VOL. 18, NO. 2 FEBRUARY 1963

Food Drug Cosmetic Law JOURNAL

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

Also

International Food Law . . . . . .

by EDMUND FORSCHBACH

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD 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.

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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

(This is a report on the annual meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association by Franklin M. Depew, Chairman of the Section.)

The eighteenth annual meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association was held on January 22. The all-day meeting and luncheon were held in the new Americana Hotel in New York City. The audience at this meeting exceeded 100, and included officials of various federal and state agencies, who wished to join with the Section in commemorating the Twenty-Fifth Anniversary of the enactment of the Federal Food, Drug and Cosmetic Act. The Section was honored to have as its guests at the luncheon, in addition to Commissioner of Food and Drugs, George P. Larrick; the Honorable David W. Peck, President of the New York State Bar Association; Commissioner Everette MacIntyre of the Federal Trade Commission; Dr. M. R. Clarkson, Associate Administrator, Agricultural Research Service, United States Department of Agriculture; R. E. Curran, Q. C., Legal Adviser, Canadian Department of National Health and Welfare; C. Joseph Stetler, Director, Legal and Socio-Economic Division, American Medical Association; Oliver Field, Director, Department of Investigation, American Medical Association; Dr. Jorge E. O'Farrell, President, Section of Food, Drug and Cosmetic Law, Inter-American Bar Association; Attilio R. Frassinelli, Commissioner, Department of Consumer Protection, State of Connecticut; Robert E. Hurley, Director of Weights and Measures, Department of Markets, New York City; Dr. Richard A. Ledford, Director of Food Laboratory, Department of Agriculture and Markets, State of New York; Delmar K. Myers, Acting Director, Bureau of Foods and Chemistry, Department of Agriculture, State of Pennsylvania; Milton Ruth, Chief, Bureau of Food and Drugs, State of New Jersey; Jerome B. Trichter, Assistant Commissioner, Environmental Sanitation, Department of Health, New York City; and William T. Brady, Chairman of the Board, The Food Law Institute.

Commissioner Larrick graciously accepted the good wishes of the audience on the occasion of the important anniversary of the basic food and drug law and went on to discuss problems of administering new food and drug laws. His remarks and those of the other speakers are reported in this month's JOURNAL.

After luncheon Chairman Depew appointed a Resolutions Committee consisting of Irving H. Jurow, Chairman, Kenneth E. Mulford, and William J. Condon, and a Nominating Committee

consisting of Vincent A. Kleinfeld, Chairman, Frederick F. Mack and Samuel A. McCain.

At the conclusion of the presentation of formal papers a business meeting of the section was convened whereupon Chairman Depew asked for a report from the Nominating Committee previously appointed. Nominations were received as follows: Franklin M. Depew, Chairman; A. M. Gilbert, Vice Chairman; Raymond D. McMurray, Secretary; and Frank T. Dierson, James F. Hoge, William E. MacKay, and Hoke S. Woodruff as members of the Executive Committee. Upon motion, duly made and seconded, the Officers and Executive Committee so nominated were elected.

The Section recorded with sorrow the sad death of Edward K. Thode, Vice President, Secretary and General Counsel of General Mills, Inc., a member of the Section since its organization. His constructive leadership, wise counsel and friendly association will be missed.

The Resolutions Committee proposed and, after discussion, the Section unanimously adopted the following resolution:

"*Whereas,* the *Food and Drug Administration* has recognized that the factory inspection provisions of the *Federal Food, Drug and Cosmetic Act* do not extend to compulsory inspection of certain records, and

"*Whereas,* the *Food and Drug Administration* has indicated that, as a matter of policy, it proposes to apply sanctions to manufacturers refusing voluntary inspection of such records and other information to which the *Food and Drug Administration* is not legally entitled by using every administrative means to withhold action on applications, petitions, regulations, certifications, and exemptions to which said manufacturers would otherwise be entitled, and

"*Whereas,* the application of such sanctions is inconsistent with efforts to develop through education cooperative compliance with the requirements of the *Federal Food, Drug and Cosmetic Act,* as recommended by the *Second Citizens Advisory Committee,* and

"*Whereas,* such sanctions are an improper and extra-legal activity and represent an abuse of administrative power,

"*Now, therefore,* be it resolved, That the *Food, Drug and Cosmetic Law Section of the New York State Bar Association* strongly recommends that the *Food and Drug Administration* discontinue the policy of applying sanctions in an effort to obtain access to records and information to which it is not entitled under the factory inspection provisions of the *Federal Food, Drug and Cosmetic Act,* and be it further

"*Resolved,* That a copy of these resolutions be transmitted by the Section Secretary to each of the following: the Secretary of *Health, Education and Welfare,* the *Commissioner of Food and Drugs,* the Chairman and Members of *the Senate Committee on Labor and Public Welfare,* and the Chairman and Members of *the House Committee on Interstate and Foreign Commerce.*"

Chairman Depew then appointed a special committee to review and report on legislative matters, including any legislation affecting factory inspection powers of the Food and Drug Administration; the committee to consist of the following members: Frank T. Dierson, Chairman, Kenneth E. Mulford, Edward B. Williams, Edwin L. Harding, Michael F. Markel, James F. Hoge, Samuel A. McCain, and George T. Scriba.

Following the business meeting of the Section there was a short talk by George Clifford of Washington, D. C., who is on the Staff of the Senate Subcommittee on Packaging and Labeling Practices, headed by Senator Philip A. Hart. Mr. Clifford informed the Section that Senator Hart had introduced a bill (S. 387) bearing many of the features of the original bill introduced last year relating to packaging and labeling practices, and that Representa-

tive Emanuel Celler had introduced a companion bill (H. R. 2382) in the House. Mr. Clifford invited members of the Section who are interested in the bill, either pro or con, to request a hearing before the Committee.

New York Bar Association Meeting.—The Introductory Statement at the Eighteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York Bar Association was presented by the President of the Food Law Institute, *Franklin M. Depew.* In the paper, which appears at page 71, he declares that the Federal Food, Drug and Cosmetic Act is "our most important commercial law as it regulates the manufacture and sale of our vital daily necessities to assure their safety, purity and integrity, and to require their honest and informative representation."

C. Joseph Stetler discusses some of the past and current interests and activities of the American Medical Association in the food and drug field, in an article which begins at page 72. The Director, Legal and Socio-Economic Division, American Medical Association concludes by declaring that the FDA has a big job ahead. "The manner in which it enforces the new drug regulations and the Drug Amendments of 1962 will have a direct bearing not only on drug manufacturers and physicians, but on the health of the American people."

The Legal Advisor, Canadian Department of National Health and Welfare, points out a number of common problems in the food and drug law field which face both his country and the United States. *Robert E. Curran* explains current legislation and regulations in Canada in an article which appears at page 76.

Efforts of the Food and Drug Administration and the American Medical Association to curb medical quackery are described by *Oliver Field,* Director of the Department of Investigation of the AMA. This report begins on page 89.

International Food Law.—An excellent and timely article on international food law appears at page 93. *Edmund Forschbach,* Ministerialdirigent, Federal Ministery of Health, Bonn, Germany, believes that discrimination based on economic and political interests must be eliminated from food laws. Other suggestions for standardized international food laws are found in this thought-provoking paper which was prepared especially for the FOOD DRUG COSMETIC LAW JOURNAL.

Legislation in the Drug Industry.—This topic is discussed by the Vice President and General Counsel, Schering Corporation, *Irving H. Jurow.* In a paper delivered before the Division of Food, Drug and Cosmetic Law of the American Bar Association, he compared the sulfanilamide episode of 25 years ago to the recent thalidomide incident and their effect on pending legislation.

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Food·Drug·Cosmetic Law
Journal

Introductory Statement

By FRANKLIN M. DEPEW

This Introductory Statement Was Delivered at the Eighteenth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, January 22, 1963, New York, N. Y. Mr. DePew, Who Is President of The Food Law Institute, Was Chairman.

I AM HAPPY to welcome all of you to this, the Eighteenth Annual Meeting, of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association. This meeting commemorates the twenty-fifth anniversary of the enactment of the basic law on this subject, the Federal Food, Drug and Cosmetic Act. Our luncheon today honors the Food and Drug Administration, and we have as our honored guest and speaker on this occasion Commissioner of Food and Drugs, George P. Larrick. We also have as distinguished guests in addition to our speakers a number of enforcement officials who wished to join with us in celebrating this occasion with Commissioner Larrick. It will be my pleasure to introduce them to you at lunchtime as well as our other distinguished guests, Honorable David W. Peck, President of our Association, William Roy Vallance, Esq., Secretary-General of the Inter-American Bar Association and Dr. Jorge E. O'Farrell of Argentina, President of the Section of Food, Drug and Cosmetic Law of the Inter-American Bar Association.

Our program today consists of seven papers in addition to Mr. Larrick's address. I am sure you will find them all timely and interesting. I hope you will enjoy the changes we have made from our traditional annual programs for this occasion. I regret to tell you, however, that William W. Goodrich, Esq. will not be with us today. I expected that he would come even though he was not on the program, but he has sent me his regrets and best wishes for a successful meeting. He promises to be with us again at the annual meeting of the American

Bar Association next August and to report on developments at that time.

The Act and Its Enforcement

Before introducing our speakers I would like to say a few words about the significance of the Federal Food, Drug and Cosmetic Act and its enforcement. I believe it to be our most important commercial law as it regulates the manufacture and sale of our vital daily necessities to assure their safety, purity and integrity, and to require their honest and informative representation. However, no matter how worthy the purpose of a law, it tends to become meaningless unless there is effective enforcement to assure general compliance. I believe the officials of the Food and Drug Administration have set a splendid example of enforcement which has been to the advantage of both the public and the regulated industries. They are worthy of our support because we know them to be outstandingly efficient, honest and devoted to their duties. It must also be said that those who have had technical differences with the agency with respect to interpretations of the law have always found them willing to discuss these problems either at the headquarters or field offices or on the occasion of these professional gatherings. If everything they have done has not been to your liking you should realize the fault may be partly yours.

We as attorneys should recognize the impact of past political pressures on enforcement policy and take appropriate steps to ease undue pressures of this kind in the future to the extent that we are able by informing the public as well as the Congress of the true situation. This is as much our responsibility under our free enterprise system as it is to speak out if the agency were to allow zeal for enforcement to bring about unsound or excessive control.

I am confident, however, that we may continue to look forward to most competent enforcement under Commissioner Larrick. This opinion is reinforced by the fact that the agency and the parent Department of Health, Education and Welfare is examining all of their activities in the light of the recommendations and criticisms contained in the Second Citizens Advisory Committee Report filed with Secretary Celebrezze last October 25. So, let us all work responsibly together to further the great public interests protected by this law, which we commemorate on this occasion.

I know you are all looking forward to hearing from our speakers who have given of their valuable time to prepare and present these papers to us. Accordingly I will now proceed with their introduction.

[The End]

Relations Between AMA and FDA

By C. JOSEPH STETLER

The Author Is Director, Legal and Socio-Economic Division, American Medical Association.

IT IS A PLEASURE and a privilege for me to participate on this program today commemorating the 25th Anniversary of the enactment of the Federal Food, Drug and Cosmetic Act and to discuss with you some of the past and current interests and activities of the American Medical Association in the food and drug field.

Since it is a popular pastime these days in certain circles to criticize Commissioner George Larrick and the Food and Drug Administration, some may think because of our controversy with the Department of Health, Education and Welfare over the Health Care for the Aged issue that the American Medical Association is a member of this unhappy little group. I hasten to set the record straight and to state that relations between the AMA and FDA are good—as they have been ever since this agency was created.

This doesn't mean that we haven't had and do not now have some disagreements. It does mean that history will show a remarkably consistent record of common goals, effective cooperation and an objective approach to differences based on mutual respect.

In preparing my remarks for today I reviewed the legislative and administrative contacts of the AMA in the food and drug field which date back over 100 years. I would like to review this history very briefly with you before alluding to some of our more current mutual interests.

Early Relations Between AMA and FDA

As far back as May, 1848, the House of Delegates of the American Medical Association memorialized Congress recommending enactment of a law to provide for the appointment of an inspector at each chief port of entry to examine all imported drugs and medicines.

A year later, the AMA House of Delegates approved resolutions which recommended the appointment of a committee consisting of

two delegates from each state to note facts on adulteration of drugs and commended the Philadelphia College of Pharmacy on its intention to publish "instructions for detecting adulterations in medicine."

In 1850, the AMA House of Delegates adopted a resolution which recommended strict adherence to the rule prohibiting the use of secret nostrums and remedies in the Code of Ethics.

Close cooperation between the AMA and the federal government in the vital area of assuring pure food and drugs began in 1905 shortly after the Association established a Council on Pharmacy and Chemistry. The then Secretary of Agriculture, James Wilson, informed the AMA that he had established a laboratory in his Department's Bureau of Chemistry for the investigation of adulteration of drugs and medicines. He added:

> It seems to me that collaboration with the great body of American physicians who form the AMA affords a splendid opportunity to carry out the work which Congress intended to be done.
>
> It gives me pleasure, therefore, to inform you that I have authorized the Chief of the Bureau of Chemistry to cooperate with the Council on Pharamcy and Chemistry of the AMA.

In 1906, the Association's Committee on Legislation voted to give active support to the Pure Food and Drug bill. Although the battle for the passage of this legislation had been going on for many years the AMA stayed out of the fight until it was in a position to give helpful advice to the agency that would be in charge of enforcement if the bill was passed.

With the establishment of the Council on Pharmacy and Chemistry, the Association was ready for action. However, the proponents of this legislation were up against an old and powerful lobby, the whisky trust, which had successfully kept this type of legislation "bottled up" in committees for years.

In spite of the fact that public opinion and the President were behind the proposal, some senators were determined to let it die in Committee. This opposition was finally overcome and the Senate passed the bill by a vote of 63 to 4.

AMA Influence on Passage of Pure Food and Drug Law

This happened a long time ago and undoubtedly many individuals and organizations were a party to the victory. Nevertheless, one monograph on lobbying has given the AMA major credit for the passage of this measure. It states:

Although there were other factors aiding in securing the passage of the bill in the Senate, it cannot be doubted that the influence exerted by the American Medical Association and its followers was chiefly responsible for winning over the Senators. The Senate had maintained its opposition . . . for seventeen years and had it not been for the lobbying of the American Medical Association there is no telling how or when the lobbying on the other side would have been overcome.

Even with passage of the Senate bill, the difficulties of the Pure Food and Drug Law were not over. It became stalled in the House of Representatives while efforts were made to compromise the House and Senate versions of the bill. To expedite matters the AMA Committee on National Legislation prepared, for presentation to Congress, a petition urging the bill's approval. When the bill came to a vote on June 23 it was passed by a large majority, and on June 30, 1906, it was signed into law.

In the 1930's the AMA was again one of the leading professional groups to urge the enactment of a new food and drug law. The Federal Food, Drug and Cosmetic Act was passed in 1938, and the AMA continued its support of effective and needed amendatory legislation in this field.

In 1951, the Association supported the Durham-Humphrey Amendment, dealing with the dispensing of prescription drugs. In 1953, the AMA supported a bill, which was enacted as Public Law 217, 83rd Congress, authorizing the Food and Drug Administration to inspect pharmaceutical manufacturing establishments without first obtaining the permission of the proprietors. In 1960, the AMA was one of the chief sponsors and supporters of the Hazardous Substances Labeling Act, which was enacted by the Congress as P. L. 86-613 and is now administered by the Food and Drug Administration.

Four AMA Groups Actively at Work Now with FDA .

Today, we have four groups at the American Medical Association actively working with the FDA. These are the Council on Drugs, Council on Foods and Nutrition, Committee on Cosmetics, and the Department of Investigation. Only last week, in Washington, D. C., Dr. Robert E. Shank of St. Louis, chairman of the Council on Foods and Nutrition, and Dr. Gerald Dorman of New York, a member of the AMA Board of Trustees, testified before a Senate Subcommittee on Aging, which conducted a two-day hearing into nutritional and medical quackery and other fraudulent practices which take advantage of the aged.

Dr. Dorman outlined the long history of AMA's battle against medical quackery and stressed the cooperative efforts between private and governmental agencies including FDA to destroy the evils of pseudomedicine.

Dr. Shank described AMA efforts to educate physicians on the current concepts and practices in clinical nutrition and to educate and encourage the public to practice good nutrition. Dr. Shank also related the close cooperation between FDA and AMA in combating nutritional quackery. He praised the FDA for being "especially active and successful" in seizing food supplement products which bilked the public.

Two years ago, the AMA and FDA jointly sponsored the First National Congress on Medical Quackery in Washington, D. C. and we are planning to hold another such meeting later this year. Following my talk, Oliver Field, Director of AMA's Department of Investigation, will tell you in more detail how the AMA and the FDA are working together in this area.

AMA Opinion on Drug Amendments of 1962

Against the backdrop of longtime cooperation and support it was natural for the AMA to be seriously concerned about the activities of the Kefauver Committee during the past four years. In our opinion, any direct or indirect participation in the headline-seeking, persecution sessions of the Committee or the politically manipulated crisis in which the Drug Amendments of 1962 were enacted and the new regulations on the clinical testimony of drugs promulgated was unwise.

Let me say quite clearly and emphatically that, in the opinion of the American Medical Association, P. L. 87-781, the Drug Amendments of 1962, should not have been enacted. The one or two desirable features which it contains are, in our opinion, outweighed by the dangerous and unwarranted grants of authority which it bestowed upon the federal government.

Recent Difference of Opinion

One other point worth discussing is a difference of opinion which we had recently with FDA concerning the procedure to be followed in issuing administrative regulations. The regulations in question which were proposed and published in the *Federal Register* on August 8, 1962, dealt with the testing of investigational drugs. Even though FDA had the authority under the Food, Drug and Cosmetic Act for over

24 years to issue regulations of this type, and even with the concurrent passage of the Drug Amendments of 1962, it refused to extend the 60-day period in which interested persons could submit comments. Still, about 400 persons and organizations, including the AMA, submitted written statements. About 90 per cent of the statements were critical of the proposed regulations.

Thereafter, the FDA turned down a proposal by the American Medical Association to hold a meeting of all interested persons in government, the pharmaceutical industry, the medical profession and the other scientific disciplines intimately concerned with the problem of investigational drugs. It also refused to have public hearings and to republish a revised draft of the regulations for further comment from interested parties.

Although officials of FDA met subsequently with representatives of certain of the interested groups such as the Pharmaceutical Manufacturers Association and the American Medical Association, this is not the proper method for preparing regulations which are obviously of great interest to at least the 400 persons and organizations which responded to the first publication.

In my opinion, the regulations, though modified from those originally proposed, impose restrictions on research that may ultimately discourage and impede the discovery of valuable new medicines.

It is, I believe, significant that throughout the period when the new drug bill was before Congress and the Regulations on Clinical Testing of Drugs were being prepared, the FDA, itself, was being subjected to severe criticism by members of Congress and other interested parties. In this type of Washington tempest, I realize that an agency such as the FDA might be pressured to act differently than it would under smooth sailing.

Criticism by Senator Hubert Humphrey

What were some of the criticisms being made of the FDA? Senator Hubert Humphrey (D., Minn.), who heads the Senate Subcommittee on Government Reorganization, held some preliminary hearings on FDA's handling of new drugs and declared that it had not done an effective job of keeping dangerous drugs off the market. Senator Humphrey also accused FDA of mingling too freely with the industry it regulates.

On this identical point, the Citizens Advisory Committee on the Food and Drug Administration in its October 25, 1962 report called for:

(1) A reorientation of the philosophy and leadership of FDA with more emphasis in the future of prevention through public education and cooperation with industry.

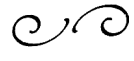
(2) Improvement of FDA relationships with industry aiming at cooperative efforts and getting away from almost entire reliance on police enforcement. Based on these viewpoints, it appears that Mr. Larrick is damned if he does and damned if he doesn't.

Conclusion

In closing, let me reiterate the fact that medicine does not believe that certain of the provisions of the Drug Amendments of 1962 represent proper delegations of authority to a federal agency. We fought hard to keep the bill from passing and we may fight hard to have it changed by Congress in the future. But while it is on the books we will do our best to help FDA make it work.

I am sure that many will feel that at a time when the Administration is proposing a $10 billion tax cut and economies on a national scale are clearly indicated, it is unreasonable to consider increases in the budget of a regulatory agency. But an agency is useless if it becomes so hopelessly overworked that it cannot function. Unless the FDA budget is realistically re-examined . . . and unless medical and scientific staff and facilities are expanded and improved . . . the mechanism for drug regulation is in real danger. It would be tragic if this nation forfeited its leadership in drug and medical progress because a regulatory agency could not keep pace.

The FDA has a big job ahead. The manner in which it enforces the new drug regulations and the Drug Amendments of 1962 will have direct bearing not only on drug manufacturers and physicians, but on the health of the American people. In this endeavor, I hope the FDA will follow the road of mutual cooperation. If it does, I am sure that we will be able to work together in harmony and with respect for the individual role each must play. **[The End]**



Neighbourly Co-operation in Food and Drug Administration

By ROBERT E. CURRAN

The Author Is Legal Adviser, Canadian Department of National Health and Welfare.

ON BEHALF of the Director of the Canadian food and drug administration, may I say how very much the invitation to join with you in commemorating the twenty-fifth anniversary of your present food and drug law is appreciated.

Apart from being the spokesman for our Directorate, I would also add by own personal pleasure and appreciation to you for your invitation. I think I have attended the majority of the meetings of this Section of the New York State Bar and always with benefit to myself in the knowledge that I have gained and the contacts that I have made. When I tell you that I returned from Jamaica yesterday in order to be here today, yon can, I think, sense the sincerity of my appreciation.

The occasion, as well as the subject title of my remarks, makes it opportune to say something about the friendly relations that have always existed not only between the two administrations but also with industry. We have shared many experiences and we have not hesitated to draw upon your knowledge in those areas where common problems arise.

Formulating a food and drug law is very much like selecting a suit of clothes for a rapidly growing boy. One obviously selects a size slightly larger than can be filled at the moment, but unfortunately it is not possible to select one that will continue to keep pace with his growth. Very much the same problem confronts us in this complicated and changing field.

Canadian Legislation

The present Canadian legislation was, of course, formulated with certain foreseeable problems or developments in view. It was intended

to meet those particular problems, but others that were not foreseen have perhaps overshadowed those that were. I speak only with respect to our situation in Canada and perhaps we have been fortunate in two respects. In the first place, we had an opportunity in 1953 to completely amend our legislation and to utilize in its development not only our experience but that of other countries. We tailor-made a food and drug law to meet the conditions as we then saw them. The second advantage is one that has been mentioned on other occasions both before this Section as well as before the American Bar Section. I refer here to our use of delegated legislation. I think perhaps our use of delegated legislation or regulations marks a major difference in our two administrations.

Delegated Legislation Described

As you know, the Governor in Council has authority under the Canadian legislation to make regulations concerning every conceivable phase of the manufacture and distribution of foods, drugs, cosmetics and devices. This we find most valuable because it provides a necessary degree of flexibility to enable the legislation to keep in step with the march of science. So much so that this has provided an opportunity to poke a little fun at our so-called bureaucratic methods.

It has been suggested that we do not need to worry about jurisprudence or courts because all we have to do is to pass an order in council and make the law as we would like it to be. This is very much an exaggeration and oversimplification of our use of delegated legislation. At the same time I think it is important to bear in mind that in Canada in the developing of regulations we do not have any formal requirements set out in the legislation. We have, however, developed procedures of an administrative character which we feel meet the needs of each type of situation as it arises. We can therefore tailor-make our procedures to whatever the necessities may be and the fact that our relations with industry are as cordial as they are speaks volumes for the efficacy of our procedures.

Influence of United States' Experience

Returning now to the question of co-operation, we have benefited enormously from the knowledge that has been developed in this country, both at the industrial or manufacturing, as well as at the administrative level. Everyone here has been most generous and helpful in giving us the benefit of your wide experience.

In another context, however, your experience is very much like what the car manufacturers describe as a compulsory option. In other words, we have no choice but to follow a course or a trend that has developed in this country. We are vulnerable to the fallout of your experience and events as they take place here inevitably affect our own administration.

Bread standards, color and food additives are cases in point where we have been influenced by trends or events in this country.

As neighbours are seldom reluctant to borrow from each other, so the Food and Drug Directorate is by no means reluctant to take advantage of your experience in comparable areas and to try to apply it to our own. Conversely, I would hope that we may be able to give you in the administration the benefit of our experience from time to time and this I think would reflect international neighbourly co-operation in the finest sense.

Canadian Assistance

Without touching on a number of areas wherein co-operation has been most apparent, I am reminded that at the White House Conference on Narcotics and Abuse of Drugs the President touched upon a new area involving abuse in certain drugs. These include barbiturates, amphetamines and some of the tranquilizers. He made reference to the need for a new legislative approach to control these substances and to eliminate a growing abuse in them. I was very glad to be able to make available to the appropriate officials, copies of legislation which we had introduced a year earlier dealing with this very thing. In making our legislation and regulations available, I endeavoured to do so on the basis of sharing our experience in a common problem but not intruding in any way in an area in which we had no right to intrude.

Increased Stature in Both Countries

As your food and drug legislation has gained in importance and stature during the last 25 years, so has ours. I think the word "importance" needs no explanation. I think the word "stature" is truly descriptive of the way in which our respective administrations ought to be regarded by those who are close to them.

In reviewing progress, I think we must all accept the fact that the present attitude to drug developments industry-wise, public-wise and government-wise has probably made the greatest single impression on the legislative policy that has taken place in the last 25 years.

Before dealing with what this has done in Canada, there are one or two matters which I think merit reference. Apart from a few local flurries, the food and drug administration in Canada has proceeded at a fairly steady and unspectacular pace. Our administration has by and large functioned smoothly. Its work has literally been unheralded and its heroes unsung. Within the past year, however, events of a variety of kinds have thrust the food and drug law and the administration squarely into the limelight of the public gaze. Sometimes the limelight may have seemed overly bright and those who complained in past years of this being a pedestrian field would certainly have no reason to complain of the amount of attention which is now focused on foods and drugs.

Unfit Meat Incident

The public came to with a rather sharp or rude jolt a little over a year ago when we uncovered an unsavoury traffic in Canada in meat from dead and fallen animals. The investigations showed that this was a highly organized and very profitable traffic. Fortunately, about 80 per cent of our meat supplies came from government inspected plants and the quality of inspection fortunately precluded any possibility of the source of meat being incriminated. So also with a great many uninspected plants where a very high quality of inspection was maintained. Unfortunately, however, there were some plants that did not scruple to utilize meat from the source I have mentioned. Public indignation was immediately aroused and almost overnight the public became very conscious of the purpose of the food and drug law to protect against health hazards and fraud. The momentum from that investigation has not been lost. In the Province of Ontario, legislation has been introduced requiring all meat in the province to come from inspected plants which within a reasonable time will be under federal inspection. Mrs. Housewife has been very conscious of her meat budget and has taken care to see that a prime rib of beef did not come from a defunct old Bessie.

The next alertment involved cake mixes. Some bacterial research had shown that certain egg products were infected with salmonella and this in turn infected cake mixes which used contaminated egg mixes. Here again public indignation did more than our daily inspection could ever have done. Action was quick in forthcoming and this was due again to public attention being focused on the food and drug administration.

Canadian Thalidomide Experience

The next area is one in which I think we have all had a common experience. True, in this country events took a somewhat different course than in Canada and it is a matter of great satisfaction that you have been spared some of the tragedies that are reported in other countries. I think we are also fortunate in that the extent of the tragedy was not greater. I am, of course, referring to Thalidomide. Here I think we must have regard to the effect which our experience with this drug has on present and future policies and it may well indeed mold for a long time the development of new drugs. We cannot be indifferent to the lesson learned. At all levels of interest—industry, government and public—there is a lesson to be gained. It is in the application of this lesson that we can all benefit.

"New Drug" Regulation

For many years the drug industry has been under fairly constant pressure to develop some form of panacea for every ailment. The optimum is, of course, a happy pill which will introduce us all to Utopia. It has been suggested by some that there has been too much complacency about the ready and rapid development of new and potent drugs. We have patterned our new drug regulations very much along the lines of those in force in this country and in some 12 years of operation have processed for introduction some 2,000 new drugs. I venture to say that our experience follows closely that of the administration here. Generally a new drug which is made the subject of an application in the United States will also be made the subject of an application in Canada. Our requirements have not differed substantially from those here. Safety has been the best criterion and the efforts of the administration directed to satisfying itself that the manufacturer had done what a reasonable and prudent manufacturer would do before developing and introducing a new drug.

Notification of Thalidomide's Harmful Effects

Evidence of testing was, of course, an important part of a new drug submission. Up to the present, at least, we have felt that our new drug regulations and procedures with the controls which they embodied have been adequate to protect the public. When the first reports of congenital malformations associated with Thalidomide were received, the immediate action which we took was to ensure that every doctor in Canada be alerted by the manufacturer to the pos-

sibility of risk in the use of this drug by pregnant mothers. The initial information which we got was far from being complete or even documented. Nevertheless the manufacturer with our concurrence alerted all doctors to the possibility of the risk that had been reported. This was considered a normal and effective procedure because this drug was available only on medical prescription and was thus subject to medical authorization. In the outcry which followed the reports from Germany and the reports of tragically malformed babies, the attention of the public was focused as never before on the food and drug administration and, of course, on drug controls.

In the light of history, our experience with Thalidomide may well serve as a crossroads or turning point in new-drug development. It has drawn attention to the fact that there is no such thing as a completely safe, yet effective drug. Here occurred a strange paradox. Many who had been the strongest proponents for new and effective drugs joined the wolf pack in snapping at the heels of the administration. Why was Thalidomide ever allowed to be sold? How could the government have been asleep? Why was prompt action not taken to guarantee that every tablet that had been distributed to doctors, as well as to patients, under the law were not instantly removed from every medical office and medicine chest in Canada? This is literally no exaggeration of the type of criticism that was made.

Cases of phocomelia were reported where Thalidomide had not been taken. Other drugs, however, came in for their share of suspicion and at the present time I would venture to say that the public at large are most conscious of the risk of taking drugs except under medical advice and supervision.

Eyes of the World on the Drug Industry

Suddenly the world press saw the possibility of dramatic and sensational stories in the work of food and drug control. The eyes of the world perhaps had been focused on the drug industry on previous occasions, but mostly in connection with price and profits. Here the microscopic examination was directed to safety, and with the pack in full cry, there was demand for the removal from the market of all dangerous drugs. Some of our most responsible news editors and reporters had suggested that the government must guarantee the safety of all drugs and that it should be a criminal offence for a drug that had the potential of doing harm being distributed. If this reasoning were literally applied, the world would not have the

benefit of the sulfa drugs, penicillin, some of the other antibiotics and cortisone. All of these drugs were demonstrated to have some potential for harm to certain people. No one, however, has suggested that these drugs should be removed from the market, but following the hysteria of Thalidomide suggestions of the kind that I have referred to were seriously advanced.

Arising out of this, it becomes useful to see what its possible future effect may be. An immediate consequence, of course, was the enactment of amending legislation for the purpose of tightening up on the development and distribution of all drugs. We have had occasion in discussing this with drug manufacturers to point out that the best friends at court in the climate that has been developed is the administration itself. We have endeavored very seriously to see that the legislation and regulations are tempered with experience and we hope with wisdom. We have endeavored not to be stampeded into controls that would only serve to hamper the legitimate development of drugs but without a corresponding benefit to the public.

This brings me to what has taken place legislatively and which I think forms part of this progress report. We were fully aware of the legislation which was introduced and passed in this country. We studied it with care. A great many of the matters which were contained in it were already contained in our regulations. However, we introduced certain amendments which I should like to discuss very briefly.

Legislation Pertaining to Drug Samples

The first relates to the distribution of drug samples to the professions. Modern merchandising of drugs and their development have resulted in widespread distribution of professional samples to doctors, dentists and veterinarians as well as other branches of the healing art. It was felt on the basis of information received respecting the present practice of sampling that some control ought to be exercised. The question to be decided—what control is reasonable having regard to the need to alert the profession to new medications and at the same time consistent with the need to control indiscriminate distribution?

Our legislation prohibited the distribution of a sample to the general public, but did permit the distribution of samples to the paramedical professions. We felt that nothing should be done by legislation to interfere with the right of a doctor to be furnished with a sample or the right of a manufacturer to give it. At the same time,

we felt that with the plethora of drugs being distributed, a doctor should be required to exercise some judgment in deciding whether he wished to receive a sample and, if so, what it should be and how much he desired. The legislation was amended to permit of conditions being prescribed respecting the distribution of samples to the professions. The effect of the proposal, therefore, is to require a doctor to provide a written order or request to receive a sample indicating how much he wishes. We do not think that this will adversely affect the industry in the practice of sampling which has been developed. On the contrary, it should, and we hope will have the result of impressing on industry, as well as on the professions, the value of samples of new and potent drugs. Instead of doctors complaining of their mail being flooded with unwanted samples as has been the case, the doctor should look forward to the receipt of a sample in which he has enough interest to request and presumably to know something of its qualities, properties and uses. This, we feel, is a desirable step and we hope that it will operate without adversely affecting the development of drugs or their introduction for legitimate use. Our regulations are, of course, subject to review in the light of experience and the present proposal will therefore be considered against the purpose of the change, the comments of the profession and the trade and the experience gained.

Lysergic Acid

The next change involves different considerations. This change prohibits the sale or distribution of a drug which is listed in a new schedule to the Act. At the present time we have put two drugs on this schedule and subject to what is later said the sale or distribution of these drugs in Canada is prohibited by law. Thalidomide naturally was one of the drugs and the other, which is Lysergic Acid, perhaps merits a word of explanation.

I can only say that it would be with the greatest reluctance that the administration would recommend a drug being put on the prohibited list. This could be regarded as unwarranted interference with the practice of medicine, and in fact, it has been so regarded according to letters, telegrams and various news articles that have reached us.

Curiously enough there has been no general criticism of prohibiting the sale of Thalidomide even though many doctors feel that it has been a very valuable drug for its recommended purpose. There are, of course, some rumblings that perhaps Thalidomide merits further

research in the field of cancer control. This I venture to suggest will be an area which will be later looked at.

Lysergic Acid is a drug, which incidentally was never made the subject of a new drug application. It has never been on the market and has not, therefore, ever been available to the medical profession in general. It had an experimental use in certain psychiatric treatments. I think it has been used in connection with drug addiction and with alcoholism. Proof of the value of the drug in this limited field is not yet available. Because of reports indicating that the therapeutic value of the drug was very much debatable and because of reports of its very real dangers, we added it to the schedule. Fortunately we had anticipated that there would be some criticism of this action by a few members of the profession. In introducing the legislation we had indicated, therefore, that a regulation would be passed which would exempt Lysergic Acid from the absolute prohibition to the extent of permitting its use in approved institutions for clinical evaluation. This in effect was the only purpose for which the drug had ever been available and this should meet the situation.

Clarification of Authority

The last change is not really a change so much as it is a clarification. As I mentioned, we have had regulations dealing with new drugs. Under the general authority to make regulations we felt that we had sufficient plenitude and amplitude of authority. Nevertheless because of the amount of public attention focused on new drugs, we felt it desirable that the legislation should clearly single out special authority in this area. We have therefore clarified the situation by enacting a special section which gives to the Governor in Council the widest possible authority to make regulations covering all aspects of the development and introduction of new drugs.

Committee of Experts Formed to Examine Procedures

Last spring with the focus of attention on Thalidomide and new drugs in general, the Minister of National Health and Welfare asked the Royal College of Physicians and Surgeons of Canada to set up a special committee of experts

> to examine critically and objectively present procedures for dealing with new drugs, the requirements of the regulations and any other matters that in the opinion of the committee are relative to the issue . . . .

A special committee of experts was accordingly set up by the Royal College and the committee has during the past six months been actively engaged in examining all phases of the development, manufacture and distribution of new drugs and of the regulations presently existing. I might say that the report of the committee has just been received and is being studied with a view to the implementation of its recommendations through whatever changes may be considered necessary in our regulatory control.

It may well be that the eventual regulations will not differ greatly from those that have been in force but undoubtedly there will be a certain tightening up of controls as well as the possibility of additional regulations as may be found necessary. A possible area will, of course, relate to clinical evaluation by qualified investigators. The other area is in the field of drug sampling. We are conscious, as indeed were the members of the committee, that no regulation should be used so as to impede or handicap legitimate medical research. We would hope that all of our regulations can be interpreted in the light of that consideration and that nothing will in any way adversely affect research and its eventual benefit to the public.

In concluding this portion of my report, we do not feel that it is a function or responsibility of the government either to guarantee the safety of a new drug or to engage in its clinical testing. This is not compatible with the true responsibility and role of a drug manufacturer in a free enterprise system. At the same time, we must recognize the necessity of legislation to insure that the manufacturer has himself done what is reasonable, prudent and proper in the development of a drug before it is available to the general public.

Interchange of Knowledge

We would hope that in this new field we will continue to share and pool our common knowledge. We would hope that important decisions affecting a particular product can be, to some extent, at least integrated with similar decisions in our country. I know there has been a great deal of interchange of information respecting action to be taken regarding a new product either by way of special caution or perhaps its withdrawal from the market. For some time to come I think we can expect new as well as old products to risk some mild criticism or incrimination; this is inevitable in their development. It is only through their experience in human use that we ever will be in a position to evaluate honestly and properly the qualities of a new

drug. Every effort should be made to screen out as many dangers as possible in the use of a drug before it is introduced. With its introduction there should be given as much information as is known respecting the drug and its contraindications. There should at this point be a continuous exchange of information between the professions and the manufacturers and the government so that as additional experience comes to light, additional information can be given.

Proposed International Exchange of Drug Information

In closing my remarks I would only like to say one further thing. A resolution was adopted at the World Health General Assembly which I think should commend itself to all countries. This contemplates the more ready exchange of information internationally respecting drugs. It contemplates some form of central clearing house.

Desirable as this international exchange will be, it will not replace the neighbourly exchange of information which has been enjoyed by our two administrations. It will not replace the type of co-operation which we have had from this country and which we would be glad to repay in kind. It however does represent a healthy advance in the recognition that we live in one world where problems in this complicated field are of interest and concern to everyone.

I have very much enjoyed the opportunity that you have afforded me to be with you this morning. Please again accept by assurances of our appreciation for past co-operation and our desire to extend even further the areas in which we can be of help to each other.

[The End]

REGULATION ISSUED FOR RUBBER ARTICLES IN CONTACT WITH FOOD

New food additive Reg. § 121.2562 authorizes the use of rubber articles intended for repeated or continuous use in contact with food if the substances used in preparation of the articles are (1) approved in the regulation, have already received approval, or are generally recognized as safe, and (2) are not excessive in amount and not intended to accomplish any effect in food. Objections may be filed before March 3, 1963.

Substances listed in the regulation include elastomers, vulcanization materials, antioxidants, antiozonants, plasticizers, fillers, colors, lubricants and emulsifiers. Extractives limitations are prescribed for articles intended for use in contact with acqueous and fatty foods.—FOOD DRUG COSMETIC LAW REPORTS, No. 358, *Regulations*, ¶ 1969QQQ.

The AMA–FDA Efforts to Curb Medical Quackery

By OLIVER FIELD

Mr. Field Is the Director of the Department of Investigation, American Medical Association.

YOU have heard Mr. Stetler recount the historical relationship of collaboration and support between the American Medical Association and the Food and Drug Administration. I would like to add a bit to that history by calling to your attention the fact that the Association, in *The Journal of the American Medical Association* for November 6, 1937, urged defeat of the Wheeler-Lea Amendment and observed that the Copeland Bill was a much better vehicle for the protection of the public than the other. This was, in the opinion of the Bureau of Legal Medicine and Legislation, a call for stronger protection of the public. The AMA continues its policy of concern for the best in consumer protection.

I came to the AMA from the FDA, where I had four years' service as an inspector. I was, therefore, acquainted with the activities of the agency, and I found that it had been the policy at the AMA to collaborate with the agency to bring to its attention violations of the law which came to our attention, to furnish the FDA our file information on physicians who were testifying against the Administration in pending lawsuits, and to furnish the names of and make some of the arrangements for the obtaining of expert physician-witnesses to testify for the Food and Drug Administration in its litigations.

Hoxsey Pills Incident

One of the cases wherein the FDA was notified with some dramatic results occurred when we alerted the agency in 1955 of the shipment of Hoxsey pills from Detroit to Portage, Pennsylvania. My assistant at that time, another former FDA inspector, was attending a meeting of quacks in Chicago, and was present when an announcement was made that the officers and directors of the group were going to have

an executive session, and that all others should leave the room, as there was to be a very important announcement. He didn't bother to leave, and, as a result, heard Mr. Hoxsey announce, with some fanfare, that a half-million Hoxsey cancer pills were being shipped by air. Upon the completion of the announcement, he called the Chicago district of the FDA. What happened after that, we do not know, except that an inspector and a deputy United States marshal were in the welcoming committee when the pills arrived in Portage. This was the beginning of the end for Hoxsey who was finally enjoined in December, 1960.

"Liefcort"

In May 1962 we received an advance copy of the *Look* magazine article on "Liefcort." As is our custom, we checked the identity of the physician, and learned, to our astonishment, that his name appeared in the files of the Department of Investigation. A male-pattern baldness remedy being shipped from Pontiac, Michigan, had been the subject of FDA seizure on the charge that the product was misbranded within the meaning of the law. The label indicated that the product was patented by Robert Liefmann. Inasmuch as the shipment was made from Michigan, we called the Detroit district office of the FDA, and the FDA officer who answered the phone recalled that there was a pending criminal action in federal court in Syracuse, New York, against the subject of the *Look* story. We contacted the Buffalo district office for confirmation of this information. I am sure that most people in the industry know that both the FDA and the Canadian authorities have put a further crimp in Dr. Liefmann's medical activities—not, however, before serious injury and death occurred to some hopeful arthritis patients.

This information from the FDA, together with a release from the Arthritis and Rheumatism Foundation, enabled us to publish a very strong warning in the July, 1962 issue of *Today's Health*.

National Congress on Medical Quackery

A better-known form of collaboration as between the FDA and the AMA occurred in Washington, D. C., on October 6 and 7, 1961. This was the first National Congress on Medical Quackery, which brought to the attention of the nation the fact that quackery had not gone out with the medicine show. It was a billion-dollar waste of money, the cause of untold suffering and death, and the sponsors and others were concerned about it.

Mr. Ribicoff, then Secretary of Health, Education and Welfare, and Dr. Leonard Larson, then President of the American Medical Association, shared a platform under circumstances which were most unusual, perhaps, in view of disagreement by them in other matters involving medical relationships.

The Postmaster General, the Department of Justice in the person of the Assistant in Charge of the Criminal Division, the Chairman of the Federal Trade Commission, and the Commissioner and the General Counsel for the Food and Drug Administration reported on the problem as it affected them in their enforcement of the law. The American Cancer Society, the Arthritis and Rheumatism Foundation, the National Better Business Bureau and the American Medical Association reported on the campaigns of private agencies. Other speakers included Dr. Fredrick Stare of Boston, Dr. Morris Fishbein of Chicago, Milton Duffy of the California Department of Public Health, and Dr. Harold Jervey, then Secretary of the Federation of State Medical Boards, who provided another panel for discussion and further answering of questions.

The press of the nation responded to this alarm, as did radio and television.

In several states similar programs have been held to point up local problems and to get necessary action to stop quackery.

Second National Congress on Medical Quackery Planned

A follow-up meeting was held in Chicago in March of 1962. At the present time plans are being formulated to hold a second National Congress on Medical Quackery. The exact time and place have not as yet been decided upon, but in all likelihood it will be in the Fall of 1963.

Mr. Depew, your Chairman, attended both the Washington and the Chicago meetings, and I feel sure he will agree that they have been profitable. There has been a stepping-up of reporting, and there has been a quickening of activities so far as the private agencies are concerned.

Krebiozen Investigation Promised

As Mr. Stetler mentioned, only last week the AMA appeared before the McNamara Committee on Aging of the United States Senate. At the same time, the Secretary of Health, Education and

Welfare released a statement that his Department would investigate Krebiozen, a controversial cancer product. Inasmuch as the AMA protested to the McNamara Committee that the government should investigate the promotion of this product, certain newspapers made it look like the FDA and AMA collaborated in the release.

We did not know of the government announcement until we read of it in the papers. We can, however, most certainly offer the government all the facilities at our disposal to have a complete critical analysis and appraisal of this widely publicized product. We hope it will clear the air once and for all.

In the circumstances, rest assured that the American Medical Association, mainly through the agency of the Department of Investigation, will continue to do what it can to assist the Food and Drug Administration in its enforcement activities against quacks and the purveyors of worthless or dangerous nostrums. **[The End]**

NEW "TRUTH IN PACKAGING" BILL INTRODUCED

Senator Philip A. Hart has introduced a revised version of the "Truth in Packaging" bill introduced in the closing days of the last Congress. Explaining the present bill, S. 397, at the time of its introduction, Senator Hart said:

"The proposed legislation directs the Food and Drug Administration —for foods, drugs, and cosmetics—and the Federal Trade Commission— for other consumer commodities—to promulgate regulations that will require packages accurately and clearly to give essential product information and fairly represent the contents.

"In the original bill the authority to draft discretionary regulations on a product-line basis was given to the Federal Trade Commission. Under the new bill, traditional lines of authority have been reestablished. The Food and Drug Administration will exercise the authority for foods, drugs, and cosmetics and the Federal Trade Commission will have jurisdiction for all other consumer commodities within the purview of the bill.

"The definition of 'consumer commodity' has been limited generally to 'kitchen and bathroom' items, these being the great majority of products sold as marketbasket items in the average supermarket. These products represent commodities for which the package has replaced the salesman as a source of information. They have given rise to the kinds of problems for which the solutions of this bill are tailored. And these solutions are designed to require this package-salesman to represent the product as clearly and fairly as we used to expect from the corner grocer.

"Retailers and wholesalers are specifically excluded from the coverage of the bill unless they are actually engaged in the packaging and labeling process in interstate commerce . . . [Also, the] fact that this is a civil antitrust measure and carries no criminal sanctions has been further emphasized."—FOOD DRUG COSMETIC LAW REPORTS, No. 356.

Wanted:
A Credo for World Food Laws

By EDMUND FORSCHBACH

Mr. Forschbach Prepared This Article Especially for the FOOD DRUG COSMETIC LAW JOURNAL. He is Ministerialdirigent, Federal Ministry of Health, Bonn, Germany, and the Vice President of the Codex *Alimentarius Europaeus*.

THE FOOD LAWS IN FORCE ALL OVER THE WORLD are a hodgepodge of archaic patchwork regulations far behind the times, the technology of food, and the needs of consumers.

Although almost all conditions of food processing have changed radically over the last hundred years, there has been no attempt to rationalize food legislation, and make it conform to what are considered—in theory at least—to be the only principles for the formulation of such laws.

A leading food scientist, Professor R. Cultrera, of Italy, expressed it recently in this fashion:

> In a world moving ahead with brain-reeling rapidity, food legislation of virtually all nations is being re-modelled with incredible and exasperating slowness. The majority of food laws now in force are still tied to basic schemes elaborated at the turn of the century, and merely retouched in haphazard fashion here and there, without a co-ordinated and harmonized view of the problem posed by the advance in knowledge of nutrition and food composition, progress in science and technology and the new needs of the consumer.

Standard International Food Laws

Moves to standardize food laws on an international basis, to bring them up to the level of today's technology and today's products, are now under way in several international and supra-national organizations. The European Economic Community is at work to standardize the laws of its six member nations. This is an indispensable requirement for a workable Common Market, since deep-rooted differences in food legislation can prove a greater obstacle to trade than the prohibitive customs duties now being eliminated.

The Food and Agriculture Organization and the World Health Organization want to create a food *Codex* based on the European

preliminary work of the *Codex Alimentarius Europaeus*, the goal of which is the ultimate harmonization of food laws the world over.

What Laws Must Be Harmonius?

But, may I ask, the harmonization of *what* laws? Is it the harmonization of laws designed frequently to protect an industry rather than the consumer, designed to discriminate against certain products because of political pressures, designed to continue outworn prejudices and bar new products?

I attended the founding conference of the FAO/WHO *Codex* in Geneva in October 1962. Food legislation leaders from some 40 countries of all continents were on hand. It was an important occasion—perhaps a turning point in the history of food legislation. It was a five-day conference, and there was a good deal of talking.

Frankly, I was disappointed. At no point during this important conference were the basic principles of food laws enunciated or discussed—except by one nongovernmental organization observer, representing the Food Law Institute, who exhorted the conferees to keep their focus on what he called the two basic watchwords—"health and honesty." (By this he meant protection of the consumer's health and the consumer's pocketbook.)

Oldest Recorded Food Law

When I visited Ankara, capital of Turkey, a few years ago, I went to a museum devoted to the culture of the Hittites, a people with a highly developed civilization who lived in Anatolia—present-day Turkey—about 3,500 years ago. Among the exhibits was a stone with an inscription consisting of two commandments:

1. Thou shalt not poison thy neighbor's fat:
2. Thou shalt not bewitch thy neighbor's fat.

This is probably the world's oldest recorded food law, yet it listed the principles of "health and honesty," stressed by the representative of the Food Law Institute.

"Thou shalt not poison . . ." means "Thou shalt bring only wholesome food onto the market," and "Thou shalt not bewitch . . ." could mean "Thou shalt not lead the consumer astray: thou shalt not take too much money out of his pocket by taking advantage of him."

This shows that even in those distant days the two principles of health and honesty were the governing rules for equitable commerce in foods. And it was these principles which have served as the base of the *Codex Alimentarius Europaeus* since its founding.

I say: Let us begin at the beginning!

It seems to me that the new organization is being built on quicksands—on the confused and frustrating grab bag of existing legislation.

Suggestions for a Better Organization

Let us first recognize officially the weakness and confusion of present food law legislation. Let us resolve officially to start building the body of food law from the ground up. Let us resolve that every food regulation must pass certain criteria before it is enacted into law.

Everyone will agree on the two criteria of health and honesty. Let everyone from now on also agree on another point—freedom of the consumer to choose what he wants. In other words, let us leave more to the law of the market place, if health and honesty are not involved.

In food legislation all over the world, we find much of what amounts to little more than "legislation of recipes." Why should the force of law be put behind a recipe? The public itself will decide whether or not it wants any recipe, any formulation. Is not this "legislation of recipes" designed to protect an industry against one member taking over the market with an improved recipe? How does this protect the public?

What Does the Consumer Expect?

Defenders of the status quo will quote one vastly misused term: *"consumer expectation."* They have used it to defend laws against the use of certain wholesome substances that the public has never heard of, or does not know are being used in a product. Is this "consumer expectation?"

What, really, does the consumer expect when he buys a food product? He expects it to be biologically safe, of course. And he expects it to have a certain taste, a certain smell, a certain feel, and a certain nutritive value. He is not concerned with what goes into the product—the ingredients.

And let us get down to the basic reality. If a consumer expects certain things of a food product and is disappointed, he will not buy it again. In our free-enterprise world, this force of the market place is infinitely more powerful than the force of law.

The consumer, by definition, is the only real authority on the subject of "consumer expectation." So why not leave the matter to him?

Discrimination Must Be Eliminated

The world's food laws are rife with examples of discrimination based on economic and political interests. The Treaty of Rome says, in a general sort of way, that such discrimination must be wiped out. And certainly all honest food legislation officials and theorists are agreed on this point. But to what extent have any food legislators, either in official conferences or in speeches and articles, emphasized this point?

I would exhort the FAO/WHO *Codex* authorities to put first things first. There must be a strong, unmistakable statement of principles—a credo, if you will—before the organization gets down to the years of dreary labor that lie ahead of it.

There must be a firm acknowledgement by this body of the deplorable state of the world's food laws today.

And what of the EEC food-law harmonization? One thing should be made clear. The EEC has no direct concern with the promulgation of the *ideal* food legislation. Its mandate is merely to harmonize *existing* laws to the limited extent necessary to wipe out barriers to intra-EEC trade, and to eliminate certain flagrant abuses. EEC's job, in short, is to come up with something pragmatic and workable, and then get on to other business.

EEC's task will be completed long before that of the FAO/WHO *Codex*. And unlike the latter's, the EEC's decision will not merely be recommendations, but will ultimately be binding.

The *Codex* body has bound itself to accept this legislation on a *de facto* basis for four years. This is undoubtedly the practical thing to do, but it must be clearly realized that the EEC's regulations will be far from the ideal document.

Developing a world-wide *Codex* is a task of enormous proportions. There will be compromise, frustration, delay and bickering over the years. Out of this travail, we hope, will emerge a food law based on the simple principles of health and honesty, a law leaving the door open to pure, wholesome products not yet developed, a law that recognizes that scientific truths are universal, and that ignores economic and political pressures from any source.

Let us begin at the beginning! **[The End]**

The Legislative Picture for the Drug Industry or "Sulfanilamide Revisited"

By IRVING H. JUROW

This Paper Was Delivered Before the Division of Food, Drug and Cosmetic Law of the American Bar Association Section of Corporation, Banking and Business Law in San Francisco, California, on August 8, 1962.* Mr. Jurow Is Vice President and General Counsel, Schering Corporation.

AS WE APPROACH THE TWENTY-FIFTH ANNIVERSARY of the enactment of the Federal Food, Drug and Cosmetic Act, it is almost ironic that we should be experiencing a "thalidomide" incident as the Congress considers legislation affecting the drug industry. A quarter of a century ago—as the Copeland Bill was slowly making its tortuous way through Congress—the "sulfanilamide" episode "jet-propelled" it into the 1938 Act. It is quite apparent, as one reads the cascade of words in the news columns, that the current tragic event has opened the floodgates for sharpening present law and may well result in excessively sweeping controls. Our only hope is that calmer and wiser counsel will prevail against rash and precipitous action.

No one will question that every effort should and must be made, and every prudent procedure adopted, which gives promise that similar disasters do not occur; but in so doing we should not "kill the goose that lays the golden egg." We must not forget that hundreds upon hundreds of drugs have been, and are being, successfully and uneventfully tested, and it is as important to preserve our ability to do so, and to discover and market the many "wonder" drugs that have been, as it is to avoid tragedies such as this. It is important, moreover, that neither the Food and Drug Administration, nor the drug

* This article was written prior to the passage of P. L. 87-781 (S. 1552) which became law on October 10, 1962. Therefore the references to H. R. 11581 (the House version of S. 1552) and S. 1552 do not reflect the provisions contained in the bill as enacted.

industry, panic in the face of Congressional demands for correction; demagoguery is not the solution to this unfortunate event.

Seven years ago—at this very meeting—I said that "it is, unfortunately, typical of our legislative process to mount, upon a temporary emergency or untoward happening such as the 'Salk Vaccine' incident or the elixir-sulfanilamide episode, an abundance of regulation of private industry." I also pointed out that the "understandable restraint which the drug industry might feel compelled to exercise in such 'emergency' circumstances" might lead it to submit to government regulation far beyond necessity and, indeed, to the ultimate detriment of the public.

Perhaps to this I should now add that, in its understandable desire to avoid criticism and to prevent similar episodes, the Administration may very well seek greater and far more exacting enforcement powers. It seems to me, however, that, in the long-range interest of continued progress in the field of public health, both government and industry should seek and support only that degree of regulation as would not discourage research or throttle progress; otherwise, we shall deny to the public more of effective health-giving and life-preserving drugs.

Legislation

It is in this frame of reference that we, as lawyers to the industry, should carefully consider the current legislative poposals.

The legislative picture for the drug industry is currently contained in two pending bills: S. 1552 (and its companion H. R. 6245) and H. R. 11581 (together with its complement H. R. 11582).

S. 1552—introduced in April, 1961—has been reported out by the Senate Judiciary Committee and is now on the Senate calendar.[1] H. R. 11581 and H. R. 11582 are still pending before the House Committee on Interstate and Foreign Commerce, where hearings have, for the time being, been suspended.

The legislative proposals to amend the Federal Food, Drug and Cosmetic Act were stimulated, in large measure, as a result of the Kefauver Committee investigation of the pharmaceutical industry.[2] Following some 15 months of exhaustive and exhausting hearings,

[1] S. Rept. No. 1744, 87th Cong., 2d Sess., Calendar No. 1703.

[2] S. Rept. No. 448, 87th Cong., 1st Sess., "Hearings on Administered Prices, Drugs," Subcommittee on Antitrust and Monopoly of Senate Committee on the Judiciary, Pts. 14-26.

during which the drug industry was roundly criticized as greedy and callous, the medical profession as dupes and pawns, and the Food and Drug Administration as somewhat less than competent and something less than vigilant, S. 1552 was introduced as the panacea for all the alleged ills and defects.

Since the theme of the Kefauver investigation had been that "by any test and under any standard the prices of most drugs are excessive and unreasonable," [3] it is not surprising that S. 1552, as introduced, concentrated on proposals ostensibly designed to achieve more intensive competition and, consequently, lower prices; its thrust was primarily an economic one.

The hearings on S. 1552, being essentially repetitive of those of the year before, were rather anticlimactic. However, a more effective presentation by the drug industry, in a better-informed reportorial climate, persuaded the Senate Judiciary Committee to focus attention more on traditional provisions for regulation of the industry than on proposals designed to achieve economic objectives. As a result, the bill as reported deals with regulation of the industry under the basic Act and has been stripped of its original patent and antitrust proposals; and, although in some ways still objectionable, is far less drastic and sweeping.

FDA's Proposals

In the meantime, stung no doubt by the harsh criticism directed against it, including suggestions of corruption, the Food and Drug Administration responded with its own legislative proposals. These, consistent with its traditional concept of responsibility for the protection of the public health, concentrated on provisions for increasing and expanding its regulatory powers in vindication of this objective. The two Harris Bills, H. R. 11581 and H. R. 11582, constitute the Administration's proposals.

What began, therefore, as an attack upon the "economics" of the drug industry—its profits and prices, its alleged excessive promotional expenditures and widespread patent abuses—has now produced legislative proposals, both in House and Senate, concerned only with traditional regulatory controls. Even a cursory review of these bills reveals that they cannot possibly produce "cheaper medicines"; indeed, it is obvious they will substantially increase the cost of doing business and, consequently, the cost of drugs. And, by adding far greater

[3] Report cited at footnote 1, at p. 33.

responsibilities in the Food and Drug Administration, will add considerably to the cost of administration. The over-all cost of maintaining our high standards of public health will thus be sharply increased.

False Promise of "Cheaper Medication"

These bills, therefore, hold out a false promise of "cheaper medication." Unfortunately, too, the hostility to the drug industry—and, indeed, to the entire health team—created by the misleading accusations and not infrequently false charges during the investigatory stage dealing with prices and profits, together with the current furor over "thalidomide," will now be misdirected in considering the desirability of the regulatory proposals.

The industry thus faces a two-pronged attack which will be extremely difficult to resist. All the more so since the public's reaction to the entire subject of health and medicine, drugs and prices, is highly emotional; and, being one of those "problems," described by Mr. Justice Frankfurter, as "entangled in popular feeling," is easily manipulated.

In the limited time at my disposal, I can only sketchily review some of the more important provisions of these legislative proposals and perhaps express an opinion or two as to their need. For it is "hornbook" to lawyers to inquire: What are the abuses or defects sought to be remedied? Are the legislative proposals fairly directed to the achievement of the objectives?

At the outset, I should state—borrowing a leaf from my government friends—that the opinions here expressed are my own. Although I sincerely believe I speak *in* the interests of the drug industry and its public responsibility, I do not speak either *for* it or for any of its associations.

"New Drug" Clearance and Suspension

Perhaps the most significant and far-reaching changes proposed in the pending bills are those which govern the marketing of "new drugs" as that term is defined in Section 201(p) of the Act. In addition to the test of "safety" for use under the conditions prescribed, recommended, or suggested in the proposed labeling, H. R. 11581 proposes that all the provisions of the Act applicable to "new drugs" be amended to require that they also meet the test of "efficacy." This would include not only the definition of a "new drug" (Section 201 (p)), but also the provisions for the initial clearance of the drug

(Section 505(d)) as well as those dealing with the suspension of a "new drug" application (Section 505(e)).

Moreover, in lieu of the present procedure, under which a "new drug" application becomes effective automatically if not rejected within the statutory period, the proposal requires *affirmative* approval of the "new drug" application, *without imposing any time limit.*

Similar provisions appeared in S. 1552, as introduced.

As reported, however, S. 1552 rejects the requirement for affirmative approval, retains the present procedure of automatic effectiveness, but increases the initial statutory period from 60 to 90 days, and empowers the Food and Drug Administration to further stay the marketing of a "new drug" by serving notice of hearing within the 180-day period. The Committee bill does, however, adopt the proposal that the applicant satisfy the test of "effectiveness" in addition to that of "safety." The Administration is required, in rejecting a "new drug" application for failing to satisfy the new and additional test, to find "a lack of substantial evidence" supported by investigations of qualified experts "that the drug will have the effect it purports or is represented to have under the conditions of use" set out in the proposed labeling.

Despite the sweeping generalization that there has been inflicted upon the public a host of worthless drugs, no convincing demonstration has been made that the present provisions of Section 505 have proven inadequate to prevent the marketing of useless or of dangerous new drugs.

Safety Requirement

True, the Food and Drug Administration has stated that, on occasion, it has been compelled to pass a "new drug" because it satisfied the requirement of safety, notwithstanding the Administration doubted its usefulness or efficacy. This observation, however, appears to be in sharp contrast with the Administration's admitted practice of considering efficacy in judging safety. Despite toxic characteristics, a drug is cleared if its effectiveness in the treatment of a serious disease state outweighs the risks involved in its toxicity. On the contrary, the Administration disapproves the marketing of such a drug if, in its judgment, its effectiveness is outweighed by the risks of harm. Indeed, even where the drug is relatively lacking in toxicity, its inefficacy in treating a life-threatening disease is a relevant factor in determining safety, particularly where other methods of therapy are available. In short, therefore, the Food and Drug Admin-

istration assertion of impotence is limited to the very narrow area of a "new drug," relatively nontoxic, for a disease state not of a serious nature, in which the Administration seeks the power to pass upon efficacy. A corollary power is sought, in the same frame of reference, to suspend the effectiveness of a "new drug" application.

Particularly in the case of prescription drugs, where the ultimate decision, whether to prescribe or not to prescribe, rests in the hands of the physician, it is important that the law impinge as little as possible upon his professional function. The choice of therapy should be made by the patient's physician, not by a blanket determination of a government agency. Effectiveness, in its fullest meaning and understanding, not infrequently is realized only after extensive use in patient treatment. For that reason, it is desirable that new drugs of significant potential for the public health be not prematurely discarded by overcautious judgment of government officials.

No Drug 100 Per Cent Safe

H. R. 11581 would, by the very breadth of the authority vested in the Food and Drug Administration, constitute it the arbiter of medical opinion. In the "delicate area of medicine," where medical opinion will always differ, appropriate accommodation must be made for conflicting views, and there is grave risk to the public health if a government agency is permitted to deprive physicians of access to new drugs on the basis of its sole judgment as to its efficacy. If, as Commissioner Larrick has said, "no drug is absolutely 100 per cent safe," surely no drug is absolutely 100 per cent effective. Thus, there will always be room for arbitrary or capricious, or at the very least predisposed, action by government. Surely, every effort should be made to avoid this.

Even the less drastic provision of S. 1552, which requires that the "new drug" application be allowed to become effective unless there is a lack of substantial evidence that the drug will have the effect claimed for it, imposes a heavy burden both upon the drug manufacturer and upon the Food and Drug Administration. The danger still exists that preconceived medical opinion entertained by government officials will work a serious hardship upon the nation's physicians and their patients. It is difficult to believe that, in practice, the standard will not be easily transmuted into one requiring absolute proof of efficacy, given the understandable reluctance of a court to override an administrative finding.

It seems to me, therefore, that the public interest might be better served if the authority of the Food and Drug Administration is not extended beyond the test of "safety" to include the test of "efficacy." For concededly, under present law and under present regulations, worthless drugs can be removed from the market by appropriate procedures now available to the Administration. Vigorous enforcement is surely the answer to the contention that existing procedures are difficult; the public interest, as well as the interests of the still private drug industry, require that the government make a substantial showing before depriving the public of the opportunity to test the efficacy of a drug through experience or the drug manufacturer of his property.

Time Limitations

The present procedure, whereby a "new drug" application becomes effective unless disapproved within six months, has worked no real hardship on the Administration and has served the public well in making safe, new drugs promptly available to the medical profession. Indeed, the Senate Committee was persuaded that the "Food and Drug Administration has ample authority . . . to keep unsafe new drugs off the market." And, in his testimony before the House Committee on H. R. 11581, Commissioner Larrick did not take serious issue with this conclusion. The enlargement of the initial period from 60 to 90 days, in light of current practice under which a "new drug" application is frequently found to be "incomplete" and, therefore, not entitled to be filed under the statute, is not consequential. However, the authority proposed to be granted to the Food and Drug Administration to stay the marketing of a "new drug," even beyond the present statutory 180-day period, by merely noticing the application for hearing, could, unfortunately, open the way for protracted delay, notwithstanding the additional proviso that such hearings be adjudicated on an expedited basis. If the flow of new drugs to the market is to be encouraged and government action assured, it would appear far better to fix a determined period of time within which Administration action must occur. It will be little comfort to the bereaved parents of a child who died for lack of timely availability of a new drug that the government was not thoroughly convinced of its efficacy.

Moreover, to require affirmative approval without time limit, as does the House bill, would bring into play the normal predisposition against accepting responsibilities, particularly since there would be the unavoidable public inference that drugs "approved" by the Food and Drug Administration have been "officially" recommended for use.

The present procedure for clearing "new drug" applications, which places the responsibility of action on the Administration, and which S. 1552 will preserve, serves to avoid otherwise painfully slow and excessively cautious government action.

H. R. 11581 would also amend Section 505(e) of the Act to reduce the standards for suspending an effective "new drug" application. In addition to the current authority to suspend such an application, if the Food and Drug Administration finds the drug to be "unsafe," it would have similar authority if it finds the drug to be "inefficacious," or if it finds that "there is substantial doubt as to the safety or efficacy of the drug."

In contrast, S. 1552, as reported, although it expands the type of evidence which may be considered by the Food and Drug Administration, retains essentially the present standard for suspension insofar as "safety" is concernd. In adding "lack of substantial evidence" of effectiveness as a further basis for suspension, S. 1552 adopts the same standard for suspension as it promulgates for initial clearance.

The Senate Committee bill would also authorize the Food and Drug Administration to refuse to clear a "new drug" for marketing should it find that the proposed labeling is false or misleading "in any particular," and to suspend a "new drug" application if, on the basis of new information evaluated with the earlier evidence, it finds a similar defect in the labeling. No similar provision appears in H. R. 11581.

On the other hand, the House bill would authorize suspension under far less exacting provisions and, indeed, would make of suspension the most formidable weapon of legal sanction. For suspension would be permitted for such apparently innocuous violations as the failure to establish or maintain required records, or to make required reports, the refusal to permit access to such records or the copying thereof, or, mark you, the violation of "any condition" attached to the approval of a "new drug" application.

Suspension, it is obvious, is far more serious than disapproval of "new drug" application. Consequently, it would seem that the drastic remedy of suspension should rest on the utmost need for the protection of the public health. It is difficult to see how, in light of the other remedies available, mere failure, for instance, to maintain records would justify suspension.

Finally, the authority contained in S. 1552 to refuse to clear a "new drug," or to suspend an effective application, upon a finding that the labeling is false or misleading "in any particular," vests the Food and Drug Administration with limitless power. In light of the argument advanced by the government as to the meaning and scope of the phrase "in any particular," in the *Kaybel* case,[4] the drug industry can look forward only with pessimism to the future of its "new drug" applications.

Registration

In its original form, and in the form in which it was first reported to the full Committee, S. 1552 provided an elaborate scheme for licensing the pharmaceutical industry. It would have required every drug manufacturer to be licensed by the Department of Health, Education and Welfare, both on an "establishment" basis and on a "drug" basis, and would have authorized the Department to establish broad qualifications for such a license.

No similar provisions appear in H. R. 11581 for the reason that the Department rejected this form of regulation, preferring to rely on other controls, such as expanded factory inspection powers, enlarged "new drug" procedural provisions, and additional controls over manufacturing standards.

Nevertheless, and despite the Administration's disavowal, S. 1552, as reported, establishes a system of registration. Every establishment in which drugs are manufactured or processed would be registered with the Department of Health, Education and Welfare. In addition to authorizing the Department to establish exemptions from registration in appropriate cases, the statute would specifically exempt pharmacies, licensed practitioners and persons who prepare drugs solely for use in research, teaching or analysis, and not for sale.

"Census Form" of Registration

Innocuous as the registration provisions of S. 1552 may appear, I am constrained to agree with the Administration's attitude toward this form of "pseudo-licensing." With its extensive power of inspection and of "new drug" clearance, supported by the formidable sanctions of seizure, injunction and criminal prosecution for misbranding or adulteration, it seems to me even the "census form" of registration provided for in S. 1552 is a needless procedure, adding to cost and

[4] *United States v. Kaybel, Inc.*, CA-3, No. 13914.

burdensome in compliance and enforcement. Moreover, registration may prove to be but a first step toward licensing—a form of government control ordinarily inimical to our free-enterprise system.

Factory Inspection

H. R. 11581 would amend Section 704 of the Act to authorize inspection, in the establishment or vehicle subject to inspection, of "all things therein" bearing on violations or potential violations of the Act. The scope of the inspection would go far beyond the current embrace of "equipment, finished and unfinished materials, containers, and labeling" and would include "records, files, papers, processes, controls and facilities." Jurisdiction to inspect would extend even to establishments where drugs (as well as food, cosmetics and devices) are manufactured, processed, packed or held *after* introduction into interstate commerce.

S. 1552 provides for a more limited expansion of the factory inspection power. The enlarged scope of inspection, similar to that found in H. R. 11581, is restricted to establishments in which *prescription drugs* are made, processed, packed or held. Moreover, exemption from such inspection is extended, as in the case of the registration provision, to pharmacies, licensed practitioners, and research, teaching and analysis operations, as well as to other classes of persons exempt by the Department of Health, Education and Welfare. In addition, specific exclusions are contained in the Senate bill covering financial, sales (other than shipping records), pricing, personnel and research data. Data relating to clinical experience with respect to "new drugs" and antibiotics is, however, made subject to inspection within the limits provided for in the "new drug" and antibiotic sections, as amended by the bill; and such data with respect to all other drugs may be inspected but in accordance with regulations "which shall have due regard for the professional ethics of the medical profession."

It is quite apparent that under these provisions the Food and Drug Administration inspector would have access to every file, every document, every paper—without limitation—which could in any conceivable way relate to violations or *potential* violations of the Act. I seriously doubt whether even a grand jury subpoena in such terms would survive attack. In addition, access to "controls," "processes," and "facilities" opens the door wide to disclosure of trade secrets, know-how, and similar areas of extreme confidentiality.

Apart from the serious question whether so broad and sweeping a power of "search and seizure" is necessary in order to adequately enforce the Act, the proposal surely raises substantial questions of constitutionality. Indeed, similar concern has been expressed in connection with the pending Civil Investigative Demand Bill (S. 167, 87th Cong., 1st Sess.), and assurances have been given by Congressman Celler that "file searches" have been "carefully precluded" and constitutional rights preserved.[5]

The 1953 amendment of the factory inspection provision specifically denied Administration access to the very documents now sought under H. R. 11581 and, in the case of prescription drugs, under S. 1552. What has occurred in the past ten years to justify reversing that decision? Concededly, such a broad "police" power would be a convenience to the Administration, but mere convenience does not justify so serious an invasion of private, constitutionally-protected rights. On balance, the private rights of industry appear to be unduly invaded by the breadth of this proposal without a corresponding need for protecting the public health.

Moreover, it is difficult to understand the justification for specifically singling out manufacturers of prescription drugs, as distinguished from other drugs, as is proposed in S. 1552. If such a power of inspection is sound in the interests of public protection and adequate Administration control, it is no less sound in the case of drugs which do not, under the Durham-Humphrey Amendment,[6] require prescription dispensing.

Manufacturing Controls

Because S. 1552, as introduced, provided a broad licensing procedure, with authority in the Secretary of Health, Education and Welfare to establish rigorous standards for qualification, the bill contained no amendments affecting manufacturing or quality controls. However, as I have already indicated, the Department did not support the principle of licensing, preferring the type of controls found in H. R. 11581. It is there provided that a drug shall be deemed to be adulterated under Section 501 of the Act if the methods, facilities, personnel or controls used in its manufacture, processing, packing or holding are inadequate, as determined under regulations prescribed by

[5] "Antitrust and Trade Regulation Report," Bureau of National Affairs, Washington, D. C., June 5, 1962, p. A-12.

[6] Act of October 26, 1951, P. L. 215, 82nd Cong., 21 USC Section 353.

the Secretary, to insure its safety, efficacy and integrity, that it will not be injurious to health and that its labeling will conform to law.

S. 1552, as reported, adopts this alternative with modifications of the House proposal to establish more objective standards than those reflected in the Administration's bill. Thus, the Senate version is restricted to "methods," "facilities," and "controls"—eliminating "personnel"—and adopts the standard of "current good manufacturing practice" to assure that the drug meets the requirements of the Act as to safety (note the absence of efficacy) and integrity. Interpretive regulations may be issued by the Secretary of Health, Education and Welfare, subject to the provisions of the Administrative Procedure Act; such regulations to be treated as *prima facie* evidence of what constitutes current good manufacturing practice in any judicial contest.

It is unfortunate that the Senate Committee rejected the suggestion that adequate provision be made in Section 304(a) to preclude "multiple seizures" of a drug which would be deemed adulterated—although not so in fact—by reason of the violations of the manufacturing standards prescribed under the regulations. No sound reason exists for burdening the manufacturer with the defense of a multiplicity of seizure, and depriving the public of faultless drugs, when the contest involves a "fictional" adulteration. In appropriate cases, the Administration could resort to the remedy of injunction, but at least this would confine the contest to a single proceeding.

Certification of Antibiotics

Both H. R. 11581 and S. 1552, as reported, extend batch certification controls to all antibiotic drugs. The Senate bill, however, limits its coverage to those intended for human use. Moreover, the Senate bill provides a definition of antibiotic drugs and, in addition, specifically requires the Secretary of Health, Education and Welfare to exercise his authority to issue exempting regulations under certain circumstances expressly stated in the bill.

No provision of these legislative proposals better exemplifies the indifference to the principle that "*mutata legis ratione mutatur et lex.*"

Batch certification, originally adopted more than fifteen years ago as a temporary measure, was predicated on the then inadequacy of methods, tests and controls to assure batch uniformity among multiple producers. No additional antibiotics have been subjected to these controls in the last 13 years. The legislative history demonstrates clearly that batch testing controls were to be discontinued

when no longer necessary and, since antibiotics are produced and controlled today with the same assurances of uniformity and quality as other pharmaceuticals, there is every reason to discontinue, instead of enlarge, this unnecessary, expensive duplication of operations.

Records and Reports

H. R. 11581 would authorize the Secretary of Health, Education and Welfare to require holders of effective "new drug" applications to maintain such records, and to make such reports to him, of clinical and other data obtained by them and relating to the drug, as he may, by general regulation or by specific order, require in order to enable him to determine whether the suspension powers of the Act should be invoked. Similarly, the Secretary would be authorized to condition the investigational-use exemption under Section 505, upon the establishment and maintenance of such records, and the making of such reports to him, of data obtained in the course of the investigational use, as he finds necessary in order to evaluate a "new drug" application should one be thereafter filed. Both types of records are made subject to access, copying and verification by employees of the Department.

Needless to say, the bill also provides appropriate sanctions for failure to comply with these record-keeping, report-making and access requirements. Failure to comply is made a "prohibited" act under Section 301, subject to all the sanctions which pertain thereto. In addition, in the case of an effective "new drug" application, such failure is ground for suspension of the application.

Except for requiring that the regulations promulgated with respect to these provisions shall have "due regard for the professional ethics of the medical profession," and shall afford the drug manufacturer reciprocal rights with respect to similar information obtained by the Secretary—provided the Secretary deems such reciprocal right appropriate—S. 1552 contains similar provisions. Moreover, similar record and report provisions are made applicable to certified antibiotics both in H. R. 11581 and in S. 1552.

To the extent that S. 1552 and H. R. 11581 would require the maintenance of records and the furnishing of reports covering clinical experience with new drugs subject to an effective "new drug" application, there is every reason to support this proposal. If, as I have indicated, effectiveness is often not fully appreciated until after extensive use in patient treatment, then it would appear to be highly desir-

able in the public interest that, as a "new drug" gains this experience through expanded use following marketing, the clinical experience so accumulated should continue to be evaluated, not only by the manufacturer but by the Administration; and I would think that the provision for reciprocity, which the Senate bill provides for, would be strongly supported by both government and by industry.

Risks Involved

On the other hand, there are risks involved in that provision of the proposal which would require similar reports and records in the investigational stage of a "new drug." Apart from the effect on the competitive position of a company, the early disclosure of the product or of the data may serve as a substantial deterrent to medical research and investigation and may very well have serious impact on the professional and confidential relationships that exist between manufacturers and clinical investigators and between physicians and patients. It is in this area, no doubt, in which the "thalidomide" case will serve as exhibit "A." However, in evaluating appropriate and adequate controls, consideration must be given to the effect of any proposed restraints upon the ability of drug producers to obtain the services of competent and qualified investigators in sufficient number to afford an adequate basis for arriving at a conclusion concerning the safety of the drug. If investigational activity becomes unduly burdensome, we may be left with no alternative but official, government testing.

The risks that may be involved in our present system of private clinical testing will not be eliminated under a government-controlled system. It will not solve the problem of inadequacy of scientific knowledge to simply impose greater and more stringent controls upon the drug industry. On the other hand, our advances in the field of medicine will surely come to a halt if restrictive measures stifle private initiative and the patient is treated not by the physician at his bedside, but the government official whose unappealable decision has foreclosed the use of what may have proved to be the therapy of choice.

High Standards in Our Country

Despite recent efforts to assail the integrity of the ethical pharmaceutical industry, the unalterable fact remains that the American citizen continues to enjoy the highest standards of health, the finest, safest, most effective drugs and a well-balanced regulatory system

of federal and state governmental controls. I believe the record amply demonstrates that the Federal Food, Drug and Cosmetic Act has effectively served the cause of American public health. Even its severest critics have paid tribute to the industry's vast contributions to the progress of medicine and medical science and to its role in creating and maintaining high standards of public health. Statistics abound on the substantial reduction in both mortality and morbidity rates in the past 25 years, and the pharmaceutical industry's contribution is attested by the more than 4,000,000 who would not be with us today but for the industry's life-saving new drugs.

No system of human design is, or should be, perfect. The English poet Robert Browning expressed this in his immortal lines: ". . . but a man's reach should exceed his grasp, or what's a heaven for?" But, though we accept this thesis and seek constantly to improve our design of drug controls, we must not be carried away, neither by the "sunshine patriot" nor the disingenuous enthusiast.

It is the burden of those who seek to extend governmental control and regulation, whether for the drug industry or elsewhere, to demonstrate that the current system is inadequate. That burden is, and should be, a heavy one; otherwise, we will suffer change for change's sake alone.

The extent to which the "thalidomide" case may be exploited is illustrated by the complaint that legislation is needed which would permit "the immediate removal from the market of a new drug where there is an immediate hazard to public health." But this power is already vested in the Administration under the "multiple seizures" provisions of Section 304; and additional power exists under the injunction of provisions of Section 302. And the demand for amendments to S. 1552, as reported, to include provisions for affirmative approval of "new drug" applications, compulsory licensing of patents, and emphasis on "generic name" labeling, can hardly be justified by the "thalidomide" case. Obviously, such provisions offer no solution whatever to that problem.

Unfortunately, however, an atmosphere of hostility toward drug manufacturers has been created and a concerted, hasty effort to change the law may very well fail to weigh the long-range consequences.

As lawyers, we surely share the public's demand for adequate safeguards to assure every possible protection against dangerous drugs; and for arming the regulatory agency with adequate weapons

of enforcement. But do we also share the popular thesis that the American citizen is an illiterate, confused and pathetic victim of profiteering, venal tycoons; that only "big brother" can adequately aid him? There may, indeed, be unscrupulous people in the health field, as, indeed, there are in all fields; but to plough under the field to uproot the few weeds may prove an egregious disservice to the public and to our economy.

Adequate and Ample Power

Were the Food and Drug Administration powerless to proceed against the unscrupulous, no one would dare argue against giving it the appropriate weapons to deal with them. But with the present sanctions of injunction, seizure and criminal prosecution in the current food and drug law, together with the criminal penalties under Title 18 of the United States Code, added to the self-interest of the industry generally, we think there is not only adequate but ample power to assure safe and effective drugs. I am tempted to believe it is a distinct service to those in authority that the law vest them with less power than they seek and perhaps even just a little less than they need. By exercising ingenuity, authority is always able to close that small gap; the public, however, is protected against abuse of power and the temptation to misuse it. **[The End]**

POLICY RULE ON DRUGS FOR PERNICIOUS ANEMIA

All drugs containing or purporting to contain "intrinsic factor" or "intrinsic factor concentrate" will have to be labeled for sale only upon prescription, the Food and Drug Administration has announced. The final statement of policy, which provides for regulation of preparations to treat pernicious anemia, was published February 20 in the *Federal Register* and becomes effective in 180 days from that date.

Intrinsic factor is a substance prepared from the intestines of food animals which increases vitamin B_{12} absorption in the human. FDA said orally administered preparations of vitamin B_{12} and intrinsic factor may sometimes mask symptoms and interfere with the diagnosis of pernicious anemia. Only vitamin B_{12} by injection is generally recognized as a wholly reliable treatment of this condition.

The policy statement requires that any orally administered drug for the treatment or prevention of pernicious anemia bear a warning to physicians stating that some pernicious anemia patients may not respond to such products. The labeling must also state that periodic examinations and laboratory studies of pernicious anemia patients are essential and recommended. The policy statement calls attention to the prohibition against adding intrinsic factor to foods, including health foods, because there is no covering food additive regulation.

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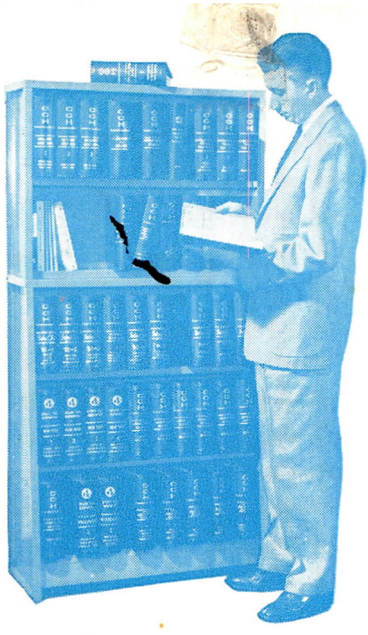

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