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Food Drug Cosmetic Law JOURNAL

Papers Presented at the 1962 Joint National Conference of Food and Drug Administration and The Food Law Institute, Inc.

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

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FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

The 1962 Joint National Conference of the Food and Drug Administration and the Food Law Institute, Inc., was held on November 26, 1962 in the auditorium of the United States Department of Health, Education and Welfare, Washington, D. C. This issue of the JOURNAL contains the papers which were presented at the morning session of the conference.

The invocation was delivered by *Frederick Brown Harris, D. D.,* Chaplain of the United States Senate. Welcoming statements were made by *Boisfeuillet Jones,* Special Assistant to the Secretary, Health and Medical Affairs of the Department of Health, Education and Welfare, and *William T. Brady,* Chairman of the Board of Trustees of the Food Law Institute.

The President of the Food Law Insitute, *Franklin M. Depew,* comments on the Drug Amendments of 1962 in the Introductory Statement which appears at page 774. He declares that the law "as enacted maintains the fine balance between public protection and the preservation of a private enterprise economy."

Looking ahead in the food industry, *C. W. Cook,* President of General Foods Corporation, declares that the food industry needs to be as bold and venturesome in the next decade as it has in the past to keep up with the foreseeable demand for more and better convenience food products. "It needs elbow room to experiment, and to probe for scientific and technological improvements, which will provide the still higher standard of living to which even our advanced society aspires." This interesting discussion of our nation's largest industry appears at page 778.

Francis C. Brown, President of Schering Corporation, views the next decade from the point of view of the drug industry. Greater emphasis will be placed on new drugs for the diagnosis, as well as the treatment of disease, and on preventive medicine. This interesting and informative discussion begins on page 787.

Regulation of the food distribution industry is looked at from the point of view of the retailer. *Paul J. Cupp,* President of Acme Markets, Inc., discusses the effect of competition on consumer protection. Manufacturers must offer the best and most satisfying product possible or face the danger of financial ruin. He believes that self-

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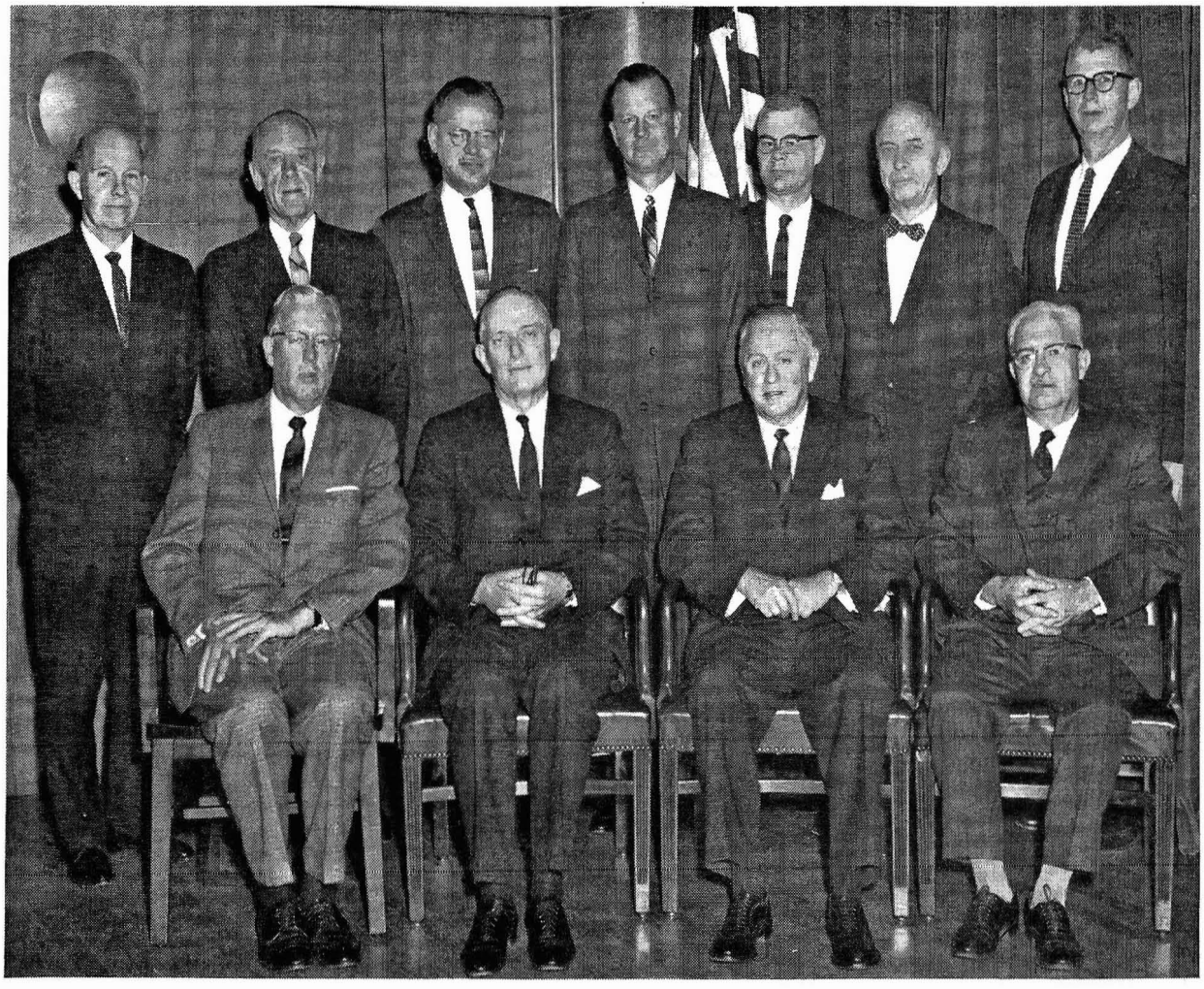

Participants in the 1962 Joint National Conference of the FDA-FLI are shown in the above photograph. In the front row, from left to right, are: Franklin M. Depew, Francis C. Brown, William T. Brady and John L. Harvey. In the back row are: Dr. O. L. Kline, Dr. Detlev W. Bronk, J. K. Kirk, C. W. Cook, W. B. Rankin, Dr. T. C. Byerly, and F. D. Clark.

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enforcement is the key to success and that nothing can be gained from adulteration, shortweight and other deceptions. Mr. Cupp's article begins at page 799.

A highlight of this year's conference was a dinner in honor of the Food and Drug Administration. *Boisfeuillet Jones,* Special Assistant to the Secretary, Health and Medical Affairs, Department of Health, Education and Welfare, discussed two topics of current interest—the new drug amendments and the recent Second Citizens Advisory Committee Report. "In the Department, from Secretary Celebrezze on down, we are acutely aware of the need for competence and judgment of the highest order in coping with the difficult problems facing the Food and Drug Administration—problems of health protection for every man, woman and child in the nation—through regulation of industries producing some $100 billion on consumer goods annually. To this task, we are thoroughly committed," Mr. Jones concludes. His paper begins on page 808.

A topic of great concern to private industry was discussed by *Fred Bartenstein, Jr.* at a seminar of the American Society for Industrial Security. Mr. Bartenstein, who is Administrative Vice President of Merck & Company, Inc., describes research espionage as a threat to our national security. He urges a revision in our criminal laws to fit the realities of a technologically advanced world, in the article which appears on page 813.

"Certainly you in pharmacy and we in FDA have much in common. We are both interested in the health and well-being of the American people. We have generally been able to work together closely to further our common goal." These were words *George P. Larrick,* Commissioner of Food and Drug, used in a discussion of the relationship of the FDA and professional pharmacy at a convention of the National Pharmaceutical Association. The address starts on page 823.

For your convenience, an index has been compiled of each article appearing in the FOOD DRUG COSMETIC LAW JOURNAL during 1962 according to author and title. In addition, the articles are listed under appropriate general subject headings in bold-face type. This index appears on page 828.

New York Bar Association Meeting. —The Section on Food, Drug and Cosmetic Law of the New York State Bar Association will hold its annual meeting at the Americana Hotel in New York City on January 22, 1963. Presiding at the meeting will be *Franklin M. Depew,* Chairman of the Section, who will make the introductory statement. *C. Joseph Stetler,* Director of the Legal and Socio-Economic Division of the American Medical Association, will discuss relations between AMA and FDA. "AMA-FDA Efforts to Curb Medical Quackery" is the subject chosen by *Oliver Field,* Director of the Department of Investigation, American Medical Association. Canada's cooperation with the FDA will be discussed by *Robert E. Curran,* Legal Advisor, Canadian Department of National Health and Welfare. Topics of interest in the field of agriculture will be discussed by *M. R. Clarkson,* Associate Administrator of the Agricultural Research Service, United States Department of Agriculture. Federal Trade Commissioner *Evcrette MacIntyre,* will discuss landmarks in fair advertising.

A luncheon will be given in honor of *George P. Larrick,* Commissioner of Food and Drugs. Mr. Larrick will address the group on the subject of "Administering New Food and Drug Laws."

The afternoon session will begin with a discussion on developments in the product liability field by *William J. Condon,* attorney for Swift and Company. *John T. Kelly,* Legislative Counsel, Pharmaceutical Manufacturers Association will speak on the new drug amendments. A floor discussion, resolutions and election of new officers will conclude the business meeting.

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Food·Drug·Cosmetic Law Journal

Introductory Statement

By FRANKLIN M. DEPEW

This Introductory Statement Was Delivered at the Sixth Annual FDA-FLI Conference, Washington, November 26, 1962. Mr. Depew Is President of The Food Law Institute.

I JOIN WITH CHAIRMAN BRADY and the officers and trustees of The Food Law Institute in welcoming you to the Sixth Annual Joint Educational Conference of the Food and Drug Administration and The Food Law Institute. These conferences are an important part of The Food Law Institute's educational program—one which represents for industry an acceptance of primary social responsibility.

I am sure that our speakers' fine talks today will contain much valuable information which should prove helpful in assuring the public that sincere and effective efforts are being made to comply with our food and drug laws. These speakers will tell you about the steps that industry is taking and plans to take to further self-regulation through education and cooperation with FDA. I think that what will be said here today will encourage FDA employees to seek voluntary compliance and will encourage industry to offer it.

I cannot let this occasion pass without mentioning that this conference, as well as those which have preceded it, is an activity which comes within the scope of one of the major recommendations made by the Second Citizens Advisory Committee in its Report of last month to the Hon. Anthony J. Celebrezze, Secretary of Health, Education and Welfare; that is, that education of producers and consumers should be emphasized by the agency. Furthermore, a major theme

of this conference is the encouragement of self-regulation, which was also stressed by the Committee. Thus, to a considerable extent, those in FDA and in FLI were really looking ahead when this theme was selected early this year.

If there is one aspect of the Citizens Advisory Committee Report which invites exception, it is, in my opinion its failure to mention the splendid cooperation we in The Food Law Institute have received for many years from Commissioner of Food and Drugs, George P. Larrick, and his staff, in our joint educational efforts, as exemplified by these conferences. They have served a most valuable function, not only in educating industry and the consumer, but in familiarizing the staff of the FDA with industry's problems. I think I can confidently say that many pressing problems in the food and drug field have been more expeditiously solved as a result of these conferences. I should also mention that William W. Goodrich, Assistant General Counsel, Food and Drug Division, gives of his time as adjunct professor to instruct in the courses of food and drug law at the New York University and George Washington Law Schools. Also that Arthur A. Dickerman, Western FDA Counsel, teaches the course in food and drug law at the Law School of the University of Southern California. We in The Food Law Institute look forward to an ever expanding program of cooperation and education with this fine agency.

While acknowledging the excellent support our program has received I should point out that in my appearances before the Congress I have suggested that improvement in the FDA programs of cooperation and education were desirable in the public interest and that the Congress should express this viewpoint for administrative guidance. I have also expressed the view at Bar Association Meetings that the FDA might have difficulty in securing the needed type of personnel for its scientific and administrative duties without an upgrading of basic salaries. I hope the Citizens Advisory Committee Report will be persuasive with the Congress in this respect.

There is one addition to the program as printed. I am most pleased to report that John L. Harvey, Deputy Commissioner of Food and Drugs, will be the final speaker this morning. He will report on "The FAO-WHO Conference on Food Standards and What It Means to American Industry." This Conference, held in Geneva, Switzerland, October 1-5, was the most important international food law development in 1962. Mr. Harvey headed the United States delegation at this Conference and was elected Vice-Chairman of the

Conference. After hearing his report I am sure you will make every effort to see to it that the United States government through the Congress takes appropriate steps to make the necessary monies available to support this program in the interest of the United States food and agricultural economy. The United States delegation deserves the thanks of the entire domestic food industry for its work at the Conference in support of guidelines which should be helpful in assuring that unwarranted trade barriers will not be established or continued by the adoption of unsound international food standards.

I mentioned earlier that Mr. Goodrich teaches the food law course at George Washington University. This course will again be given next semester and enrollment is now open. I recommend it to all of you who are located in Washington and point out that it is not restricted to law students.

This afternoon a panel of distinguished FDA representatives is available to answer your questions. I suggest you take full advantage of this opportunity. Please hand your questions to Winton Rankin or to me sometime this morning, or leave them at the registration desk.

In accordance with the past practice of the FLI of recording historical developments in the food and drug field I believe it would be appropriate to comment briefly on the Drug Amendments of 1962. This important legislation will have quite a profound effect on the development of drug law not only in this country but throughout the world. I believe this legislation was fashioned into final form in accordance with the best American tradition of industry-government cooperation. The law as enacted maintains the fine balance between public protection and the preservation of a private enterprise economy. Efforts to correct the unfortunate thalidomide tragedies might have been expected to bring about hasty and ill-considered legislation. Instead the law as passed has been generally accepted by industry as in the public interest even though some have observed incidental defects of significance for future research. I congratulate the drug industry on its presentations before the Congress, and the Congress on the action taken.

In addition to establishing additional requirements with respect to new and experimental drugs, the law strengthens the factory inspection authority of FDA in respect to prescription drugs. A most important provision of the law is that requiring the registration and periodic inspection of all domestic drug manufacturing establishments, regardless of whether they are engaged in interstate or intrastate commerce.

The law also importantly affects the food industry. For instance, the federal courts are given jurisdiction to issue injunctions against refusal to permit *any* plant inspection authorized by the Food, Drug and Cosmetic Act. Previously, the only remedy for refusal to permit inspection was criminal prosecution. Another provision permits the use in animal feeds of ingredients which could cause cancer, provided any such ingredient in feeds causes no harm to the animal and provided there are no residues of the ingredient in the meat or other products reaching the consumer.

Finally, I call your attention to that portion of the Drug Amendments which provide that: Nothing in the amendments made by this Act to the Federal Food, Drug and Cosmetic Act shall be construed as invalidating any provision of state law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of state law.

This language seems to adopt the prevailing judicial sentiment with regard to all provisions of the Federal Food, Drug and Cosmetic Act. It will be interesting to see its effect on subsequent decisions. A possible interpretation of its language would be that the federal law pre-empts the field except in respect of the Amendments themselves. On the other hand this statement of policy may be judicially regarded as governing the entire field of the Act's jurisdiction.

[The End]

COCOA BEANS SEIZED

A half million bags of cocoa beans, valued at an estimated $16.6 million, were seized at warehouses in Philadelphia and New York on charges of insect infestation and storage under insanitary conditions (Philadelphia lots) and insect infestation and mold (New York lots). The Philadelphia seizure was one of the largest in FDA's history.

United States marshals seized 451,592 bags averaging 140 pounds apiece at Philadelphia and 31,166 bags averaging 141 pounds apiece at the New York warehouse.

The insect contamination of the cocoa beans at Philadelphia was discovered after the Food and Drug Administration inspected a New Jersey candy manufacturer and found infested beans which were traced to the Philadelphia warehouse. The New York lots were discovered by a routine inspection.

After proper fumigation, cleaning and separation of unfit stocks, FDA will recommend the release of the good material for processing and sale. The seizures will insure prompt action to clean and fumigate beans and preventing spread of the infestation to other lots of beans which were in good condition.

Looking Ahead in the Food Industry

By C. W. COOK

Mr. Cook, Who Is President of General Foods Corporation, Delivered This Address at the Morning Session of the FDA-FLI Conference.

A DEEP SENSE OF RESPONSIBILITY accompanies the warm appreciation I feel for this opportunity to participate in this meeting. I consider it an honor to have a part in this annual gathering of business and government people dedicated to enhancing the well-being of the American consumer. Of itself, that cause is so vital in our economy of consumption that it cannot fail to stir a feeling of responsibility in one dealing in consumer goods.

Additionally, on the personal side, I have a responsibility for carrying on what executives of my own company have contributed over the years to the fine and fruitful cooperative efforts of the Food Law Institute and the United States Food and Drug Administration.

In looking back to 1949, when the Institute was formed to complement the work of The Nutrition Foundation, it is gratifying for me to recollect that the first formal meeting of the Institute was held in General Foods offices and that a General Foods executive became its first chairman. Also, I am proud to say, my company played a leading role in establishing the Nutrition Foundation in 1941.

Concern for Public Health All-Important

Their solid records of sound accomplishment make both the Nutrition Foundation and the Food Law Institute continuing manifestations of the food industry's abiding concern for the public health and protection. Both, as you know, work closely with and enjoy the confidence of many government, as well as private, agencies and organizations which are dedicated to the public interest. We who support them are proud of these *pro bono publico* endeavors, which foster and encourage nutrition research and education and better

understanding of our food laws. And we are keenly aware that they, together with individual food company research efforts, have contributed importantly to the food industry's progress in providing the American consumer with the most healthful and wholesome—as well as the most varied and abundant—food supply the world has ever known.

But we are not here to review the past. This sixth annual idea-exchange conducted by and for industry and government people is designed for a look-ahead. It is most appropriate that the attendance this year again includes consumers and representatives of consumer organizations. For consumer protection problems can best be solved by business and government working together in an atmosphere of mutual trust and respect.

It is in that spirit—one which presupposes that business and government both have responsibilities and that they are on the same side, the side of the consumer—that I undertake my assignment here today. While I am billed as a spokesman for the food industry, I do not, of course, have any such broad delegation of authority. I can speak only of the package grocery business, and of that only from the point of view of my own company. But I am confident—based on first-hand knowledge of how competitive pressures affect all of us in the food business—that the thoughts I express are very apt to reflect the views of other food companies, and perhaps of other segments of the food industry as well.

My invitation to speak here suggested I look ahead with respect to market trends, consumer desires, and the all-important matter of regulation, including self-regulation. It would be well first to establish a benchmark that indicates just how well the food industry in our country is taking care of the consumer today.

Many of you may have read the article, "Why Our Food Is A Bargain," which appeared in the September issue of *Reader's Digest.* It was written by John Strohm, a leading agricultural writer, and was based on his presentation at the recent Fifth International Food Congress. I should like to read his opening paragraph:

> "If I could show any visitor from abroad just one thing in the United States, I would turn him loose in a small-town supermarket with $25—the average amount the American homemaker spends weekly to feed her family. For food is our Number 1 success story, a far bigger bargain here than in any other nation."

Flattering as this reputation is, it's also a sober challenge to the food industry. For it poses the need to do still better. We know from what we went through to acquire such a reputation that maintaining it will be even more difficult than earning it was. And I can assure

you that we did earn it—by day-in and day-out performance, by constant catering to the consumer, by providing her with what she wants, when and where she wants it, and processed and packaged in the way she wants it.

In the food business to a greater extent than in almost any other, the customer writes the rules. She wields the yardstick to which we have to measure up.

"Revolution in the Kitchen"

Especially since World War II, the American homemaker has been the beneficiary of what has aptly been called a "revolution in the kitchen." Although it is a benign one, this revolution is inseparably related to American's high standard of living and, to a significant extent, is responsible for it. For food is *the* prime requisite of any living standard. And our free-choice system has made it possible for the food industry to add value upon value for the consumer in the wide variety of foods available to her out of our nation's abundance.

What her grandmother might have regarded as sheer magic, today's homemaker not only casually accepts, but *insists upon having.* "Ready to cook," "heat and serve," and "instant" are package directions with which every housewife in the country is familiar. Even more than the present generation, tomorrow's homemaker will *expect* ever-better convenience foods, not only as a way of life, but as her *right.*

The still-spreading sociological as well as economic impact which convenience foods have made on life in the United States foreshadows an even greater demand for these products in the future. The trends are so clear that the food industry is gearing itself to produce more and better products with built-in service.

At this point I want to make it clear that the enthusiasm of America's homemakers for convenience foods is not due merely to their desire to reduce kitchen work. They want to gain time for many important things—for work outside the home, for performance of a vast number of good works in the communities in which they live, for family and cultural activities, and so forth.

Consumer Sets High Standards of Quality and Taste

But "quick and easy" is not enough for the homemaker. As the "boss" of the food industry, the consumer sets high standards of quality and taste as well as of convenience. Two examples come readily to mind. Frozen foods and instant coffee were on the market

a long time before they were accepted by appreciable numbers of homemakers. It wasn't until we improved these products, and made them more appealing to consumers' tastes, that they became *useful* convenience foods.

Today's homemaker also has high nutrition standards. While she wants foods that take the drudgery and gamble out of cooking, she also wants to maintain a balanced diet for her family. More and more she relies on the processor to help her attain these goals.

Living up to the homemaker's demands—meeting her high expectations in the kitchen revolution—has not been "quick and easy" for food processors, either. We have reduced the homemaker's kitchen hours from an average of five and one-half to one and one-half. But in taking over kitchen chores—in substituting factory hours for home kitchen hours—our standards of quality, nutrition, flavor, appetite appeal and wholesomeness have had to be meticulous. For every one of the millions of times each day that a woman takes a food package off a grocery shelf, a manufacturer's reputation is at stake.

One-Time Sales Aren't Profit-Making

Maintaining a good business reputation is merely a matter of enlightened self-interest. An unsatisfactory product gets only a single ride in a consumer's shopping cart, and no profit is *ever* made on one-time sales. So as food processors, unless our products consistently measure up to our sense of responsibility to provide wholesome products honestly packaged, we can't survive, much less make our business grow.

Let's examine the economic factors constantly at work in the interests of the consumer. First, there is the incentive of profit and second, the compulsion of competition. If the lure of profit does not entice a company constantly to improve its products and its service, then competition from other makers of the same type of product will soon compel it to do so. This is a very practical and highly effective form of regulation imposed upon us by the competitive enterprise system in which we function. It is frequently overlooked in discussion of self-regulation, where the tendency is to think only in terms of self-imposed industry-wide rules.

To those in business—especially in the fiercely-competitive food business—it has long been apparent that the most effective approach to more successful enterprises is to offer a better product or service, a better value or higher consumer benefit, than your competitor. It is

this compulsion of competition which contributes immensely toward insuring that the consumer will continue to be a winner in the market place.

Add to the incentive of profit and the compulsion of competition the watchful eye of government, and you have a system of consumer protection that's mighty hard to beat. I'm convinced that the consumer knows this. Witness the fact that in spite of recurring headlined clashes about additional external regulation that some feel may be required from time to time, millions of consumers every day buy hundreds of millions of packages of processed foods. And they do so with complete confidence.

"The Consumer Speaks" Survey

A yardstick for measuring this confidence has been provided by a survey conducted in the last few months by the well-known A. C. Nielsen Company. Its field auditors interviewed 1,173 supermarket shoppers in all parts of the country in a survey called "The Consumer Speaks." They report that 92 out of every 100 consumers interviewed say the grocery manufacturer is doing a good or excellent job in supplying their needs. Further, Nielsen reported only about one per cent—13 people out of the 1,173 interviewed—suggested that quality be improved. As a matter of fact, when asked specifically for suggestions on improvements they would like to have passed along to grocery manufacturers, only four per cent of the shoppers had any suggestions at all.

By and large, consumers do not know—nor is there any reason why they should trouble to absorb the details—about the myriad steps and controls which make up the self-regulation aspects of the food industry's watchfulness in their behalf. Safeguarding the consumer is a process which goes on all the way from farm furrow to family table. Many food companies, my own included, conduct extensive horticultural research, seeking better seed strains, better soil care and more efficient cultivation, growing and harvesting practices in the interest of obtaining better raw materials from which to produce better food products.

At processing plants, raw materials are carefully checked for adulteration, contaminants, spoilage, pesticide concentrations, or other imperfections which might cause harm to the consumer. In many instances, self-imposed raw material acceptance standards adhered to by reputable food companies are stricter than those imposed by gov-

ernment regulation. And high quality standards are maintained through each food processing step, including accurate package fill.

Control in Frozen Food Industry

You in government, I'm sure, are aware of the too-numerous-to-recite ways in which industry exercises its own controls for product betterment and consumer protection. Let me offer just one example. Quality control in the frozen food industry has presented a particularly stern challenge—that of maintaining zero degree temperature from the time a package of food is quick-frozen until it is taken by the consumer from the retailer's frozen food cabinet. Food processors, warehousemen, transporters, wholesalers and retailers are all at work, individually and cooperatively, on improving frozen food handling procedures.

Currently, the Birds Eye Division of General Foods is enlisting the help of consumers in a test program to monitor the cumulative temperature experience of its frozen foods right up to the time the package is opened in the home. A tiny time-temperature indicator, developed by an instrument manufacturing company, is being inserted into random packages. A simple form enclosed in the package asks the homemaker to cooperate—and offers modest payment for her cooperation—by marking on a sketch of the time-temperature device the exact temperature reading when she opened the package.

When the homemaker returns her marked sheet and the tiny device to the company, Birds Eye will have its first look at the cumulative above-zero temperatures to which the product has been exposed all the way from plant freezers to the consumer's kitchen. These data will help us determine the extent to which our product quality may be affected by exposure to temperatures above zero. It will enable us to make a thorough check of distribution procedures designed to prevent quality loss through temperature rises.

The use of the indicators in consumer packages is only one phase of our company's time-temperature research program. Another will involve all stages of distribution—primary warehousers, truckers, distributors and retail store managers. Indicators will be placed in selected cases, and these cases will be tagged with instructions as to which participant in the distribution system should remove the device from the case and return it to Birds Eye with the filled-out form. We believe that the time-temperature indicator may provide the foolproof check on frozen food storage and handling that the industry has long sought.

Technological Progress Sought

Technological progress is constantly being sought in other food industry areas besides frozen foods. We—and other companies—are exploring possibilities in such areas as dehydration, ultrasonics, irradiation, dehydro-freezing and freeze drying. The food industry feels a responsibility for pursuing these techniques because, as everyone in this room knows, in our highly urbanized society each of us cannot grow his own food. So greater and greater reliance has to be placed on mass production of food through application of scientific developments, including the use of additives. Others here are far better qualified than I to discuss the complex subject of additives. But I do want to register three points:

(1) There is inherent danger—to progress and advancement in food technology—in the spreading notion that additives are necessarily badditives.

(2) Additives do much *for* the consumer. They heighten nutrition and improve food flavors, stability, appearance and color.

(3) Government and business both have a stake in avoiding unnecessary "scares" with respect to our food supply.

Without additives, we simply can't feed America, much less other parts of the world. At a recent consumer conference conducted by the American Association of University Women, an example was cited which sharply points up the fallacy of generalizing by always ascribing "good" to natural foods and "bad" to chemicals added to foods.

At the conference there was reported a series of tests applied to an emulsifier for the purpose of determining whether or not it could be metabolized—that is, completely utilized during the physiological changes that occur in the body. The test required tagging the compound under study with a radioactive isotope and following it through the digestive processes where it might be located in or measured in different organs or tissues. When the series of tests had been completed, it was possible to account for every part of the compound and thus to establish that no part of it had accumulated to cause pathological reactions.

It was also pointed out at this conference that, because of procedures like the one I have just described, more is known about the chemical composition and the action of some additives than is known about many components of natural foods. For example, artificial grape flavor is a relatively simple product made up of four or five components, all of which have been tested and found safe. *Natural* grape flavor, on the other hand, is made up of perhaps as many as 17

or 18 identified components. The toxicological effects of only four or five of these have been established by tests. As a matter of fact, it is my understanding that this whole subject of natural toxicants is now being studied by the Food Protection Committee of the National Academy of Sciences-National Research Council.

My point here, of course, is that all of us—in business, in government, in consumer organizations—have a responsibility to contribute to better public understanding of a few incontrovertible facts:

(1) Nowhere in the world is the consumer more meticulously cared for and ardently courted than in the United States. This is only a matter of enlightened self-interest—the only way to build a successful business.

(2) There is no monopoly on concern for the consumer. Business as well as government is exercising extreme care with respect to consumer protection.

(3) Concern for the consumer is an indispensable ingredient of our competitive enterprise system, which is responsible for the continued success of our American economy.

(4) With so much—our freedom and our very survival—depending on our ability to accelerate that economy, we cannot afford to let temporary differences of opinion obscure the all-important point that business and government are on the same side, the side of the consumer.

America's Largest Industry

To keep up with the readily foreseeable demand for more and better convenience food products, the $80 billion food industry—American's largest industry—needs to be as bold and venturesome in the next decade as it has been in the last. It needs elbow room to experiment, and to probe for scientific and technological improvements, which will provide the still higher standard of living to which even our advanced society aspires.

The food industry's track record is good. We have demonstrated that our thinking starts with people and their needs and wants, rather than with products. Moreover, we have demonstrated a deep and abiding concern for consumer protection. And we can be sure that in the future as in the past, food companies will remain alert to the fact that the solid foundation for consumer confidence is product quality. The unceasing quest for quality will be accelerated as new products and new technologies are developed, and self-regulation will always play a vital role in the food industry.

As we compete aggressively with the ultimate objective of influencing the decision of the individual consumer, we respect the government's function of establishing rules of fair play and, in turn, we seek respect for our own sense of responsibility.

Our entire private enterprise system is a natural outgrowth of the political principles of individual freedom which govern our country. Our system of government and our system of private enterprise are interdependent. Each makes the other possible, and both contribute to the broad-based character of the American economy.

Leaders in business and leaders in government have a continuing and shared responsibility to avoid extremism in what we do and what we say in presenting our respective points of view. Meetings such as this one offer proof that our system works to those parts of the world where democracy is as yet untried; that given reasonable freedom to operate, our system can create and maintain the high-volume, low-unit-cost method of serving the public which keeps bringing an increasing number of new and desirable products within price-reach of an ever-greater number of people every year.

Careful Consideration of Proposed Legislation Needed

We at General Foods feel that legislation should be considered carefully from the standpoint of how it might restrict freedom of choice in the market place. We believe that *all* consumers must be kept in mind, with the long-range view of not legislating today what might impair economic freedom and progress tomorrow.

As we ponder consumer protection problems which are inevitable in a democratic free enterprise society, all of us—in government and in business—have a responsibility to keep uppermost in mind the fact that under today's world conditions we cannot afford to let our system fail—or even falter. I am confident that meetings such as this one—conducted in a spirit of sharing knowledge and experience—will go a long way toward wise and reasonable solutions. **[The End]**

The Drug Industry —1962-1972

By FRANCIS C. BROWN

Mr. Brown, President of Schering Corporation, Spoke on Behalf of the Drug Industry at the Morning Session of the FDA-FLI Conference.

IT IS BOTH A PLEASURE AND AN HONOR for me to appear before this distinguished audience and to participate in this challenging program. Nor is that pleasure diminished by the difficulties of trying to predict what the drug industry may be like in the next decade. Short range crystal-gazing is usually far less reliable than that which spans centuries.

In the field of science, predictions are more difficult still. Who among us, in 1940, would have even imagined that within 25 years man would have orbited the earth in a matter of hours and would be building vehicles for a trip to the moon? Who would have dared promise the advances in internal medicine which the pharmaceutical industry has achieved in the last two decades?

Today, as yesterday, it takes a certain boldness to forecast the pharmaceutical future. For ours is anything but a clear and simple path. We deal with the complex human body—with human beings—each of whom has his own peculiar strengths and weaknesses and idiosyncracies; not with mass-produced mechanical engines containing interchangeable parts. And inevitably, the actions of our products are influenced by human emotions which are inextricably intertwined with organ functions in sickness and in health. Thus, as the human factor—individual differences in body and in mind—is always there to confound our products in the hands of physicians, so the sum total of the emotions of the body politic confounds our prophets and obscures our future.

Yet there are certain generalities which we can state with some degree of certainty. We can be assured that between now and 1972 pharmaceutical science will enjoy magnificent triumphs and suffer discouraging setbacks; it will progress far beyond our present hopes and will meet with disappointments and misunderstandings.

These misunderstandings are inevitable, for they will stem from unavoidable causes—the tragedies which invariably precede or accompany scientific victories, the layman's inability to comprehend the mechanisms essential to scientific progress, and the sympathetic tendency of the political community to find a scapegoat for every misadventure.

The "Golden Age of Medicine"

In recalling past achievements of the pharmaceutical industry, it is apparent that many of the scientific problems which were tackled were overcome, and our exercise of practical wisdom in administering these advances was unquestioned. The decade 1948 to 1958, for instance, has been described as the "Golden Age Of Medicine," and truly it was.

In this short span of *ten* years death attributable to common infections of persons under 15 years of age dropped 80 per cent. Isoniazid, a new discovery (1952), joined with the postwar antibiotics in providing a new hope for tuberculosis victims. Two years after this discovery (1954), the oldest private establishment for the treatment of tuberculosis patients in the United States—The Trudeau Sanitarium near Saranac Lake—closed its doors.

Looking Back

At a meeting this fall, sponsored by the New Jersey pharmaceutical industry, Dr. Morris Fishbein, distinguished medical author and lecturer, spoke of his 50 years in medicine. In the course of outlining great discoveries made by the pharmaceutical industry which contributed to advances in medical care he related, "there was one condition which we called invariably fatal—100 per cent fatal—that was pernicious anemia." He then traced experimental research conducted by a drug company on liver extracts and the final discovery of vitamin B^{12} of our industry in 1948. He added, "today this (pernicious anemia) is no longer considered at all, in any sense of the word, an invariably fatal disease." He also related to how medical advances and new antibiotics reduced the death rate from pneumonia at Cook County Hospital, Chicago, from 35 out of 100 patients in 1913 to 5 out of 100 in 1962. Deaths from pneumonia today, he said, are usually among the elderly or infants.

Experts, alarmed over the rapid increases in mental illness, had predicted a sharp rise in the number of hospital patients for the late 1950's and the decade of the 60's. Tranquilizers changed all this.

Last year, the research director of New York's Rockland State Hospital estimated that between 1956 and 1961 the number of mental hospital patients decreased by more than 85,000 persons, the first decrease in 200 years!

The average life expectancy of Americans in 1900 was 45 years. During the decade of 1948 to 1958, this life expectancy jumped from 65 years to approximately 70 years.

One of the tremendous satisfactions of our industry achievements is that these figures are not merely statistics—they represent more than 4 million human beings alive today who otherwise would be dead; human lives returned to productive channels of living through our scientific acumen.

This scientific achievement continues as the goal of every ethical pharmaceutical manufacturer. In accomplishing these advances, our industry operated in the traditionally private sector of our economy, assuming on its own the tremendous risks involved in exploring new pathways to health, cooperating fully with reasonable laws and governmental controls which provide for the public safety, and gathering its just rewards.

A Combination of True Science and Business

The American pharmaceutical industry is a mixture of true science and true business. One could not survive without the other. However, our most outspoken critics in recent years have attempted to divorce the two and portray unfairly to the public only its business aspect. Not only is this unfair—it is illogical. Success does not just happen. Men of vision and courage in our industry have undertaken risks which more often resulted in failure than in success. The reasonable rewards which provide the incentive for this activity are profits. Without them our industry could not operate as it does. The perverted sense of values which has been forced upon us in recent years draws the broad implication that because our industry is commercial we should be suspect; the word profits has been portrayed as having an evil connotation; most recently we have been depicted as an industry willing, for profit, to foist "unsafe" drugs upon an unsuspecting public. Nothing could be farther from the truth. We progress commercially only as we progress scientifically and only because we understand and fulfill our moral obligations to the public we serve.

Favorable Political Climate Necessary

The future success of the American pharmaceutical industry—whether we consider the next ten years of the next 100 years—will depend upon the continuance of its scientific progress in a political climate favorable to business. Past progress in the private sector of pharmaceutical research has depended upon private corporations assuming risks, with the expectation that their discoveries would provide continued and adequate profits to justify these risks and, more importantly, to underwrite future research—research which yearly becomes more difficult and costly, with diminishing likelihood of success as more and more doors of opportunity are closed by past successes.

The scientific knowledge which our industry has amassed to date provides great hope for the next ten years. Today diseases of the heart and circulatory system are the leading cause of death and disability in the United States. These diseases cause at least three times as many deaths as does cancer and seven times as many as do accidents on our highways and in our homes. The most prevalent causes of death are arteriosclerosis and hypertension. The onset of arteriosclerosis is now known to occur earlier in life than had been previously suspected and it progresses with advancing years. Once the precise order of progression of the disease is known, it is not too much to expect that the chemists and biologists of our pharmaceutical industry will be able to develop potent agents to counteract these changes. Within the past five years the pharmaceutical industry has developed many highly effective drugs to combat hypertension. Considerable progress is now being made in this area and we expect within the next few years to see newer compounds introduced which will be more specific and consequently more effective in treating high blood pressure.

Cancer Control Possible

Hopefully, in the next most important disease area, cancer, our industry's vast screening and testing program should yield results within the next ten years. At present, hundreds of thousands of chemical compounds are being carefully screened to determine their possible effects on various forms of cancer. Although there is no definite way of knowing whether this search will yield results, highly qualified scientists in the field believe that the current approach is the best in the absence of more positive clues. It is the drug industry's hope that we will hit upon a class of chemical compounds that will

not only retard the reproduction of cancer cells but also will reveal the basic key to the nature and control of cancerous growths.

Perhaps two of the areas of most significant advance in the next decade will be greater emphasis on new drugs for the diagnosis as well as the treatment of disease and also upon preventive medicine. New biochemical approaches will permit more profound exploration of human body cells, allowing greater emphasis upon catalysts and regulators of body metabolism, this is, the enzymes and the coenzymes. Future diagnostic approaches to illness should relate more and more to metabolic disorders of the cells, rather than the usual clinical symptoms and syndromes. As greater advances are made in the study of body cells, we can assume that drugs may be developed which will prevent or alter the effect of inherited cellular abnormalities.

Increased attention on appropriate screening methods to spot tendencies toward certain illnesses early in life may well result in development of preventive medicines to offset such diseases as cancer, coronary artery disease, hypertension, arthritis and certain mental diseases. Although it will take much longer than ten years, we should eventually see drugs developed which can be administered prophylactically throughout an individual's lifetime to deter the development of these serious illnesses. There will undoubtedtly be major advances in the field of immunology which will open up dramatic possibilities for organ and tissue transplants in human subjects. Considerable work has been done on this with success in many medical schools throughout the nation. However, there is still the need for proper chemical or drug agents to offset the adverse response which occurs through the introduction of a transplant into another subject. We can look forward to the day of the world heart bank, the kidney bank and the liver bank.

Present Problems

Today, as we stand on the threshold of great new health horizons, we must take our present problems into account. First of all, there are the scientific problems associated with the investigation of useful drugs. In this area only the application of scientific knowledge, based on past experience, can reduce the element of risk to a responsible degree. However, since man is unique, it is not possible to eliminate all risk in the research of various drugs. What happens in a hundred laboratory animals may not necessarily happen in man. In the face of this uncertainty, we must avoid unduly hampering competent physi-

cian-researchers from freely investigating new drugs in human disease. No matter how significant a scientific development appears in the laboratory or in lower animals, its true use and benefit will never be realized until it has been thoroughly studied and tested in humans.

On August 26, 1962, the *New York Times* carried the front page headline "Scientists Fear New Laws May Curb Drug Research." The *Times* reported, "these authorities—eminent scientists from universities, major hospitals, independent institutions and government research centers as well as the pharmaceutical industry—agree to a man that drug practices need tightening. But they fear that new controls may restrict the sound scientific practice that is necessary for the discovery and development of vitally needed new drugs." Since this article appeared, many similar warnings have appeared in the lay, as well as the scientific, press cautioning against the threat to medical progress inherent in rigid governmental control over experimental drugs.

The future of the industry's scientific achievements must be based on drug evaluations made by highly skilled, independent clinical evaluators. These men must make the decision as to a new product's probable use and usefulness based on their assessment of the response of the patients under their close observation. In the discharge of their responsibilities reliance must be placed upon their dedication to their patients and their professional traditions and ethics. Any substitute for this scientific approach would mean the creation of a central, demagogic control which would be dictating clinical investigations, not on the basis of immediate patient supervision, but on the basis of remote control in which scientific necessity will inevitably be comprised by the expediency of political dangers.

Hastily Conceived and Unreasonable Legislation Could Present Serious Difficulties

For the foreseeable future, the greatest obstacles placed in the path of scientific discovery in the field of ethical drugs could well be hastily conceived and unreasonable legislation to meet over-simplified problems, and excessive government control of normal business operations in a hostile political climate.

Our industry has become vitally concerned with public opinion, which we must now consider to be the "fourth dimension" of our future. The need to consider the public as its new "fourth dimension" was, in effect, forced upon the industry through the intrusion of the Congressional investigations and the increasing press criticism leveled

at its activities. We must dispel the air of mystery and secrecy which inaccurately surrounds us in the public mind.

Today both the role of the physician and the role of the pharaceutical industry are undergoing rapid and dramatic changes. The public has become generally better informed on medical care, and in many cases its information has been obtained not from the source but from critics of the source. Unfortunately, our "news" consists almost entirely of "what's wrong," because one must assume there is little readership interest in the vastly greater area of "what's right" about life and business. Therefore, both the medical profession and the ethical drug industry have a new challenge: to provide to the public factual information on medicine and medical care without disturbing the important, highly personal, physician-patient relationship.

A Void in Communication with the Public

We have always assumed the responsibility of informing doctors and pharmacists about our products. In fact, it is this very circumstance which has, perhaps, been a main factor in creating an unnatural separation between our industry and the general public whom we serve. Our intraprofessional advertising has absorbed all our effort and has therefore left a void in our communication with the public. I cannot help but feel that this gap—our failure to inform the public—has contributed more than any other single factor to the success of the criticism leveled against us in the past three years.

Traditionally, pharmaceutical products have always been marketed through professional channels. The written prescription of the physician and the dispensing services of the professional pharmacist are intended not for convenience, but rather to provide the best control over total medical care for patients. The physician-patient relationship is the focal point for all drug marketing and communications efforts. Drugs are intended to aid the physician in providing the best in therapy for each individual patient. In order to cure, every drug must have properties which will attack or in some way alter the functions of the living organism; as they cure, they also damage, if only in a transitory fashion. Therefore, only the physician can make the ultimate choice as to drug therapy because this involves a balancing of the benefits to be expected from the drug, the degree of need of the particular patient and the damage which the drug may inflict in the process of curing or aiding the patient.

There are always some who fear the consequences of allowing other people to exercise a judgment. Many sincere people are uneasy about the freedom which the medical profession has enjoyed in resorting to many different drug choices in treating their patients. They seek the unobtainable ideal of drugs potent enough to cure which are otherwise completely harmless. Yet in medicine and in the drug industry it is well known that only the enert placebo is harmless—yet even it produces numerous reports of side actions.

Critics of our existing system attribute the dangers largely to the profit motive which they say has spurred our industry to make a plethora of drugs, and to rashly advertise their benefits while suppressing or minimizing their adverse effects. If our industry has been guilty of such excesses, and while there are always some exceptions, it certainly must be said that they are very rare indeed. We must take great care that in correcting these evils we do not move into a new system whereby a central committee would be the authority relating to all practices in the health field. This may happen sooner than we think. We are moving to a national health system under the authority and control of the federal government. Should it succeed with medical care, the course of federal action would be to extend its controls in all health areas, including drugs, ostensibly to assist patients economically to obtain these services.

Soviet Drug Manufacturing System

In this regard it is most enlightening to study statements made by Dr. Raymond A. Bauer of Harvard University who has conducted extensive studies of the Soviet business and manufacturing systems. In testimony before the House Interstate and Foreign Commerce Committee last August, Dr. Bauer said the Soviets allege that their drug manufacturing system, highly state-controlled and centralized, prevents needless duplication of reseach facilities and promotes drugs on a conservative basis. Dr. Bauer testified that "The Soviet medical press contains constant criticism of the high prices for drugs." He also said that the Soviet medical press "contains repeated complaints about the inadequacies of the promotional system." These inadequacies in promotion and advertising result in Soviet doctors being uninformed about new drugs. The treatment of patients suffers, says Dr. Bauer, and Russian druggists spend needless hours in compounding drugs which are already available in prepared form. Also in the Soviet press (wholly owned and operated by the government) are constant pleas to Russian pharmacists to inform doctors about new drugs.

Those who say it can't happen here may be deluding themselves. It can and it will if we permit it. Under such a system, the many dangers in excessive governmental control over pharmaceutical research would be with us day after day, stifling initiative and halting progress. Perhaps the gravest of these dangers—as the *London Times* has pointed out—would be the shifting of personal responsibility for evaluation and judgment from the physician to an impersonal, and therefore much more easily absolved, government bureaucratic group.

There have been tragedies at the price of scientific progress long before the drug thalidomide. We must ask ourselves what would be the public reaction if these were excused with the alibi, "The *government said* the drug was safe and efficacious." In the field of regulatory law, as it embraces the pharmaceutical industry of the future, there certainly should be most careful study of what really promotes the general public welfare in health and what impairs or could impair it. The ultimate decision whether to prescribe or not to prescribe must rest with the physician as he deals with patients according to their individual peculiarities and needs, and not according to statistical averages. Thus, it is important that the law impinge as little as possible upon the professional function.

I do not believe that any degree of legislative restriction or governmental regulation can materially reduce or alter the risk involved in medical drug invention or testing. Yet the more rigid the controls, the greater the reluctance of both industry and scientists to overcome the obstacles and run the risks inherent in progress and the less bright will be our medical and pharmaceutical future by comparison with our recent past.

Better Cooperation in the Future

What the ethical drug industry wishes for the future is a modern and workable system of cooperation between competitive industry and government for the benefit of Americans and of all humanity. It is encouraging to note that the Citizens Advisory Committee in its recent report on the Food and Drug Administration had, as its first recommendation, a reorientation of the philosophy and leadership of FDA to "a more constructive approach to the problems of consumer protection." (FOOD DRUG COSMETIC LAW JOURNAL, October, 1962 at p. 588. The better course, it said, would be to "create a sincere desire on the part of industry to assist in the development of stand-

ards and to comply voluntarily with the standards established in the interest of the health and welfare of the consumer. Such a course of action will . . . create a feeling of cooperation and respect among the many ethical producers who honestly desire to put out the best possible product and serve the public interest." (FOOD DRUG COSMETIC LAW JOURNAL, October, 1962, at p. 599.)

As one who has been privileged to witness at firsthand the remarkable advance of pharmaceutical science in the last two decades, I am deeply concerned that it be maintained in the next decade. If restrictive measures stifle private initiative; if the patient is no longer entirely in the hands of the physician at his bedside; if the unappealable decision of a government official has foreclosed the use of what might have been the therapy of the physician's choice, surely our advances in the field of medicine will come to a halt and the public interest will be poorly served.

When the 1960's began, the American people enjoyed the highest standards of health; the finest, safest and most effective drugs; and a well-balanced regulatory system of federal and state governmental controls. The record shows that the Federal Food, Drug and Cosmetic Act effectively served the cause of American public health. But I wonder whether the prospects for a still better future are not seriously threatened. I would be less than frank if I were to forecast for the ethical drug industry in the next decade an immunity to epidemic socialism spread by carriers professing to believe that every evil has an instant remedy which the government is duty-bound to produce.

The New Drug Amendments

After extensive hearings and consideration, Congress recently passed the "Drug Amendments of 1962." Before the public hysteria arising from the tragedies attributed to thalidomide and the legislators' reaction to it, many sincere people in the drug industry and many sincere legislators considered certain of the provisions of this bill to be unnecessary and undesirable. But the need for a scapegoat was such that the bill had to pass and the industry had to be regulated as a matter of political necessity. We now have this law and in keeping with the best traditions in America, we must all join hands to make it work. Industry is sympathetic to the enormous problem which the enforcement authorities face in gathering the information needed as a background for reasonable and proper regulations under the new law. They will need a penetrating understanding of the industry's opera-

tions, with their many and varied ramifications, and the industry will attempt to provide needed facts and advice where it is afforded the opportunity to do so. But industry has been accused of so many wrongdoings of which it has not been guilty that there is great danger of political criticism of the administrator who regulates reasonably and great danger to the progress of medicine if he regulates excessively under the pressure of political demands and public hysteria. Therefore, I solicit the support of the same reasonable men who oppose censorship legislation, notwithstanding the fact that much evil abounds in certain publications, because they realize that an open door in this area could bring governmental domination in all areas of public expression. Those whose voices cry out for continued freedoms in other areas should not remain silent when the basic freedoms of business are unreasonably attacked. Our industry has not, and would not, deliberately act unethically or against public morals. Therefore, we are concerned here with legislation aimed rather at answering a public demand than in correcting a genuine evil.

To resist the power-seekers and to protect the public welfare, it is necessary to see beyond day-to-day abnormal situations and avoid hastily proposed cure-alls. This need has been the guide-rule for the pharmaceutical industry in America.

Merely to comprehend many of these scientific problems requires a profound knowledge of the subject matter. The public and their legislative representatives cannot understand this complexity. This lack of understanding must somehow be overcome, since, if anything, scientific problems will increase in difficulty in the future. The ultimate success of scientific advance in the health field will depend upon a better understanding on the part of the public and government as to what these problems are and how they must be handled.

National Advisory Board on Science and Health Proposed

The Citizens Advisory Committee Report on the Food and Drug Administration,[1] issued last month by the Secretary of Health, Education and Welfare, recommended the establishment of a National Food and Drug Advisory Council to aid the Food and Drug Administration in its future programs. I strongly support this recommendation and would suggest an extension of the concept to create a national advisory

[1] The October, 1962 FOOD DRUG COSMETIC LAW JOURNAL contains the full text of this report.

board on science and health—a board which would serve as the public's interpreter of research facts and problems. I see this board as composed of the best minds from medicine, the pharmaceutical industry, the federal government and the universities.

Such a group could bring about a closer working relationship among scientific bodies in all sectors of American life. Problems such as the needs of clinical evaluations in humans, if first studied by such an advisory group, would be seen with the rational balance which was so lacking when the thalidomide tragedies were first revealed. I do not envision this group as a regulatory or enforcement body, but rather as an association of gifted and respected men who could bring about not only a greater understanding of the problems we face in scientific progress, but a number of solutions as well.

Such a body, I feel, would go a long way toward preserving individual freedom and initiative throughout the medical and pharmaceutical world—freedom to exercise foresight and choice—which has been the great strength of America, where liberty prevailed over power. If this freedom be lost, then we shall see the decline not only of our effective system of public health, but of our nation as a whole. If this freedom be preserved, then we shall see a brilliant American advance in science, ethics, law and public health. What we do in the next year or two under this law will determine what we are in 1972. The choices are still open. **[The End]**

INADEQUATE LABELING CHARGED IN SEIZURE

Large quantities of a drain opener and a drain cleaner were seized at Seattle, Washington and St. Louis, Missouri on charges of violation of the Federal Hazardous Substances Labeling Act.

United States marshals seized over 1,400 cases of the drain opener in labeled and unlabeled bottles, quantities of another drain opener and a drain cleaner at three places in the Seattle area and a quantity of the same products near St. Louis.

Court papers stated that the products were manufactured by a California firm. FDA said the products contain a high percentage of sulfuric acid, and were packaged in fragile plastic containers with poor closures which could reasonably be expected to leak.

According to FDA, the labels failed to bear all or part of the information required by law, such as the common or usual name or the chemical name of the hazardous substance, an affirmative statement describing the hazard, precautionary measures describing action to be followed or avoided, instructions for first aid treatment, the statement "keep out of the reach of children," and the word "poison."

A Retailer Looks at Regulation

By PAUL J. CUPP

The Author, Who Is President of Acme Markets, Inc. and Former Chairman of the Board of the National Association of Food Chains, Delivered This Address Before the 1962 Joint National Conference of the FDA-FLI.

IT WAS WITH GREAT PLEASURE that I accepted the invitation of your president some months ago to address this distinguished gathering. Laws governing the way food is produced, processed and distributed to consumers are receiving perhaps more public and governmental attention today than at any time since the Pure Food and Drug law was passed in the early 1900's.

As one of the regulated, I'd like to give you some of my own views about the comments that have been piling up—pro and con—about the laws regulating the way in which the food industry operates and about some of the agencies which do the regulating.

As a preamble, let me say that I believe there are two institutions at work which insure American consumers a safe and abundant supply of food.

One, of course, is the government at every level. There is no reason here for me to go into the long list of agencies charged with consumer protection. You know them and the laws under which they operate far better than I do. I believe as a general rule that they do a good job. But the question is what role and how much of a role should government play.

We need pure food and drug laws for the same reason that we need any other kind of policemen. It is the nature of the world in which we live that a few men put personal gain ahead of public welfare. So we need these laws and they must be enforced.

Influence of Competition

But there is another—and I believe far more powerful—influence guaranteeing consumer protection. And that is the influence of competition.

I don't believe it is necessary to tell this audience that the American food industry today is perhaps the most competitive in the world, at all levels from the farm right on through to the retailer.

The implications of this are almost without number, but the important thing here is the fact that consumers—acting with the freedom of choice assured them by a self-service distribution system —have a tremendous number of alternative products and outlets offered to them each time they go shopping. The manufacturers of these alternative products must offer the best and most satisfying things they are capable of making or they face the very real danger of financial ruin by being voted out of the supermarkets by consumers.

Another facet of this same competition-private enterprise protective device is the changed nature of the American corporation. There was a time, I suppose, when there was some truth to the "robber baron" conception of the American businessman. But the economics of modern America are such that that day has passed.

Self-Enforcement Is Key to Success

Ours is an era in which business management is not really ownership but stewardship. Ownership has, for most of the major companies in every industry, at least, passed from private to public hands. Among other things, this means that almost all business leadership gains by obeying and enforcing the law, not by avoiding the law. And it means that there is no real useful purpose to be gained in turning a few quick profit dollars. The corporation will survive and prosper only as long as it continues to grow in the sunshine of continuing long-term public acceptance. This is a dictation of public interest action far more compelling than any regulation of law. And most stockholders are buying this growth, rather than the illusory gain of a few quick profit dollars, when they invest their money. This brings a real element of self-enforcement to food and drug laws. And self-enforcement is the key to the success of the entire effort.

Intelligent management today, as a result, looks to the future —even to future generations. Therefore, shortsighted gambling with adulteration and shortweight is worse than illegal—it is stupid.

I know there is evidence from time to time that a few companies do gamble in this way. But I think that the great shock caused by a few revelations is an indication of the fact that they are uncommon.

To sum up my preamble, then, I believe that government and an enlightened business management work hand in hand today to guar-

antee consumers safe and economical food and any attempt to destroy this essential partnership is folly.

Parenthetically, let me say one more word on the subject of competition. Of twin concern to the food industry to this problem of food and drug law enforcement is the problem of a changing view of the role of competition. A whole body of amendments to antitrust laws has been introduced in Congress, the aim of which, according to the authors, is the "preservation of competition." But when these proposals are analyzed, we find that the aim is not the preservation of competition but of certain groups of competitors.

Somewhere we have misplaced one basic truth about competition. We all know the phrase "competition in the public interest is the controller of a profit-making economy." But people seem to have forgotten that the key words in the phrase are "public interest," not "competition" or "profit." Competition is good not because it's one of the things we generally believe in or because it is a system under which some people make profits. It's good because it is the best way yet devised for meeting the needs and wants of all the citizens, including products, jobs, security and even government.

The very nature of free competition forces it to serve the public. When legislation turns it around and enacts things one way or another in favor of a few competitors, the whole system is turned around and the public becomes not the master but the servant.

When analyzed in this light—and I think legislation on this subject should always be analyzed in this light—this legislation takes on its true coloration—a very generous and human effort to protect the least efficient, not in the public interest, but in the interest of a few groups of competitors.

With this background, let me give you some of my thoughts on the Pure Food and Drug Act and the Food and Drug Administration, both so much in the news today.

Importance of Food and Drug Act

To my mind, the Pure Food and Drug Act is a highlight of the Constitutional free enterprise system. This is so for two reasons:

First, because it offers consumers of food and users of medicinal products the assurance of their government that these essential things are safe and will do what the labels say they will do.

And second, because the law is preventive—rather than punitive—and to a large extent provides guidelines under which it can be en-

forced *by the regulated.* If Congress would take the time and trouble to write all regulatory laws this way, it would earn the eternal gratitude of all businesmen, and, indeed, serve the public interest.

Certainly we must all deplore the thalidomide disaster. And it makes little difference to the agonized parents of deformed babies whether they bought the drug or were given it as a sample. But it seems to me that the very fact that this sort of thing has happened only once in the more than 20 years since the drug section of the law was tightened, demonstrates the fact that the law is good and that industry—with very, very few exceptions—is living up to its obligations under it.

And administering the law is the Food and Drug Administration. It is hardly necessary to note here that FDA is under fire.

Congress investigates and finds that it is too friendly with industry. An advisory group investigates and finds that it is not friendly enough. What is the truth? I think we ought to split the difference; I think FDA is acting just about the way it should act.

I said a minute ago that I think the Pure Food and Drug Law should be used as a model by Congress. I believe, by the same token, that FDA administration of that law by and large should be used as a model by government regulatory bodies of every kind.

Two Methods of Law Enforcement

We must always remember that there are two basic concepts of law enforcement. One is the punishment and example concept which holds that violators—willful and accidental both—should be immediately punished as an example with the hope that the punishment will make others more careful.

The other concept is the preventive method, which holds that the object of the law is compliance and not necessarily punishment. Under this concept, those who violate the law are told to stop, officially but quietly. Those who ignore the warning are punished, but the warning comes first. It seems to me that FDA takes this approach, as a rule, and that this builds up a record of compliance which is far superior to that built by the punishment and example method. And I might note that the beneficiary of this latter approach is the general public.

The only trouble is that the case record is the way Congress has tended to judge the effectiveness of the regulatory agencies. The ultimate result of such a Congressional tendency to evaluation is that

if an agency does such a good job that there are no violations of the law it is charged with enforcing, and, thus no examples of cases to report, Congress assumes that the agency has failed in its duty of protection.

I think this is a topsy-turvy, Alice in Wonderland approach. On the local level it has about as much validity as throwing out the police department of a local community because it hadn't caught any murderers when the fact is that the department had done such a good job of prevention that no murders had been committed.

FDA Commended

I am not saying that FDA or its administration have been perfect. But I don't know offhand of any government agency that does a better, more effective day-in and day-out job than FDA does.

This will probably be the kiss of death—coming as it does from the regulated—but I think that the credit for this accomplishment must go to George Larrick and his staff.

I have not had a great deal of contact with the Commissioner myself. For this I am grateful in a professional sense, but sorry in a personal sense. But friends and colleagues in my industry tell me that he has through the years built up a reputation for vigorous—but fair—enforcement of the laws which he administers.

Furthermore, the administrative record has been one of consistency and continuity. And this is tremendously important to this vital issue of self-enforcement. As long as we know what the law is and how it is going to be interpreted from day to day, we can make sure that we obey it. If the ground rules change from day to day—as they do with some government agencies—we can't be sure whether we are obeying the law or not. Inconsistency—besides making us all very nervous—tends to breed disrespect for both the law and the agency charged with its enforcement.

As a result of what I consider a fine record, I can only view Mr. Larrick's growing band of critics with amusement. Congress, on the one hand, saying he isn't tough enough on industry, and industry, on the other hand, saying he is too tough. And I say this as one who was caught with warehouses well stocked with cranberries during the big crisis several years ago.

Aside from the basic fallacy of the case-record method of judging an agency's effectiveness, I think both Congress and, in many cases, industry people, miss an important point about FDA. That is that

the American people must be guaranteed a safe and adequate food supply and that they must have confidence in it, as well. If FDA were administered in a way other than it is, one of these two twin goals would fail to be met.

If FDA were less strict, those who are inclined to cheat would start doing so. The retribution of the market place I talked about earlier, brought about by competition, would react strongly, but it takes time. On the other hand, if FDA fired off a press release at the first hint of illegality, the confidence of the American people in its food supply would be shaken. So it is a very thin line that FDA must walk. And I happen to believe it walks the line very well.

Suggested Improvements

I think some improvements could be made, both in the way FDA operates and in the way industry complies with its regulations. In order to make an improvement, I have two specific suggestions, one for each side:

To FDA, I would suggest the establishment of a joint industry-government committee on packaging and labeling.

Although they are neither as wide-spread nor as serious as the Hart Committee hearings would indicate, I think there are some packaging and labeling abuses that need correction. I think they could be cleaned up simply in two ways:

First, by industry action. We should each take steps now to strengthen our own buying techniques with an eye to screening out as much as possible packages and labels which tend to be confusing. Incidentally, on this point, I think a line has to be drawn between packages and labels which are actually deceptive—since these are already illegal—and those which are confusing. For myself, I think confusion should be cleared up by the industry, with the help of FDA.

Just as an example, I know that one food industry packager—and not a tremendously big one, either—has spent $150,000 remaking the printing plates for its labels just as a result of a self-analysis brought about by the Hart Committee testimony. Undoubtedly there are many examples of the same thing although industry would probably not want to spend a lot of time talking about it.

The second way to clean up whatever serious packaging abuses exist now is to have FDA and industry together work out a few changes in current FDA regulations which will make industry's self-policing efforts more effective.

Working out these new rules is only one thing an industry advisory committee could do. Another would be to act as a go-between between other members of the industry and FDA.

Need for Thorough Explanation

For example, I think the motives behind FDA's proposed new dietary food regulations were good. But I don't think they were explained to industry very well. As a result, many companies which would either not be affected at all, or which would be affected only slightly, became greatly concerned and raised protests of a magnitude far beyond what the circumstance actually warranted. I recognize that most of the protests FDA has received have been from health faddists of one kind or another. But many legitimate companies expressed more concern than they would have if industry people had helped FDA communicate the purposes of the proposal—perhaps paragraph by paragraph.

To industry, I would suggest that top management send the word downward among its employees that the Food and Drug Administration has a job to do and that it should be helped to do the things that it is empowered and required by law to do.

I sometimes wonder if the food industry actually understands how much FDA does for us—how much of a load it takes off of our shoulders. Just as an example, how would we ever be able to afford all of the expensive testing equipment it takes to determine the amount of pesticide residue on fresh fruits and vegetables? Somebody has to do it and somebody has to check it. No reputable retailer would sell potentially dangerous foods and FDA makes sure we don't have to worry about it. This is a tremendous service and FDA should be helped to provide it.

At the same time—and this is a simple, but very important suggestion—food industry top management must make it clear to employees that warnings by inspectors must be heeded and reported and not ignored. This sounds elementary, and it is.

But I can think of three occasions off-hand in which warnings by government inspectors to down-the-line employees of food companies about various practices were never reported, and were, in fact, ignored to the point that costly seizures—in terms of both money and prestige —were necessary.

It would help, I think, if every company in the industry would require from its employees full written reports each time a govern-

ment inspector visits an installation and that any documents left at the installation be sent immediately along with the report to top management.

If these two suggestions were carried out, I think FDA and industry could both perform their services more efficiently and with greater harmony.

In closing, I'd like to make a few remarks about the general subject of food and law.

Closing Remarks

As we all know, the general subject of consumer protection has been close to stage center for more than a year.

We should welcome this kind of attention because it gives us a chance to demonstrate a little and brag a little about the essential goodness of our food and the tremendous efficiency with which we as a food industry literally feed a nation for the smallest portion of spendable earnings in any country in history.

On the other hand, every American is a consumer nearly every moment of his life. I think it is a mistake to try to separate consumer aspects from all the other facets of the life and make them appear different than they are really.

As one who has spent his whole life trying to identify and meet consumer wants and needs when people are actually acting as consumers, I can tell you there's no magic formula. People do what they do for an almost infinite number of very personal reasons. Companies have spent millions of dollars trying to probe these reasons and cater to them. Some have succeeded and some have failed. I doubt that Congress or the President's new Consumer Advisory Committee will have better luck.

We have laws now—good laws which are vigorously and fairly administered—which insure that food when it reaches consumers is safe from adulteration and that the packages it comes in are clearly marked with the amount and ingredients of the contents. I wonder how much farther government can effectively go.

I don't want to get into a partisan political debate here, and I know you don't want that, either. But someday I would like to hear a full and honest debate on the extent to which the federal government can effectively and efficiently work in this area of consumer protection.

I'm not raising the specter of Socialism here at the moment. I'm talking about efficiency and practicality.

Compared with the problems of Cuba and Berlin, nuclear energy and manned flights to the moon, it seems to me the fact that some people have difficulty in comparing "a full eight ounces" and "a big half-pound" is a matter so inconsequential that Congressional attention almost seems like malingering.

Aside from the question of practical values, there is the question of enforcement. As the laws governing the way in which consumer goods reach shoppers become more restrictive, the cost of enforcement must rise to a significant degree. I'm not questioning whether or not consumers are worth the money. I am questioning, though, whether they'll get their money's worth in protection.

It seems to me that Congress should ask itself one question each time it is faced with legislation on such subjects as refinements in packaging and labeling laws. "Is this really a matter of substantial and material concern to all the American people?" If the answer is an honest affirmative, then and only then should new regulations be adopted.

Another thing Congress should question is the actual knowledge of some of its witnesses about industry methods and practices. Several of the witnesses before Senator Hart's committee gave the impression that the entire process of packaging food products for retail sale is actually a dark and subtle modern variation of the old thumb on the scale routine. Actually, the truth is that packaging is vital to the self-service system. When packaging fails, self-service fails. And should self-service fail, the cost of food to the American people would jump from the less than 20 per cent of income it is today back toward the 50 per cent of income it was about 50 years ago.

There is a very real danger, it seems to me, that Congress will legislate so much protection that the food industry will no longer be able to offer consumers values.

To sum up, I believe the American people have the safest, most abundant, most honestly offered and most economical food supply in history. I believe they enjoy these things because of a food industry ruled by competition in the public interest and supervised by an alert and vigorous Food and Drug Administration. And I believe that any effort to upset or meddle too deeply into the system by further extensions of federal power or regulation would be wasteful and futile.

Not all of you will agree with these judgments, I am sure, but I think them to be accurate and urge their consideration. **[The End]**

Consumer Protection Activities

By BOISFEUILLET JONES

A Highlight of This Year's FDA-FLI Conference Was a Dinner in Honor of the Food and Drug Administration. Mr. Jones, Special Assistant to the Secretary, Health and Medical Affairs, Department of Health, Education and Welfare, Presented This Address on That Occasion.

THIS MORNING, I had the privilege, for Secretary Celebrezze, of representing the Department of Health, Education and Welfare in extending a welcome to those participating in the sixth annual Joint National Conference of the Food and Drug Administration and the Food Law Institute. I repeat now, for emphasis, my expressions of gratitude and reassurance occasioned by the fact that responsible representatives of the food, drug and cosmetic industries spend a day each year with responsible government officials reviewing regulatory and scientific problems of paramount interest to the general public.

To the Food Law Institute, I express special appreciation for your recognition of these vital consumer protection activities through the medium of this dinner and the invitation to address you.

I shall speak briefly and generally on two subjects of current interest, the proposed Food and Drug Administration new drug regulations and the recent Citizens Advisory Committee report on the Food and Drug Administration.

Proposed New Drug Regulations

Following publication of the proposed new drug regulations in the *Federal Register* of August 10, the Food and Drug Administration received over 300 communications commenting upon the proposed regulations. These have been examined in detail by the FDA and supplemented by conferences with various interest groups.

The proposed regulations have been redrafted by the FDA, taking into account numerous suggestions made by individuals and groups concerned with clinical testing of drugs, and are now under study in the department. Individual consultants representative of the broad scientific community have been invited in for discussion of the proposed modifications. Secretary Celebrezze, after further study, will probably release the regulations in December.

I can assure you that it is his intention that the regulations assure protection of the public in the development of experimental drugs and at the same time avoid unnecessary interference with research leading to new drugs and with the traditional physician-patient relationship.

Second Citizens Advisory Committee Report

In order to provide an objective review of the Food and Drug Administration, the Secretary of Health, Education and Welfare in 1955 appointed a Citizens Advisory Committee, which submitted a report in 1956. Many of its recommendations were useful in strengthening the program. A Second Citizens Advisory Committee was appointed in 1961 for the same purpose. This Committee submitted its report to Secretary Celebrezze on October 25, 1962.[1] This report represents a year of intensive study by a well-informed, representative group with professional staff—all from outside the government. The Committee was chaired by Dr. George Y. Harvey, Professor of Political Science at the University of Missouri. Dr. Harvey is a guest this evening and I wish at this time to express appreciation to him and to his colleagues for the effective study and report.

There has been much interest in this report and in the department's reaction to it. I would say in general that the report is highly constructive and has much in it which the department and the Food and Drug Administration will utilize. We are at work analyzing its 70 recommendations in relation to policy, administration and legislation. We have no intention of reacting premurately or opportunistically. We do intend for our reaction to be considered, feasible, and actively constructive. Dr. Harvey and other members of the Committee have agreed to make themselves available for interpretation of their report as we translate our reaction into operation. It is understood—and

[1] The full text of the Second Citizens Advisory Committee Report on the Food and Drug Administration appears in the October, 1962 issue of the FOOD DRUG COSMETIC LAW JOURNAL.

the report clearly stated—that specific recommendations were intended to be illustrative rather than definitive. Obviously we will not follow the letter of all recommendations.

Ten Major Recommendations of the Report

I shall comment now in general terms on the ten major recommendations without quoting them precisely.

(1) *The philosophy and leadership of the Food and Drug Administration should be reoriented.*—This recommendation emphasizes the need for preventive action through education, communication and broad scientific participation in professional judgments rather than to rely primarily on after-the-fact enforcement. With this view, consistent with consumer protection, we are in full sympathy.

(2) *The organization for the administration of the Food and Drug Administration should be fundamentally revised.*—We agree that such reorganization is timely and necessary, although not precisely as set forth in the report. Such reorganization planning is actively under way.

(3) *The scientific programs should be strengthened.*—There is no question but that this is a valid comment. Just how this is to be done is not yet clear. That it will be done, however, is certain.

(4) *A national advisory council is recommended.*—There is some question as to the precise protocol for such an advisory group, but certainly advice from nongovernmental sources, such as the Citizens Advisory Committees themselves, is highly desirable.

(5) *FDA-industry relationships should be improved.*—This relates, as I understand it, to the need for continuing encouragement of industry to provide for itself standards for consumer protection consistent with the requirements of the Food and Drug Administration. Voluntary compliance is far more effective than enforcement, but this does not imply laxity in the inspection, control and enforcement activities which are basic to a regulatory program.

(6) *There is a need to upgrade personnel and provide better training opportunities for staff.*—This recommendation is inherent in any constructive program designed to improve administration.

(7) *There is need for more effective program planning.* This recommendation comes into focus particularly by virtue of the highly complex problems with which FDA now deals, primarily because of scientific advances, as compared with their problems of some years ago. This rapid development in science and its application to food

production and processing, the development of new drugs and the increasing use of chemicals in the environment all indicate the need for more sophisticated planning, just as it does for a greater strength in science and management functions.

(8) *Sound educational programs should be developed.*—Certainly we do not dissent from this recommendation. Again, this is inherent in the strenthening of the entire program of consumer protection. The regulatory burden of the agency can be much more realistically managed if there is a maximum of consumer and industry understanding.

(9) *In the interest of better consumer protection, there should be closer cooperation between FDA and the Public Health Service and other governmental agencies.*—The department has a major responsibility for assuring coordination among its operating agencies in the field of health, and the Secretary has directed specific action toward this end. Certainly, health protection, where such responsibility rests in several agencies, is dependent on effective and continuing liaison and coordination among them. The department will move rapidly to achieve this.

(10) *Federal-state regulatory programs should be improved.*—It is recognized that much of the responsibility for protection of the consumer rests in state and local regulatory operations. It is a responsibility of the federal government to coordinate these activities in relation to its statutory responsibility for activities primarily in interstate commerce, and emphasis must be given to the strengthening of the cooperative effort as between the federal government and the states.

These comments relate to the major recommendations. I regret that we are not yet in position to announce specific steps that are to be taken, but such announcements will be forthcoming.

FDA Will Be Strengthened

In general, I would like to repeat that we have much to do in strengthening the Food and Drug Administration. This in no way belittles its past accomplishments nor the dedicated service of its career public servants. It means that its program for the future will be bolstered, particularly where the passage of time and the advances of science have left deficiencies. I am not impressed with such criticism of the Food and Drug Administration as that growing out of the thalidomide incident when it was the FDA which prevented the marketing of this drug in the United States and thus prevented wholesale tragedies such as occurred in other countries.

The President, as was made clear in his 1962 consumer protection message, is determined that the American public be properly and adequately protected. In the department, from Secretary Celebrezze on down, we are acutely aware of the need for competence and judgment of the highest order in coping with the difficult problems facing the Food and Drug Administration—problems of health protection for every man, woman and child in the nation—through regulation of industries producing some $100 billion of consumer goods annually. To this task, we are thoroughly committed. I am confident we shall succeed. **[The End]**

LARGEST SEIZURE IN FDA HISTORY

Almost one million amphetamine tablets were seized November 30 in multiple raids over three states which also resulted in the arrest of a man who offered to sell FDA and Tennessee investigators a half million tablets at one time. The amphetamine seizures were the largest in the history of the Food and Drug Administration. Amphetamines are stimulant drugs which can legally be sold only on prescription.

This move against illegal traffic in "pep pills" was called on 24 hours notice after a five-month-long investigation by FDA inspectors and the police of Alabama and Tennessee. The investigation began last June when an Alabama county official reported the arrest of a "pill pusher" with over 20,000 amphetamine tablets in his possession. A number of inspectors were sent to an FDA Criminal Investigative Course where specialists in the Federal Bureau of Narcotics and in state and local agencies gave instruction in undercover work. FDA inspectors who received this training participated in the investigations which led to the amphetamine seizures and arrests.

The FDA and the Alabama state authorties began investigations to uncover all links in the distribution chain. Contact was made with [T], of Alabama, who sold the inspectors some 46,000 tablets in 10 transactions. Purchases from [T] led the inspectors to a man and wife team, [Mr. and Mrs. A], from whom they started buying 20,000 tablets at a time. Information then pointed to the supplier, [M], of Tennessee manager of a laboratory, and [R] of Georgia, a peddler.

On November 29, [M] told the inspectors and Tennessee investigators that if they wanted a "big buy"—half a million tablets—they had only two days to make the deal because he was going on a long vacation. United States Attorneys in the three states area rushed preparation of the necessary legal papers. The next day United States marshalls, FDA inspectors and state authorities converged at a number of points. [M] was arrested by a U. S. marshall after bringing 514,000 tablets to a Nashville motel. He was charged with nine counts of selling amphetamines without a prescription and an associate was charged with two similar counts. At [M's] laboratories 280,250 tablets were seized in the building and 59,500 in one of [M's] delivery cars. In Alabama and Georgia, the other known peddlers were picked up and more tablets seized.

Research Espionage: A Threat to Our National Security

By FRED BARTENSTEIN, JR.

This Highly Informative Paper Was Delivered at the Eighth National Seminar of the American Society for Industrial Security in Washington, D. C. on September 25, 1962. Mr. Bartenstein Is Administrative Vice President of Merck & Company, Inc.

I AM PLEASED to be here today and to be able to pay my respects to your organization. It is a comfort, to those who sense the need, to know that yours is a profession and that there is a profession and an organization dedicated to the task of giving America maximum internal security without interfering with our traditional freedoms. I claim, on the basis of experience, to be one who senses that need.

Threat to Our National Security

I want to focus today on a very special type of threat to our national security, one that is new, and I believe one that will grow—research espionage. The military spy, whose modern counterpart is the Klaus Fuchs looking for the secrets of atomic weapons, is as old as tribal warfare. The science spy is as new as penicillin and the transistor. He will look not for new weapons, but for the secrets of the nation's industrial strength. He is being created by the shift in the struggle from the military to the economic.

This shift has taken place so gradually that most of us are not yet fully aware of its implications. Yet the real danger of Communism today is epitomized by Khrushchev's boast that he will bury us—not under radioactive debris, which would bury him too, but under the massive weight of the Soviet economy.

Our Secret Weapon

The weapons in this new struggle will not be missiles or armed satellites or nuclear warheads. They will be healthy and striving economies, sound currency, full employment and resilient, resourceful businesses. I believe we have a secret weapon in our own arsenal—one that the Soviets cannot hope to match as long as they retain their Communist system. This weapon is research carried on and sponsored by our private aggregations of capital. It is this research which has been quietly revolutionizing our economy and becoming the dynamo for our national growth and future power.

Historically, America grew strong in an economic sense when a vigorous people subdued and settled a vast wilderness and created the modern world's first market of continental proportions. This was in reality a common market, and it was a fertile stimulant for the technological revolution that brought mass production of goods that the average citizen could afford. Soon after the turn of the century, we forged into international economic leadership, and the extension of our political power around the globe followed behind.

Challenge to Our Economic Privacy

Inevitably, the rest of the world came to copy our techniques of mass production. They have come further. Both the Russians and Western Europe have now created their own mass markets. The latest tools of volume production are installed in modern factories everywhere. Our economic primacy—the source of our political influence—is being challenged.

But American industry is meeting this challenge. Starting uncertainly and experimentally in the earlier years of this century, a few corporations with vision and the needed resources began to forge working relationships with the scientific world. By 1945, when the first nuclear explosion over Alamagordo retaught the ancient lesson that knowledge is power, hundreds of company laboratories all over the United States with first-rate research and development experts were

already turning out new knowledge on an organized basis. By 1962, this "industry of discovery," entirely in private, competitive hands, had become a $10 billion giant.

Importance to Our Economic Growth

The explosive force of this giant is so unprecedented that its central importance to our future economic growth, and thus to our worldwide political power and influence, are just beginning to be grasped. A multitude of industry research laboratories, manned by teams of scientists of many disciplines, given access to current collected knowledge, furnished equipment and materials, and oriented and organized to discover and to develop—these give the world the products of the future, maintain America's competitive edge abroad, and protect our high standard of wages and living at home. From them have come the automatic computors, the light and durable metals and plastics for building, the vistas of television, the ways of making the life-saving gift of penicillin, and from them almost daily come the new miracles of electronics and chemistry. They explore for us and for government the awesome power of nuclear fission and produce knowledge and instruments that extend us and our senses to the outer realms of space.

Unique Partnership

It is a massive building on an ever-growing knowledge in all fields. Despite Russia's sputniks and Khrushchev's boasts, the side, productivity, and efficiency of this broad partnership between science and industry is not duplicated anywhere in the world.

But if the sum of these systems is an American strength, the vulnerability of each unit to attack is an American weakness. If new scientific discovery, new technology, new knowledge will be the dynamo that keeps our economy strong in a competitive world, the difficulty of protecting that knowledge and of preserving the morale and incentive needed to build it is a forboding threat. And I can tell you, gentlemen—on the basis of what has happened to my own company and what we have recently seen happening to others in our industry—that threat is a real one.

My particular company derives its character from long association with the medical and chemical professions. Most of its $225 million sales are in the field of prescription drugs. It draws from its research laboratories its present strength and much of its hopes for the

future. They have already made important contributions to the discovery or development of such things as penicillin, streptomycin, cortisone and vitamin B_{12}. The company's commitment to science has grown regularly since the 30's, until last year it approximated $21 million, about 10 per cent of its sales. The research heart of the enterprise is a group of more than a thousand men and women from about 40 different scientific disciplines who devote their working lives to the making and testing of discoveries in the field of health. It is a place, in short, where you are likely to find a treasure of newly discovered and costly ideas.

I ask you now to assume for that you are, with me, inside this company.

Development of a New Drug

Back in the 1940's your chemists, biologists, and veterinarians found, out of a human drug research program, a compound that would combat a parasitic disease costing the poultry industry in this country alone about $100 million a year. Your people extended the finding to revolutionary new methods of treatment and prevention. A decade passed, and you had built a substantial market.

But with time, the parasites start to build a resistance to the product and you seek and develop new ones. But these products have their problems too, and one, then two, then three competitors produce products for the same parasitic disease.

Pressing hard, a team of your chemists, who by this time have as much front-line experience fighting this parasite as any group in the world, find an entirely new compound and a new approach to parasite control. In preliminary tests, it works. If you are lucky, maybe at long last you are on your way to wiping out a costly disease, and if you are, the rewards will be commensurate.

But this, for you and your research organization, is only a signal—a beginning. The first compound is a member of a large family of molecules and is not the best one for the job. Your chemists make variations. Before they get through, they have synthesized 150 basic ones.

You evaluate them all. Some turn out to be too toxic, or unstable, or costly to make. Others have varying combinations of strengths and weaknesses. Finally, your research staff must pick one. The combination of factors would puzzle a computer. But they make a judgment and drive ahead.

All known methods of making compounds of the general class are uneconomic for the purpose. Chemical work is started to find better methods of synthesis. Pilot plant operations and process development work begin. Programs are intensified to confirm safety and efficacy—involving first a few, then thousands of birds of different species, through several generations, in different sections of the country. Metabolic and residue studies are begun. Dosage levels are worked on. Carriers are selected. Engineering work is initiated and plans are laid for capital expenditures for plant and equipment. Finally, after a very long time and a mammoth effort, a new drug application is filed with the Food and Drug Administration. It is a very heavy document.

All this time, as research has been building a new bridge over the risky chasm of the unknown, you have, figuratively, been holding your breath. Though you have lived through the collapse of hundreds of such bridges before, the crash of a new failure always comes with a sickening sound. This one would have brought down with it many, many dollars of research effort, and also the hopes and long hours of duty of scores of chemists, toxicologists, veterinarians, doctors, biologists and engineers. But in this case they had got the bridge all the way across. You relax.

Sign of Trouble

But too soon. One of your people reads an abstract of a lecture to be given on a discovery in the same field. The compound is not named, but it sounds like a member of your new family. It makes you uneasy. The man to deliver the paper heads an organization whose research is hardly worthy of the name.

In the meantime, a fantastic break has long been developing for you. That same man—not knowing that you were negotiating for the purchase of a small company abroad—has approached that company to sell your product and process knowledge to it. You learn that about the time you hear of the coming lecture, and in a little over a week, know that the compound he is selling is the precise one from the precise family that your chemists had chosen, and on the basis of statistics alone, you know your research has been stolen.

You have to move fast. The research thief is wasting no time. You learn that he has filed patent applications here and in several countries. He has been actively selling your process information and engineering data as you have been developing it. He has five customers, all well established companies—two in the United States, and

one each in Great Britain, France and Switzerland. Innocent of the source, they are going ahead with testing and engineering.

You get more of the documents being peddled by the research thief. They contain wording and drawings identical to those in your own files—even to cost data and mistakes. Is this enough to prove your case in court?

Then you get another break. Through some long and devoted hours of effort by a lot of top people—and a rare touch of luck—you track down the spy in your employ. Faced with the evidence, he confesses.

But the master spy has already skipped the country. He is indicted both here and abroad, and he skips to a third country. He files suit against you there, charging that you stole his invention. He tries to weaken your fortitude by sending from the haven of his third refuge a barrage of accusations to press, government and industry. When you finally tighten your grip on him, will he slip to a fourth country?

As the storm of this incident fades into the distance, and becomes a long turmoil only for the lawyers, the remainder of your employees breathe an almost audible sigh of relief. Gone are the days of lost motion, tension and deterrence from main effort. This is particularly so for the scientists, those who had labored so hard to bring something from the void, to justify themselves to their company and their compatriots, to get satisfaction and credit for their achievements. They give thanks not only that all is well in their own organization, but that a thief shall not enrich himself with stolen efforts, and get, of all fantastic things, the scientific credit for what they themselves accomplished.

Another Area of Trouble

But you and your team are not to be let off so easily. It is a tribute to the value of your research, although a backhanded one, that you are not. The storm strikes again, this time from rings that are taking advantage of missing drug patent protection in one of the countries of the Western World. It is a good country, a country that has contributed much to science. But because it refuses patents on drug invention, it has become a haven for those who copy invention and a market for stolen drug research data.

You learn that trouble is on the wing from there. A visitor from that country is found in the home of one of your chemist em-

ployees. He is associated with a company who has taken advantage of other's inventions in your field, and your suspicions again run high.

There is nothing in your chemist's record or behavior that would lead you to suspect he is being subverted. But you have his home watched with no results. The visitor leaves, heading for New York and for Europe. You must get the evidence quickly or he will be gone from your reach. If any research secrets have been stolen, they are probably already irretrievable. On the other hand, perhaps the whole rendezvous is innocent.

Evidence Found

At this point your security people get the trash emanating from the house. There, among discarded tin cans, garbage and old newspapers, you find a vast jumble of cut-up pieces of paper. When you put the jig-saw puzzle together, what you have are the outside borders of a series of research memoranda and documents. The company designation, the dates, the addressees, and the names of the men who wrote the documents have been cut off. It is evident that the memoranda themselves, shorn of this identifying evidence have been put in shape for sale in the international research espionage market. Priceless research data hitherto recognizable as stolen property has been rendered into a highly negotiable commodity by the simple expedient of a pair of scissors.

Not an Isolated Phenomenon

This is the nature of two of our stories. It has become apparent to us that we have not been dealing with isolated phenomena. We have evidence now of other situations. Unfolding before our eyes have been, not the reality of single cases, or single rings—but evidence of multiple rings, with centers here and in other continents, and with markets for stolen research data so developed that spies can steal with the assurance of ready sale.

Some of our data may have been taken behind the Iron Curtain, or it may not have. It makes no difference. Whether or not research theft is enemy inspired, it threatens, frightens, weakens and demoralizes. It poses imponderable problems.

Problems to Be Considered

How, for example, can you zero in on those in your own company involved in research theft without casting the shadow of suspicion over all employees and damaging morale and productivity by making your men and women suspicious of one another? They must sense, as

you do, that a determined agent with an eager market for the right pieces of paper can almost always find a willing tool in the best of organizations. But it takes strength on their part to go forward with their best work, depending on their security officers to protect them, and trusting their management to trust them through such periods.

I have asked you to look at two of the incidents in the experience of only one company. There are more. But these two are enough.

With the rapid advance of science and technology, research and development costs have risen and must continue to rise even higher. As we move into the deeper recesses of the unknown, the research trail becomes more difficult. More equipment and facilities are needed. More people are needed, more disciplines, more time, more energy, more intelligence, more coordination. The successful fruits of research come to be assets of enormous value—increasingly tempting to thieves.

By stealing, thieves obtain the enterprise and genius of others. They deprive the innovator of credit for accomplishment and of tangible reward for his risk and effort. Thieves are helped into quick competition with innovators—at competitive advantages, because they have no cost of research and development. Undeterred, reaping rewards from innovations they do not make, they will in the end inevitably discourage innovation and sap the strength of the innovators.

Thieves attack a scientific organization at a vital point in its structure. A many-membered scientific team of differing disciplines must communicate freely—both orally and in writing. Stimulation of though and action in a laboratory comes from communication. A research group must store and readily retrieve stored data. It must in one segment be aware of what is going on in another. It must be coordinated at all points. The ultimate in security protection—clamping data in vaults—would destroy the spark and very life of such an organization.

The material of scientific communication is at the same time an elusive commodity. Paper, its usual vehicle, is carryable, copyable and hidable. The knowledge itself, separated from its paper, is intangible. It cannot be seen, found, returned or destroyed, and it can be used forever. Its theft is a subtle and sophisticated wrong.

Laws and Their Enforcement

And what of laws and law enforcement? Here, understanding has not caught up with reality.

Even in the dawn of social organization, man enforced standards of morality that frowned on theft. Society insisted on formally protecting itself against the taking of animals, crops, weapons and food. That idea progressed ages later to the copying of intellectual property. Early copyright and patent statutes formalized a moral standard; they encouraged intellectual pursuits in the interest of society. In the case of the patent law, society made a bargain with the innovator: that new and useful inventions shall for a temporary period be positively protected by government and law in return for full immediate disclosure and free use after the temporary period. That has carried to this day.

But our laws have not evolved yet to protect society adequately against the positive act of stealing secret knowledge and data, as opposed to copying the final product based on that data. Thieves who steal these precious commodities do so with advantages not had by stealers of tangible property. Intangible knowledge is not, for example, a commodity covered by the National Stolen Property Act. Under that act, stolen documents and samples having a value of $5,000 or more may not be transported in interstate commerce, but it is too often difficult to attribute provable values to inventive work only on the verge of commercialization. State laws, too, are beamed at touchable things.

Enforcement officials, hamstrung by limitations on investigation and discovery procedures, find it overly difficult to detect and prove the act of stealing intangible and documentary material.

And finally, the public—that ultimate source of power which insists that its laws correct moral wrongs and encourage performance for the benefit of society, and preserve the security of the state—the public is not aware and cannot easily be made aware of the meaning of what we talk about. As science and technology become more remote from lay comprehension, the ability to articulate and portray the wrong, to convey understanding of the threat and to encourage the cure gets weaker.

These, as I say, are all real causes of concern.

The final and ultimate concern is that undeterred theft of these commodities weakens not only those scientists and those organizations who do the best work. It adds intolerably to the already large risk of research, and it saps America at the very strategic point of its strength to withstand the onslaught of a massive economic attack.

Our private research and production centers must be alerted, as I hope our government and military centers are alterted, to the dangers of debilitating theft, whether the theft is or is not enemy-directed, and they must be encouraged to take measures to protect themselves.

Once alerted, it is you and those like you who have the primary responsibility for protecting the security of research effort. It is a delicate and vital responsibility, calling for discipline, understanding and judgment of a high order. Information, the protected commodity cannot be clogged or slowed in its channels. Scientists with whom you deal are highly intelligent and sensitive people. They do not like restraints on freedom to perform or to communicate. They must be helped to see how the security that is needed is necessary to assure their own larger goals.

Revision in Laws Needed

In order that you and those you serve will not have to work forever against odds— and in a losing cause—our criminal laws must be revised to fit the realities of a technologically advanced world. They must be made to reflect the reality that products of the mind have value as great as products of the hand. They must be revised in the national interest to protect our multitude of privately supported research and production centers as well as our government centers, and thereby revised to protect directly and forcefully the greatest hope and strength of our economic system—its research productivity.

Knowing what we know, we must try to help the public understand the value of your mission in order that it can give you the tools you need.

I am encouraged by the interest and the dedication that brings you here to share, evaluate and extend knowledge in your field. Industrial security has a most vital role in assuring that America survives, and I know it will have an expanding role. You have a valuable mission. **[The End]**

The FDA and Professional Pharmacy

By GEORGE P. LARRICK

This Address was Presented at the Annual Convention of the National Pharmaceutical Association, Washington, D. C., on August 8, 1962.* The Author Is Commissioner of Food and Drugs, Department of Health, Education and Welfare.

IT IS A PLEASURE to meet with you today. Although I am sure many of you are familiar with certain aspects of Food and Drug Administration work, I thought you might be interested in a broad view of our activities.

Our principal job is to enforce the Federal Food, Drug and Cosmetic Act. The Act provides that foods must be safe, pure and wholesome, and made under sanitary conditions; drugs and therapeutic devices must be of proper composition and purity; cosmetics must be safe and prepared from appropriate ingredients; and that all of these products must be honestly and informatively labeled and packaged.

As a part of our job of overseeing the purity, quality and labeling of foods, drugs and cosmetics, we (1) make periodic inspections of food, drug, device and cosmetic establishments; (2) collect and examine samples from interstate shipments of these products; (3) enforce the law against illegal sales of prescription drugs; (4) check the labeling and range of usefulness of therapeutic devices, and take action against dangerous or bogus devices; (5) test insulin and five of the most important antibiotic drugs and their derivatives, for purity and potency before they are sold; (6) set up standards which guarantee the com-

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

position and real value of food products in line with the Congressional mandate to "promote honesty and fair dealing in the interest of consumers;" (7) check imports of foods, drugs, devices and cosmetics to make sure they comply with United States law; (8) and cooperate with state and local officials in the inspection of foods and drugs contaminated by disasters, such as floods, hurricanes, explosions and fires, and in the removal of dangerous items from the market.

In addition, we enforce the Federal Hazardous Substances Labeling Act, which requires warning labels and antidotes to appear on household products that are toxic, corrosive, irritants, strong sensitizers or generate injurious pressures.

Safety Is Primary Concern

In assessing whether a product complies with the pure food and drug law we are interested in the product's safety, wholesomeness and the honesty of its labeling. But our first concern is always safety. A new concept of public protection has been developing during the last quarter of a century. The 1906 Pure Food and Drugs Act allowed a manufacturer to market products without any advance clearance by the government. But this did not provide good consumer protection. In 1937 a small drug manufacturer put out an elixir of sulfanilamide containing the poisonous antifreeze, diethylene glycol. The elixir killed 107 people before we could get it off the market. To guard against a recurrence, when the law was modernized in 1938, a new-drug provision was included. This requires the manufacturer of a new drug to test the product for safety and to submit an application for our evaluation which contains the evidence he has compiled.

The determination which we make is: "Is this product safe under the conditions of use proposed in its labeling?" If we determine that the data do support the proposed use of the drug, the manufacturer is notified that the new-drug application is being made effective. The drug can then be sold commercially under the labeling proposed in the new-drug application.

This premarketing requirement enabled us recently to forbid the marketing of a sleeping pill containing thalidomide because our medical officers were not satisfied that it had been proved safe. The same drug was sold in several countries where its use by pregnant women was associated with the births of deformed infants—the most widely publicized deformity was the presence of rudimentary arms or legs, resembling sea flippers.

This modern concept of testing products for safety before they are sold is being applied to other areas through amendments to the 1938 law.

Recent Amendments

In 1954 a law was passed requiring pesticides to be tested for safety and allowing only those residues on food crops that our scientists find are safe.

A 1958 law similarly requires other chemicals used in food to be tested and employed only according to safe conditions established in our regulations.

A 1960 law requires color additives for foods, drugs and cosmetics to be tested and approved by the government for their intended uses.

We believe this same kind of premarketing safety testing should be required for cosmetics and therapeutic devices. Proposed legislation to bring this about is now before the Congress.

Last March, President Kennedy in his Consumer Protection Message outlined a four-point program of consumer rights. He said the consumer has: first, the right to safety; second, the right to be informed; third, the right to choose; and fourth, the right to be heard.

The President also recommended changes in the food and drug laws, two of which I have just mentioned, to afford the consumer greater protection. Two others have particular significance to pharmacists.

The first is more effective factory inspection authority to determine whether food, drugs and cosmetics are being manufactured and marketed in accordance with the law. A bill to carry out the President's recommendation in this and other areas, H. R. 11581, is now under consideration by the House Committee on Interstate and Foreign Commerce. It would provide for the review of prescription files in drugstores by FDA inspectors. I would like to outline briefly why we need authority to examine prescription files.

Pharmacists Given a Clear Guideline

During the debates which led to the passage of the Food, Drug and Cosmetic Act in 1938, a record was established which shows that the Congress clearly intended that safe drugs should be available to the layman so that he could treat minor diseases without consulting a physician. The law specifically required unsafe drugs to be sold on prescription, but its labeling provisions accomplished this effect in

an ambiguous manner. By the early 1940's we found it necessary to bring legal actions against pharmacists who sold dangerous drugs to the laity without prescription. The cases we brought were against a few druggists who flagrantly violated the law. However, these actions caused considerable concern among law-abiding druggists who wondered if there was any danger that they might innocently run afoul of the federal law. This was an understandable concern. Because of the ambiguity of the Act, drugs that were in a borderline category might be labeled by one manufacturer for over-the-counter sale and by another for sale only on prescription. Responsible elements of retail pharmacy believed the federal law should be clarified to require the prescription legend on all drugs that should be used only under a doctor's supervision, and to forbid use of the legend on all drugs that may properly be sold without prescription. The Durham-Humphrey Amendment of the Food, Drug and Cosmetic Act, passed in 1951, accomplished this. This gave pharmacists a clear guideline—drugs without the prescription legend could legally be sold over-the-counter, drugs with the legend could not.

A Substantial Step Forward

This amendment was a substantial step forward in protecting the health of the American people. It makes the sale of prescription drugs without a prescription a criminal offense. But there is a gap in the consumer protection afforded by this amendment. The pharmacist is required to keep detailed records of each prescription he fills, but the law makes no provision for these records to be subject to review by FDA representatives who are responsible for enforcing the law. This is an unrealistic approach. We believe such examinations are appropriate in cases such as those where we have reason to believe there have been violations of the Durham-Humphrey Amendment. Such examination is also clearly needed to permit the complete removal of dangerous drugs from the drugstore shelves and home medicine cabinets.

The other recommendation of particular interest to you, which is also embodied in the same bill, would provide an enforceable system of curbing the illicit distribution of habit-forming barbiturate and amphetamine-like drugs. As you know, a widespread bootleg traffic in these drugs has developed. Extensive illegal sales of barbiturates and amphetamines are occurring both in pharmacies and outside the drugstore at such places as truck stops, roadside taverns

and service stations. Present provisions of the Food, Drug and Cosmetic Act are not appropriate to deal with the underworld traffic we have found to exist. The proposed legislation would require manufacturers and handlers of these drugs to register with the Department of Health, Education and Welfare. It would require them and all other firms or individuals, except licensed practitioners, dealing in such drugs to prepare and maintain records of all receipts and disposition made for such drugs.

In another area of mutual interest, a recent change has been made in the drug regulations. At one time brochures about drugs could be sent only to physicians. Later, at the request of pharmacists, we adopted a policy that allowed manufacturers to send the brochures to pharmacists for "professional use." But this left much to be desired from your standpoint. The recent "full disclosure" regulation will make information about each drug readily available to all pharmacists and will give those who wish to operate on the highest professional level an opportunity to be of further service to the physicians.

Each pharmacist will be able to keep abreast of the therapeutic representations for and side effects and contra-indications of the drugs he dispenses. Thus these regulations will help the pharmacist increase his professional stature. They will make full information about a new drug and its uses and hazards available in every drugstore.

Conclusion

Certainly you in pharmacy and we in FDA have much in common. We are both interested in the health and well-being of the American people. We have generally been able to work together closely to further our common goal.

We will continue to work with all groups representing pharmacy on matters of mutual concern. Right now we are planning a meeting with some of the state enforcement officials to explore the federal and the state roles in administration of laws that regulate the distribution of drugs through pharmacies. We will welcome the assistance of your Assocation in the future and will be glad to work with you.

[The End]

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