VOL. 22, NO. 4 APRIL 1967

Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the Meeting of the American Bar Association Division on Food, Drug and Cosmetic Law

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

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

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

April, 1967
Volume 22 • Number 4

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

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . April, 1967

VOLUME 22 NUMBER 4

Printed in the United States of America

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

1966 Annual Meeting of the Division of Food, Drug and Cosmetic Law of the American Bar Association.—The concluding papers presented at the meeting are featured in this issue of the JOURNAL. Previous papers presented were published in the March issue.

Vincent A. Kleinfeld, a member of the District of Columbia Bar, discusses recent developments in "Some Observations on the Current Status of Drug Law," beginning on page 200. In speaking of FDA's construction of the 1962 Amendments, the author notes certain fallacies inherent in those liberal interpretations of the statute claimed to be "in the best interests of the industry" or "for the good of the public."

In "Industry Problems in the Drug Field in Canada," several of the major problems encountered by Canada's Pharmaceutical Manufacturing Industry are discussed by *Frederick R. Hume,* Q. C. His article begins on page 211.

"Food and Drug Advertising and Pricing Problems Under the Combines Investigation Act" begins on page 222. *David H. W. Henry,* Q. C., Director of Investigation and Research under the Combines Investigation Act, discusses the three broad classes of conduct prohibited by this Act: (1) combinations that prevent or limit competition unduly; (2) monopolies operating against the interest of the public; (3) unfair trade practices mainly relating to pricing policies.

In "What the Public Expects of FDA —A Third Party Arbiter," beginning on page 234, *William W. Goodrich* examines public expectations and FDA's response to them. Mr. Goodrich is Assistant General Counsel, Food and Drug Division, U. S. Department of Health, Education & Welfare.

Question and Answer Panel of the FDA—FDLI Tenth Annual Educational Conference.—The Question and Answer Panel held during the afternoon session of the Tenth Annual FDA—FDLI Educational Conference is featured on page 238 in this issue of the JOURNAL.

Members of the panel were: *William W. Goodrich,* Assistant General Counsel to the Department of Health, Education & Welfare; *Robert J. Robinson,* M. D., FDA; *Douglas C. Hansen,* Director of the Division of Program Operations with the Bureau of Regulatory Compliance, Food and Drug Administration; *Irving H. Jurow,* Vice President and General Counsel of the Schering Corporation, Bloomfield, N. J.; and *L. Paul Sinotte,* Director, Quality Control, Merck Sharp & Dohme, West Point, Pa.

Wanted—Lawyer-Statesmen. — The Charles Wesley Dunn Memorial Lecture is presented as the article beginning on page 242. The lecture was delivered by *Bradshaw Mintener* at the New York University School of Law on October 18, 1966. Mr. Mintener, who is with Mintener & Mitchell of Washington, D. C., outlines the achievements attained by Charles Wesley Dunn.

Industry Views on FDA's Labeling Proposal and State Regulations.—In these remarks, beginning on page 254, *Edward Dunkelberger,* Counsel for the National Canners Association, discusses the labeling regulations issued by FDA under the Fair Packaging and Labeling Act.

Vol. 22, No. 4 April, 1967

Food·Drug·Cosmetic Law
Journal

Some Observations on the Current Status of Drug Law

By VINCENT A. KLEINFELD

The Following Article, Reprinted from *The Business Lawyer* (November 1966, p. 175) with the Permission of the Publisher and of the Author, Was Presented at the Division of Food, Drug and Cosmetic Law of the Annual Meeting of the American Bar Association in Montreal on August 10, 1966. Mr. Kleinfeld Is a Member of the District of Columbia Bar. The Three Succeeding Articles in This Issue Were Presented at the Same Meeting.

IT IS CLEAR TO ANYONE CONNECTED, however remotely, with the drug industry or with the disciplines involved in diagnosing, treating or preventing disease that we live in a world of medicine entirely different from that which existed when the Federal Food, Drug and Cosmetic Act was passed in 1938. It would seem primitive indeed to the fledgling practitioner to practice his art without having at his fingertips the various and potent antibacterial agents, hormones, steroids, tranquilizers for the neurotic and psychotic, and other categories of products which, in fact, can be denominated as wonder drugs.

But virtually by definition, the birth and growth of these tremendous weapons in the battle against disease and aging created concomitant hazards, side effects and contraindications. There was no question, therefore, that greater precautions were necessary with respect to these new and marvelous weapons, and that if the Federal Food, Drug and Cosmetic Act of 1938 did not in fact require such vigilance, further legislation was essential. In any event, if any doubts

existed as to whether there would be additional legislation in the drug area in the 1960's, these were resolved by the thalidomide case.

The Drug Amendments of 1962 were considered revolutionary when they were enacted and, of course, many important changes in the 1938 Act were made. Actually, much of what was added by Congress to the then existing statute was being or could have been required by the Food and Drug Administration (FDA) or taken care of by court action or threat of regulatory proceedings.

New Drug Applications

For example, consider the criterion of effectiveness which was added to the definition of a "new drug" by the 1962 Amendments. Most of us know that, before the passage of the Amendments, a new drug application for an inefficacious product offered for a serious condition would not have been permitted to become effective by the FDA. Either the government would have "incompleted" the application by repeated communications on the basis of various arcane reasons, or the direct approach would have been taken that a drug, although demonstrated to be directly safe, could not be said to be free from hazard if it had not been shown to be effective for the serious ailment for which it was offered.

And as far as other new drugs, not utilized for serious disorders, were concerned, a strong letter from the FDA permitting the application to become effective but including the caveat that the claims of efficacy were on the manufacturer's responsibility and were by no means being approved by the government, or a subsequent seizure predicated on Section 502(a) of the Act, or a citation hearing under Section 305, could cover most situations. Even where a doubt could be said to exist with respect to effectiveness, Section 201(n), providing for the affirmative disclosure of material facts (a tremendously powerful section never employed to its fullest extent), certainly could be interpreted as requiring a label disclosure of the actual facts—that a doubt as to the effectiveness of the product existed. It is to be borne in mind, also, that the far-reaching investigational new drug regulations could have been, and finally were, issued on the basis of the authority vested in the FDA prior to the passage of the 1962 Amendments.

This is not to say that the Amendments were not a distinct step forward in the direction of greater governmental controls (which it appears will lead inevitably to complete licensing), but rather that

it was Congress which specifically set forth, at least in some instances, its mandate and philosophy concerning the authority it wished the FDA to have in various areas, including new drugs, prescription drugs and antibiotics. Yet, anyone who is familiar with the construction which the FDA placed on many sections of the 1938 Act and would nevertheless state that the Agency could not have taken, prior to the passage of the 1962 Amendments, many steps which were subsequently required by the Amendments would be falling into the error of the scientist who proved that the wing area of the bumblebee is just too small to support the creature in flight.

Because of thalidomide, the FDA probably could have gotten from Congress as part of the 1962 Amendments virtually any authority it wished. Nevertheless, hardly had the Amendments been passed when various sections were administratively construed to a point which Congress had not appeared to contemplate. Certainly the Amendments do not state specifically, for example, that the established name of a drug must accompany each appearance of the proprietary name in labeling and advertising. The position taken by the government may have pleased some of the Congressional sponsors of the 1962 Amendments, but that is hardly a sound or affirmative reason for reaching a conclusion which is of little utility. How is the physician or the public protected by a requirement that the generic name must follow the proprietary name of a drug each and every time the latter is employed? Would not a requirement that the generic name appear in the most prominent spot, or at the beginning and the end, or perhaps on each page, suffice? It would seem that a different position could have been and should have been taken by the government, although I admit that some of our friends in Congress might have been offended.

The late Mr. Justice Brandeis once stated that "Experience should teach us to be most on our guard to protect liberty when the government's purposes are beneficent. The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning, but without understanding." It is not only in this field of law that the officials concerned take stands on the basis that they know what is good for us, so that any construction of the statute involved which will aid in achieving the beneficent end of protecting the public is warranted. In any event, let us consider briefly some aspects of current drug law in this general context.

The Amendments Interpreted

It was expected that the deletion in the Drug Amendments of 1962 of any provision for the automatic approval of a new drug application upon the expiration of a stated period of time would result in the removal of the "incomplete" ploy. Since there was no automatic approval, the practical, if not the legal, rationale for the "incomplete" stratagem no longer existed. This ingenious artifice is still employed, however, "for the good of the industry," although the practical basis for it has disappeared and it is doubtful that any legal basis ever existed.

The regulations creating exemptions pursuant to the "directions for use" section (Section 502(f)(1)) for prescription drugs under specified conditions are still of interest, if only from an academic viewpoint. Is it not a tenable position that a drug manufacturer may not wish to be granted an exemption by administrative regulations and may follow the statute by employing adequate directions for use in the labeling of his product? The government, as we know, has always taken the stand that there can be no adequate directions for the use of a prescription drug. Whether this is true in every factual situation is a matter for some conjecture. Is it not reasonable to hold that the Rx legend may constitute adequate directions for use? As far as the legend itself is concerned, no one appears to have pursued the lead given by the Supreme Court in 1948 in the *Sullivan* case. In the second footnote of its opinion, the Court pointed out that the use of the legend then required by the FDA "would appear to constitute adequate directions since it is required by regulation issued by the Administrator pursuant to authority of the Act."

The problem also remains whether, as a matter of law, all promotional material (with the exception of a reminder price) forwarded to physicians is "labeling" under Section 201(m) of the statute so that, as required by the FDA's regulations, there must be a full disclosure of side effects, contraindications and the like. Again, as in the case of the "incomplete" piece of sleight of hand, perhaps there was some practical rationale for the position originally taken by the FDA, although the legal basis for it always seemed somewhat dubious. This is because, prior to the 1962 Amendments, the FDA did not have direct control of prescription drug advertising and the Federal Trade Commission (FTC) had not seen fit to enter that area. But under the Amendments (Section 502(n) of the Act) all advertising "and other descriptive matter" (it is interesting to note that the term "labeling" is not employed) must contain information in "brief sum-

mary" relating to side effects, contraindications and effectiveness. We now have the anomalous situation where a piece of promotional material, obviously an advertisement, which is forwarded to the doctor must contain a "full disclosure" although the identical material in a medical journal may contain only a "brief summary." This just does not make good sense or good law.

The difficulty is compounded by the vagueness and ambiguity of the terms employed and the undisputed fact that men of honesty, experience and good judgment (including physicians) may disagree as to what is full disclosure and what constitutes a brief summary. Thus, one medical officer may be of the opinion that it is sufficient, at least in "advertising," to advise a physician that a drug is contraindicated in asthma; another medical officer may insist, for some reason, that the reasons for the drug being contraindicated in asthma must be set forth. As a practical matter, what is gained by requiring a full disclosure in every single piece of printed material which mentions dosages or indications? To be absolutely safe with respect to the reaction of every government medical officer or official who may review the material, it is probably necessary to employ the entire lengthy and laborious package insert. This, instead of guiding and aiding the busy practitioner, may only keep him from reading the really significant data, which he might be much more likely to do if he were presented with a sensible brief summary. In other words, the full disclosure requirement in all material forwarded to doctors (which, in my opinion, is more properly denominated advertising) may well be self-defeating.

There are omens, signs and portents that some officials intend to construe "liberally" (I employ the term in a most invidious manner) the statement in section 502(n) that the subsection "shall not be applicable to any printed matter which the Secretary determines to be labeling as defined in section 201(m) of this Act." These officials appear to hint, rather delicately at this time, that the FDA, in its complete discretion and, in reality, without reference to section 201 (m), may convert "advertising" into "labeling."

It certainly can be argued with reason that Congress did not insert the language in question into section 502(n) without some purpose in mind. Perhaps Congress contemplated that there might be grey areas where the determination whether promotional material was labeling or advertising should be resolved by the government. But section 201(m) has not been stricken from the statute and it

would be absurd to take the position that an advertisement in the *Journal of the American Medical Association* or on a closed circuit TV program directed to doctors was "labeling."

"Me Too" Drugs

An unpublicized change may be taking place in the thinking of the FDA in connection with at least a certain category of "me too" drugs; that is, drugs similar to products which were on the market on October 9, 1962, and which latter preparations on that date were no longer new drugs since they had become generally recognized as safe. Apparently, when the problem was originally considered by the FDA, there were two schools of thought. The "hawks" took the position that "me too" drugs should not be given the grandfather protection which appeared to be conveyed by the Amendments. The "doves" took the contrary stand, perhaps because of the realization that otherwise unmerited monopolies would be vested in the manufacturers of various preparations. The sensible view of the "doves" prevailed, although no formal pronouncement or statement of general policy or interpretation was ever issued.

Without any fanfare or pronouncement, the FDA may be attempting to reverse itself. This is probably due to the unfair criticism of the agency by congressional committees and the press that the government has been "soft" on the producers and distributors of drugs. The bruised and battered industry knows, of course, how erroneous this is, but it always makes a good story to lambaste drug manufacturers. In any event, requests (these letters, of course, might better not have been transmitted) for opinions on the status of "me too" drugs which companies now wish to manufacture or distribute are receiving disingenuously worded replies that it would be "advisable" to submit new drug applications.

It seems clear, from the Drug Amendments of 1962, that "me too" drugs which are essentially identical in formulation and labeling to the "once new drugs" they are mimicking may be marketed without the filing of a new drug application, although the facts in each instance must be appraised carefully. Certainly, the "Proceedings FDA Conference on the Kefauver-Harris Drug Amendments and Proposed Regulations, February 15, 1963" substantiate this. And in a speech by a prominent official of the FDA in 1963 it was made clear that although the ultimate fate of a "me too" drug might depend on what happened to the drug it imitated, the "me too" drug could be marketed

without the submission to the FDA of a new drug application. It appears to me that industry had and has a right to rely on these public pronouncements. Thus, in the contemporary FDA *Reports on Enforcement and Compliance* the following statement is made:

> Food and Drug Administration Speeches are Source Information for Industry—speeches presented by FDA officials reflect official policy and the information they contain may assist regulated industries to voluntarily comply with the Federal Food, Drug and Cosmetic Act and other Acts enforced by the Food and Drug Administration.

The FDA has taken and still takes the position that a product which had lost its new drug status prior to October 10, 1962, does not have the grandfather protection with respect to effectiveness possessed by products which were never new drugs. This problem has not been resolved by the courts, but it would appear unreasonable to construe the Amendments so as to afford grandfather protection to a product which had never received approval as to safety from the FDA and not to grant the protection to a drug which at least had received such sanction in the past. The applicable language of the Drug Amendments does not support the FDA's stand. A reasonable approach is that Congress played safe by excluding from the grandfather exemption not only products which were still new drugs on October 9, 1962, and were covered by effective new drug applications, but also products which were in fact new drugs since they were not generally recognized as safe but nevertheless were being marketed without effective new drug applications.

It is the view of the FDA that an article not falling within the definition of a "new drug" today because it is generally recognized by experts as safe and effective in the conditions for which it is offered may become a new drug tomorrow on the basis of new evidence raising a question of either safety or effectiveness. This would seem to raise a definite Constitutional problem, aside from the patent ambiguity of the language of the new drug section. If the FDA's position is correct, a manufacturer acting in complete conformity with the Act who ships a drug which is not a new drug today may be committing a criminal offense the following day with respect to every shipment not then generally recognized as either safe or effective. This can occur without the manufacturer's being in a position to determine from day to day the important change which renders him subject to severe and serious criminal penalties, since criminal intent is not an element of the offense. I should think this situation is not altered as a matter of law by reason of the fact that the FDA, in the exercise of its discretion, may decide under Section 305 of the Act

not to refer the facts to the Department of Justice for criminal prosecution. Further, if the view of the government is correct, at the very least the manufacturer must cease all shipments immediately unless and until a new drug application is prepared, submitted and ultimately approved.

The new drug regulations were revised in January of 1965 to permit manufacturers (without first securing the approval of the FDA) to change the labeling of a new drug by adding needed information concerning side effects and contraindications and by deleting claims for effectiveness not supported by reliable data. It is to be realized, of course, that behind this obeisance to common sense is the requirement that a supplemental drug application must be submitted thereafter. The practical problem still remains, therefore, whether such a submission will raise, to a new and earnest medical officer who reads newspapers, the whole question of the effectiveness of the product.

The Question of Full Disclosure

Mention may be made of the distribution of reprints of articles which originally appeared in medical journals. If the article is disseminated by the author or publisher, who is in no way associated with the drug firm, there is no requirement that full disclosure accompany the reprint. It seems clear, however, that if the article is distributed on behalf of the manufacturer, full disclosure is required. Further, in the case of a new drug, if the article indicates that the drug may be used for conditions not covered by the new drug application, or, in the case of an old drug, for purposes other than those generally recognized as safe and effective, the only reasonably safe course of conduct for the manufacturer to pursue is to send the article only in response to a specific request from a physician. Even with the limited distribution pursuant to physicians' requests, it would be advisable to notify the physician that the article relates to uses for the drug which are not established and to enclose a "full disclosure" insert.

The question of the status of house organs and of material sent to detail men is still of interest. The FDA apparently assumes that material of this character on behalf of a prescription drug constitutes "labeling" and consequently should contain full disclosure whenever mention is made of indication or dosage. The validity of this view is by no means free from doubt.

The FDA (or at least some segments of the agency) now states that a motion picture film itself must contain full disclosure. I prefer to

accept the reasonable viewpoint expressed by a prominent official of the government at the "Proceedings FDA Conference on the Kefauver-Harris Drug Amendments and Proposed Regulations February 15, 1963." The following question was put and answer given:

Q. Would a medical convention display booth be considered an advertisement, and would it have to meet the requirements for full disclosure regardless of the impracticability? Also how about other advertising media, such as medical movies, which mention products?

A. These questions are admittedly difficult. However as to the exhibit, it does not seem impossible or unreasonable to require the "full disclosure" information to appear in connection with the exhibit. As to the movies, we'll agree it is a little more difficult. We believe that unless the movie presents the whole story about the drug, then the persons who view the movie should be presented with a full disclosure brochure containing all of the information needed for proper use of the drug.

It also seems to be the position of the FDA that if any indications for use of a product are given in a price list or catalogue, full disclosure must be provided. Only if a reference to a drug falls into the category of a mere reminder piece would full disclosure not be required, in the opinion of the government. Presumably, the courts eventually will decide whether to accept this administrative construction of the Act.

Exportation of New Drugs

The government has declared that, despite the provisions of Section 801(d) of the Act, a new drug which is not covered by an approved new drug application may not be exported except under the Investigational New Drug Regulations. This appears to be an overly-technical construction of the law and one which Congress did not contemplate. Section 801(d) provides that a drug intended for export shall not be deemed to be adulterated or misbranded if it accords with the specifications of the foreign purchaser, is not in conflict with the laws of the foreign country, and is labeled on the shipping package to show that it is intended for export. Clearly, Congress did not wish to impose our requirements upon foreign countries and felt that other nations could decide for themselves what drugs they wished to receive. Thus, even dangerous and improperly labeled drugs may be exported if the provisions of Section 801(d) are met.

It is, of course, a generalization that exemptions from statutory provisions are not to be extended unnecessarily. In the present instance, however, the intent of Congress is clear and should not be thwarted by a conclusion based on the hypertechnical contention that the introduction into interstate commerce of a new drug which does

not possess an approved new drug application is a separate offense and not one involving adulteration or misbranding. There is not the slightest indication in the legislative history that Congress meant to make a distinction between new drugs and adulterated or misbranded drugs as far as exports are concerned. Could Congress possibly have intended, and would it make any sense, to prevent the exportation of new drugs not covered by effective or approved new drug applications and permit the exportation of potent uncertified antibiotics and antibiotic-containing drugs? Yet, the latter types of drugs may legally be exported if the requirements of Section 801(d) are complied with. It would appear that the government should be concerned with and interested in complying with the intent of Congress rather than in taking a position inconsistent with it. As pointed out by Mr. Justice Douglas in the *Kordel* case, "there is no canon against using common sense," even in construing a criminal law.

As a matter of fact, under the language of Section 201(p) of the Act, it appears clear that a bulk drug, not in dosage form, which is not generally recognized as safe and effective by experts may be exported pursuant to the provisions of Section 801(d) if the conditions for which the product is to be employed do not appear in the labeling. Section 201(p) defines a "new drug" as a drug which is not generally recognized by experts as "safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." It follows, therefore, that if the labeling does not specify the conditions, the product will be misbranded but will not be a new drug.

Conclusion

There is a desperate fear of publicity on the part of most segments of the regulated industries. This is understandable. Yet, if industry can realize that it must rid itself of this phobia and resist when it sincerely believes, as a matter of both law and policy, that it is right and the government is wrong, it is possible that this action may have a somewhat braking effect on the constant effort to extend the boundaries of the Act beyond those which Congress has established. A few decisions such as the *Demi* "Imitation Margarine" decision[1] in the food area could have a salutary effect on the doctrinaire official who shrugs off dissent from any administrative action with the statement that "they can always meet us in court." Of course, it does not cost this official any large sum of money to engage

[1] *U. S. v. 856 Cases * * * Demi*, CCH ¶ 60,138, 254 F. Supp. 59 (DC N. Y. Food Drug Cosmetic Law Reports, 1966).

in litigation, and he need not fear the frequently damning and damaging publicity which frequently ensues, win, lose or draw.

There are definite and unmistakable milestones in the history of the FDA. There were the enactment of the 1906 Act and the passage of the various amendments to it. Then came the far-reaching 1938 statute with its new drug provisions and the subsequent passage of the Pesticide Chemicals Amendment, the Food Additives Amendment and the Color Additive Amendments. Subsequently we had the thalidomide tragedy and the passage of the Drug Amendments of 1962 and, most recently, the 1965 Drug Abuse Control Amendments.

Perhaps the most significant change of all, however, was the recent appointment of a new Commissioner and the creation of the new slogan, "By Goddard, things are going to change around here." Certainly a transformation has taken place. Whether this will be good or bad from the viewpoint of the agency and the consumer only time can tell. Whether attacks upon the drug industry as a whole render a service or disservice to the public is a debatable point. The effect (added to over-regulation) may be to terrify the industry, drive the small manufacturer out of business, raise the cost and therefore the price of drugs, cause the drug industry to fear spending funds in the development of new products, and result in a growing tendency on the part of government personnel to play safe by saying "No" (since congressional committees, the press and the fringe consumer groups will never criticize you for keeping a drug off the market inasmuch as side effects cannot possibly materialize). If this occurs, it can hardly be considered to constitute progress. If this tendency continues, more and more research and the addition of new weapons to the arsenal of the physician will be done outside this country. Could penicillin and chloramphenicol obtain approval in the present Washington climate? It is doubtful that aspirin could; at best it would be required to be sold on a prescription basis for many years.

We are familiar with Icarus, the son of Daedalus who, in escaping from imprisonment, fell into the sea when the wax of the wings which had been fastened to his body melted as he flew too near the sun. The constant attacks upon the manufacturers of drugs as a whole, and the ever-increasing regulations and restrictions, may well end in a slow but constant decline in the marketing of valuable and life-saving therapeutic products. This, in turn, may result most unfortunately in a deceleration in the constant progress throughout the years of the practice of medicine. **[The End]**

Industry Problems in the Drug Field in Canada

By FREDERICK R. HUME, Q.C.

The Following Article Is Reprinted from *The Business Lawyer* (November 1966, p. 185) with the Permission of the Publisher and of the Author. Mr. Hume Is a Counselor-at-Law in Canada.

A BRIEF REVIEW OF THE HISTORY of the Canadian Food and Drug Act is important to any understanding of the problems in this field. Shortly after the creation of Canada under the British North America Act of 1867, an Act was passed which attempted to deal with food and drugs but was more concerned with the problem of adulteration of the product. Prescription drugs were mostly the result of the pharmacist's skill in mixing fairly uncomplicated chemicals and herbs, and the early Statute simply banned substitution of an inferior ingredient. The early Canadian Act was based upon the British Statute but the wording of the Statute was so vague that it was virtually ineffective. In 1884 an act entitled The Adulteration Act was passed and this might be regarded as the first important step in the development of Federal food and drug law. The Act defined the adulteration of a drug and it has been suggested that this definition, which was passed in 1884, was copied in the United States in your first Federal Act of 1906. It would appear, however, that the definition borrowed somewhat from an earlier New York State law and so both our countries have had a hand in the early development of legislation in this field. Under the Statute of 1884 there was a Chief Analyst appointed by the Federal Government and he was supposed to ferret out and prosecute cases of adulteration. The basis of this Statute was criminal law, and it was deemed that the release of a harmful product on the market would be treated as a criminal act. The division of legislative authority between our Federal Government and the various Provinces is such that property and civil rights are assigned exclusively to the Provinces, whereas the Federal Government has a series of headings including the heading of criminal law.

In 1920 and again in 1927 Food and Drug Acts were passed which contributed to the further development of legislation in this field.

A distinction was recognized between adulteration and misbranding; first with respect to foods in 1920 and later with respect to drugs in 1927. It should be noted that the changes regarding labeling and advertising, while applying to ethical pharmaceuticals, were really directed towards so-called patent medicines. It was recognized, however, that certain standards with respect to ethical pharmaceuticals had to be fixed. I think it can be said that the legislation of the 1920s marked a recognition by Government that the manufacture and distribution of pharmaceutical products had become an industry. It is also interesting to note that the Pharmaceutical Industry in this country joined with Government to formulate the legislation.

Between the time of the passage of the legislation in the 1920s and certain amendments in 1939, there developed the Food and Drug Directorate with regulations and requirements that were designed to safeguard the public interest. It was recognized that certain products should be prohibited if they were injurious to health when used either as a food or a drug, and the power to make regulations prohibiting the indiscriminate sale of these products was included in the amendments. The Statute was consolidated in 1952, but substantial changes were made again in 1953. The 1953 Statute removed many inconsistencies of the various previous amendments; the penalties for breach of the Statute were stiffened and there was an awareness that some machinery had to be developed to regulate the production of new products. Our Act of 1953 has been carried forward and with certain amendments comprises the present legislation in Canada.

I have indicated that the legislative competence of the Parliament of Canada to deal with this matter on a Federal basis was settled by our Courts as being within the criminal law heading assigned to Parliament. In the early days the question was raised as to whether this sort of legislation was really the regulation of a particular industry—and therefore property and civil rights within the jurisdiction of a Province—or whether it was in fact a matter of criminal law. The constitutionality of the Federal Act was challenged in a case in British Columbia and there the Courts found it to be a matter of criminal law. There is an interesting argument in Canadian Constitution Law as to whether or not more recent drug legislation has departed from the strictly criminal law aspect, and as to whether or not the Courts have slightly altered their views on the interpretation of the legislative headings assigned to Federal and Provincial jurisdictions. There is a certain nervousness that can be detected in the official views which indicates that maybe the Government is not entirely satisfied that, if the constitutionality of

the present Food and Drug Act were brought into question before modern Courts, the same result would flow; but, for the purposes of our discussion, this short historical review can terminate on the basis that as of the present time the Food and Drug Act is within the legislative competence of the Parliament of Canada and is in effect throughout the entire country.

Having thus concluded a very brief and somewhat incomplete history of legislation in this field in Canada, may I now turn to one or two of the problems which may be peculiar to Canada and with which you may not be entirely familiar.

The Drug Benefit List

The first problem to which I should like to refer is the establishment in one of the Provinces of Canada of a drug benefit list for welfare patients in that Province. Under the system, a physician is expected to prescribe only those drugs which are listed in the drug benefit list, and if a physician wishes to prescribe a non-listed product, he must apply in writing to a Drug Advisory Committee. The physician is therefore expected to prescribe by generic name and in fact is urged by the instructions "To prescribe by the proper (generic) name shown in the drug benefit list to avoid the necessity of time-consuming callbacks by pharmacists." I understand that this practice exists in certain States in the United States. Since it does limit the physician's freedom to prescribe the ethical drug of his choice, it also constitutes a problem for the medical profession as well as the Drug Industry, as it appears designed to encourage substitution. A restrictive drug list does discriminate against welfare patients as, if the physician does prescribe by generic name alone, the pharmacist is expected to provide the cheapest listed product. While the physician may prescribe by brand name (if the brand name product is on the drug benefit list), the system puts strong pressures on the physicians to prescribe by generic name alone. The pharmaceutical manufacturer who cannot get his product on the benefit list because there happens to be a cheaper generic or imported product, does not have an opportunity to provide this medication to the welfare patients. The manufacturers believe that in addition to all other reasons for opposing this program, a physician's choice of dosage form and a manufacturer's brand may be just as important as the choice of the actual therapeutic agent. Perhaps the essence of the problem is that the emphasis is put on price; this does not take into account the costs for research and development of drugs, which normally result in a higher cost of the brand name products.

A related problem is the provision in the Pharmacy Act of another Province which allows a pharmacist to substitute a generic product for a name brand product in a doctor's prescription unless the doctor indicates that he wishes the specific named brand product supplied. The position of the pharmacist might be difficult if the substituted product was not a precise equivalent and produced harmful side effects to the patient. He is substituting his judgment for that of the physician. In a damage action it would probably avail him nothing to plead that the Provincial Statute gave him the right to make the substitution.

Governmental Inquiries

The second problem to which I might refer relates to the large number of inquiries that have taken place over the past three or four years by the various arms of Government in this country into the Pharmaceutical Industry. The first of these inquiries arose by a decision of the Director of Investigation and Research under The Combines Act that he would embark upon an inquiry under Section 42 of The Combines Act. That section provides that the Director may, upon his own initiative, carry out an inquiry concerning the existence and effect of conditions or practices having relation to any commodity which may be the subject of trade and commerce, and which conditions or practices are related to monopolistic situations or restraint of trade. Having carried out an inquiry under this section, the Director produced a volume dated the 28th of February, 1961, entitled "A Statement Relating to the Manufacture, Distribution and Sale of Drugs" which was known during the inquiry as the Green Book. The matter was referred to the Restrictive Trade Practices Commission, a Commission set up under The Combines Investigation Act to whom the Director must refer matters relating to combines, mergers and monopolies; and that Commission, having invited submissions from the public, held public hearings in the principal cities across Canada. The Commission concerned itself in its report, which was dated January 24th, 1963, with pharmaceutical nomenclature, classifications of drugs, the drug manufacturing industry, medical research in Canada, drug patents, quality control, inspection, cost of advertising and trade promotion, and similar subjects. It concluded a five hundred page report with certain recommendations: that there should be more stringent regulations under The Food and Drug Act with respect to the manufacture and introduction of drugs; that the staff of the Directorate should be considerably enlarged; that all premises used for the manufacture of food and drugs should be inspected; that new drug submissions should be

extended; that all advertising and promotion activities should be brought under the supervision of the Food and Drug Directorate; that there ought to be an authoritative Government publication giving all necessary particulars concerning new drugs; and that patents with respect to drugs should be abolished. The Commission also noted that certain compulsory licensing provisions of The Patent Act were not being sufficiently used. It was the opinion of the Commission that their recommendations provided the only effective remedy to reduce the price of drugs in Canada. In passing it should be stated that the Commission found no evidence of monopolistic situations or activities in restraint of trade in the industry.

The Pharmaceutical Manufacturing Industry, of course, was very active in the presentation of material to the Commission and had Counsel present to cross-examine witnesses and to adduce evidence of matters in which the Commission appeared interested.

At about the same time the Province of Ontario was having a similar inquiry with somewhat different terms of reference, and a Select Committee of the Ontario Legislature on the cost of drugs was formed and took evidence on which it subsequently made a report dated the 26th of April, 1963. This again involved the Pharmaceutical Industry in the preparation of material and a brief, and in a presentation to the Committee.

Shortly after that a Royal Commission on Health Services was set up by the Federal Government. It held hearings in all the principal cities of Canada and was, of course, concerned with pharmaceutical products. It was necessary for the Pharmaceutical Industry to again prepare the appropriate submission and to make representations in presenting its point of view to that Commission. Finally, the Parliament of Canada set up a Parliamentary Committee (now adjourned until the Fall) which has been occupied for over two years, first with drug safety and now with the cost of drugs. This has again involved the Pharmaceutical Industry in the preparation of detailed information and a brief. The Canadian Pharmaceutical Association has made five appearances before the Committee on matters of drug safety, the registration of manufacturers and on the general submission with respect to costs. The questioning on the brief is only partially completed and will resume next Fall.

Four important and major inquiries in a space of three or four years have given the manufacturers an opportunity of presenting their views to the various Boards and Commissions and Committees, but they have created a problem as a considerable amount of manpower

and effort must be devoted to the making of a proper submission. I am aware that the multiplicity of inquiries to which I have just referred and in which I have been personally involved as Counsel for the Association is not a peculiar problem to Canada and that you in the United States have had similar inquiries which I understand are still carrying on. It is, of course, our function as attorneys and counsel for our respective clients to present their points of view and to represent them on these occasions.

Granting of Patents and Compulsory Licenses

A third industry problem in the drug field in Canada, and perhaps the most important, relates to the matter of patents. I had indicated that the Restrictive Trade Practices Commission in 1963, while hearing very little evidence with respect to the effect of patents in the drug field, decided that the abolition of patents (which of course are in themselves a monopoly and the antithesis of all those things for which the Restrictive Trade Practices Commission stands) would reduce the price of drugs. In coming to this conclusion the Commission argued that the compulsory licensing provisions of the Patent Act were not effective to "reduce the cost of drugs." This recommendation has not received implementation. It has been severely criticized because it would mean that Canada would be getting a free ride on the coattails of other countries where the patent system requires disclosure of a pharmaceutical product or process, and that manufacturers in Canada could therefore steal the benefits of the patent without having to pay the price. Many people argue that it is unthinkable that Canada would abolish patents in this international industry. In this connection it is rather interesting to note that The Combines Investigation Act contains a special remedy under Section 30 which gives our Exchequer Court the right to take away the benefits of a patent in certain circumstances, but the section concludes that no order can be made which is at variance with any treaty, convention arrangement or engagement respecting patents with any other country to which Canada is a party. As Canada is a party to the Patent Convention, the abolition of any patents in this field would require a drastic change in Canada's international position. I am therefore going to assume that patents will not be abolished and to discuss two sections of the Canadian Patent Act which relate to a problem peculiar to the Canadian Pharmaceutical Industry.

Let me begin with the premise that a patent has three principal purposes: (1) to stimulate invention and search for new applications

of knowledge; (2) to promote the introduction into public use of new devices and processes; and (3) to require full disclosure so as to make available to others skilled in the trade the new inventions so that they may be used in the public domain after the patent period has expired. (Because a patent confers a temporary monopoly, the Restrictive Trade Practices Commission has recommended its abolition, and this view has also been expressed in part in the report of the Royal Commission on Health Services.) Now let us consider Section 41 (1) of The Canadian Patent Act which provides as follows:

> In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specifications shall not include claims for the substance itself, except when prepared or produced by the methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalent.

In short, in Canada you cannot get a patent for a pharmaceutical product but only for the process by which that product is established. Sub-section (2) provides that in any "action for infringement of a patent where the invention relates to the production of a new substance, any substance of the same chemical composition and constitution shall, in the absence of proof to the contrary, be deemed to have been produced by the patented process." In other words, there is a presumption that if someone else produces the identical product, that it was produced by the patented process but this presumption can, of course, be rebutted by establishing that it was produced by another process. So the first problem is simply that in Canada it is impossible to obtain a patent on a pharmaceutical product but only on the process. It is my understanding that this is different from the provisions of the United States Patent Act, and that in your country you can not only patent the process but you may also patent the product.

This, of course, is a "problem" in the pharmaceutical field but it is not nearly as serious a problem to the pharmaceutical manufacturers as the third sub-section to Section 41. I should like to quote the sub-section to you and then describe how the problem arises:

> In the case of any patent for an invention intended for or capable of being used for the preparation or production of food or medicine, the Commissioner (that is the Commissioner of Patents) shall, unless he sees good reason to the contrary, grant to any person applying for the same, a license limited to the use of the invention for the purposes of the preparation or production of food or medicines but not otherwise; and in settling the terms of such license and fixing the amount of royalty or other consideration payable, the Commissioner shall have regard to the desirability of making the food or medicine available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention.

First let me point out to you that there are two other sections of the Patent Act which safeguard the public interest if an invention is not

being used. Section 67 contains effective provisions for action through compulsory licensing to prevent the abuse of the patent. If then an invention is not worked, after the expiration of three years the Attorney General of Canada, or any person interested, may apply to the Commissioner of Patents asking for relief under the Statute with the effect that a compulsory license would issue. Similarly Section 19 of the Act gives the Government of Canada the right to use any patented invention upon payment of reasonable compensation. Notwithstanding these safeguards, what has happened is that after a pharmaceutical manufacturer acquires a process patent on a pharmaceutical product which becomes popular, anyone wishing to cash in on the popularity of the product can apply to the Commissioner of Patents for a compulsory license. Now the origin of this sub-section was based upon a British Statute and the original English enactment was explained in the Sargast Committee Report of 1931 in the following terms:

> During the war it became apparent that Great Britain was suffering from a lack of medicine and drugs, many of which were the subject of patent rights in this country. On the other hand it was found that in many European countries (for example France, Germany, Switzerland) such substances were not capable of protection under the patent laws of those countries. In this state of things it was considered expedient to modify to some extent the monopoly consequent of the existence of patent rights in regard to such substances.

The origin of Section 41 (3) was the danger of shortage of drugs in England but it was copied into the Canadian Act to meet a situation which in no way applies in Canada today. Under this Section any person may apply for a compulsory license and Parliament has said that the Commissioner shall, unless he sees good reason to the contrary, grant to the applicant the license.

The wording of Section 41 (3), plus the way in which it has been administered and interpreted, intensifies the problem in Canada. The final decision as to the granting of a compulsory license is made by the Commissioner of Patents. Now the Commissioner of Patents from time to time is no doubt extremely well qualified in patent technicalities but he does not necessarily have the experience either of the economics of the industry or of the medical or scientific aspects. Further, under the present regulations, he is not required to obtain any advice from experts in these areas. The covering letter forwarding the recent report by the Hilliard Committee to the Minister of National Welfare dated July 12th, 1965, made the following observations:

> It was a shock to the members of the Committee to find the heavy responsibility put upon the Commissioner of Patents. Many of the newer drugs are so complicated in their formula that part of the products, the isomers, might

not be active therapeutically though chemically pure and some dangerous impurities may not be sufficient in amount, in small samples, to be detected.

The section provides that the Commissioner shall grant a license unless he sees good reason to the contrary. He is thus designated to make the decision whether the exclusive right of a patentee shall become the subject of a matter of a license. The Courts have refused to interfere with this decision on the grounds that the section provides that the decision is one for the Commissioner to make and the Courts have also refused to lay down what matters constitute grounds for refusal of a license. The section contains no objective standard for judgment by the Commissioner—no guidance is given by the section and no guidance has been given by our Courts as to what matters the Commissioner should examine or investigate to determine if good reason does in fact exist for the refusal of a license.

No principle having ever been enunciated by the Court upon which the Commissioner should act, it is significant that no decision has ever been overturned by a Court on appeal. The Supreme Court of Canada has held that the Commissioner is within his rights to refuse to grant an oral hearing. It is difficult for lawyers to see in what circumstances the Commissioner can act without evidence, since the material before him would consist of nothing more than blanket statements and since the claims of the applicant are not subject to the test of cross-examination. The present Commissioner has rejected all arguments to the effect that the applicant had previously infringed the patent, or could not produce economically the product in commercial quantities; or that the market was already adequately supplied. In the light of these rejections the drug patentee may be pardoned for being perplexed about the intent of the Parliament of Canada in imposing the limitation that a license should be refused where good reason to the contrary exists. This section as it is now administered appears tantamount to the granting of a license as of right even though the patentee is fully supplying the market with a pharmaceutical product of high quality at a reasonable price.

To sum up, Section 41 (3) of the Patent Act subordinates the real interest of Canadians in the availability, quality and safety of pharmaceutical products and in the stimulation of research in one of the most vital areas of human endeavour, to limited and temporary price advantages.

Establishment of Royalties

A second offshoot of the same problem is in the establishment of royalties. The Commissioner is required to fix the amount of royalty

or other consideration payable and in doing so he must have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with the giving to the inventor of due reward for the research leading to the invention. In all applications to date the royalty has been established on the selling price of the bulk chemical. In a recent appeal from the Commissioner to the Exchequer Court (as provided for in the Statute), the Exchequer Court President reversed the finding of the Commissioner and made the following statement:

> I have come to the conclusion that the Commissioner fell into error in thinking that the "finished material in dosage form, packaged and labeled" was "outside the scope of the patent" and "immaterial" to him. On the contrary, the drug in the dosage form, if it is made in accordance with the patented process, is just as much the subject matter of the patentee's monopoly as it is when it is sold in bulk. It is precisely the same product as it is when it is in bulk except that it has been packaged so as to be in the form in which it has a value as a merchantable commodity.

In that case the Commissioner of Patents had granted a royalty of 15 per cent of the selling price of the bulk active ingredient. This would have amounted to $37.15 per kilogram on a probable selling price of $250.00 per kilogram in bulk. The proposed selling price for the finished dosage form amounted to $3,500.00 per kilogram so that the royalty is equivalent to less than one per cent of the patentee's selling price. Since the applicant in this case had done no research and offered little by way of medical information and had not made a new drug submission to the Directorate, he would be enjoying substantial profits through the obtaining of a free ride on the essential functions performed by the patentee and it is clear that this scale of compensation awarded by the Commissioner would effectively destroy the value of a patent subject to any such compulsory license. The President of the Exchequer Court's royalty amounted to $525.00 per kilogram or 15 per cent of the licensee's selling price. Although this sum does not begin to cover the cost of research and medical information borne by the patentee, it was some recognition of the desirability of awarding the patentee more than a mere pittance. However, the matter was further appealed to the Supreme Court of Canada and in a Judgment delivered in January this year the Supreme Court of Canada overruled the decision of the President of the Exchequer Court and returned the royalty to that established by the Patent Commissioner. The Supreme Court of Canada regarded the Commissioner's award as being more consistent with "the lowest possible price" referred to in Section 43 (1) (3). The state of the law is there-

fore that the reasoning of the Exchequer Court has been overruled and the reasoning of the Patent Commissioner has been reaffirmed. The applicant for a compulsory license will get the right to copy the patentee's dosage form so as to claim that this copy has the same therapeutic effect as the original. In so doing he is, at minimal cost and with no lasting commitment, taking advantage of the substantial market created by the patentee. He will enjoy all the benefits resulting from the patent and the amount of royalty that he will have to pay would amount to approximately fifteen per cent of the selling price of the bulk active ingredient. I think it is safe to say that the responsible drug industry in Canada advocates the abolition of the compulsory license provision, but, if it is to remain, then the Industry argues that there should be some guide line set out in the Statute to indicate the basis upon which the Commissioner would act and a realistic royalty would be paid.

The Hilliard Committee, whose report to Parliament was tabled about a year ago, considered the matter of compulsory licensing and recommended that such a license should not be granted until there is first furnished to the Commissioner of Patents a favourable report or certification by the Director of the Food and Drug Directorate as to the competency of the applicant for such a license to manufacture or produce such substance including the adequacy of manufacturing facilities and the various controls required by the regulation. The Committee urged close collaboration between the Commissioner of Patents and the Food and Drug Directorate which did not exist previously because there was nothing in the Statute requiring any such collaboration. The Committee was also concerned about the efficacy and quality of the imitating product.

Those of you who have had anything to do with a new drug submission and are aware of the costs and problems in introducing a new drug at the present time under current regulations, will appreciate that the effect of a compulsory license being granted with a minimum royalty requirement might have a serious effect upon further research.

These then are a few of the problems that relate to the drug industry in Canada and upon which that industry is making submissions at the present time. As most of the large pharmaceutical manufacturing concerns in this country are subsidiaries of foreign companies, there are no doubt problems relating to that subsidiary relationship. As I do not act for any particular pharmaceutical manufacturer but only as general Counsel for the Association, I have deliberately refrained from any comment in this area. **[The End]**

Food and Drug Advertising and Pricing Problems Under the Combines Investigation Act

By DAVID H. W. HENRY, Q.C.

The Following Article Is Reprinted from *The Business Lawyer* (November 1966, p. 195) with the Permission of the Publisher and of the Author. Mr. Henry Is Director of Investigation and Research Under the Combines Investigation Act.

AS I UNDERSTAND MY ROLE in this panel discussion today, it is to place before you for discussion the main outline of the Combines Investigation Act so far as it relates to food and drug advertising and pricing problems. This statute is drafted in general terms and as its provisions relate to articles or commodities that may be the subject of trade or commerce without specific reference to any particular goods or classes of goods, it will suffice for our purposes today if we have a general understanding of these provisions which, unless statutory exceptions can be found, apply to food and drugs as well as to other classes of commodities.

Free Competitive Enterprise

The purpose of the Combines Investigation Act, as judicial pronouncements have affirmed, is to protect the public interest in free competition. Parliament has accomplished this by enacting this statute in criminal form, creating prohibitions with corresponding penalties. The language of the statute is prohibitive rather than regulatory, by which I mean that it becomes an indictable offense (with one exception) to violate the prohibition; at the same time no power is given to any Minister, board, agency or official to make exceptions to the rules laid down in the statute to permit conduct by particular persons or in particular circumstances that is otherwise prohibited by the statute, to prohibit a person from doing anything that is not made unlawful by the statute, or in any other way to regulate business conduct.

Parliament has sought by this statute to preserve and facilitate the working of the free competitive enterprise system. In such an economy, subject of course to a number of identifiable exceptions, resources are allocated and prices are set by the forces of competition in the marketplace. Generally speaking, this system is to be contrasted with a state-administered economy which, theoretically speaking, would be characterized by bureaucratic administration of the economy through such devices as production control, market allocation, direct price control and profit control. At the other end of the scale one might envisage an economy in which the various trades and industries are administered by the members of industry themselves, a sort of businessmen's bureaucracy, collectively deciding what shall be produced, how much, who shall produce it, and at what prices. Both these extremes are incompatible with the philosophy of the Combines Act. Therefore, it would take a further statute to permit either of these arrangements or variations of these arrangements to operate lawfully. Such statutes exist in the form of legislation creating marketing boards for agricultural commodities, boards that regulate the transportation industry including the fixing or approval of air, rail or trucking rates, the liquor control boards which set the prices of beer, wines and spirits, and the like. The distinction between regulation or partial regulation of an industry by a government agency and similar activities by members of the industry itself is that the government agency is ultimately responsible through a minister to the legislature, and the public interest is therefore, constitutionally at least, protected, whereas in the case of self-regulation by members of industry, there is no such responsibility and no such protection.

Generally speaking, in the Canadian economy there is relatively little direct price and production control. There are, as I have said, some exceptions and these are, for the most part, direct controls of a regulatory nature imposed upon particular industries by legislation of the provinces enacted pursuant to the legislative authority conferred on the provincial legislatures by section 92 of the B.N.A. Act. Except in time of war or other emergency, as a general rule the federal parliament and the federal authorities are not empowered to impose such controls.

You will understand from what I have said that price, generally speaking, tends to be a function of the marketplace. The Combines Act seeks to ensure that, in the absence of valid statutory controls, the price of an article shall be determined by the forces of the market uninhibited, so far as that is practically possible, by restraints im-

posed upon competitive forces by members of industry acting collusively or through the abuse of market power.

To accomplish this, Parliament has, through the Combines Investigation Act, prohibited three broad classes of conduct:

(a) Combinations that prevent or unduly lessen competition in the production, purchase, sale, storage, rental, transportation or supply of commodities or in the price of insurance;

(b) Mergers or monopolies that may operate to the detriment of the public;

(c) Unfair trade practices, including price discrimination, predatory pricing, certain promotional allowances, misrepresentation of the regular price and resale price maintenance.

A breach of these provisions (except section 33C—misrepresentation of the regular price of an article) constitutes an indictable offense which is punishable upon conviction by a term of imprisonment not exceeding two years, or a fine, without limit, in the discretion of the court, or both such fine and imprisonment; provision is also made for injunctive proceedings to prohibit the continuation or repetition of the offense, or to dissolve a merger or monopoly that contravenes the Act. Other remedies permit the government to adjust the tariff to subject unlawful combinations, mergers and monopolies to stiffer foreign competition, or in the case of the abuse of a patent or trademark, permit the court to place limitations on the licensing or use of the patent or trademark or to nullify it.

It is quite impractical to deal with pricing policy in any depth under the three main divisions of the Combines Act in the short time available. A brief word, however, about broad principles will perhaps be helpful.

Collusive Pricing

First, as to collusive pricing. Section 32 of the Act makes it an offense for two or more persons to conspire, combine, agree or arrange to limit competition unduly in the production, manufacture, purchase, barter, sale, storage, rental, transportation or supply of an article. Not every agreement to limit competition is unlawful, but the prohibition extends to any agreement the object or effect of which is to limit competition *unduly*. Generally speaking, the courts have taken the position that competition is limited unduly when the parties to the agreement account for a substantial segment of the market. A price-fixing agreement is a typical form of combine and a number

of such agreements have, over the years, been struck down by the courts and the offenders convicted and sentenced. As a general rule it may be said that any price-fixing agreement is suspect and most are indeed unlawful.

Monopoly Prices

Secondly, a word as to monopoly prices. It is not unlawful by itself for a firm to be in a monopoly position. The Act, however, aims at preventing monopolization in that it makes unlawful a merger which limits competition to the detriment or against the interest of the public whether consumers, producers or others. *Prima facie,* a merger which eliminates competition and so produces a monopoly is contrary to section 33 of the Act. A lawful monopoly, however, may continue to operate so long as the monopoly is not abused. The principle of abuse is described as operating the monopoly "to the detriment or against the interest of the public." Such abuse may take place if the monopolist so conducts his affairs as to continue to preserve his monopoly position by predatory activity which inhibits new entrants from becoming established in the industry, thereby stifling initiative, innovation, technological improvements and efficiency in production and administration. A monopoly may also be abused by failure to allow competition to develop at the different levels of distribution for the product of the monopolist, for example by unduly limiting or denying supplies to responsible outlets, creating a network of exclusive dealerships or instituting tying arrangements whereby the power of the monopoly is extended to other products of the supplier with respect to which the supplier does not enjoy a monopoly. Similar forms of abuse may be practiced with respect to a product or process for which the supplier holds a patent and this can be of considerable significance in the pharmaceutical industry. In the absence of such abuses, however, a monopolist is free to set his prices according to his own judgment. If he does not price his product intelligently, sooner or later his unduly high price will attract others into the market and competition will develop to bring about a more realistic price level. If this occurs, or is threatened, the monopolist must be careful not to adopt predatory pricing tactics (that is, selling at an unreasonably low price for the purpose of inhibiting competition), as this could constitute an abuse of his monopoly position and so attract an inquiry or other enforcement proceedings under the Act.

The foregoing is necessarily only a broad general comment on the conspiracy, merger and monopoly provisions of the Act. Par-

ticular situations require a much more sophisticated analysis of the law in relation to the facts and businessmen are well advised to take advantage of our program of compliance by coming into the Combines Branch for consultation concerning the application of the law to the particular business problem at hand.

The third category of pricing problems falls within what I might call the unfair trade practices provisions of the Combines Act. These provisions, sections 33A, 33B, 33C and 34, have a more direct bearing on pricing policies and I will therefore deal briefly with each of them.

Price Discrimination

Price discrimination is dealt with in section 33A, and you will recognize this provision as the counterpart of section 3 of the Robinson-Patman Act in the United States. To constitute the offense a number of ingredients must be present:

(a) There must be two or more sales that can be compared;

(b) There must be a discount, rebate, allowance, price concession or other advantage granted to one purchaser that is not available to another;

(c) The persons between whom there is discrimination must be purchasers who are in competition with each other;

(d) The discriminatory prices must apply to articles of like quality and to like quantities thereof;

(e) The discriminatory transaction must be part of a practice of discriminating.

Because discrimination must be a practice, the section does not prohibit discrimination on a one-shot basis such as the giving of a special price for a store-opening special, anniversary special, and the like. This provision, moreover, unlike the American legislation, does not require cost justification for the conferring of a volume discount. The result is that volume discounts can be given on an unlimited basis so long as the quantity or volume discount is available to all competing purchasers who buy in the same quantity or volume. Indeed, many suppliers have set up a scale of discounts varying according to the quantity or volume purchased, the large volume buyers being entitled to the best price or greatest discount. This has given rise in Canada to the organization of a number of "buying groups" who organize their purchases through a central buyer for the purpose of achieving larger discounts by combining their requirements in the hands of a single purchaser. Such arrangements, in order to

be lawful, must be set up carefully with sound legal advice; the important point here is that the quantity or volume discount must apply to the purchases of a single purchaser and cannot apply to the total volume of a number of purchasers even though they place their orders through a single agency. The central buyer therefore must legally be the purchaser as principal and he must, in turn, distribute to the members of the group; if the arrangement is properly set up, the central buyer is entitled to the same discount as competing purchasers for an equivalent volume or quantity.

According to the view that I take of the Act, year-end rebates are lawful if made available to all competing purchasers achieving the same volume over the period in question. Functional discounts, however, where customers classified differently for discount purposes are in competition with one another, will give rise to question since they depart from the simple and singular test laid down by the statute, namely, the volume or quantity of the goods purchased, assuming like quality. For the same reason, discounts available to customers competing with one another which are based upon the fulfillment of a condition, which all may be unwilling or unable to accept, would *prima facie* attract an inquiry.

The United States Supreme Court in the *Borden* case[1] recently held, as I understand it, that under the United States law an identical product sold under a national brand and also under a private label must receive the same price treatment. This situation arises in Canada and has not as yet been the subject of judicial pronouncement. In determining whether an inquiry is warranted, however, I have consistently taken the position that notwithstanding the similarity of the product itself, the package sold under the national brand and that sold under the private label differ in quality so that different prices may be charged without violating the price discrimination section.

Predatory Pricing

Predatory pricing is an activity made unlawful by section 33A. The first of its provisions is also sometimes called regional price discrimination because it contemplates a price differential between two geographical areas in Canada. The differential, however, of itself does not give rise to illegality; it must be accompanied by the predatory design, effect or tendency mentioned in this paragraph.

[1] *FTC v. The Borden Company*, CCH TRADE CASES ¶71,716 (1966).

Basically the elements of predatory pricing under section 33A (1)(c) are:

(a) The supplier must sell at an unreasonably low price; the unreasonableness of the price is, in administrative practice, related to the cost of the goods to the supplier, although this is not invariably a sound test since there may be circumstances such as depression of the general level of the market in which an attempt to dispose of production or inventory at less than full cost is perfectly reasonable;

(b) There must be a "policy" of selling at the unreasonably low price; what constitutes a policy may be somewhat difficult to determine and as in the case of all provisions in the Act, this must be determined in the light of the particular facts;

(c) The policy once established must have the effect or tendency of substantially lessening competition or eliminating a competitor, or must be designed to do so.

The only judicial decision on this provision to date is the *Producers Dairy* case[2] in which the Ontario Court of Appeal appears to have laid down the principle that a short-term (3 days) reaction to a competitor's price cut designed to allow him to penetrate the market does not amount to a policy within the meaning of the section, notwithstanding that the effect of the alleged predatory pricing was to discipline the market and so bring about an end to a short-term price war.

Disproportionate Promotional Allowances

Disproportionate promotional allowances are dealt with in a provision enacted in 1960 as section 33B. This provision deals solely with allowances given for advertising or display. Care must be taken not to confuse the activity to which this section relates with price concessions that are not given for advertising or display and which therefore may fall within the discriminatory pricing provisions of section 33A. The offense consists, in effect, of failing to offer benefits in accordance with the formula prescribed in this section in connection with the granting of a promotional allowance. The following are the important points to be kept in mind if the granting of the allowance is to be regarded as lawful.

[2] *The Queen v. The Producers Dairy Ltd.* (unreported).

(a) The allowance does not fall within the section unless it is given for advertising and display and is not applied to the selling price;

(b) The allowance must be offered (not merely made available) on "proportionate terms" to all competing purchasers from the supplier;

(c) Proportionate terms means first, that the amount of the allowance offered to each competing purchaser must be proportionate to the volume of business done by the purchaser with the supplier; and second, if services are required to be performed in return for the allowance, the cost-burden to be borne by the recipient must also be proportionate to the volume of business he does with the supplier;

(d) Unlike price discrimination, the failure to meet the requirements need not amount to a practice—the offense can be committed by one failure to comply with the section.

(e) The section can be complied with quite simply by setting up a formula for computing the allowance by reference to a percentage of sales for the period of the promotional deal; many firms have adopted such a formula and, if properly administered, there is no likelihood of a breach of the section;

(f) Incentive bonuses, which provide an allowance calculated by reference to an increase in performance in relation to some prior period, do not meet the test of the section and could give rise to an inquiry.

There is no jurisprudence on this provision. It is, in common with section 33A, enforced mainly through our program of compliance whereby businessmen take advantage of consultations with the Branch in order to ascertain whether or not the promotional scheme they wish to adopt will attract an inquiry under the Combines Act.

Misleading Advertising

Section 33C of the Act deals with a particular type of misleading advertising—misrepresentation of the so-called regular price of an article. You will note that, unlike the other offenses, this offense is punishable on summary conviction. This section has given rise to considerable litigation. Proceedings to enforce it are regularly reported in the Director's annual report. Briefly, it is an offense to misrepresent the regular price of the goods, and I have from time to time stated publicly that I would be obliged to commence an inquiry,

or at least seriously consider doing so, if an advertisement for a product would be likely to mislead an average member of the buying public as to the price at which the goods have been, are or will be ordinarily sold. It will be apparent that there are a number of devices which can be used in advertising material to convey the impression of a regular price. Such expressions as "Regular $ . . . ," "Hundreds sold at," "Compare at," "Comparable value," "Regular value," and the like are regarded by us *prima facie* as references to the regular price because they would likely be regarded as such by the buying public. In these circumstances, if the price is not that at which the articles are ordinarily sold in the relevant market, then an inquiry and prosecution would likely result. It is a very simple matter for a seller to prepare an advertisement which will truthfully and accurately reflect the regular price of the article; attempts to distort that truth by use of the numerous devices available will, if they come to the attention of the Combines Branch, become the subject of enforcement proceedings in order that the device may be tested in the courts.

On the basis of the jurisprudence developed thus far, the following are several important points that have emerged:

(a) The so-called regular price must be the price at which the goods have actually been sold by the majority of the dealers in the market in question; it is not sufficient, therefore, that one or two qualifying sales have been made by the seller himself at the so-called regular price;

(b) It is not a defense for the seller to assert that in publishing his advertisement he was unaware that the regular price represented by him was not that prevailing in the market;

(c) The preticketing by the manufacturer of an article with a price represented as the regular price gives rise to an offense by the manufacturer where the preticketed price is not the price at which the goods are ordinarily sold and is intended to be marked down by the retailer to show a bargain;

(d) An off-label deal (i.e., a label attached to the jar or package marked "10 cents off" or the like) is, in effect, a representation that the ordinary price is correspondingly higher and can give rise to liability by the manufacturer who applied the label if the "deal" is continued under circumstances in which the discount is no longer calculated on the actual regular price of such or like goods in the market either currently or in the recent past.

Resale Price Maintenance

In the cases where the manufacturer is guilty of an offense, it also follows that the retailer who publishes the price comparison is also guilty of the offense. Resale price maintenance is covered by section 34, and is prohibited outright in Canada with no provision made in the federal act for exceptions in the form of fair trade laws of the provinces, such as is found in the United States. The offense of resale price maintenance may be committed in two ways—by a supplier, by agreement, threat, promise or any other means, requiring or inducing (or attempting to do so) another person to resell an article at a price specified by the dealer or established by agreement, or at a price not less than a minimum price specified by the dealer or established by agreement; and in the second place, by denying supplies to an outlet because the outlet has refused to resell the article at a specified price or at not less than a specified minimum or has, in fact, resold at less than the specified price or minimum price.

Recognizing that some dealers are capable of abusing products of manufacturers through their pricing and advertising policies (and this is no doubt particularly true of brand-name products) Parliament, in 1960, provided by subsection (5) what is essentially a defense to a charge of resale price maintenance. Where such a charge has been laid on the basis of a refusal to supply goods to an outlet, no inference unfavorable to the person charged shall be drawn from that evidence if he satisfies the court that he had reasonable cause to believe and did believe that the other person was making a practice of using articles supplied by the person charged as loss-leaders—that is to say, not for the purpose of making a profit thereon but for purposes of advertising. This defense also extends to bait selling, misleading advertising of the supplier's goods or failing to provide the level of servicing that purchasers of such articles might reasonably expect from the outlet. In each case, the person charged must have reasonable grounds for believing that the outlet was making a practice of these activities.

This provision was recently challenged in the courts on constitutional grounds and the Supreme Court of Canada, in the early part of 1966, dismissed an appeal by the accused, thereby establishing that section 34 is within the powers of the Parliament of Canada as legislation in relation to criminal law and criminal procedure.[3]

[3] *Regina v. Campbell*, 46 D.L.R. (2d) 83, Appeal to Sup. Ct. of Canada dismissed.

I should add that in the *Moffats* case[4] the Ontario Court of Appeal has held that the offense of resale price maintenance was committed where a co-operative advertising allowance was available to a retailer only if he agreed to advertise the manufacturer's product at the manufacturer's suggested list price, notwithstanding that he was free to sell at a lower price. Reference should also be made to the *Sunbeam* case[5] in which the manufacturer was recently convicted of the offense of resale price maintenance by having established a range of prices, the lowest of which was known as the "minimum profitable resale price"—the price below which, in the judgment of the manufacturer, a reasonably efficient retailer could not profitably sell the articles in question. This decision is, at present, under appeal.

The *Campbell* case[6] is of particular interest to this audience in that a manufacturer's agent in Canada was convicted as a party to a scheme of resale price maintenance by Bard-Parker Company Inc., an American manufacturer of surgical blades sold to Canadian hospitals through jobbers. As the manufacturer was entirely outside the territorial jurisdiction of Canada, the charge was laid against the Canadian agent who was within the jurisdiction of the courts. The accused agent arranged contracts between jobbers and hospitals for the supply of surgical blades on a yearly basis at specified quantity discounts from the manufacturer's published list prices. Copies of the contracts so entered into, and invoices covering sales to hospitals, were sent to Bard-Parker and the accused agent. Schroeder, J. A., of the majority, in the Ontario Court of Appeal found as follows:

> In the present case the logical effect of the arrangement under consideration was to induce the suppliers to sell Bard-Parker surgical blades at a price not less than the minimum price specified, i.e. the printed list price. The resale price of the blades is prescribed by Bard-Parker in its published list price and in the printed form of contract prepared by it. In addition to enjoying the benefits accruing to him as a party to the contract procured in most instances by Bard-Parker or the respondent, the supplier is given a 5% rebate on all blades sold by him to the hospital pursuant to the contract. I can reach no other conclusion upon the whole evidence than that Bard-Parker and the respondent, by means of the hospital contracts binding both the supplier and the hospital to Bard-Parker's consumers' list price, did attempt to require or induce its purchasers to resell Bard-Parker surgical blades at a price not less than the minimum prices so specified. . . .

---

[4] *Regina v. Moffats Ltd.* (1957) O.R. 93.

[5] *Regina v. Sunbeam Corporation (Canada) Ltd.* (unreported).

[6] Cited at footnote 3.

Program of Compliance

He also adopted the view expressed by the Ontario Court of Appeal in the *Moffats* case[7] that to attract liability the attempt to induce maintenance of the resale price need not in fact be successful. The reasons of the majority were adopted by the Supreme Court of Canada.

This brief review of provisions in the Combines Investigation Act dealing with pricing policies and advertising will serve mainly to raise questions in the minds of this audience. Our program of compliance, which I have already mentioned, is designed to encourage businessmen to bring their problems relating to the Combines Act to us for discussion in order that we may clarify for them the position that I, as Director, would take with respect to any particular conduct or business decision that may appear to give rise to question under the Act. Through this program many businessmen have come in for consultation and the trade practices sections to which I have referred have in large part been administered on this basis. I should like to emphasize that any businessman is free to take advantage of this program. While the Director has no power under the Act to determine the law or give any binding decision concerning its application, in view of the fact that he must regularly make decisions as to whether to commence an inquiry on the basis of his having reason to believe that the Act is being or is about to be violated, he is in a position to state whether or not in particular circumstances an inquiry under the Act would result. This has apparently proved helpful to many businessmen and their legal advisers, and as a result it is my intention to continue this program into the future.

[The End]

SPONSORS WILL RECEIVE STATUS REPORTS OF THEIR NDAs

Sponsors of pending New Drug Applications will receive periodic reports of the status of their applications. The Food and Drug Administration mailed the first status reports on April 10, 1967. The reports show what stages of the review process the applications have completed. Also reflected are recommendations of the division handling the applications.

Since applications are considered confidential until they are approved, the status reports are only mailed to the sponsors. Unless an application has been under review for more than six months, the reports will be issued on a quarterly basis. Otherwise, they will be issued on a monthly basis.

---

[7] Cited at footnote 4.

What the Public Expects of FDA —A Third Party Arbiter

By WILLIAM W. GOODRICH

This Article Is Reprinted from *The Business Lawyer* (November 1966, p. 205) with the Permission of the Publisher and of the Author. Mr. Goodrich Is Assistant General Counsel, Food and Drug Division, U. S. Department of Health, Education & Welfare.

LAST APRIL THE FOOD AND DRUG ADMINISTRATION (FDA) stood at the beginning of an "agonizing reappraisal" of who it was, where it had been, how it got there, and how it should move to meet the challenges of the future. Fresh in its ears were Secretary Gardner's words that it had come of age; its responsibility was great; and it was charged with a venture worthy of the best resources of talent and energy. The swift moving events of the past seven months have shaken FDA and the industries it regulates. This reappraisal and adjustment is not yet over—indeed, it never will be —unforeseen events have a way of shaping the course of destiny.

There is more to this than a new Secretary of Health, Education and Welfare deeply dedicated to excellence, and a dynamic new Commissioner determined to perform in the pattern of excellence. FDA has a new visibility for the public which influences what it does—and how. And this calls for a better understanding of what the public expects from the Agency, as well as how the Agency is equipped to meet these expectations. The true measures of what the public expects are hard to come by. Last November, Secretary Gardner made the point that the average citizen can not easily comprehend the dimensions of FDA's task, but has largely taken the work of the Agency for granted.

Dr. Goddard recently expressed this with the thought that most consumers simply assume that "they"—some unidentified group of somebodys—would not allow the sale of any food, drug or cosmetic unless completely safe and true to its labeling. "They" is the FDA, and its authority and capabilities are not all that some of the public expect.

Last Friday, I picked a random group of letters to our Consumer Inquiry Branch for examples of what the public expects.

One woman wrote:

I appreciate it very much that you are taking care of all these drugs and also food. I am sure many people are grateful to you for being the new commissioner. Could you caution them about tranquilizers and anti-depressants? They go to my head. . . .

Three young ladies wrote about cosmetics. One wanted to know why she did not get the advertised results. She said she got the opposite result — without explaining just what that was. Another wanted to know whether her beautician was right or wrong in saying that a nationally sold hair preparation might make her hair fall out. And the third wanted to know what hair spray smells the least.

A man from a very small town in Texas wrote—enclosing a label —and said that since the truth in packaging bill is now law (an erroneous assumption) we should do something about the product.

Others wrote about additives of many kinds, some asking for information and some demanding the immediate banning of all artificial color, artificial flavor, and "harmful" preservatives. A mother wanted to know why raisins are treated with artificially flavored vegetable oil. Another complained about an anti-oxidant in yeast.

And there were complaints about excesses in television promotion of analgesics, the "high cost" of prescription drugs, and the refusal of the pharmacist to allow the patient to see the package insert for a prescription drug so that she could assess the danger.

Two writers complained that mayonnaise does not have a paper cover inside the cap to prevent people in the supermarket from opening the bottle and dipping out a serving with the finger.

And, of course, we have hundreds of letters on the new regulations for special dietary uses. One manufacturer said that they violated his constitutional right "to be left alone." Many consumers were alarmed because they thought vitamins were to be made Rx drugs. Some of these concerned consumers expected too much; some were badly informed on what we are doing; and some were suggesting regulatory action in areas wholly beyond our control. But they do show a wide area of interest in what the FDA is doing about our foods, drugs, and cosmetics.

The Kefauver Committee, then the Humphrey Committee, the Fountain Committee, the Long Committee, the Ribicoff Committee, and the Rogers Subcommittee on Investigations in the House Committee on Interstate and Foreign Commerce—all have shown interest in both the adequacy of the public laws we administer, and the level of our performance in discharging our duties under these laws. In a very short time this spring and early summer we were called upon

to account for the administrative handling of investigational new drugs, prescription drug advertising, LSD and other hallucinogenic drugs, the administration of the patient consent provisions, and the use of electronic equipment in enforcement operations.

This listing is incomplete, but each Congressional inquiry was welcomed by the FDA as an occasion for self-examination and for making any needed improvements.

Newspapers, magazines, radio and TV—all are interested in what FDA is up to. But they would not be interested unless the public was widely concerned. In explaining ourselves to the public, there are several basic points that should be noted. FDA's responsibilities have vastly increased. Since 1954 six broad amendments—each of major significance—have extended the scope of its charge. And they have changed the fundamental nature of its task.

FDA's Response

FDA's physical plant had to be rebuilt from the bottom up. But despite the accession of a new headquarters and laboratory building in the shadow of the Nation's Capital, many employees are housed in rented space in Virginia, in an abandoned nurses' home, and in World War II temporary buildings. Bringing the Agency together again as a compact unit is no longer possible. FDA's staff has grown from a few hundred in 1955 to a few thousand in 1966, but the average length of service of its inspectional staff is less than four years. Most of its employees are new. Recruiting and training have become major activities. Sweeping reorganizations are under way to improve the performance of the Bureau of Medicine and the Field staff. A study is being undertaken by an outside management consultant firm to explore the adequacy of the organization of the Field staff and its proper relationship to the headquarters.

The sophistication of products—foods, drugs, devices, and cosmetics—demands new methods and the latest equipment and personnel skills. We have had to embrace automation in our laboratories and in handling our data. Much remains to be done. Again to quote Secretary Gardner, "FDA is in the business of making difficult decisions, not just occasionally but every day of the week. . . . Most of them involve a deliberate weighing of benefit against risk. In some cases a wrong decision can deny the public valuable, even lifesaving, protection, or could expose the public to devastating injury."

When I first came to FDA, we were initiating about 3,000 enforcement cases each year. Today, the annual rate is about 1,000. But the 3,000 were largely concerned with filth and decomposition.

The 1,000 are largely concerned with drug abuse, cancer quackery, unwarranted claims, the control of new drug distribution, and the promotion of prescription drugs and devices.

Our major controls now are exerted through the administrative process of new drug, pesticide, food additive, and color additive preclearance and surveillance. In the early 40's our administrative proceedings were concerned with economic issues—standards for basic foods. Today, we are conducting hearings on the potentiality for abuse of three widely prescribed prescription drugs. Not long ago, I was somewhat surprised to read in a trade newsletter a statement to the effect that FDA now has virtually complete control over the promotion of drugs cleared as new drugs and antibiotics. While this is an over-statement of the case, we do have new means for assuring the reliability of all the claims that are being made to promote thousands of drugs that have cleared our new drug procedures over the past 28 years. And the sheer magnitude of the task has called for a unique approach, in which expert consultants selected by the National Research Council are assisting in a broad review of the claims of efficacy for about 4,000 previously approved drugs.

Dr. Goddard has said that there can be but one standard for all drug producers. This means that there is much to do to improve the quality and the validity of claims for thousands of drugs prepared by more than a thousand producers. The single standard must be a high one, because it involves one of life's vital interests—the safety and comfort of the patient at the end of the line of drug distribution.

If, as Boswell said: "The law is the last result of human wisdom acting upon human experience for the benefit of the public."—we must be ever alert to what experience teaches and prepared to act without undue delay.

And, if John Galsworthy was right when he said: "Public Opinion is always in advance of the law," we must be responsive to public opinion to keep our food and drug laws up with the rush of events in these dynamic industries. The public expects FDA to act as a third party arbiter; to respond to the new technology in production and promotion of food, drugs, and cosmetics so that it serves the consumer's interest as well as that of the producer; and to enlarge its role of public protector in matters in which the purchaser is unable to protect himself.

Congress, which expresses what the public expects, has provided a strong mandate for action. FDA is moving to meet its challenge.

[The End]

Question and Answer Panel of the FDA—FDLI Tenth Annual Educational Conference

The Following Material Is from the Afternoon Question and Answer Panel Featured on November 28, 1966 at the Tenth Annual Educational Conference of the Food and Drug Administration and the Food and Drug Law Institute.

Questions Addressed to William W. Goodrich

Q. Has the Food and Drug Administration (FDA) set a date for issuance of the definitive regulations regarding prescription drug advertising?

A. The notice of proposed rule-making should issue some time in April 1967.

Q. How many firms must use a practice before it is established or adopted as a minimum standard good manufacturing practice for industry?

A. In the case of promulgating the penicillin cross-contamination regulations, some people contended that we adopted a guideline in advance of industry practices, before it was a widely accepted good manufacturing practice. However, since no one formally complained of it, and it involved a serious health hazard, the regulation was promulgated on the basis of the hazard involved rather than "widespread use."

Q. Explain the FDA-FTC role in newly marketed Over-the-Counter (OTC) drugs.

A. The Federal Trade Commission (FTC) has asked us to make available to them any scientific data we have on these drugs. The FTC will measure this available data against the claims in the advertising, in much the same way the FDA is now doing for Rx drugs.

Q. Is there any responsibility placed on the journal in which a false or misleading ad appears?

A. So far, we haven't taken action against the media. However, we feel that the responsibility is shared by: (1) the person who creates the ad, (2) the person who places it, and (3) the person who runs it. It is possible to hold any or all of these responsible in a regulatory action.

Q. How can the FDA now declare a drug a "new drug" when it was previously stated that it was not a new drug?

A. The test of a new drug is whether it is generally recognized as being safe and effective, or, pre-1962, whether it was generally recognized as safe for its intended use. Medical opinion changes over the years. We are interested in the current opinion regarding the safety and efficacy of a product. Current opinion may be different from what it was some time ago. If industry is not satisfied with our opinions, the burden rests on the FDA to prove that the drug is not so generally recognized.

Q. What is the American Medical Association (AMA) position regarding Rx drug advertising? Do they support the recent FDA activities in this area?

A. The AMA has a code of advertising ethics which appears in their journal each month. We subscribe to the same principles spelled out in this code. However, we review the ads in greater depth than the AMA, because we have more available information, especially in our New Drug Applications (NDAs).

Q. How much information will the FDA divulge to a plaintiff lawyer with reference to a drug company in a product liability action?

A. This has been tested many times in court with variable results. The new Freedom of Information Law which becomes effective in July 1967 will certainly make more government records accessible. The Department of Justice is now preparing guidelines for this law. The FDA will continue to use great care and consideration in making public any information from new drug files. However, not everything in our files is confidential.

Q. To what extent do the FTC and the FDA cooperate on over-the-counter advertising?

A. The Commissioner had at least three meetings with Mr. Dixon of the FTC and implementation of the cooperative program is under way.

Q. Will publication of FDA policy in "FDA Papers" have equal weight with publication in the *Federal Register*?

A. The law requires that any regulation or statement of policy, to be effective, must be published in the *Federal Register*.

Q. How much time does the FDA permit when requiring a change in an NDA labeling?

A. The amount of time is variable, and depends on the degree of health hazard. Generally, if there is no health hazard present, we have permitted the pipe lines to be cleared of the existing product. If there is a health hazard, a recall is necessary.

Q. Why does the FDA use the surprise technique in a seizure of a product because of false or misleading Rx advertising, while Section 306 of the Act permits and recommends less drastic action?

A. We don't believe anyone has been surprised by any of the FDA actions. We have made seizures where there was gross exaggeration regarding the safety and efficacy of drugs, above and beyond the claims made in the brochure and other labeling.

Q. Is there any regulation which bars the FDA from contacting a firm regarding an Rx advertisement rather than using a surprise technique such as a seizure?

A. None whatever.

Questions Addressed to Robert J. Robinson, M.D., FDA

Q. What criteria does the Bureau of Medicine use to determine the level of a drug recall?

A. The level to which a drug recall is conducted is directly related to the degree of the health hazard. For instance, the Bureau of Medicine will recommend that the recall take place all the way down to the consumer level, if the threat to public health is serious. Actually, there is no hard and fast rule dictating the level of a drug recall. Each case must be evaluated on its own merits.

Q. Is the Bureau of Medicine planning a physician educational program with reference to drug recalls?

A. The new publication "FDA Papers" should provide a significant amount of assistance to physicians in keeping them up to date on FDA matters.

Q. Do you believe doctors are strongly influenced by drug advertising and are capable of evaluating the ads?

A. Whether a doctor is capable of evaluating the truthfulness of a drug advertisement depends upon a number of factors, including how busy his schedule is and the level of his training.

Questions Addressed to Douglas C. Hansen

Q. What precautions does the FDA take to insure that the inspector does not request a recall for minor technical violations?

A. Only two people in the FDA can authorize a recall—the Commissioner and the Deputy Commissioner. The inspector is only an agent carrying out their instructions. The FDA understands the serious consequences involved in requesting a recall. As a result, the Bureau of Medicine and other concerned FDA units carefully review all available data before making the serious decision to recommend to the Commissioner's office the recall of a drug.

Q. If a firm voluntarily recalls a product because of "pharmaceutical elegance," does the FDA list this in its recall records?

A. We have recently issued instructions to our District offices not to report any recalls made solely because of "pharmaceutical elegance" where no hazard to health or violation of the law is involved.

Q. What is the proportionate number of recalls between large, medium, and small drug manufacturers?

A. We haven't made such a specific study. However, all are generously represented.

Q. Explain the term "pharmaceutical elegance."

A. This is not an FDA term; it is an industry term. I assume it relates to such things as off-color tablets, unpalatable products or dirty labels.

Q. What is the FDA basis for prosecution in a violation of good manufacturing practice regulations?

A. Any deficiency resulting in a violative product would receive serious consideration for prosecution.

Questions Addressed to Irving H. Jurow

Q. Where does the physician get his information on a prescription drug other than from advertisements?

A. There are three ways to get this information: (a) from the package insert which he can easily get from his local pharmacy, (b) from the company detail-man, or (c) by contacting the company directly.

Q. What is the AMA position regarding Rx drug advertising? Do they support the recent FDA activities in this area?

A. I don't know what the AMA position is.

Questions Addressed to L. Paul Sinotte

Q. How do you handle label and quality control for physicians' samples of prescription drugs on samples manufactured in your plant?

A. On samples manufactured in our own plant, we have designed things so that each product has its own specific layout. All work is checked by our quality control inspectors and auditors.

Q. Shouldn't consumer groups be consulted by government and industry as to the kinds of new drugs that should be researched? For example, there is only a limited market for new drugs needed for people with rare diseases, but these should not be ignored.

A. Many times our firm (and I'm sure others) markets a product even if it does have limited uses and does not contribute to the net profit. **[The End]**

Wanted—Lawyer-Statesmen

By BRADSHAW MINTENER

The Following Article Was Presented as the Charles Wesley Dunn Memorial Lecture at the New York University School of Law on October 18, 1966. Mr. Mintener Is with Mintener & Mitchell, Washington, D. C.

I HAD THE PRIVILEGE AND PLEASURE OF WORKING VERY CLOSELY with Charles Wesley Dunn and was inspired deeply in this experience during the last thirty years of his distinguished life and career.

If there ever was a Lawyer-Statesman, it was Charles Wesley Dunn. His many significant accomplishments and efforts have given us permanent monuments and glowing evidence which verify Emerson's immortal statement that "Every institution is but the lengthened shadow of some Man."

I mean by the term "Lawyer-Statesman" a lawyer who goes beyond his limited or broad professional practice and responsibilities to create and to devote himself and considerable thought, energy, money and time to projects, programs and causes which are in the broad public interest and which benefit a far larger and more extensive constituency than his own legal practice.

I mean by that term a lawyer who spends hours, days, weeks and months helping others and creating, sponsoring, improving organizations and causes which inure to the benefit of large segments of the public generally and helpfully.

Charles Wesley Dunn epitomized, exemplified and personified the Lawyer-Statesman as no man within my acquaintance ever did.

I am proud and thankful that I had the opportunity to know him so well and to work so closely, as I was privileged to do, over the years with Mr. Dunn. I am a better person, or I should be, for having known and worked with Mr. Dunn. He was for me a living, working example of what a Lawyer-Statesman can and should be and in fact, is.

So today, we honor the memory of Charles Wesley Dunn, almost seven years after his death. If he had not lived and worked among us, and if he had not done so much for so many, we would not be here today.

Accomplishments of Charles Wesley Dunn

When I list the activities in which I worked with Mr. Dunn, I am utterly amazed.

In 1933 Mr. Dunn invited me to go to New York and Washington to work with him on the proposed new Food and Drug Law, which was ultimately and successfully sponsored and guided through the United States Senate by the distinguished Senator Royal Copeland of New York. I was fortunate to be able to work on several committees in writing the New Food and Drug Law which was passed in 1938 and became the Federal Food, Drug and Cosmetic Act in June, 1938, when it was signed by President Franklin D. Roosevelt. Those were also the days when I worked and became well acquainted with Mr. Charles W. Crawford of the Food and Drug Administration (FDA), one of the most competent, knowledgable, dedicated public officials in the federal government and one of the finest gentlemen I have been privileged to know. The federal service lost one of its outstanding members when he retired as Commissioner of Food and Drugs in 1954 and was succeeded by another distinguished colleague, George P. Larrick.

I worked with Mr. Dunn in enlarging and improving a Products Liability Claims Index File which proved to be valuable to me as General Counsel of The Pillsbury Company in many cases and claims during the after-depression years when scores of baseless Products Liability Claims were made and suits filed against our company and other food manufacturers.

We worked together and organized the Nutrition Foundation and Mr. Dunn persuaded Dr. Glen King to become its Director. This Foundation has been a great service to the food industry.

We organized, with the help and cooperation of many other lawyers, the Food, Drug and Cosmetic Section of the New York State Bar Association, which was the first of its kind in the U. S. and remains active today as a valuable forum for the presentation and discussion of authoritative papers in the important field of Food, Drug and Cosmetic Law.

Under Mr. Dunn's leadership, we organized the Food, Drug and Cosmetic Division of the American Bar Association (ABA). This

was more difficult because of the complicated labyrinth of procedural problems inherent in the organization of the ABA. But Mr. Dunn persisted and finally succeeded, and today this Division of the ABA still lives and functions in an important way.

Then Mr. Dunn organized, with the help of a number of us, the Robinson-Patman Section of the New York State Bar Association which has become the Anti-trust Law Section of that Association. The Anti-trust Law Section of the ABA is a companion Section.

In the mid-1940's, Mr. Dunn began talking to me about the necessity and desirability of teaching the Food and Drug Law in our leading law schools. He and I and others had a number of meetings to discuss this project. I remember so well and so pleasantly going up to the Dunn's farm in beautiful Vermont on several occasions to talk about his dream of a network of courses in the food and drug law in law schools across the country.

In 1948 we developed a law school program and we were ready to discuss it with officials of law schools. I outlined our plan to General Eisenhower, then President of Columbia University, and he was very interested and arranged through his Provost, Dr. Albert C. Jacobs, now President of Trinity College in Hartford, a meeting with Dean Young B. Smith of the Columbia Law School. Mr. Dunn, Mr. John Prescott, General Counsel, Mr. William Robbins, Vice President of General Foods, and I met with Dean Smith. Although he was very favorably impressed with our program, Dean Smith expressed the fear that his academic freedom would be interfered with by this food industry program. We were all shocked at such a reaction and frankly annoyed by this attitude, so Mr. Dunn went to Dean Russell Niles of this law school and the Food Law Institute's program was launched. Fellowships were provided. Mr. Dunn was given the rank of Professor of Law here and we were off the ground. He and I then made a trip out West and outlined our program at the Law Schools of Minnesota, Southern California, Stanford and California at Berkeley. You know what has happened since those early days. The Food Law Institute, now The Food and Drug Law Institute (FDLI), is an established, successful and influential entity under the able leadership of its President, my good friend and a distinguished lawyer, Franklin M. Depew. I know that Mr. Dunn would be delighted to know that Frank Depew is carrying on so ably as President of the FDLI.

Mr. Dunn founded the Food, Drug and Cosmetic Law Journal which has attained a high place as an important and useful tool for every lawyer in this area of the law.

While I was Assistant Secretary of the Department of Health, Education & Welfare (HEW), and in charge of the FDA, Mr. Dunn discussed a joint Food and Drug Administration—Food Law Institute Conference on the Food and Drug Law with me. This was worked out, and each year this Joint Conference is an important and valuable forum for the discussion by representatives of government and industry of current and important problems which have arisen in relation to the Food, Drug and Cosmetic Law.

Mr. Dunn was one of the most important and leading members of the First Citizens Committee to study the FDA, which I had the honor of setting up for Mrs. Hobby, the first Secretary of HEW. Its report was the blueprint for the expansion, increased budget and reorganization of the FDA.

Mr. Dunn organized and promoted the celebrations of the 40th and 50th anniversaries of the passage of the Food and Drug Law. The 50th Anniversary was the occasion of an outstanding program in Washington.

Mr. Dunn pioneered a comprehensive research program in the Food Law Institute. We now have an authoritative and most useful set of textbooks dealing with various phases of the Food and Drug Laws.

This list, and I am sure it is not complete, staggers one when we realize that each of the activities, programs and projects to which I have referred, was inspired, conceived, promoted and set in action by Mr. Dunn—principally, of course with the help and cooperation of others; but he was the spark plug, he was the inspiration, he was the "never say no" gentleman who was primarily responsible for each and all of these activities which I have listed.

These were the dreams of Charles Wesley Dunn. Fortunately most of them were fully realized during his lifetime. What a Lawyer-Statesman he was! His motivating urge was the public interest. Today it would be called the "Interest of the Consumer." He believed with deep conviction that the Food and Drug Law was the most important commercial law ever placed upon the statute books. Oh, yes—he spearheaded the first organized attempt to develop a uniform State Food and Drug Law which he hoped would be adopted and enacted into law in the various states.

It has been written that Charles Wesley Dunn was a "Man with a Mission." How true this is, and his mission was to help build a

better food and drug industry through a better and better-known Food Law (*Food Processing,* September, 1959).

All of these successful and significant accomplishments of Mr. Dunn were "extra curricula" outside his broad and distinguished legal practice. No one can possibly know, except those of us who worked with Mr. Dunn over the years, how much thought, "blood, sweat and tears" he put into the projects. Some here know even more intimately than I do because they worked with Mr. Dunn daily; for example, Frank Dierson, his great protege and right bower for many years.

We, who were privileged to know Mr. Dunn so well, loved, admired and respected him and were continually amazed and inspired by his indefatigable energy, his dogged determination and persistence and his high standards of moral and ethical conduct.

He loved and was very proud of his profession, the Law. He was a living example of a Lawyer-Statesman and gentleman who "saw a need and took it upon himself." He illustrated the truth of the statement attributed to Benjamin Disraeli, Prime Minister of England under Queen Victoria, "The secret of success is constancy to purpose."

Today we are living in a world in which we as lawyers must become involved outside and beyond the confines of our daily law practice. Lawyers are closer to the people today than any other group in our society, except possibly, clergymen and physicians. We as lawyers are called upon when people are in trouble in numerous areas, or when they want advice as to how to avoid trouble. We are called upon to counsel people in various kinds of crises, to plan and prepare for the handling of property after death and for the later years of life. We are asked to advise in a multitude of personal and intimate problems and matters. We are by the very nature of our profession brought close to and are needed by people of all ages, in all walks of life, all segments of the population. These opportunities for the carrying on of our legal practice and of making a living at it, involve many and broad responsibilities and obligations to be statesmen, to go beyond the daily call of duty, and to see the needs of the communities in which we live and work and take them upon ourselves. We belong to an old and honorable profession and we must never confine ourselves merely to setting and collecting fees as members of the Bar. If we, as lawyers, do not measure up to our responsibilities and the challenges they present to us, we will be poorer citizens and this

nation of ours will be the poorer. On the other hand, if we do measure up, we shall be better men, better Americans and we and the nation will benefit and profit.

The Need for Lawyer-Statesmen

Today we live in a world that has contracted manyfold since I graduated from Yale more than forty years ago. We can fly anywhere in the world in a few hours. We can communicate with other persons almost anywhere in the world in a few minutes. We can watch a simultaneous telecast via satellites from England, France, Germany and elsewhere. Someone recently said that Sir Winston Churchill was born before the telephone was invented and his funeral was telecast around the world by Telstar simultaneously with the event.

We have the benefit of miracle drugs and medical and surgical procedures and techniques unknown fifteen or twenty years ago.

We rocket men into space and they orbit the globe in a few minutes. We land rockets on the moon, receive pictures and radio messages from satellites circling the globe in details undreamed of a few years ago. Such pictures and messages have great scientific value.

We have witnessed the history-making series of young astronauts as members of the Mercury and Gemini Space teams orbiting the earth and their successful return from each flight through space. The entire world breathlessly watched and listened to their hourly progress. They have made us all proud. Truly we live in an extraordinary day.

We also live in a world of revolutions and rising expectations.

More men, women and children are politically free and on their own today than ever before, perhaps more than was even contemplated years ago.

We are the beneficiaries in our beloved America of a standard of living which is the highest in the world. We have more necessities and luxuries of life than can be found anywhere else. We have what is claimed to be the best educational system in the world and it is available to more people than in any place in the world.

I believe that there is no community, large or small, in America today which does not have important and difficult political, economic and social problems to be solved. For you students here, yours is the generation we must look to carry on after we are gone, and

I hope and pray that you will do a better job, which you can, than mine and recent generations have done to maintain peace, promote the general welfare, and preserve the American ideal throughout the Free World. These problems which beset every community and which you will find when you settle down in your community are needs to be met.

Someone has so truly said that, "What a man does for himself dies with him; what he does for his community lives long after he has gone." The heroes of history have been those men and women throughout the ages who have seen the need and have taken it upon themselves. "He Took It Upon Himself," was the title of an inspirational little book written by Margaret Slattery, the famous social worker of Chicago several years ago. The theme of Miss Slattery's book grips one's imagination and thrills the deep places of one's soul. "Seeing the need, he took it upon himself." That's vital. There's life in it. It contains the secret of all genuine and lasting success and service. That is the spirit and motivating urge that should carry every public servant to his goal. It certainly is the driving force which carries teachers, social workers and other voluntary service workers through their daily tasks. No one can read history and biography in the light of that theme without discovering that in the face of need and public service, "A sense of responsibility, personalized and individualized, lies back of every great life and every titanic movement."

Emerson has reminded us that "every institution is but the lengthened shadow of some man. . . . A movement is but the projection of some monumental personality." Service more than any other activity of man is the reason for grateful remembrance which ripens into fame. It was ever thus.

Back of the Reformation towers Martin Luther who saw a mighty need and took it upon himself.

Back of the saving of our own Union, stands great, gaunt Abraham Lincoln with his deep-set, poignant eyes and understanding heart, who saw the need and took it upon himself.

"Always to date and eternally always, somewhere in the process, somewhere there is a man or a woman who sees that need and feels personally responsible."

To live is to be responsible. You cannot finally escape that fact. There is a need to be met, a work to be done, and someone must do it.

Mulberry Bend here in New York City was transformed by Jacob Riis, a Danish immigrant, who out of a full heart said, "I cannot sleep for the burden of the city's children with their hunger for play and their playground only the street, beset with danger of body and soul." It was a heavy burden, to be sure, but Jacob Riis took it upon himself and became the unselfish benefactor to the street urchins of America. He knew and told us "how the other half lives."

Why have these hero-servants through the ages done what they have done?

Some call it consecration
And others call it God.

There are many of us—too many—who see the need today but pass it by. We too often, as individuals, fail to meet our responsibilities or fail to play our role as our "brother's keeper, helper, or brother." That was one of the reasons why the "Master of Men," to whom men came for shelter in the shadows of his wings, told us the story of the Good Samaritan.

Many of us see the need but minimize our ability to do anything about it. "What can I do—little me? I'm no genius. I do not have half a talent, let alone two or five," or "I simply do not have the time," or "Someone ought to do it—someone—but it's not my business or responsibility."

We talk a great deal about community and public conscience. Neither community nor public conscience are mysterious things. I am the community conscience. I am the public. I am the church, else there is no community conscience, no public, no church. The community conscience is the sum total of the consciences of one man and another and another. The public is one individual plus another plus another. The church is one church member plus another and another. When I say "The community ought"—"The public ought" —"The Church ought"—I really mean that "I ought" or it means nothing.

If I will not act, then thousands will not or cannot act. Someone, which means one, in the presence of the need, must take it upon himself, else the need is never met.

Throughout the history of our nation, there have been statesmen, churchmen, scientists, soldiers, lawyers, public servants of every kind who have seen the contemporary need and took it upon themselves. When the men who founded our nation formulated a Declaration of

Independence based upon the principle that all men are created equal and are endowed with certain inalienable rights by the Creator and then proceeded to draw up a Constitution that would guarantee respect for those rights on the part of the government, they were giving substance to aspirations that men have cherished since the dawn of history.

Men have always striven, sometimes successfully, often in vain, to achieve such an ordering of affairs as would safeguard the rights and prerogatives of the individual and at the same time promote the general social good.

Faith in human nature, in the integrity and worth of the individual men and women, is the necessary basis for free government. Our Founding Fathers had no fear of self-government, no distrust of people. They had faith in human nature; they believed in men and women. Because they had faith for which they were willing to fight and die, they dared to embark on what has proved to be the most ambitious and successful adventure in free government that the world has even seen. It epitomizes the role of man in seeing the need and taking it upon himself.

As a nation we have prospered and grown great. Working as free men and women, the people of the United States have, in less than two centuries, developed a noble and dynamic civilization where before there had been little save a vast wilderness. They have cleared their forests to make way for human life and industry. They have planted, and the rich soil has yielded them an abundance. They have harnessed the floods and have found ways of bringing the forces of nature to serve their needs. Comforts and conveniences undreamed of in the past gradually became daily necessities within the grasp of almost everyone, and wealth has abounded on nearly every side.

Why has all of this been possible? Because our nation has been blessed with scores of leaders such as Charles Wesley Dunn in every walk of our national life who have seen the needs of their times and have taken those needs upon themselves.

"Ask not what your country can do for you, ask what you can do for your country."

That is the statement made by President Kennedy in his brilliant, memorable Inaugural Address and quoted so often since. This is the question you should ask of yourselves in the future and if you get involved and become Lawyer-Statesmen, you will do so.

No privilege exists today without a corresponding responsibility or duty. You and I have been privileged to receive a legal education and have or will have been admitted to the Bar. You and I now have a responsibility and duty to Get Involved in the rendering of service in the community in which you live and work, in short to become Lawyer-Statesmen.

Conclusion

In closing, I should like to bring to your attention statements of three of the greatest leaders of our generation who in these statements have summarized the things I am trying to say to you today much better than I could.

The first is former President Herbert Hoover, who, 71 years ago (1895), graduated from Leland Stanford University. He was a poor, orphaned boy, who worked his way through college, became one of the world's outstanding and most successful engineers, and was elected to our highest office in America, the Presidency. Fortunately, he lived to see himself vindicated and absolved of the baseless and unfair criticism levied at him during his political life. He died a revered and beloved senior statesman. On his 80th birthday, President Hoover spoke about some of the uncommon men of history, and how every generation needed such people. His words offer a challenge to all of us. He said,

> The greatest strides of human progress have come from *uncommon men and women*, men like George Washington, Abraham Lincoln and Thomas Edison.
>
> When we get sick, we want an uncommon doctor. When we go to war, we yearn for an uncommon general or admiral. When we choose a president of a university, we want an uncommon educator.
>
> The imperative need of this nation at all times is the leadership of the *uncommon men and women*. We need men and women who cannot be intimidated, who are not concerned with applause meters, who will not sacrifice tomorrow for cheers today.

The next two great leaders, former President Eisenhower and Sir Winston Churchill, have also made statements worthy of note. I hope you will pardon personal references in these two instances. I happen to have had the rare and good fortune and privilege to have been a close friend of General Eisenhower for many years. He is now and always has been, in my opinion, one of the greatest exponents of salesmen of Americanism and our way of life. Several years ago I was having lunch with General Eisenhower when he was President of Columbia University, and as I was leaving the house, he gave me a copy of an address which he made before the American Bar

Association in St. Louis which I was privileged to hear. As I was riding in the taxicab from General Eisenhower's home to my hotel, I was particularly reimpressed with the first paragraph of the address because it is such an eloquent statement of what I am trying to tell you today.

> Every gathering of Americans—whether a few on the porch of a crossroads store or massed thousands in a great stadium—is the possessor of a potentially immeasurable influence on the future. Because America has freedom of speech, freedom of communication, the world's highest educational level, and untapped reserves of individual initiative, any group of people, fired by a common purpose, can generate a decisive strength toward its achievement. Some of the most inspiring chapters in our history were written by a handful of people who joined to talk over among themselves an idea or a principle that struck a note which revolutionized the world's thinking. That capacity still resides in every gathering in this country,

and I say it resides right here in this group at NYU Law School as we honor the memory of Charles Wesley Dunn.

Finally, while a student in England back in the early 1920's, I had the rare opportunity and privilege of meeting Sir Winston Churchill on several occasions. I have long been a great admirer of Sir Winston Churchill and I believe that he was by all odds the Greatest Citizen of the 20th century.

I believe that Sir Winston Churchill's speeches will be among the greatest, if not the greatest, literature to come out of the World War II era. In England's darkest years he rose to his greatest heights of oratory and leadership and rallied the English people to their heroic stand *alone* against the hordes of Hitler while we were forging the "arsenal of democracy" and preparing to invade Europe and defeat Fascism. We, as a free people, should be eternally thankful to Mr. Churchill and for the fact that his unforgettable and eloquent pronouncements have been preserved for us for all time—the greatest of which may well have been in the first speech after he was elected Prime Minister of Great Britain, "I have nothing to offer but blood, sweat and tears." In fact, that is about all he had.

Many of you here today may remember Mr. Churchill's broadcast to the world in February, 1941 during the darkest days of the war. That address was delivered to the people of Britain and America and Mr. Churchill concluded that now famous broadcast by giving an answer to a letter he had received from President Franklin D. Roosevelt introducing Mr. Wendell Willkie, whom he had sent to England to make a study and report to him personally on the situation of the war. President Roosevelt in his own handwriting at the

end of the letter had quoted to Mr. Churchill those famous lines from Longfellow's poem:

> Sail on, O ship of state.
> Sail on, O union strong and great.
> Humanity with all its fears,
> With all the hopes of future years,
> Is hanging breathless on thy fate.

and President Roosevelt said that those lines apply equally to the people of Great Britain as well as to the people of America. Mr. Churchill replied to that letter in that broadcast in what I believe is now an immortal statement. He said:

> Put your confidence in us. Give us your faith and your blessing, and under Providence all will be well. We shall not fail or falter. We shall not weaken or tire. Neither the sudden shock of battle, nor the long drawn trials of vigilance and exertion will wear us down. Give us the tools and we will finish the job.

So I say to you, let us resolve today to become Lawyer-Statesmen, so sorely needed in our America, as exemplified by the life and work of Charles Wesley Dunn.

Let us follow his life and his example, an inspiration to all who knew him.

You and I can become Lawyer-Statesmen by getting the best academic and legal education available to us. Then, we can develop the best law practice available to us in accordance with the best ethics and principles of our profession.

As we become successful in our practice let us look beyond our profession and our day-to-day practice and see the needs of our community and take them upon ourselves. There are so many needs, so much to be done but so few to do them.

As we meet these specifications we will become Lawyer-Statesmen, we shall be "uncommon men" so desperately needed today; we will be influential members of a segment of our society which, if we are "fired by a common purpose," will enable us to do almost anything we set out to do, and finally, if we get so involved, we shall be able to say to our friends and neighbors and to the entire community in which we live, "give us the tools and we will finish the job."

If we do become Lawyer-Statesmen—so wanted today—we will be filling a great need among lawyers today—"Wanted—Lawyer-Statesmen"—one of whom surely was the gentleman we are honoring today—Charles Wesley Dunn. **[The End]**

Industry Views on FDA's Labeling Proposal and State Regulations

By EDWARD DUNKELBERGER

This Article Was Presented before the Association of Food and Drug Officials of the Southern States, Roanoke, Virginia, on April 3, 1967. Mr. Dunkelberger Is Counsel for the National Canners Association.

I HAVE HAD THE OPPORTUNITY—or bad luck, depending on how you look at it—to follow the Fair Packaging and Labeling Act from the first hearings held by Senator Hart in June of 1961 through hearings by three different Congressional committees, final enactment at the close of last year's session, and now the first stages of implementation by the enforcing agencies. And if the Food and Drug Administration's (FDA) proposals are any indication of what is to come in the way of administration and enforcement, it looks as if I will have to resign myself to continuing work in this area for quite some time.

In this connection, I am reminded of the reply of a food industry lawyer to the question of whether his clients could live *with* the bill as finally enacted. He answered that he was not certain of that, but that he was sure he would be able to live *on* it for some years to come.

The intense controversy between industry and Federal officials —or to use a more fashionable phrase that is currently receiving a consensus in Washington, the continuing dialogue between the private and the public sectors—as to the need for new federal packaging and labeling legislation is a matter of common knowledge. The grocery products industries, including the National Canners Association, felt strongly that the consumer had been very adequately protected by thorough and competent state regulation, as well as

by the FDA and the Federal Trade Commission (FTC) in their administration and enforcement of the federal Food, Drug and Cosmetic Act and the Federal Trade Commission Act.

Indeed, the principal areas of Senator Hart's concern had very recently been the subject of extensive consideration by both industry and state officials, culminating in the promulgation of revised Model Weights and Measures Regulations by the National Conference on Weights and Measures. These regulations for the first time spelled out detailed requirements for declaring the quantity of the contents, specifying the size of type in relation to the label area and requiring placement on the principal display panel in a prominent, conspicuous manner, without confusing or deceptive qualifying words.

Efforts of the Canning Industry

For our own part, the canning industry devoted a great deal of time and energy to this cooperative industry-state regulatory effort. For many years the National Canners Association Descriptive Labeling Program recommended, with the FDA's approval, that the quantity declaration be placed on the information panel of the label, immediately to the right of the principal display panel on a cylindrical container.

Under these recommendations, the packer would place his brand name, an appropriate vignette and the full name of the commodity on the principal display panel, reserving the information panel for the presentation of such additional required information as the quantity of the contents, list of ingredients and name of the packer, as well as supplementary factual data about the product.

Although we had received no indication that consumers individually or collectively had any criticism of this labeling approach, we agreed to accept the concept that the quantity declaration should be placed on the principal display panel. We fully endorsed the regulations as revised by the National Conference, and supported their adoption in many states throughout the country.

In opposing enactment of the so-called "Truth-in-Packaging Bill," we urged upon Congress the view that any problems that might have existed in this area had been dealt with effectively by the National Conference, and were adequately covered by existing federal law. Although Congress ultimately enacted the Bill, it did eliminate the compulsory packaging controls that were so strongly opposed by industry.

As enacted, the Fair Packaging and Labeling Act contains three different approaches to achieving the Congressional policy as stated in section 2 of the Act: "Packages and their labels should enable consumers to obtain accurate information as to the quantity of the contents and should facilitate value comparisons."

The term "value comparisons" was substituted for "price comparisons" by the House Committee shortly before final Congressional action, but there is no clear understanding of what it means or what it was intended to mean. The Congressman who proposed the change said his purpose was to restrict the scope of the Act and to emphasize that only essentially identical commodities should be compared as to quantity and price.

Senator Hart, on the other hand, hailed the change in wording as a broadening of the Act, an extension of its scope to consideration of quality differences between products, not just price differences. You can thus take your choice between the sponsor of the amendment and the sponsor of the Bill.

Three Approaches to the Congressional Objective

But to return to the three approaches for achieving Congress' policy—whatever that policy may be understood to be—attention at the present time is focused primarily on the mandatory labeling regulations under section 4(a). The second approach is contained in section 5(c), which authorizes the FDA and the FTC to adopt certain additional regulations for individual commodities when it is found that such regulations are necessary to prevent the deception of consumers or to facilitate "value comparisons." As you can see, that troublesome phrase pops up throughout the Act. These regulations would:

—establish terms for describing package sizes;

—regulate the use of "cents off" label statements;

—require listing of ingredients on the label; and

—prevent nonfunctional slack-fill of packages.

Because the agencies are now preoccupied with the mandatory labeling regulations under section 4(a), we anticipate that consideration of section 5(c) regulations will be postponed, at least for a while.

The third approach in the Act is to direct the Secretary of Commerce to determine whether there is undue proliferation in the weights or quantities in which particular commodities are packaged

for retail sale, and whether such proliferation impairs the reasonable ability of consumers to make—you guessed it—value comparisons. When he makes such a finding, he must request manufacturers of the commodity to participate in the development of a voluntary standard that would seek to limit the weights or quantities in which the commodity is sold. Failure to develop a standard, or failure by manufacturers to observe one that is adopted, could give rise to no enforcement action, but the Secretary is directed to report such facts to Congress along with his recommendation for corrective legislation. This has been called voluntary legislation—with a little bit of muscle.

Mandatory Labeling Regulations

Getting back to the mandatory labeling regulations under section 4(a), the Act is not scheduled to become effective until July 1 of this year, but the FDA has made it clear that this effective date is not going to prevent it from proceeding to adopt regulations under this provision. Some may question how the agency can formally propose, and then adopt, regulations under an Act that is not yet effective. But that is a technical nicety that apparently will not stand in the agency's way.

Industry is, of course, keenly interested in the nature of the regulations that will be adopted to implement section 4(a) of the Fair Packaging and Labeling Act. Indeed, the same informal Industry Committee that worked so closely with the National Conference on Weights and Measures undertook a comprehensive exchange of information and views in order to develop proposed regulations for consideration by the FDA in drafting its own proposal. I will not dwell in detail upon the Industry Committee's proposal, except to note that it took full cognizance of the recommendations of state officials through the National Conference and called for uniformity of federal and state regulation.

The FDA's proposals for foods were published less than three weeks ago, and although in some respects they are consistent with existing state and federal controls, in certain very important ways these proposals would introduce a number of unique departures from existing regulation, not all of which can be attributed to the requirements of the new Act. Some people have expressed the view that the FDA proposal reflects a disregard for the extensive work and consideration which state officials have given to these problems. You will have to judge for yourself whether that is the case. More to the

point, I would like to comment on just a few of the provisions of the FDA proposal that differ significantly from most existing state requirements.

Departures from Existing Regulation

Whereas the National Conference recommends—and many states have adopted—a reasonable and widely accepted type-size scale for the quantity declaration, the FDA's proposal, with no readily apparent justification, seeks to impose a type-size scale that would usually double or triple the required size of type. Certainly nothing in the legislative history of the Fair Packaging and Labeling Act suggested Congressional dissatisfaction with the type-size scale that has been promulgated by so many states in recent years, and there have been repeated suggestions throughout this legislative history that the work of the National Conference was highly regarded.

But the FDA has proposed a type-size scale that will produce ludicrous results on many smaller labels, particularly in view of the new statutory requirement that the declaration be both in terms of pounds and ounces, and in total ounces. The manufacturer's problems will be further aggravated by the FDA's proposal to eliminate the exemption for small packages—in spite of the fact that the federal Food, Drug and Cosmetic Act directs that exemptions for small packages shall be established.

Another significant departure in the FDA proposed regulations is the requirement that the quantity declaration be placed in the bottom 20 percent of the principal display panel. The Fair Packaging and Labeling Act, of course, requires that the quantity declaration be placed in a "uniform location" on the principal display panel, but the Industry Committee has proposed that this be interpreted in a reasonable manner, so that manufacturers would have some flexibility in choosing an appropriate location for this declaration.

We proposed that manufacturers be given a choice of placing the declaration in either the top or bottom quarter of the principal display panel. This flexibility was thought to be justified in view of the disparity in sizes and shapes of labels and packages, the differing ways in which commodities are displayed for sale, long-standing labeling practices, and consumer expectation. But, at least in its initial proposal, the FDA has rejected an approach that we believe is both reasonable and permissible under the Act.

Another provision of the FDA proposal that departs significantly from existing regulation—and which is not clearly required by the Act—states that the declaration shall accurately reveal the quantity of food that may be delivered from the package exclusive of wrappers, propellants and other materials packed therewith. First, it should be noted that by excluding propellants from the declared weight or quantity, the FDA is rejecting the present practice which was developed through the joint efforts of industry and regulatory officials.

But this provision could create even greater difficulties for virtually all forms of packaging, for it requires a declaration of the quantity of food that may be *delivered* from the package, rather than the quantity of food *contained* in the package. Who is to say how much peanut butter is left in the bottom of the jar, how much whipped cream is left in the can, or how much paste is left in the tube when the consumer is finished with it? Some consumers may be extremely careful to extract all of the commodity from the package, but the usual practice is to leave some amount in the bottom or clinging to the sides. This would appear to be another example of the ambiguity and uncertainty that is introduced, rather than eliminated, by the FDA proposal.

Minimum Quantity of Contents

Perhaps the most troublesome feature of the FDA proposal is one that came as a surprise to virtually everyone in industry, and which would appear to have no justification in the Act. It is well known that existing federal and state laws approve and permit the practice of declaring the quantity of the contents in terms of the average quantity in a lot of merchandise. This average concept is deemed to be satisfied if there are no unreasonably large minus variations and if the average of the lot equals or exceeds the declared label quantity. It is consistent with high-speed mass production food plant operations, and is in accord with recognized statistical quality control procedures.

But in spite of this long-standing, widely accepted approach to quantity declaration, the FDA has now proposed that the quantity declaration express the *minimum* quantity of the contents, presumably with the requirement that no individual package fall below that minimum. We cannot conceive of why the FDA seeks to impose

this novel requirement that rejects many years of experience under state and federal laws.

If this provision is adopted in the final regulations, the manufacturer clearly will have to change his existing packaging and labeling practices in some way, for all lots of merchandise packed under existing methods would be in violation. One approach might be to put more of the commodity in the container, but this assumes that the manufacturer is not now filling to capacity. We are not aware of any responsible charge that all or most food packages are slack-filled. And a certain amount of head space is absolutely necessary for the effectiveness of the canning process.

Since more food cannot reasonably be put in the cans to bring every can up to the declared weight, another approach might be to increase the size of each can slightly and to add a sufficient amount of the product so that every container will comply with the existing declaration. There surely is no need to point out that this approach could hardly be justified, in view of the massive costs to industry of converting to slightly larger cans and packages for every commodity.

A third approach, and probably the only one that could reasonably be adopted, would be to lower the quantity declarations on all labels. I have no idea how much declarations would have to be lowered before statistical analysis could assure that every package would contain at least the amount specified on the label. Whereas a container is now labeled 1 pound, it might have to be labeled 15½ ounces, or a package now labeled 8 ounces might have to be labeled 7¾ ounces. Such a result would be ludicrous in view of the repeated demands by proponents of the Act that fractional ounce declarations should be avoided wherever reasonably possible. Almost certainly, consumers would believe that the reduction in the quantity declared reflects a reduction in the amount of the commodity in the package.

Conclusion

In conclusion, I hope that each of the states will study these proposals in the light of their existing laws and regulations, and consider whether it might not be appropriate to express their views directly to the FDA. In spite of the FDA's rejection of so many of the provisions found in state regulations and recommended by the National Conference, we cannot believe that the agency would take lightly the views of experienced and knowledgeable state food and drug and weights and measures officials. **[The End]**

Got yours yet?

FAIR PACKAGING AND LABELING ACT

WITH EXPLANATION

This helpful new CCH book clearly tells what companies must do to comply with the unique new Fair Packaging and Labeling Act of 1966, why they'll have to take a closer look at their packaging and labeling practices. It explains the new rules in detail, reproduces full text of the Act plus pertinent sections of the Federal Food, Drug, and Cosmetic Act and the Federal Trade Commission Act, and contains a quick-glance comparison of the three laws. Department of Commerce Regulations that can be used by industry to establish voluntary package size standards are also included for added convenience.

Having this book on your desk will forewarn you of the coming new regulations controlling use of such phrases as "giant quart," "4 servings," "large size," "5¢ off," "economy package" and the like. Knowing the rules now can ward off future packaging and labeling problems. In all, topical index, 72 pages.

Order Your Copies Today!

To order your copies, write to Commerce Clearing House, Inc., 4025 W. Peterson Ave., Chicago, Ill. 60646. Just ask for *Fair Packaging and Labeling Act with Explanation* (5344) at the following prices: 1 to 4 copies, $1.50 ea.; 5-9, $1.30 ea.; 10-24, $1.20 ea.; 25-49, $1.10 ea.; 50-99, $1 ea. (Remittance with order saves postage, handling and billing charges. Include sales tax where required.)

COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS

NEW YORK 10017
420 LEXINGTON AVE.

CHICAGO 60646
4025 W. PETERSON AVE.

WASHINGTON 20004
425 13TH STREET, N. W.

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS OF TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN REQUESTED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION