely as concerns of "corporate conscience" or "goodwill." Today, survival itself is at stake.

Can industry contribute toward ending hunger and malnutrition . . . toward alleviating pollution of the air, water and soil . . . toward educating and training the disadvantaged . . . toward solving these and other problems of a societal rather than strictly of an industrial nature? I believe so.

For these contributions are intimately involved in the profit process itself. Recognizing this, we will continue to serve the American people's welfare—and assure the prosperity and growth of American business.

That is the ultimate challenge of Consumerism.

Are we equal to the task? **[The End]**

Analysis and Recommendations—The Food & Drug Administration Organizational Review

By FREDERIC V. MALEK

This Report and the Succeeding Articles in This Issue Were Presented at the Thirteenth Annual Joint Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration, Held in Washington, D. C., on December 11 and 12, 1969. Mr. Malek Is Deputy Under Secretary of the Department of Health, Education and Welfare.

THIS BRIEF REPORT summarizes the findings and recommendations of the review of the organization and operating procedures of the Food and Drug Administration (FDA) conducted by a Departmental team chaired by the Deputy Under Secretary, Frederic Malek, and directed by James McLane, Special Assistant to the Under Secretary. Secretary Finch directed that such a review be undertaken in late October, 1969 because of his growing concern over the FDA's ability to carry out its consumer protection responsibilities effectively.

It was recognized that there are a number of substantive problem areas in the FDA which have to be resolved. The large backlog of new drug applications, the long list of food additives classified "generally accepted as safe" which have yet to be tested. and the intramural versus extramural research question are only a few.

It was also recognized that these problems and others are due in large measure to the rapid growth and diversification of FDA's responsibilities, and to the inability of the FDA to adjust properly to these changes. Therefore, the focus of this review was on FDA's basic structural and procedural difficulties, which inhibited its response to a rapidly changing environment. The objective was to develop a plan of action to create a strong foundation on which FDA

could build solutions to many of these very critical problems of consumer protection.

Objectives and Conduct of Review

The specific objectives of the review were to:

Evaluate the organizational placement of FDA within the Department of Health, Education and Welfare (HEW);

Determine the optimal internal organization of FDA;

Develop appropriate means of improving communications both within FDA, and between FDA and external groups;

Evaluate the adequacy of present management procedures and recommend improvements; and

Identify other operational improvement opportunities which could be implemented once the solid organizational and procedural framework was established.

To accomplish its objectives, the team:

Critically reviewed thirteen past studies of the FDA dating back to 1955;

Conducted intensive interviews with over sixty FDA, Environmental Control Administration (ECA), National Air Pollution Control Administration (NAPCA), Consumer Protection and Environmental Health Service (CPEHS) and other Public Health Service (PHS) personnel at all levels;

Interviewed over thirty-five interested outside parties, including Congressional staffs, consumer protection groups, ex-FDA personnel, industry representatives, state health representatives, and environmental specialists;

Analyzed findings, isolated major trends affecting the FDA, and identified major problem areas;

Developed alternatives for a more effective FDA and criteria against which to evaluate those alternatives; and

Analyzed alternatives and made recommendations to the secretary of HEW.

Major Problem Areas

(1) *Internal to the FDA*

As a result of (a) the increasing complexity of its traditional products and continual assignment of responsibility for new products, (b) greater awareness of, and pressures from, consumers for broader and more effective protection, and (c) its own increasingly sophisticated ability to identify potential health hazards, the FDA has

experienced tremendous growth and diversification of its responsibilities in the past fifteen years. This growth (from a $5.1 million agency in 1955 to a $72 million organization today), which is expected to continue, has caused serious organizational and procedural problems:

Neither an effective organization nor formal procedures for pinpointing authority and responsibility have been developed.

The mechanism for top-management planning and control of FDA's activities is inadequate.

Personnel are used inefficiently, despite the large backlogs. "Crisis" items emerge with little forewarning to top management.

(2) *External to the FDA*

At the same time that FDA's internal problems are mounting, it is becoming increasingly clear in retrospect that, despite the conceptual appeal of dealing with problems arising from the "total chemical environment" in an integrated way, the July, 1968 placement of the FDA in the new Consumer Protection and Environment Health Service has weakened, not strengthened, both HEW's consumer protection activities, and its more purely environmental activities. There has been little practical interaction between the FDA and the other CPEHS components.

The FDA's pressing regulatory responsibilities preclude CPEHS from conducting broad chemical-environmental research. In addition, sensitive FDA issues have forced the CPEHS staff to divert valuable time from environmental policy to FDA operational matters. Finally, the injection of the CPEHS staff between the Office of the Secretary and the FDA has hindered communication between the FDA and other groups.

(3) *Summary*

In summary, neither the internal organization and procedures of the FDA, nor the current organizational placement of the FDA within HEW, are truly conducive to a strong FDA or a strong CPEHS. The following recommendations are intended to remedy these structural and procedural inadequacies, and to provide a basis for further substantive improvements in both key areas of major departmental concern—environmental health and consumer protection.

Recommendations

(1) *A new "Environmental Health Service" should be established to replace the present Consumer Protection and Environmental Health Service.*

Environmental problems are emerging as key issues of the 1970s. To date, environmental programs in HEW have not received the priority attention that they deserve. HEW should recognize this opportunity to improve significantly its environmental effort, particularly as it relates to health hazards to man arising from his environment.

Accordingly, we recommend that a new Environmental Health Service be established to coordinate and focus all of the Department's environmental efforts in one operating agency. This new agency is to devote its full attention to problems directly related to the environment, without distractions from matters less directly related to its principal mission. The present ECA, NAPCA, and balance of the CPEHS staff should form the nucleus of this new agency.

(2) *A top-level Task Force on HEW Environmental Programs should be established.*

We recommend the establishment of a top-level Task Force on HEW environmental programs, reporting directly to the Secretary and consisting of key HEW officials as well as outside experts, to:

Define what HEW's environmental policy should be, and how HEW efforts should mesh with those of other Departments;

Examine the current HEW effort in environmental health and make recommendations for needed changes; and

Define the mission, functions, and organization of the new Environmental Health Service.

(3) *The FDA should be separated from the CPEHS, and become a fourth major health agency reporting to the Assistant Secretary for Health and Scientific Affairs.*

With the exception of certain limited savings from consolidation of administrative services, the combination of consumer protection and environmental programs in the same operating agency (CPEHS) has resulted in few practical benefits. On the other hand, the combination has caused some major problems which have weakened both consumer protection and environmental programs in HEW.

CPEHS has not been able to focus its principal attention on its intended mission—a coordinated attack on environmental problems. Rather, the CPEHS staff has tended to become embroiled in FDA operating matters because of their significance and sensitivity. In addition, the creation of the CPEHS staff has drained needed manpower from the FDA and has caused a serious morale problem with FDA personnel. Lastly, the evolution of a strong environmental

agency within HEW will continue to be undermined if FDA is a part of this agency, due to the independent importance of the FDA.

Thus, we conclude that both the FDA and the remainder of CPEHS will benefit from the separation.

(4) *A Deputy Assistant Secretary in the Office of the Assistant Secretary for Health and Scientific Affairs should be established to help coordinate the environmental and regulatory health activities of the Department.*

The issue of how man's total chemical environment affects his health is of great importance and must be dealt with in the new organization. It is our conclusion that, because of the impact of each of the health agencies on this issue, it can best be addressed at the policy level rather than at the operating level. Accordingly, we are recommending that a Deputy Assistant Secretary with a small staff in the Office of the Assistant Secretary for Health and Scientific Affairs be charged with the responsibility for coordinating the various environmental and regulatory programs in the four health agencies.

(5) *The present Bureaus of Science, Medicine, and Compliance should be abolished and should be replaced by a Bureau of Foods, Pesticides, and Product Safety and a Bureau of Drugs, each with full responsibility and authority for all activity from initial research to final regulatory action.*

The Bureau of Veterinary Medicine should be retained as presently constituted, drawing on the Bureau of Drugs for necessary outside investigation and compliance support. The positions of Associate Commissioner for Science and for Compliance should be retained to provide staff policy advice and to assure a strong medical, scientific, and regulatory stance by the FDA.

Problems With the Present Organization

Under the present FDA organization, authority and responsibility for research, investigation and compliance actions pertaining to any single product or problem are fragmented. Because responsibility cannot be pinpointed below the Office of the Commissioner, even minor decisions are forced up to that level. At the same time, the fragmentation of authority permits research planning decisions (particularly decisions to review previously approved products) to be made at a low level in the organization. Finally, the Bureau of Medicine, without its own laboratories, has little leverage to assure adequate and timely laboratory support from the Bureau of Science.

Advantages of the Reorganization

The recommended organization allows authority and responsibility to be pinpointed within a particular bureau. It enables each bureau to concentrate on its major product areas without jeopardizing other product areas. It permits greater use of a multi-disciplinary team approach to problem-solving. It establishes clearer lines of authority to FDA's field compliance activities, which currently must work simultaneously with the Bureaus of Compliance, Science, and Medicine, the Assistant Commissioner for Field Coordination and the Associate Commissioner for Compliance on the same product. No one person is accountable for ensuring positive coordination and action.

Implications of the Reorganization

The actual reorganization required as a result of this recommendation is slight.

The Office of Product Safety will be transferred to the new Bureau of Foods, Pesticides, and Product Safety. Although FDA's product safety efforts presently are too small to warrant a separate bureau, the Office of Product Safety will be strengthened—wherever possible, by transferring related scientific units to the Office—both to provide a stronger initiative in the relatively new area of product safety, and to prepare for eventual elevation to full bureau status.

Drug-related units of the Bureau of Science[1] will be transferred to the new Bureau of Drugs. To preserve intra-disciplinary interaction, no scientific units will be physically relocated. All activities of the Bureau of Compliance, already largely divided internally along product lines, will be assigned to the two new "product" bureaus.

Despite the limited personnel shifts involved, this reorganization significantly alters the focus of the FDA. Responsibility and authority are clearly delegated to the new bureau heads. The multi-disciplinary approach to investigation is encouraged. Finally, by relating compliance activities more closely to the scientific and medical activities, the organization should foster more rapid compliance actions and permit greater guidance to industry.

[1] The Division of Pharmaceutical Sciences, the Drug Pharmacology Branch and part of the Pathology Branch of the Division of Pharmacology and Toxicology, and parts of the Division of Microbiology.

(6) *The following additions to current operating procedures should be instituted to supplement the above organizational recommendations:*

Implement a planning and control system through which the Commissioner can direct (according to his set of priorities) and monitor key research and investigative activities.

Install a simple procedure by which anyone in FDA can initiate a "critical problem report" to go immediately to the Commissioner.

Designate, for each new application or marketed product to be investigated, a "product manager" who will be held responsible for all activities relating to that application or product, including final recommendation to management.

Expand the concept of using part-time science advisors from the private sector (now in each District Office) as "ombudsmen." Each headquarters bureau should have both a science and medical advisor.

Adopt the proposal to set up public forums on specific problem areas through the National Academy of Sciences, with representation from industry, consumer groups, universities, and interested government agencies.

Next Steps

The above recommendations, which should be substantially implemented by February 1, 1970, should provide a sound basis for more substantive and far-reaching improvements in FDA's operations. The following is a list of possible areas for additional improvements which warrant further in-depth study after February, 1970:

Improving recruitment, training and career development programs to upgrade the quality of all FDA personnel;

Increasing the efficiency of operations in the Bureau of Drugs (present Bureau of Medicine) through greater use of paraprofessionals and more efficient utilization of medical doctors;

Streamlining all application review processes in the FDA;

Identifying and evaluating new investigation and regulation alternatives, such as: self-certification by industry, investigation by an independent quasi-governmental body, broader use of industry fees to finance costs of regulation, and delegating authority for scientific decisions to advisory groups;

Improving the adverse reaction reporting system; and

Creating a Consumer Advisory Committee.

[The End]

Progress in Consumer Protection

By HERBERT L. LEY, JR.

Dr. Ley Is the Former Commissioner of Food and Drugs, Food and Drug Administration.

OUR PROGRAM PLANNERS have given me a good title for this paper, but were I to have a choice I would call it "Inside FDA." This has the proper air of mystery, which is appropriate because so much of what I shall tell you has not been reported by the news media. I'm sure it isn't news that during this past year the Food and Drug Administration (FDA) became responsible for activities to:

Assure safe milk supplies through cooperation with state and municipal milk control authorities;

Assure safe food, water, and good sanitary facilities for travelers on trains, planes, ships, busses and the interstate highways;

Promote sanitary practices in restaurants and other food service facilities;

Assure that shellfish are harvested from unpolluted waters and handled in a sanitary manner;

Protect victims of accidental poisoning by providing physicians with information needed for emergency treatment;

Investigate cases of poisoning by pesticides and study the effects of pesticide exposure on human beings;

Determine the causes and find means of preventing accidental injuries from use of consumer products, including flammable fabrics and mechanical and electrical products.

Intensified Drug Inspection Program

During the same period, we launched a new approach to better drug quality, the Intensified Drug Inspection Program or "IDIP,"

as we call it. The program combines the regulatory and voluntary approaches to compliance in a new way. Its aim is to insure that manufacturers either apply current good manufacturing practices or stop making prescription drugs. The method is to help them identify their problems so they can improve their practices.

The intensified drug inspection differs from past drug plant inspections in three ways. First, there is an in-depth study of manufacturing and control facilities by teams of highly trained FDA drug inspectors and chemists. Sufficient time is set aside to examine carefully every important step in manufacturing and control. Second, special efforts are made to keep the firm's management currently advised of findings and of their significance. Representatives of management are often invited to visit FDA district offices for informal conferences with district directors and other top FDA officials. These conferences, together with on-the-spot exchange of information with inspection teams, provide a maximum opportunity for voluntary correction of deficiencies. Finally, the intensified inspections are continuous until the manufacturer's production and control facilities are in full compliance, or until it is evident that the firm will not make effective corrections voluntarily, in which case court proceedings can be started.

During the past fiscal year, 220 intensified inspections were started. At the end of the year, 131 were still in progress. All but six of the eighty-nine completed inspections were terminated after voluntary corrections brought operations into compliance with the law. The cooperation of management with our inspection teams has been excellent. Many drug manufacturers are making the capital investment necessary to insure the quality of the nation's drug supply. One firm in the Midwest spent half a million dollars for this purpose. Other manufacturers have reduced production when necessary so that manufacturing and control facilities are not overworked. They have stopped making products they are not equipped to make. A few have voluntarily gone out of the prescription drug business. Efforts to objectively measure changes and trends in the industry's manufacturing practices are under way.

Now, for the first time, I would like to announce still another new approach toward better drug quality. It represents a significant departure from past policy.

An important by-product of the IDIP inspections is an extensive list of the kinds of errors or malpractice found in these inspections. From this we derive the instructions given to our field districts as to when court actions should be started. These Administrative Guidelines should be extremely helpful to management to check their operations for compliance, and we are planning to make them available for this purpose. Such lists and Guidelines are not a substitute for the regulations, which are based on the law. Nor can any such list anticipate all possible mistakes which can cause violations. But regulations, on the other hand, are not a substitute for experience, although the Good Manufacturing Practice regulations closely reflect what has been learned through these inspections. So what we have is a list of illustrations which should make the regulations more effective, and a statement which defines what we consider to be actionable under the law.

Expanded Responsibilities

To return to the major expansion of the Food and Drug Administration's responsibilities: These were brought about through the transfer of consumer protection activities which originated in the Public Health Service, but which were related and complementary to FDA's mission and programs.

Little known to the public, the importance of these programs is obvious from their content. Perhaps in FDA they will have greater visibility. Unlike other FDA programs which are directed to administration of specific and detailed statutes, these activities are based generally on the broad authorities in the Public Health Service Act to protect the public health—through research, technical assistance, and cooperation with state and local health agencies. I say *generally* because the Interstate Travel Sanitation Program is based on the specific Interstate Quarantine Regulations which are authorized by law.

In the milk and food sanitation programs, model ordinances and codes, developed with federal collaboration, are adopted and enforced by state and local agencies. It is a distinct system of control which has achieved considerable success. Recognizing the results achieved, FDA is committed to a continuation of the operation of these programs in substantially the same manner as in the past.

Within the Food and Drug Administration, important organizational changes were made. Plans to merge the Bureau of Volun-

tary Compliance and the Bureau of Regulatory Compliance were carried out, with General Fred Delmore as Acting Associate Director of the Bureau of Compliance. The Bureau of Voluntary Compliance (BVC) was established in 1964 to carry out recommendations of the Second Citizen's Advisory Committee that FDA should develop and strengthen its educational activities to protect consumers by preventing law violations. Under General Delmore's leadership, education for voluntary compliance became an integral part of FDA's method of administration. In fact, the consolidation of these educational activities with the law enforcement program was based on the realization that they are an essential part of a total strategy, so that all compliance efforts were coordinated in a single bureau.

Included in the new bureau was a new Division of Sanitation Control, established to conduct the milk, food service, shellfish, and interstate travel sanitation programs transferred from the Public Health Service. The research activities associated with these programs, and their laboratories at Cincinnati, Ohio, became part of the FDA's Bureau of Science, headed by Dr. Keith Lewis, who for many years was associated with the milk and food programs.

The accident prevention programs which I mentioned, and the National Clearinghouse for Poison Control Centers, were placed in a new FDA Office of Product Safety. In addition to the problem of accidental poisoning, this Office was concerned with injuries resulting from electrical, thermal or mechanical hazards of products and appliances used in or around the home. The Toy Safety Act, passed in November, expanded the authority previously granted to ban the distribution of toys that are hazardous.

Hazardous Substances

In FDA, this is a new field of consumer protection, yet one closely allied to our enforcement of the Hazardous Substances Act. It is estimated that 18,000 deaths and 90 million injuries annually are associated with consumer products other than poisonous substances. To obtain better data on this problem, a national network of 126 hospitals has begun reporting such injuries to FDA for computer tabulation. During the past year, incidentally, over 100,000 clinical reports on poisonings were received and processed for the Poison Control Centers. Through such data we hope to determine what future steps will be needed to prevent accidental injuries.

The pesticide research programs which were transferred to FDA have great significance. Particularly, they are investigating the impact of pesticides in the environment on the bodies and health of human beings. These activities, with laboratory facilities at Atlanta, Georgia, Perrine, Florida, and Wenatchee, Washington, were consolidated with FDA's long-continued and highly successful research on analytical methods in the Bureau of Science. Our total scientific capability in the area of pesticide safety will be greatly strengthened by the addition of these new programs.

Multiplying the number of pesticide chemicals by the number of crops on which their use is permitted, over 3,300 pesticide tolerances have been officially established since 1954 when the Pesticide Amendment was passed. The methods for detecting and measuring residues have been developed to the point where they are fantastically sensitive and accurate. We can say with great assurance that compliance with the tolerances is very high, and that our foods are safe. On the other hand, residues far below the safe legal tolerances are detectable on a very wide scale. Over half of some 12,000 samples analyzed in 1969 contained residues of one kind or another. This is a situation which requires constant vigilance and a major research effort to resolve the many questions that are still unanswered.

Organizational Changes

In another organizational change, the FDA's Consumer Specialist Program was transferred to the Consumer Protection and Environmental Health Service. This program was established in 1952 by the late Commissioner Charles Crawford. It was a pioneering effort by a Government agency to inform itself about the consumer's problems, and to inform consumers about the protection provided by law. In addition to continuing their educational activities in regard to FDA programs, the specialists were given a new assignment to provide information services in the areas of air pollution and environmental health.

Still another organizational change of great importance was the establishment of a National Center for Micro-Biological Analysis at Minneapolis. Its function is to test, continuously, and on a large scale, samples of products which are subject to contamination by disease organisms. The need for such a facility was made evident in our efforts to reduce the incidence of Salmonella in certain foods and drugs.

Here I should call your attention to the very comprehensive study and program to eliminate this menace to health which was drawn up by an expert committee of the National Academy of Sciences under a contract with FDA and the Department of Agriculture. This remarkable 200-page plan of action contains some fifty-five specific recommendations for the many public and private organizations which are concerned with food safety. I urge your careful attention to this "Evaluation of the Salmonella Problem," for the FDA is doing its utmost to carry out its share of this long-range effort. During the fiscal year of 1969, there were some forty recalls from the market of foods that were found to contain Salmonella.

Enforcement of the Federal Food, Drug, and Cosmetic Act continues to be FDA's major obligation to consumers. More than $100 billion each year of the nation's commerce is in products subject to this law—a conservative estimate in the light of today's prices. Our policy continues to emphasize preventive measures rather than court proceedings. Court actions are necessary, and it is our duty to use them when there is negligence, fraud, or persistent disregard of the law. But as a means of consumer protection, court proceedings can be extremely slow, expensive, and ineffective. The number of court proceedings to enforce the Federal Food, Drug, and Cosmetic Act has continued to decline, from a total of 839 started in fiscal 1968 to 513 in fiscal 1969. Instead of going to court so frequently as in the past, we have been relying heavily on product recalls to provide faster, more effective consumer protection. In the year ending June 30 we had 910 product recalls, about the same number as in 1968 when 902 were recorded. The majority of these, 709 in 1969, were drugs. Of these, 78% involved prescription drugs and 18% over-the-counter drugs for human use, while 4% involved veterinary drugs and medicated animal feeds.

Substandard Drugs

Defective drugs, due to errors in manufacturing, packaging, labeling, or control procedures, have continued to be one of our most serious problems. Some of the recalls have involved large quantities of critically important products. For example, millions of bottles of intravenous solutions, a major hospital item, had to be recalled because of bacterial contamination due to defective containers.

Several approaches are used to reduce the frequency of substandard drugs. One is the testing program that we started at

our new National Center for Drug Analysis at St. Louis. Here, ultra-modern equipment is making it possible to handle large numbers of samples by mass production. Over 2,000 samples of cortisone were analyzed in one such survey. Two important improvements in drug regulation are made possible by such a study: First, an informed judgment about the overall quality of important groups of drugs. Where high defect rates are found, special attention can be given to identifying the causes. Second, by repeating surveys, progress can be measured. For example, one study of this kind shows a significant improvement in the quality of reserpine tablets in 1969, as compared with 1967.

Another approach to drug quality is by the development of guidelines in the form of regulations. We have completed the first comprehensive revision of the Current Good Manufacturing Practice Regulations for Drugs, originally issued in 1963. If adopted, these regulations will require labels of all drugs to bear expiration dates reflecting the results of stability tests. These rules also reflect what has been learned in the past six years with regard to manufacturing and control procedures.

All of you know that the Food and Drug Administration is engaged in an unprecedented effort to clear the market of ineffective drugs, and so to carry out the mandate of the law that drugs shall be shown to be effective as well as safe. The nation's leading experts on therapeutics were empaneled by the National Academy of Sciences-National Research Council to evaluate some 4,000 new drugs for human and veterinary uses which had been approved between 1938 and 1962 on the basis of safety alone. They have made their reports and recommendations. We have an unparalleled opportunity to make rational therapeutics a reality insofar as products and their labeling are involved. The drug industry is fighting us in the courts, and thus far they have had some success. Far too much is at stake for us to relax in this effort. We shall continue to proceed against ineffective drugs, by court action, if necessary, and it seems to be necessary wherever a large financial interest is concerned. Fortunately, only a small part of the total drug supply is involved.

More Inspections Needed

Due to the higher priority of health-related activities, we are seeing a further decline in activities to protect the consumer's pocketbook. The Intensified Drug Plant Inspections, for example, took 195

man-years in fiscal 1969, by an inspection staff which averaged only 590. The inspector's job is constantly more complex, requiring more time in the plant. In consequence of these trends, there was a substantial decrease in the total number of inspections made and samples collected. I wish it were possible to devote more time to such problems as short weight, deceptive packaging, and enforcement of the food standards. If we encounter any real breakdown of compliance in these areas it may be difficult to regain it.

Legal actions in this field involved a "chocolate" milk; seizures of egg noodles, egg yolks, breaded shrimp, mozzarella cheese, and a salad dressing which failed to conform to standards; mixed salted nuts consisting mainly of peanuts but with label illustrations showing substantial quantities of other kinds of nuts; strawberry preserves low in fruit but not labeled "imitation"; and "orange" juice blend, which was also an imitation and not so labeled.

The major purposes of food standards are to protect the health, nutrition, and pocketbooks of consumers by preventing debasement in the composition of foods, and to require truthful and informative labeling. We believe the dollar benefits to consumers are very substantial, but to measure them has been most difficult. A research contract was awarded recently to develop a procedure whereby these dollar benefits can be calculated.

There has been little enforcement of the Fair Packaging and Labeling Act because of lack of funds, but eleven men were assigned to this program, so that we could move ahead quickly in this field.

The food labeling regulations were effective July 1, 1968, but when it became apparent that virtually all food packages and labels would have to be changed, we issued a statement prescribing conditions under which existing stocks could be used until June 30, 1969. More than 3,300 firms applied for time extensions and met the conditions.

A really tremendous effort was made by the food manufacturers and the packaging industry to change practically all of their labels to comply with the new law. Although we made no survey, we believe that a large majority of the food packages now in the stores are in compliance. Fourteen exemptions were issued, dealing with problems of special types of packaging, such as penny candy, egg cartons, soft drink bottles, etc.

Labeling regulations for cosmetics and over-the-counter drugs went into effect on December 31, 1969. In general, these are like the food labeling regulations.

We have been working with the Federal Trade Commission to draft regulations dealing with "cents off" promotions, where they have jurisdiction over products other than foods, drugs or cosmetics. Regulations on deceptively slack-filled packages have not been drafted. These projected regulations involve considerable research on production technology, requiring substantial time and manpower.

Our appropriations increased—including funds for programs transferred from other units of the Public Health Service to FDA, from $67.2 million in fiscal 1968 to $75.7 million in 1969, with $78.8 million budgeted for the current fiscal year 1970. Approximately 20% of these totals was for the transferred activities. Government-wide pay raises, however, estimated to cost FDA $7.1 million in fiscal 1969 and 1970, necessitated a net reduction in both ongoing and projected activities amounting to about $3.4 million over the period. Allocation of funds by product categories reflected the priority of health protection, with an increase of over $3 million for drug activities in fiscal 1970.

Sharing the Responsibility

Technology and law combine to make food and drug protection a very large and specialized field. I have become convinced that it is impossible for anyone to know *everything* that is going on "inside FDA." In fact, very few people know the whole story about those few developments which are well publicized. This creates problems for all of us.

When the late Charles Wesley Dunn conceived the idea of the Food and Drug Law Institute, and secured the support of far-sighted business leaders, he created an institution of great value. Here we have the opportunity to put essential facts on record, to compare opposing views, and to the best of our ability, to tell it like it is. I only wish it were possible for all the consumer and business leaders, educators, and scientists of our entire nation to share in these discussions. I'm sure it would do great good. **[The End]**

Nutritional Considerations in Foods

By DALE R. LINDSEY, PH.D.

Dr. Lindsey Is Associate Commissioner for Science of the Food and Drug Administration.

THE QUALITY STANDARDS FOR FOOD in the United States have changed very little in recent years, and, on the basis of acute need, there has been relatively little cause for changes in the past. Standards of quality are based primarily on tradition, and the tradition has been established through home preparation of foods. These types of quality standards reflect nothing of the nutritional value of the food. In fruits and vegetables, quality is determined by color, size, absence of bruises and marks, etc. Meat grading has been largely based on conformation, or "show" quality, and on the content of intermuscular fat or marbling; both may be of negative nutritional or economic significance and may have little to do with taste appeal. In no instance is flavor a consideration of standards, although individuals will rank it high in selecting foods.

The Food and Drug Administration (FDA) in particular has had very little to do with nutritional considerations as long as the food was safe from harmful added chemicals, was processed in a sanitary manner, and was free from objectionable microbial spoilage. Some spoilage, as in cheese, is perfectly acceptable and even highly prized.

Three agencies share primary responsibility for protecting the consumer's food. The Department of Agriculture's (USDA's) field staff is by far the largest, but of no more importance to the public than the staffs of FDA and the Bureau of Commercial Fisheries of the Department of Interior. In a more tangential but a highly important respect, the Federal Trade Commission (FTC) oversees the advertising of foods. All four agencies are becoming increasingly

aware of the need for nutritional standards, although the USDA long has sponsored studies of nutritional quality. One of the recommendations shared by several panels of the White House Conference on Food, Nutrition, and Health was for the consolidation of food regulatory functions in one agency, the Department of Health, Education and Welfare.

Whether this consolidation takes place or not,[1] the FDA must develop its resources in nutrition, simply because nutrition is equally as important to the health of the consumer as any other quality. How long it will take to add nutritional quality to FDA standards is unknown, but it could happen quickly. Working together with the FTC, an educational program could be mounted which could influence public standards of acceptance without altering the legal standards, but neither the FDA nor the FTC has the resources to do it.

Nutritional Inadequacy

Poor nutritional quality is often associated with traditional foods and their cooking. In this country, pellagra was probably the most notable of the nutritional diseases that we have had over a geographic area, but Dr. Arnold Schaefer's studies reveal that nutritional inadequacy is still with us in many parts of the country. Most parents recognize and deplore some of the eating habits of their children, but many of these same parents are at least equally addicted to convenience foods which may have nutritional deficiencies.

Even harder to overcome are the ingrained habits of peoples who have suffered malnutrition for generations. In Central America the introduction of a protein-fortified foodstuff called Incaparina (after the Institute of Nutrition for Central America and Panama) was hard to achieve because it was strange, even though it had been carefully designed to substitute for accepted foods. The eating habits of the people who needed it were hard to change and they remain so. Where Incaparina has been successful, the success was due to the dramatic response to adequate diet produced in some infants where kwashiorkor was not too advanced.

[1] *Editorial Note:* As of December 11, 1969, FDA was placed directly under the authority of HEW's assistant secretary for health and scientific affairs. Further internal changes replaced the existing bureaus with a bureau of drugs and a bureau of foods, pesticides and product safety.

The Peruvian Indian was thought to be hereditarily small in stature but when, as a child, he was given an adequate diet he was found to be of normal size for man in general; the small stature was a hypocaloric reflection. While genetics certainly dictates size potential in the individual, we don't know how often small size is the result of inadequate nutrition, whether from the quantity and quality of food, or the metabolic inadequacy of the individual. Work is needed as much on nutritional quality as on the other possible factors.

Among food experts, it is generally conceded that the world's supply of food-available protein will be sorely taxed by the so-called population explosion. Thus, in the midst of affluence and technological miracles, we are faced with the same problem of protein deficiency often found in primitive people. While it is true that the agricultural productivity of many areas of the earth can be improved as dramatically as it has in the United States, the exponential nature of today's population growth may outstrip progress in agricultural production. If it does, it will constitute an effective control of population, but that would hardly be an acceptable method.

Our greatest hope lies in manufactured and in fortified natural foods. The difficulty with new foods will remain, as it always has, in the acceptability of something new. All parents have had experience with the child who protests that he doesn't like something when he couldn't possibly know whether he did or not, never having tasted it before. The parents' tactics to overcome such refusal are varied and sometimes self-defeating, but we'll have to use all of the good ones and more to gain rapid acceptance of new food. Nonacceptance of new foods can cause extreme shortages of acceptable foods, so organoleptic quality is a prime factor in good nutrition.

FDA's Position

It is interesting to speculate on the role of the FDA at the point in the too-near future when traditional foods must be augmented. It is already hopeless for regulatory practices to anticipate all the technological changes that occur, and there will be increasingly significant changes as the pressure for protein builds. It is small wonder that many people who are concerned with our present maldistribution of available foods charge that our present regulatory procedures are specifically designed to impede change and maintain the status quo. Unless we give new and significant attention to nutritional

qualities, to complement or to exchange for our traditional standards, we are going to be in real trouble.

I would like to quote from an early recommendation of the Panel on Food Quality of the White House Conference on Food, Nutrition, and Health, because it incorporates the thinking of competent and concerned people:

> IT IS RECOMMENDED: That a permanent body be designated within the U. S. Government to establish and revise nutritional guidelines for various classes of foods and food combinations. It is expected that this body would bound its scope so that foods making trivial contributions to nutrient intake would be defined out of its purview and therefore not clutter its considerations. Foods complying with the guidelines could then be authorized to display a prominent and distinctive symbol constituting the processor's guarantee of compliance. It could then be left to the pressures of the marketplace to enforce use of the symbol. Non-compliance with guidelines of food marked with the symbol would then constitute misbranding and could be controlled by existing mechanisms. It is contemplated that maximum as well as minimum nutrient levels be established and that, the advice of expert bodies such as the National Academy of Sciences would be freely used. Variations in nutritional properties within the guidelines are to be expected and permitted if properly described in label statements. There should be no regulatory impediment to disclosures of food composition of nutritional significance.

The "permanent body within the U. S. Government" was not specified in this particular recommendation, but in other recommendations of this and other panels it was almost always the Department of Health, Education and Welfare, among presently existing agencies.

Present Methods

At present, fortification of foods is generally restricted (1) to nutrients for which there is a shortage in the food supply, and (2) to the restoration of nutrients that have been reduced through processing. The following additions of nutrients to foods have been permitted: The enrichment of flour, bread, degerminated corn meal, corn grits, whole grain corn meal, and white rice; the retention or restoration of thiamine, riboflavin, niacin and iron in processed food cereals; the addition of vitamin D to milk, fluid skim milk, and nonfat dry milk; the addition of vitamin A to margarine and to fluid skim milk and nonfat dry milk; and the addition of iodine to table salt. Even so, the present fortifications are not sufficient, because the customary diets of many people do not include enough of these enriched products, and fortification as needed is not mandatory.

Information to the consumer via the label is seldom found to be adequate to the need, and it constitutes a major problem in public education. Such information is often incomplete, partly because of the limitations of space, and partly because more detailed information is not required. Even if it were required and followed, there is doubt that the consumers most needful of the knowledge would read and heed such advice. A better way of educating the consumer is needed irrespective of improved labeling.

Everyone has a right to know what is in the food he eats. In order for him to know this, procedures will have to be established for making full information available to the public about the ingredients that are added to processed foods. Many experts declare that trade secrets on the use of food additives are of little benefit to the food industry and should no longer be legally protected as privileged information in FDA files but, of course, they must be unless the laws are changed. The kind of information that would be useful to the consumer would include the identity of the additives, the quantities used or available in specified quantities of the product, the methods for chemical analysis, and references to the full evidence upon which the additives were judged to be safe.

Acceptability

Now let us return to the subject of acceptability. If I seem to dwell too much on this subject, it is for emphasis and because it is an extremely important part of the improved or maintained quality of nutrition. No matter how nutritious a product is, it must be eaten to be of benefit to the person who needs it. Food technologists and nutritionists recognize that fact, and so must the agencies regulating food standards. In some effective fashion, and in the near future, FDA must respond to the challenge. We intend to begin by building our competence in nutrition and proceeding from there.

[The End]

The Right to Excellence

By ERMA ANGEVINE

Erma Angevine Is Executive Director of
the Consumer Federation of America.

THE STORY IS TOLD of the zoo visitor who hurried among the various animals until he found the camels contentedly chewing their cuds. He placed a carefully selected piece of straw squarely on a camel's back. Then he stepped aside and waited. Nothing happened. As he walked away, he muttered, "Wrong straw."

When does the proverbial straw break the camel's back? At what point did American consumers become so fed up that they reacted? What made us so angry that we began demanding the excellence this conference addresses itself to today?

No one can give an exact answer. However, I'd like to offer a suggestion. My generation of American consumers discovered Washington in 1962, when President Kennedy enunciated four basic consumer rights in a message to Congress: the right to choose, the right to safety, the right to be informed, and the right to be heard. We learned on March 15, 1962, that somebody in the nation's capital believed that consumers had rights. We've been asserting them since then.

With this introduction, I also state my bias: I believe that consumers have the right to excellence, and that American business and government have the obligation of excellence. John Gardner states, "Excellence implies more than competence. It implies a striving for the highest standards in every phase of life." Let us take a look at what this means to the consumer.

Auto manufacturers build competent cars. Yes. Excellent ones? No. In fact, for years U. S. auto manufacturers opposed making either smaller or safer cars. Consumers bought more and more small foreign cars. The government made several safety measures mandatory.

In mid-1968 General Motors announced—for the first time—that its 1969 cars would include a new safety feature not suggested by government action, a safety feature General Motors would unquestionably have opposed if the government had demanded it a few years earlier. Does this herald a new era, as E. B. Weiss suggests?

> The era of industry's automatic resistance to government—and to the academic community—has barely begun to wane. . . . There will emerge this new form of competition, a race to lead competitors in the development of more socially responsible products, a whole new concept.

Can we look for competition for excellence? I hope so, but the record isn't too promising. Too often change comes through tragedy and not through social responsibility, for example, drug protection after the thalidomide tragedy.

The Manufacturers' Responsibility

If color television can emit dangerous radiation and is a fire hazard, why must we legislate corrections? The consumer has a *right* to safety. A manufacturer should not market an unsafe product. If he does so unwittingly, he should remove his product and proceed to improve its quality as soon as he learns of its danger. Why should consumers be warned where to sit for protection from radiation and where to place the TV to reduce the fire hazard? Such hazards don't belong in the home. Until the TV is safe, it should not be sold.

No threat of loss of profits should give the manufacturer of baby food pause in removing unsafe food from the market. How many mothers bought blenders to avoid monosodium glutamate in infant food? Will these mothers ever trust processed baby food again? From the hysterical calls I got, I seriously doubt it. For these women said that neither the government scientists their taxes support nor the industry they paid for food cared about their babies. Both, they told me, cared only about industry profits. That's a harsh judgment. Have we any evidence that it is a wrong one?

Last week a West Virginia attorney called me. He wanted to know how to stop the sale of a child's overcoat. He told of a four-year-old boy who was hospitalized with third degree burns. The child stood about one and one-half feet from a heater—not an open fire, the man said. "The new overcoat blazed." The attorney continued, "I can take care of the legal work on this, but I want to stop

anyone else from buying that coat. I've reread the mail order description and nothing would alert you to any flammability danger. Yet someone must know that coat is dangerous. Why—why do they use material like that for children's clothes?"

Or consider the woman who wants to make her food budget go as far as possible. In one store she finds the same brand of cheese in a variety of packages: eight slices for 39¢, sixteen slices for 59¢, or sixteen slices for 65¢. What is she supposed to make of this? Which is the best buy?

The best buy happens to be eight slices for 39¢. Why? Each slice is a full ounce; total cheese for 39¢, eight ounces. For some unexplainable reason the sixteen-slice package has only twelve ounces of cheese, each slice weighing three-fourths of an ounce. If eight ounces cost 39¢, twelve ounces should cost 58½¢, not 59¢. The 65¢ package is apparently the new, improved previously-priced 59¢ package.

Why are the slices 25% thinner in the sixteen-slice package? The consumer has a right to be informed—and to choose.

A *Wall Street Journal* story asked just after Thanksgiving, "How much pesticide did you eat for Thanksgiving?" The story tells how Campbell Soup warned the United States Department of Agriculture (USDA) about the high level of pesticide in Arkansas turkeys. The turkeys were stamped "Inspected for wholesomeness by the U. S. Department of Agriculture." Campbell Soup, like other food processors, operates a residue monitoring system to detect chemical traces in ingredients meant for its soups, TV dinners, and other products. Its alert stopped thousands of turkeys from reaching Thanksgiving tables. How many USDA "wholesome" stamped turkeys were marketed? Why did USDA wait four weeks to tell the story? How can consumers believe USDA protects them in the face of such a record?

The *Journal* quotes the usual unnamed USDA "aide who helps formulate pesticide policy:" "There's a tradition in the whole agricultural community, not just the USDA, of getting jobs like the turkey problem done without alarming the public. But this is a different public. It has to be alerted. There are going to be some changes."

Manufacturers of five wonder drugs settled a price-fixing case out of court and agreed to pay treble damages for overcharging con-

sumers millions of dollars for these drugs. Consumer Federation alerted its member organizations at the same time that ads were carried throughout the country. We spelled out in detail how consumers could file their claims against the companies. After this information was published in the *Machinist* newspaper, I got some curious letters. The same story came from all parts of the country.

When the consumer asked his local pharmacist for help in verifying his drug purchases, he was told he'd be charged $5 an hour for searching the records. He was warned that he could not possibly recover what it would cost to search the records.

Did the same manufacturers who met to fix prices also meet to agree on how to keep the consumer from recovering his money? Why did all pharmacists have identical stories?

Most of the consumers who wrote me were living on pensions and needed the money they were overcharged. I found this unhappy incident sickening. The consumer is without armor in a battle with an adversary equipped with computers, a giant corporate structure largely concerned with making profits, far-reaching influence on the Congress and the Administration, and almost unlimited access to financing. This Goliath can ignore the law, and even if proved guilty can deduct from its income taxes the cost of repaying the consumer. Yet it chooses to make it impossible for the pensioner to prove his simple case. We often talk of shoddy merchandise and fly-by-night operators. What of the unfeeling corporate giant?

Consumers were delighted in August when Virginia Knauer, Special Assistant to the President for Consumer Affairs, told us that the Administration would support class action and was indeed drafting a bill. Although the President's consumer message recognized the need for consumers to band together to get counsel, it erected a barrier to the use of such class action and disappointed consumers.

The President said the Justice Department must first initiate and win a suit before citizens can bring suit. In effect, he would require the consumer to be dependent on cumbersome bureaucracy for its protection. Consumers should not have to wait until the Attorney General acts to get their own money back. For that matter, why should the consumer need to go to court, if the Government has won its case?

The consumer should be entitled to protect his rights in a court by bringing suit, whether or not a Government official or agency has acted. Government is not known for swift action.

The Federal Trade Commission took thirty years to get "little liver" out of Carter's pills. They took thirty years to settle the Holland Furnace case. Why should the consumer wait on such ponderous machinery?

Rising Expectations

I'm sure many of you believe I've nothing good to say about business. Let me hasten to correct this.

The most hopeful document I've read in recent weeks is the report of the Council on Trends and Perspective of the U. S. Chamber of Commerce. This Council said many of the things I've said today in their economic analysis of "Business and the Consumer—a Program for the Seventies." I urge you to study the report, to evaluate its twelve recommendations, and to consider what the next decade would be like with such corporate leadership.

I urge you to take off your corporate hat and put on your consumer hat more often.

President Kennedy's consumer rights opened an era of rising expectations for consumers. We expect industry to consider our needs as well as its profits. We expect retailers to improve consumer services along with making a profit. We expect local, state, and federal governments to recognize consumer rights and to hear our voice. We believe both corporate and government institutions have an obligation of excellence.

Let me close with the introductory quotation from the Chamber of Commerce report, a quotation from Elting Morison:

> How to give individual men the evidence they need to make sensible judgments about the kind of world they want to live in and how to give them the power to make their judgments stick, that is the unfinished business of the next third of a century.

[The End]

Buyer's Rights

By VIRGINIA H. KNAUER

Virginia H. Knauer Is Special Assistant to the President for Consumer Affairs.

ONE OF THE "BUYER'S RIGHTS" listed by President Nixon in his Consumer Message to Congress was the "right to expect that his health and safety is taken into account by those who seek his patronage."

This right is so basic to human needs, it isn't likely to incite any great controversy among responsible producers of food and drugs. Nor is it new to the Federal Government, which is empowered under the Constitution to protect the health and welfare of its citizens.

However, I think that you will all agree with me when I say that there *is* controversy as to the best way to achieve the goal.

There are those, for example, who still advocate a "laissez-faire" policy that would close the door to Government intervention now and, hopefully, forevermore in the affairs of industry. On the other hand, there are those who favor strict Government controls—and the stricter the better.

This Administration rejects both extremes. At the same time, we are not satisfied with the status quo, a sentiment which is fully shared, and is now being effectively voiced, by the American consumer.

From drugs to deodorants, from tonics to toothpaste, we are the most vitamized, vaporized and vitalized nation on earth—and as a consequence—the most victimized. Our national food platter is laden with the most tempting of frozen delicacies, with "supercharged" cereals and "calorie-free" desserts that would have astounded housewives a generation ago—and yet, so many in our society are underfed and undernourished and utterly confused by the products' ingredients. The question is: Why?

We all know the answer. Technological advances since World War II have been so swift and so numerous that we inadvertently left something very important behind. Incredibly enough, it was

the consumer himself, and the trend hasn't changed. New products are put on the market before we even have time to understand the old ones. Before we can fully grasp the publicized "miracles" of a new drug, an even newer one makes it obsolete. And just as we begin to take the safety of food additives for granted, along comes the word that a certain cyclamate sweetener may not be so safe after all!

The cyclamate issue is one example. There are others, such as monosodium glutamate in baby food, or even salt, when it isn't needed. As a result, the President has asked the Secretary of Health, Education and Welfare to initiate a full review of food additives, and to re-examine the safety of substances which are now generally recognized as safe. Being *reasonably* sure just isn't good enough.

The Panel on Food Safety proposed that food additives be barred from products unless they have been proven safe, and either improve the quality or nutritive value of the food, or lower the food's cost.

The Panel on New Foods which I attended recommended, at my suggestion, an immediate program of fortification of at least six basic foods that are commonly used: bread, flour and cornmeal, rice, two processed meat products, citrus and soft drinks, and protein fortified teething biscuits. The panel further recommended that "industry and food manufacturers should restrict price increases for these fortified foods to no more than their actual cost for fortification." This cooperation will not go unnoticed by the consumer.

The President's Recommendations

Asking the Secretary of Health, Education and Welfare to undertake a thorough re-examination of the FDA, the President said:

> What further financial and personnel resources does the FDA require? Are laboratory findings communicated as promptly and fully as is desirable to high Administration officials and to the public? What should be the relationship of the FDA to other scientific arms of the government? What methods can bring the greatest possible talent to bear on the critical questions the FDA considers?

Specifically, in the area of drugs, the President recommended that the Congress take action which would make possible, for the first time, the rapid identification of drugs and drug containers in a time of personal emergency. Some manufacturers are already doing this voluntarily. It's time all drug producers followed suit.

President Nixon also sent to Congress "The Consumer Product Testing Act of 1969," which would give my office the central responsibility, with the Office of Science and Technology advising, of setting priorities and initiating the review of the adequacy of methods

for testing consumer products. These two offices would designate the appropriate federal agencies, such as the National Bureau of Standards or FDA, that have the expertise to evaluate the testing procedures used by private testing laboratories.

The efficacy of these testing procedures would be published in the *Federal Register* and translated in the proposed new *Consumer Register,* which my office would publish. If no standard of testing methods exists, the Government agency reviewing this area could establish one—if the industry involved did not move quickly enough.

At the same time, the President specifically directed me to develop a program for the release and publication of Government product information, or "purchasing expertise," that would be relevant to the consumer and not unfair to anyone. This information has been gained through the development of Government procedures for evaluating the products it purchases, and the President feels that it can be shared with consumers to develop their shopping sophistication.

In the meantime, Congress is considering more than a dozen bills relating to drugs. They range from safety closures for drug containers to the provision of generic titles on labels. Obviously, the consumer has taken his case to Congress.

Perhaps the most discussed issue currently is the one on generic equivalency. Are generic products as safe and reliable as trade name drugs? Are there different therapeutic effects from compounds containing the same active ingredients? It is clear that there is conflicting evidence on this important issue.

I am sure that many of you remember FDA's Manufacturer and Marketing Survey in which generics rated well against trade names. Also, FDA testified in 1967 that it had been able to uncover only twelve instances where the inert ingredients or some other factor produced differences in therapeutic activity. FDA asked the drug industry to forward any other examples, and I understand that some evidence on specific drugs has been provided by industry.

During the previous Congress, a national formulary bill passed the Senate but failed in the House. The Congress settled on a request to the Department of Health, Education and Welfare (HEW) to study the issue. The report of HEW's Task Force on Prescription Drugs, submitted during the last Administration, has also been evaluated by many officials of this Administration. The Task Force recommended the establishment of reference standards for generic drugs.

In short, the push is on to insure the quality and equivalency of generic products in an effort to facilitate lowering of drug costs.

This drive will no doubt intensify if, and when, prescription drugs are covered by Medicare.

The ultimate solution may be a formulary approach with a reimbursable price range gauged to the lowest priced drugs of acceptable quality, with regard to drugs for which the Government foots the bill.

While everyone is concerned about the increase in the cost of drugs, the question remains: What can we do to slow or reverse this trend? Certainly the Government has a large role in this effort. No drug should be dispensed that will not do the job for which it is intended. We must support FDA in its effort to achieve "zero defects" in the drug marketplace. Patent policy and profits must be investigated and reviewed. Conspiracies in drug marketing and cartels controlling supplies of drugs, such as quinine and quinidine, must be eliminated through the full force of the Federal Government.

Efficacy Review

There is still another major issue. As a result of the National Academy of Science/National Research Council efficacy review for drugs marketed between 1938 and 1962, many commonly used drugs may be removed from the market as ineffective. FDA has, and will, initiate corrective actions to be taken through the administrative process and the Courts. But drugs declared ineffective, but which present no safety hazard, may remain on the market for years pending judicial settlement.

For example, it is becoming standard procedure to file suits for declaratory judgments to initiate withdrawal from the market as soon as announcements are published. Six suits have already been filed, and the first one, filed a year ago, is still in the discovery stage. Even after these court cases and appeals are finished, the manufacturer may still be entitled to a public hearing and further legal appeals. When such a prestigious group of scientists makes a finding that a drug is ineffective, it seems inconceivable to me that consumers should still be exposed to the product for years!

In the long run, whether it's a problem of safety, high cost, or just plain ineffective products, someone must answer to the consumer, because it's the consumer who pays for the goods.

Will it be left solely to industry or solely to Government to provide the answer? Or will the problems be solved by the mutual efforts of industry and Government, with the cooperation of the consumer?

This Administration endorses the latter. I am delighted that it is an endorsement strongly supported by the Food and Drug Law Institute. **[The End]**

The National Better Business Bureau

By RICHARD MAXWELL

Mr. Maxwell Is President of the National Better Business Bureau, New York.

I WOULD LIKE TO BEGIN by talking a little about the purpose of the National Better Business Bureau (NBBB). We go back to 1912, to a day when fraudulent advertising was commonplace rather than the exception, when snake oil men were playing fast and loose with the public health, when the victims of false advertising, harmful drugs or tainted food had little or no chance for redress. The Pure Food and Drug Act was just six years old, and it was enforced by the little Bureau of Chemistry within the Department of Agriculture. Some of the most flagrant abuses were under attack, but many other forms of preying on the public remained beyond the reach of the law.

All a wronged consumer could do was chalk up his loss to experience and resolve to be more careful the next time. In this corrosive atmosphere, the principle of self-regulation was developed by a group of men whose business practices were dictated only by their sense of fair play. These men, who founded what is today the National Better Business Bureau, set down this code:

> We believe in truth, the cornerstone of all honorable and successful business and we pledge ourselves each to one and one to all to make this the foundation of our dealings to the end that our mutual relations may become still more harmonious and efficient.

Although the outrageous frauds of those days have been refined to deceptions and misrepresentations, today, as then, truth in advertising and ethical selling practices are our main concern. Our weapon now, as then, is the machinery of voluntary compliance.

Organization of the NBBB

The National Better Business Bureau and the more than 130 local Better Business Bureaus are independent, non-profit organiza-

tions supported by reputable business firms and advertising media as a means of protecting themselves and the public from fraudulent, misleading and unfair advertising and unethical selling practices. The national Bureau's membership is composed of national or regional firms, and we are concerned with national advertising and marketing practices. The local bureaus operate the same way at the local level.

Affiliated with the NBBB through membership are some 850 Chambers of Commerce which, together with the local bureaus, constitute a network of over 1,000 agencies serving marketing areas throughout the country.

Getting down to the health area, our health and safety division deals with the advertising and selling of products, services, processes, and devices in the food, drug and cosmetic fields. In appraising a firm's advertisements, promotions, mailings and other contacts with the public, the staff reviews our files to find out what experience we and our affiliates have had with the firm. When we have doubts about claims for the product based on its ingredients or method of use, we ask the firm for scientific substantiation. When necessary, we consult the appropriate specialists who comprise our scientific advisory committee, a group of distinguished doctors and scientists who serve without remuneration. We keep their names and affiliations confidential to encourage them to speak freely. To assure objectivity, we seek several opinions. In presenting the material, we abstract the claims made by the firm and its statements to substantiate them, plus our own file material as well as official rulings and published articles which may be relevant. The consultant is asked to respond to hypothetical questions formulated by the staff in light of the facts and their implications. To further assure objectivity, we do not name the product or firm.

If the firm's documentation and interpretation of data are satisfactory, we indicate we have no objection. If there is no substantiation, we urge termination of claims pending acquisition of proof. If the claims cannot be backed up, we may request modification or discontinuance. Our record of obtaining voluntary cooperation is a testament to corporate responsibility. In those few cases when we do

not achieve voluntary cooperation, we may issue a media bulletin advising newspapers, magazines and broadcast media of our finding, or refer the matter to the appropriate government agency if there appears to be a violation of the law. We also enjoy the cooperation of organized medicine, professional societies, and voluntary health organizations, as advisers who often join with us in public education and, occasionally, in supporting sanctions. However, we usually are able to achieve compliance on the basis of sound scientific information and persuasive negotiations with the advertiser.

Preventive Activities

As you can see, our emphasis is on prevention. By encouraging the review of advertising brought to our attention, either by advertisers or media, we assist business to keep its advertising clean, and at the same time, we protect the consumer from questionable representations before they appear. Ironically, because we do not publicize our successes on compliance, we are best known for our action on questionable advertising after it has appeared.

To supplement our direct contacts in advertising, we publish a comprehensive looseleaf service for advertisers, agencies and media called "Do's and Don't's in Advertising Copy." This is an authoritative compilation of important court decisions and regulatory agency proceedings affecting advertising and selling practices. They have been analyzed, synthesized and correlated to applicable subjects for handy reference. Trade practice rules for leading industries are summarized. Voluntary industry codes are included. Supplements are mailed to subscribers every month to keep the contents up to date. Subscribers also receive a monthly newsletter containing items of current interest on proper advertising procedures.

Among the sixteen general sections, which contain nearly 450 chapters, is one whole section on food and another section devoted to drugs and devices. The subscribers include a virtual "Who's Who" of the advertising industry. One interesting user is the American Pharmaceutical Association. To acquaint readers with the copy acceptance criteria of mass media, each chapter of its "Handbook of Non-Prescription Drugs" contains an excerpt covering the remedy under discussion, such as antacids, cough depressants, dentrifices,

and so on. This approach serves both the public and industry. I would like to see more of it done by other organizations.

Yet another preventive activity is our media luncheon group. Comprising copy acceptance executives from magazines, newspapers, radio and television networks, the group meets once a month at a dutch treat luncheon with NBBB representatives to exchange information on copy acceptance problems. Four times a year, we have a guest speaker. At our December meeting, the guest speaker was Commissioner Mary Gardiner Jones of the Federal Trade Commission.

To give you an idea of our day-to-day operations, you may be interested in our Health and Safety Division's most recent quarterly report. During the last three months, the division handled more than 1,500 mail and telephone inquiries and complaints made directly by the public or industry, or indirectly through local Better Business Bureaus and Chambers of Commerce.

At the request of media, the Health and Safety Division evaluated advertising claims for such products as an isometric glove designed to produce a cosmetic effect on the hands; a sonic denture cleansing device; grapefruit diets; an asthma nasal spray; an exercise device; a pep pill; obesity cures; and a laxative.

The division communicated directly with advertisers to obtain substantiation of advertising claims made by a figure control salon and a thirst-quenching soft drink; to question the advertising copy of a home electrolysis device; to discuss fulfillment practices with a mail order house that sells a health device.

Among the general bulletins published by the division was one warning of the promotion of copper bracelets as an arthritis remedy. Another was about the advertising of pain relievers for arthritis and rheumatism. The division also prepared informational reports on five companies to be sent to persons or organizations inquiring about them.

Our educational activities contribute substantially to the preventive aspect of our work. Through our booklets and leaflets, Better Business Bureaus make people aware of what to look for before they buy. An informed consumer is the best method we have found to achieve consumer protection.

While the information gap is a very real and pressing problem, it will not be solved by booklets and audio visual materials alone, for it runs deeper than just an absence of facts. It is up to industry to take the initiative in demonstrating its willingness to tell the consumer what he wants to know.

Progress in Protection

There are growing signs that business is working harder than ever to demonstrate concern for the consumer in ways other than sales. Recently, an advisory group of the Chamber of Commerce of the United States recommended that business take an active leadership in meeting the demands of what it called "The New Consumerism." One of its suggestions was to make Better Business Bureaus consumer ombudsmen.

We have come a long way since the early years of the century when the buyer literally had to beware at the peril of his health or even his life when he put his money on the counter. The dual partnership of law and self-regulation has given the consumer better protection and information than he has ever had. And yet, more must be done. But whatever the shortcomings, no responsible business leaders are trying to hide our problems or deny that they exist. This very awareness is our strength.

The Better Business Bureau movement is based on the belief that problems between the public and business must be resolved in an atmosphere of mutual trust and respect. By acting as a neutral third party between the two, we rely only on the facts, not on any bias favoring one or the other. In this role, we have shown time and again that reasonable people can be brought to mutually agreeable solutions.

Mutual trust is what has kept our country economically strong. As we enter the 1970s, business must redouble its efforts to reach the consumer. And the consumer can do no less than make his wishes known to business. To this end, business and the public will be served by a Better Business Bureau movement that recognizes the challenge ahead and is moving to meet it with a history of successful service and a recognition of the vast job yet to be done. **[The End]**

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