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# Food Drug Cosmetic Law JOURNAL

## Environmental Control—Challenge and Opportunity ..... CHARLES C. JOHNSON, JR.

## Additional Papers Presented at the American Bar Association Meeting on Food, Drug and Cosmetic Law

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

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**Environmental Control — Challenge and Opportunity.**—*Charles C. Johnson, Jr.* prepared his remarks on page 568 for presentation at the 33rd Annual Educational Conference, National Association of Sanitarians, held on June 23, 1969, in Houston, Texas. Mr. Johnson is concerned that decisions regarding management of our environment must recognize the inseparable relationship of all the facets of the environment in their total impact on man's health and welfare.

**1969 Meeting of the Food, Drug and Cosmetic Division of the Corporate, Banking and Business Law Section of the A. B. A.**—Additional papers presented at this meeting of the American Bar Association are included in this issue of the JOURNAL. Other papers presented at the meeting were published in the November, 1969 issue.

*Stanley H. Willig* takes a look at some of the legal considerations inherent in labeling, advertising and promotional activities with regard to drugs, cosmetics and related products in his article, "Some Present Responsibilities in Labeling and Advertising" (Part 1), beginning on page 578. Professor Willig believes that regulations and statutes can create criteria for sanction and enforcement, but that the more these approach codification and subcodification, the more rigid, but not necessarily lucid, the structures become. Professor Willig is Director of the Food, Drug and Cosmetic Law Unit, Institute for Law and the Health Services, Temple Law School, Philadelphia, Pennsylvania. The second part of this article will appear in the January issue of the FOOD DRUG COSMETIC LAW JOURNAL.

"What's New at FDA?" is the question answered by *Paul A. Pumpian,* FDA's Director of the Office of Legislative and Governmental Services, in his article beginning on page 589. He explains organizational changes and cooperative programs, so that legal representatives of regulated industries will know where to go in FDA with their problems, and what to expect from state officials and FDA when their functions overlap.

**Fair Packaging and Labeling.**—This article is by *Walter R. Moses,* Chief of the FDA's Food Case Branch, Division of Case Guidance, Bureau of Compliance. Mr. Moses describes the functions of the Food Packaging and Labeling Act, and tells how its purpose can be fulfilled most effectively. The article begins on page 597, and was presented originally in the October issue of *FDA Papers.*

**Antitrust Questions in Voluntary Industry Standards.**—*Lionel Kestenbaum* prepared this article for delivery before the National Association of Manufacturers Conference, sponsored by the Marketing Committee, and held in New York on October 9, 1969. This timely address, beginning on page 606, presents a helpful guide in dealing with various antitrust problems presented by voluntary standardization procedures. Mr. Kestenbaum, formerly Chief of the Policy Planning Section, U. S. Department of Justice, is now a member of the Washington, D. C. law firm Bergson, Borkland, Margolis & Adler.

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Food·Drug·Cosmetic Law
Journal

# Environmental Control—Challenge and Opportunity

By CHARLES C. JOHNSON, JR.

Mr. Johnson Is Administrator of the Consumer Protection and Environmental Health Service, Public Health Service, of the U. S. Department of Health, Education and Welfare, Washington, D. C.

I AM PLEASED TO HAVE THE OPPORTUNITY to address the National Association of Sanitarians this year. Over a quarter of a century ago, one of our great wits, H. L. Mencken, pointed out what makes sanitarians so important to our American society. Mr. Mencken said that Americans suffer from a major psychological failing—their "libido for uglification" is over-developed. Twenty-five years after this indictment, we can see the results of our poor housekeeping everywhere.

## A Special Challenge

Your discussions this year, it seems to me, are being held at a time when we in the field of environmental health are faced with a very special challenge and, at the same time, are offered an unparalleled opportunity to help the nation move forward toward a more healthful and livable environment.

The challenge exists because we have come another year closer to the environmental crisis which may threaten man's ultimate survival on Earth.

The pace of technological change, our soaring population, urbanization, the build-up of chemical contaminants in our environment—all these things threaten our nation—and indeed the world—with environmental disaster unless we act, and act quickly, to halt the present trend.

This is the challenge we face, and it is a grave and difficult one. But, at the same time, the opportunity for effective action to save the environment has never been so great as it is today.

The opportunity exists because never before has there been such general public interest in achieving more sensible use of the environment, and furthermore, this public interest is being manifested while there is still time to reverse the current trend.

A few years ago, someone observed that "the American public isn't concerned about air pollution because so far it hasn't affected television reception." Well, polluted air still hasn't affected television reception so far as I know, but the American people are concerned about it. And they are concerned about polluted water, and about the mountains of waste which we seem helpless to manage; they're concerned about pesticides, about radiation and about noise. Furthermore, their concern is not limited to a fear for direct health risks associated with these environmental changes. They are concerned about the *quality* of life which we are building for ourselves, and this general uneasiness is reflected in the unrest, and in the questioning of our national purpose, that are so much a part of the current social scene.

For a good many years, sanitarians and other environmentalists have been able to say, with some justification, that our progress was slow because "the public just doesn't understand the importance of what we are trying to do." We can't say that anymore, in my opinion. Throughout our society, people are demanding a more rational use of our precious resources. They are no longer content with an industrial system that gives an abundance of goods but pollutes the very air and water that give us life. They recognize the absurdity of building high speed thruways on which high-speed cars often travel bumper-to-bumper at horse-and-buggy rates. They are aware of the disaster that lies ahead if rural blight and urban deterioration are allowed to continue.

The public press has joined in the fight to save the environment, the Congress is concerned, and the President has established a new Cabinet-level Council on Environmental Quality to help plan a sound approach to these matters. But, as so often happens in a democracy of educated people, the people themselves are probably several steps ahead of public policy. They are finding that all our successes in science and engineering and medicine and economics have somehow failed to produce the kind of good life which was our purpose. They want an end to pollution. They want an end to unplanned, heedless manipulation of the environment on which their lives, and the lives of their children, depend. They are beginning to recognize that all

the systems and subsystems which we devise to maintain ourselves on the planet—systems of agriculture, economics, transportation—ought to contribute to the *total* health and well-being of the society they were designed to serve.

Yes, I believe the climate is right for our nation to make real progress against our environmental ills. But I believe, as well, that there is still a great deal of uncertainty, both among the people and among the makers of public policy, about the nature of the problem itself. And this lack of full understanding is a major obstacle to the development of clear goals and purposes.

## Impact of Environmental Quality

The fact is that all concern for environmental quality is essentially a concern for man; decisions as to management of the environment must recognize the inseparable relationship of all the facets of our environment and their total impact on man's health and welfare. In other words, we shape our environment, and then our environment shapes us.

There is no longer any doubt that the environment we are shaping for ourselves in this modern age contains direct health hazards that are already reflected in our health statistics. Moreover, the multitude of stresses to which we are subjected strains the adaptive capability of the human species in ways that we are only beginning to understand.

As Dr. Rene Dubos pointed out, "The modern environment is dangerous on two accounts: it contains elements that are outright noxious; it changes so rapidly that man cannot make fast enough the proper adaptive responses to it."

Dr. Hugh H. Iltis, of the University of Wisconsin's Botany Department, puts it even more graphically: "As unique as we may think we are, we are nevertheless programmed genetically to need clean air and sunshine, a green landscape and unpolluted water, and natural animal and vegetable foods.... If the concrete and steel city... turns man into an asocial, erratic, and sick animal, if urbanization degrades human society through increased emotional stress, crime, delinquency, slums, and other neuroses and psychoses, it is because the genetic flexibility of the human animal... is not great enough.... Our human genetic adaptations are here simply out of evolutionary context."

The health problems posed by environmental change today are also social problems, and economic and political and cultural problems. If those of us who understand these things do not make our

voices heard, now, we will have no right to complain if the world continues to move toward what increasingly appears to be a kind of environmental chaos.

For social, economic, and political decisions will be made—as they are being made every hour and every minute today—that affect the health and welfare of man. And they will be made—as they are being made all too often today—in pursuit of national goals which are good in themselves (economic efficiency, fast transportation, agricultural abundance, for example) but with little regard for their combined and often synergistic effect on the total environmental system upon which the health and welfare of man depends.

The problem of our time is not to choose between a healthful environment and the manifest benefits made possible by our technological and scientific progress. The problem is to assure that we have both. But if we are to do this, we need to keep our eyes on the broad purpose that encompasses all our goals—*the total health and welfare of man.*

It is up to environmental health professionals to help keep the eyes of the nation fixed on this broader purpose. As the country moves to meet the crisis we are facing in the environment, there will be no lack of spokesmen for industry or agriculture or other legitimate, but specialized, interests. It is up to us—sanitarians, engineers, physicians, and all who shoulder the responsibility for public health—to try to provide a focus on human health and welfare in the decision-making process.

## The Common Goal

What I am saying, in effect, is that we must broaden our view of what constitutes "environmental health." We know that not all the decisions that affect human health and welfare are made in the health department—and we cannot ignore them just because this is so. Whatever the difficulties and whatever the constraints which hamper this broader view, we are going to have to overcome them, or fail in our responsibility to the people.

Those of us who are oriented toward public health must recognize that we have many natural allies—the conservationists, consumer groups, and others primarily concerned with safety or with beautification—with whom we can, and must, make common cause. Despite differences in approach, all of us have a common goal—a better, more livable environment.

We in the Consumer Protection and Environmental Health Service have committed ourselves to carrying out a vigorous pro-

gram at the federal level in accord with the principles I have just been talking about.

We are moving ahead as rapidly as we can to create a program that will have a lasting impact on our environmental problems.

We believe that we have a responsibility to the public, and to all those whose daily decisions affect the environment, to define as well as possible and to enunciate as clearly as possible what is happening to man in the contemporary environment.

We have enunciated criteria on some of the hazards which must be dealt with in the areas of occupational health, air pollution, food and drug protection, and radiological health.

We are thoroughly reviewing the state of our knowledge in these and other areas, with a view toward assuring that our research and development resources are directed toward the enunciation of criteria, wherever possible at the earliest moment.

In my opinion, we cannot overemphasize the importance of making what knowledge we have available, even though it may never be as complete as we might like, so that it can be applied to the problems of environmental health and consumer protection.

Where we have regulatory authority, we intend to use it fully and fairly, and we will seek new authorities where we find they are needed.

We recognize that goals we are seeking cannot possibly be reached without application of the incomparable talents and resources available in industry — and we will seek ways to bring these talents and resources to bear upon our environmental and consumer problems.

We will cooperate fully with state and local governments and will provide technical and financial assistance within the limits of our resources to help strengthen environmental and consumer protection programs throughout the nation. For it is my view that, without viable programs at the state and local levels, the public cannot be adequately protected.

The new Service brings together the Food and Drug Administration, (FDA), the National Air Pollution Control Administration, and the Environmental Control Administration. It makes it possible for us to take a more holistic view of the impact of the environment on man, to coordinate our total effort, and to make sure that no important line of research is neglected.

## Potentially Hazardous Trends

I want to speak now on what I view as trends which those in the state and local governments should be turning their attention to.

Let me begin with food, since this is one of the most basic requirements of man. We all know that maintaining uncontaminated food is a continuing, and indeed, a growing problem. What is more, the use of various food additives is increasing, and each of us now consumes an average of three pounds of these chemicals yearly. We have problems of pesticide residues and traces of veterinary drugs in food products — all this in addition to the chemical barrage that reaches us from other parts of the environment.

As many of you probably know, the FDA is working toward a fuller partnership with the states which should benefit both interstate and intrastate food programs. It is developing agreements with the states which will involve a full interchange of activities and resources —and, most importantly, will help to assure that foods marketed on a strictly intrastate basis are safe and wholesome. Some states have entered into formal arrangements to accept or share responsibilities for the inspection of medicated feeds, and others are developing their capability to do so. We intend to move ahead as quickly as possible to extend this partnership approach to other areas of food protection.

The voluntary programs for food and milk sanitation which have operated so well for many years through cooperation between the Public Health Service and the states are being brought together with other food programs in FDA. This broadens the base of scientific support for these programs and permits unified planning and support. It is not intended that the voluntary, cooperative programs will change in purpose or direction. I would recommend, however, that just as we are seeking to develop a more effective partnership with the states in this area of concern, the states and local agencies work toward fuller reciprocity, with a view to avoiding duplication of effort and the consequent drain on scarce manpower and resources.

Adequate state pesticide programs are a practical necessity, for, as we all know, federal regulatory authority in this area covers only interstate shipments. Yet the truth is that most states are not doing enough to protect their consumers against ingesting toxic pesticide residues on food. It requires laboratories, crop analysis and inspection, control or permit systems to deal with major spraying and dusting operations; and it requires an informational and educational program to increase voluntary compliance. This is an area which no state can afford to neglect.

About two months ago, Robert Finch, Secretary of Health, Education and Welfare, announced the appointment of a Secretary's Commission on Pesticides and their Relationship to Environmental Health to explore this field of environmental pollution and its con-

sequent risks to the health of our citizens. The Commission is to report back with specific suggestions for action in six months.

I realize that insuring the safety of therapeutic drugs has, in the past, been treated generally as though it could be separated from other environmental concerns. At the federal level, we have recognized the fallacy of this view and the necessity of considering all facets of the environment as part of the total impact on man. After all, the human body seldom differentiates as to the origin or route of entry of environmental insults. Just as the air we breathe, the water we drink, and the food we eat form part of our total environment, so do the medications we ingest, and they constitute, indeed, an important part of the total chemical impact on modern man. We must recognize a similar relationship with regard to other hazards from which the consumer must be protected—poisons, hazardous substances, and the multitude of consumer products which, more and more, offer potential hazards.

## The Need for Adequate Legislation

Of course, the first requirement for protection in the whole area of food and drugs is an adequate legal base, and many states need to modernize, update, and strengthen their legislation.

Some have food and drug laws based on the original 1906 Federal Statute, now grossly out of date and inadequate. Others have patterned their laws after the more modern Federal Act of 1938, but do not include important later provisions requiring a preclearance for safety of food additives, pesticide chemicals, and color additives.

Even in the area of drug protection, we cannot place all our reliance on federal controls. Lax state laws encourage quackery, and even some of the most sophisticated people fall victim to "miracle" drugs and unproven medical devices, as we can see from the recent exposures of weight-control nostrums.

Before I leave the general subject of legislation, I think I should mention another legislative area which should be given high priority for action. This is protection against hazardous substances and products: poisons; products which are corrosive, irritant, flammable, or explosive; products which offer threats from radiation. This is a growing problem, with thousands of new and untested, inadequately labeled products being rushed to market every year. Some 3,000 deaths occur every year from accidental ingestion of poisons. In addition, other types of accidents, not including highway accidents, take the lives of about 50,000 Americans yearly, and many involve unsafe products or misuse of products.

We have moved ahead at the federal level. We have a new Radiation Protection for Health and Safety Act which provides for Federal regulation of products that produce harmful ionizing or non-ionizing radiation. These may include color television sets, microwave ovens and the like. Furthermore, we are now able to ban from interstate commerce any hazardous substance intended for use by children, or any which would not be adequately controlled by a label warning. But many such substances are produced and distributed locally, and can be controlled only by state statute.

I can't urge you too strongly to move ahead rapidly in this whole area of consumer protection.

I certainly don't need to tell you that the air pollution control is a problem which must engage your best efforts at the state and local levels. It is not a problem that should be left entirely to the cities, for it knows no jurisdictional boundaries. Wherever your state stands with respect to air pollution today, if you're growing you're going to get dirtier, unless you take steps to prevent it. It always reminds me of a story about two little boys who were playing together when one held up his hand and said, "My hand's dirtier than yours." "No wonder," said the other one, "You're a year older."

We are moving ahead with the designation of air quality control regions throughout the nation, under the Air Quality Act of 1967. This places upon the states responsibility for developing standards and a plan for implementing control, and for a joint planning effort where interstate pollution is involved.

We are entering a crucial period in our efforts to control atmospheric pollution, and the success of our national efforts is now coming to depend upon state action. I hope you will press with all your energies for sound, effective action in your own states.

## Increasingly Serious Problems

I want to mention with particular emphasis another environmental program which I believe should be given priority. This is occupational safety and health, the oldest and yet one of the most neglected of the whole spectrum of environmental problems. Thousands of workers suffer from cancer, lung disease, hearing loss, dermatitis, or other preventable diseases because industry, unions, and government at all levels have failed to give adequate attention to occupational hazards. We are finding every year new and subtle threats to workers' health, growing out of our new technology—and yet we have made almost no progress in the last fifty years against some of the oldest occupational diseases of man.

As you probably know, we have recently made an effort to initiate an effective attack on the age-old plague of coal miners—"black lung," as it is called, or coal workers' pneumoconiosis, by issuing a recommended standard for dust in soft coal mines. If adopted, we believe that this standard can greatly reduce the incidence of coal workers' pneumoconiosis and slow the progress of the disease in persons already affected. It is long overdue in the United States. Today, 100,000 soft coal miners suffer, to a degree, from this serious disease.

This is only one of several serious occupational diseases which we, as a nation, have neglected far too long. We intend to give more attention to occupational health and safety problems at the federal level, and I urge that you do so at the state level, as a means of protecting the health and strengthening the economy of your areas and the nation.

The truth is that very few states in the nation have occupational health programs that even approach adequacy, and there is need for stronger legislation, both at the state and federal levels, to protect workers from occupational disease and injury.

Let me suggest another problem of growing seriousness which should engage your concern. That is the quality of drinking water. Most of the community water supply systems in this country were initially constructed over thirty years ago and were designed to serve population densities that were twenty to forty percent less than today's. Despite efforts to modernize and increase capacities, many systems have fallen behind and are failing, in many respects, to meet today's needs.

These systems were designed to treat a high quality of raw water for removal of bacteria, with little or no capability for removing toxic chemical or virus contaminants. Today, both ground and surface water supplies have deteriorated. In recent years, moreover, state surveillance and health controls over public drinking water supplies have tended to lag. Many of our states and communities have become complacent about the safety of drinking water. The time has come when we can no longer afford to be complacent.

There is no question that existing systems for getting rid of solid waste are largely obsolete and inadequate. I strongly urge you to begin now, if you have not already done so, to plan for solid waste management on a statewide and regional basis.

## "Comprehensive" Health Programs

We, in the Consumer Protection and Environmental Health Service, want to assist the states in every way possible in planning

and implementing their environmental programs. But I want to point out that one mechanism which many states are overlooking as a means of planning their environmental programs is the assistance available under the Partnership for Health—the Comprehensive Health Planning program authorized under Public Law 89-749. The intent of this legislation is to assist states and communities to achieve the "highest level of health attainable for every person, *in an environment which contributes positively to healthful individual and family living,*" and it offers financial assistance to accomplish this.

But we are finding that not too many of these "comprehensive" health plans give adequate attention to the environmental factors. The first requirement, obviously, is inclusion of environmentalists on the Comprehensive Health Planning advisory councils.

I certainly would recommend that each of you make sure that problems of environmental control are given consideration in the preparation of your state and area health plans. I realize that every state has a multitude of health needs which this federal program can help to meet. But we cannot ignore the fact that environmental deterioration, and particularly the terrible morass of environmental problems which afflict our inner cities and poorer rural areas—are health problems. No health plan can be regarded as comprehensive unless it gives consideration to environmental improvement—for this is the first step in preventing disease.

## The Essence of the Challenge

I spoke at the beginning of both a challenge and an opportunity. In closing, it may be difficult for any one of us to say which is the greater. As Dr. Robert Ebert, Dean of the Medical School at Harvard University pointed out recently, "We seem to be living in an age when nothing seems impossible—largely as a result of science and technology—yet no one seems to know how to alter the system of making choices. There seems to be little time to make reasonable judgments about alternatives and no time to determine the approach to the solution of our social problems. We plunge headlong from crisis to crisis, and we patch rather than remodel and build." In computer language, as Dr. Ebert puts it, "We have yet to be programmed for a new civilization."

I think Dr. Ebert has expressed the essence of the challenge that we face. I hope that we in the environmental health field can, in some small way, help the nation get "programmed for the new civilization" before the accelerating pace of environmental change destroys the opportunity. **[The End]**

# Some Present Responsibilities in Labeling and Advertising

# Part I

By STANLEY H. WILLIG

This Article and the One Following Were Presented at the 1969 Meeting of the Food, Drug and Cosmetic Division of the Corporate, Banking and Business Law Section of the American Bar Association, Held in Houston, Texas, on August 13, 1969. Professor Willig Is Director of the Food, Drug and Cosmetic Law Unit of the Temple Law School.

THOSE OF US INVOLVED with the legal permutations and combinations of food, drug, cosmetic and device products are wary of oversimplification. However, perhaps to bridge the annual professorial migration from Food, Drug, Devices and Cosmetic Law per se, and Product Liability we allow ourselves some liberties along these lines.

Hence, we take the two major Federal Food, Drug, and Cosmetic Act (FFDC Act) violations, adulteration and misbranding, and project these as two conditions evolving as either negligence or Breach of Warranty in terms of Product Liability.

Actually, we need not go too far afield, since a misbranded article in the ultimate sense is untruthful in its labeling or advertising. Or, it fails of adequate warnings or descriptions for use, and are not these the stigmata of product liability in negligence?

The adulterated product is of course apt to result from negligence in design, quality control, packaging, etc., yet since it has been offered as something which it is not, (a product of fitness, merchantability and integrity), it is in usual "breach of warranty" style.

Add to these extrapolations the fact that misbranding and/or adulteration are usually statutory violations, utilized by plaintiff as indicia of negligence (per se) and so recognized by the court.

Therefore the care, the language, the manner in which a product is labeled, advertised and promoted, is as much a part of product liability prophylaxis, as is the excellence of its manufacture, the purity of its ingredients and whatever measures are taken to maintain its safety and efficacy as it goes into commerce.

Further, there is not a tremendous difference in the concepts (although statutes and regulations have created differentials in the minutiae) behind the labeling, advertising and promotion of products directly to the consumer, or the consumer via professional intermediaries such as a pharmacist, physician or dentist.

A drug product may be reasonably safe and useful, well-labeled and properly advertised and promoted, but an intervenor may turn it into an injurious or harmful compound. Here, frequently product liability becomes professional malpractice. An oft-cited case in point is *Marcus v. Specific Pharmaceuticals Inc.*[1] This was an instance where a physician prescribed suppositories for an infant resulting in the latter's death from overdose. The manufacturer distributed and labeled as such both adult and children's size suppositories. He made no size for infants. Said the court on dismissing the complaint against the defendant manufacturer:

> In the absence of any ground for belief by the manufacturer that a physician would disregard his own knowledge of the effects of drugs, or would prescribe without knowing the information given by the manufacturer, there is no negligence on the part of such manufacturer.

Almost the same language was used by the Washington Supreme Court in finding for the drug company co-defendant in *Douglas v. Bussabarger.*[2] The physician, in exceeding the manufacturer's recommended dose of tetracaine, showed he had not relied on the manufacturer's instructions in this case where paralysis followed an overdose.

It is often true, as was stated in the *Marcus* case above, that a prescription drug product is promoted by means of advertisements in medical journals. There they advise physicians as to its uses, ingredients and the like. The defendant physician in the *Marcus* case averred that the medical profession was not generally familiar with the product, and dosage information was unclear or insufficiently emphasized. In short, he was claiming that the defendant's product was misbranded.

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[1] 191 Misc. 285, 77 NYS 2d 508 (1948). [2] 438 P. 2d 829.

As the court stated in its opinion in the *Marcus* case, "to physicians it did make representations. And should any of them be false it might be claimed with propriety that they were made for the benefit of the ultimate consumers." While at that time this theory of the physician as agent for the patient was helpful to outflank the bulwark of privity, its far greater significance was once more to emphasize that the labeling that either precedes the drugs' prescription or administration, as well as accompanies it on its interstate journey, must carry the responsibility for effectuation of its claims on its approach to the physician.

That which the Act defines as labeling is bound to comply with Section 502 of the Act with complementation of Sections 505 and 507 as they apply, as well as with the implementive regulations that cover packaging and labeling. Further, the Food and Drug Administration (FDA) has the primary responsibility of enforcement whether the subject product is a proprietary drug, a prescription drug, a food, cosmetic, or device. If it is a prescription drug, then the labeling, except for certain exemptive circumstances, must be fully disclosive as to the indications, dosage and claims, as well as the side effects, contraindications and all pertinent precautionary information. A product liability approach would cite labeling as being required to set forth ground rules for use, every claim, every disclaimer.

Disclaimers that affect classes of patients or classes of reaction phenomena should be set forth in the labeling and the advertising of proprietary drugs, as well as prescription drugs.

They may serve to limit culpability for negligence when they are in the nature of an adequate warning as to use and safety. Disclaimers may also assist defending a claim based on breach of warranty if they satisfactorily qualify or limit the expectations of use in a straightforward and obvious manner.

Nonetheless, if the producer emphasizes unqualified safety, advertises his product as "absolutely safe," pseudo-disclaimers in the rest of the advertising or labeling will likely fail to nullify his liability on express warranty even to a sensitive user.[3]

Disclaimers also serve to protect the sponsor against charges of violation of the various laws and regulations enforced by federal and state governmental agencies, where they separate the known from the uncertain, the normal accepted claims and usage from experimental findings and procedures.

[3] 252 N.Y. Supp. 2d 852.

It is not enough for us to construct and recognize them in our advertising copy and other promotional materials. They must be obvious to the user or to one who serves his interests.

It has been frequently held, in keeping with an FDA concept of some seniority, that where the dangers of a drug are well known to the professional intermediary, and it is excluded from direct sale or use by laymen, the warnings are not necessary.[4]

While some courts have held that warranty is not intended to extend to one whose physiological idiosyncrasy or abnormality makes him subject to an atypical reaction from a drug or cosmetic,[5] in any case, the manufacturer's position is certainly strengthened by his clear recitation of a warning or limitation which in effect acts as a disclaimer. As a carryover from tort principles, this may be the seedling of the nullifying effect of voluntary assumption of risk.

However, as to assumption of risk by a consumer who has seen complete disclosure, it is generally held that one must appreciate the nature and extent of the risk, or might reasonably be expected to do so, before his claim can be stricken.[6] Normal judgments and evaluations as to risk made by a reasonably prudent consumer can be weighted to his harm by surrounding the information with exhortations and assurances of safe and good results. In short, the "oversell" may weaken a defense of "assumption of risk."

There have been efforts made to have marketers of drugs and cosmetics place users on notice as to dangers of excessive dosage or improper administration. While this might be of conceivable defensive advantage, courts have reacted variously to this theory. For the most part, there is some reluctance to hold the manufacturer liable for failure to incorporate such warnings into his labeling and advertising since he cannot know or control the ultimate user. The law does not contemplate that the latter will be an idiot, a fool, or one bent on self-harm, but rather that the average consumer is a reasonably prudent person.

In the case of prescription drugs, concomitant use of other drugs, foods, alcoholic beverages, or pre-existing patient conditions that would be contraindications to the use of the product, frequently appear in the labeling. While this is accomplished in accordance with the Federal Food Drug and Cosmetic Act, it was an early requirement noted in the courtroom.[7]

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[4] 105 N.Y. 2d 735.
[5] 336 Mass. 709.
[6] 269 Fed. 356.
[7] 82 NYS 2d 194.

The need for labeling to bear *information "material" to the uses described* is stressed in Federal Trade Commission regulation as well as that implemented by the Food and Drug Administration. It has, of course, made its way into advertising regulation as well. In the new prescription drug advertising regulations, this is stressed.[8]

This language is found frequently in older case law dealing with FDA enforcement. The FDA early found labeling the route to proprietary drug advertising control.

In the *U. S. v. Kuriko*,[9] the FDA prosecuted a well-advertised proprietary preparation through its labeling in much the same manner that they achieved more publicized success in *Kordell v. U. S.*,[10] where they attacked an elaborate promotional program through Section 502(f) vulnerability. The court urged in *Kuriko* that "in determining whether or not any statements made . . . are misleading . . . take into account . . . not only representations made or suggested by the statements, but also the extent to which the labeling may fail to reveal facts material in the light of such representations."

A district court, some years later, following *Kordel* found no difficulty in upholding the FDA's contention[11] that newspaper or television advertisements which recommend a proprietary product for certain medical uses can misbrand the product if its labeling does not contain adequate directions for lay use in such ailments or excludes their mention.

In this respect, Sections 502(f), 503(b) and 21 C. F. R. 1.105 are a formidable trinity to overcome aberrant proprietary drug advertising. If the proprietary drug manufacturer features in his advertising some claim for his drug which promotes use in a condition the FDA opines requires a physician intermediary, then he has converted it into a "503(b)" drug and it is unlegended and misbranded.

At the same time, since Section 502(f) requires adequate description of usage and dosage, the manufacturer would have to provide same in his labeling—this in the face of the FDA's contentious concept, that no adequate labeling can be written to explain

[8] 21 C.F.R. 1.105(e)(5).
[9] 158 F. 2d 667.
[10] 335 U. S. 345, U. S. Sup. Ct. (1948), aff'g CA-7.
[11] *U. S. v. Thirty-Eight Dozen Bottles of "Tryptacin,"* 114 F. Supp. 461, DC Minn. (1953).

to a layman the clinical use of a drug that requires a physician's learned skill and judgment for proper utility.

Additionally, as a technical requirement, 21 C. F. R. 1.106(a), which applies to non-prescription drugs as well, requires labeling to present adequate directions for safe use of the product without omitting or incorrectly specifying *statements of all indications for the drug's use,* including those noted in the distributor's oral, written, printed or graphic advertising.

The only waiver is for proprietary drug promotion going directly to physicians. Here, obviously, both FDA and FTC, regardless of how the promotional material is defined, are satisfied so long as it is not false or misleading in any way.

In *U. S. v. John J. Fulton Co.*[12] advertisers defendants made no direct statements or representation that certain over-the-counter (OTC) drugs had curative or therapeutic value. Instead they reported the gist of letters from physicians. Since the defendants had such letters, they said that their labeling was not false or misleading. Court held that if the drugs are worthless, the proprietor should not be allowed to hide behind study reports or testimonials.[13] When you say "recommended for the treatment of" on a label or in labeling or advertising, or illustrate the same by testimonials, it is the sponsor who is saying that the drug has a therapeutic or curative or alleviative value in such disease entities. This applies even when you go so far as to have the one giving the testimonial offer to respond personally to those who are interested in further questioning.

## Devices

As defined in the Federal Food, Drug, and Cosmetic Act (Section 201(h)), devices are "instruments, apparatus and contrivances, including their components" intended for medical use. The definition, though broad enough to include X-ray machines, sunlamps, toothbrushes and clinical thermometers, does not supravene the drug definition as interpreted by the Food and Drug Administration. So, in the *Amp* case,[14] a surgical suture was termed a drug.

Although the Durham-Humphrey Act, Section 503(b) of the FFDC Act, statutorily establishes its guidelines specifically for a

[12] 33 F. 2d 506. CA-9 (1929).

[13] 502 (a) violation see also *Barrels of Vinegar,* 263 U. S. 438.

[14] *AMP Incorporated v. John W. Gardner, HEW Secretary,* 389 F. 2d 825 (CA-2 1968, aff'g DC N. Y.); cert. denied, U. S. Sup. Ct., Oct. 14, 1968.

division of drugs into "prescription" and "non-prescription" classes, the same effect is accomplished for devices through regulation.

Therefore, OTC devices with suitable labeling, containing adequate directions for use which includes information as to how to use the device for each indication for which it is to be employed, enjoy considerable advertising and sale.

Since the misbranding provisions are jointly set forth with drugs in Section 502 of the FFDC Act, the prohibitions are similar. The labeling of a device must not contain any statement which is false and misleading in any particular.

Derivatory advertising is therefore held to the same truthful presentation of the indications for use, the safety and effectiveness of the device.

If the device does require the supervision of a practitioner licensed by law to use it, it must bear the legend: "CAUTION: Federal law restricts this device to sale by or on the order of a physician." In appropriate circumstances the word "physician" can be replaced by another licensed practitioner such as "dentist," "podiatrist," or "veterinarian."

Every manufacturer has a duty of reasonable care in his manufacture, in his labeling, and in the promotional efforts that accompany his devices to this market. Labeling reflects anticipation, on the part of the manufacturer, of language to promote safe and efficient use of his product based on knowledge possessed by him. To this latter, jurists, the public and their governmental spokesmen add the knowledge available to others in similar position, or a total fund of knowledge which a reasonably prudent manufacturer would possess.

Following the Cardozo reasoning in the *McPherson*[15] case, the New York Appellate Court in *Boyd v. American Can Company* (249 App. Div. 644) said that the manufacturer "may not be charged with negligence where some unusual result occurs that cannot reasonably be foreseen and is not within the compass of reasonable probability."

Where this knowledge includes a possibility of danger, the relative labeling requirements are never as great as where there exists a probability of danger.

[15] *McPherson v. Buick Motor Company*, 217 NY 382, Cardozo on the general principle of inherently dangerous products.

One of the unpopular burdens that 21 C. F. R. 1.105, 1.106 has placed on the manufacturer is to give him the legal responsibility to include *possible* damages from use or misuse or abuse of his prescription drugs, along with those warning statements and precautionary considerations that are based on probable findings. For OTC devices, as for proprietary drugs, experience has led to the use of special warning statements required and cited within Title 21 of the Code of Federal Regulations.

No one will gainsay the claim that if a product is inherently dangerous or is known to contain hidden danger, a relative duty rests on the manufacturer,[16] or the one marketing such products as his own,[17] to give fair warning or instructions to the using public.

In the *Cleary* case, where the complaint was dismissed on the merits, the product, a nipple shield, was constructed in a manner and for a use known over a hundred years. The court repeated a definition of inherently dangerous things as "things which in their normal operation are implements of destruction."

## Cosmetics

Cosmetics are deemed to be misbranded and violative of the prohibitions spelled out in Chapter III of the FFDC Act if "the labeling is false or misleading in any particular." This goes to substance, to form, to size of print, etc.[18] "Goods are misbranded if they bear any statement which would deceive or mislead any purchasers who are of normal capacity and use that capacity in a common sense way. That is the test and whether there be any or few so deceived is not material."[19]

While cosmetics have label and labeling requirements much like proprietary drugs, there are special label considerations arising from coloring ingredients.[20]

For example, in the matter of the hair dye preparations which contain skin irritants such as paraphenyldiamine, labels must carry

[16] *Cleary v. Maris*, 173 Misc. 954, (N. Y.).

[17] *Willson v. Faxon, Williams and Faxon*, 208 N. Y. 108.

[18] Section 602, FFDC Act.

[19] *U. S. v. Pinaud, Inc.* (DC NY 1947), FSA Notices of Judgment, Cosmetics, No. 152.

[20] *Toilet Goods Association, Inc. v. John W. Gardner, HEW Secretary*, CCH Food Drug Cosmetic Law Reports ¶ 40.285, 278 F. Supp. 786, DC N. Y. (1968).

a statutory warning (Section 601(a)) and its labeling must have adequate directions to make the tests indicated in the warning.

For some years now, in scanning cosmetic labeling for technical requirements and avoidance of false or misleading statements, the FDA has been watchful for medical claims. Where such are made, they have been successful in classing the product as a "drug" also and requiring the labeling, and in some instances the general New Drug procedure, to be followed.

Said the Circuit Court of Appeals in *U. S. v. "Line Away . . . Coty,"* Chas. Pfizer and Co. Inc. in an opinion filed July 24, 1969, which upheld a judgment of condemnation entered in a seizure action, (U. S. District Court for District of Delaware):

> Some "puffery" may not amount to representation of a cosmetic as a drug, but when "puffery" contains the strong therapeutic implications we find in the Line Away promotional material, we think the dividing line has been crossed.[21]

On reading Chief Judge Hastie's opinion in "Line Away" one wonders how the government's case would have fared had the product been offered as a cosmetic protein face mask for temporary and superficial anti-wrinkle action, made by a leading cosmetic manufacturer, a "helpmate to the illusions of youth and beauty."

To avoid product liability in terms of negligence, it is required that the manufacturer exercise his ordinary responsibility of due care to warn contemplated purchasers and users of the cosmetic product of any dangerous qualities or possibilities of hazard which is known to him.

Adequate warning through product labeling and instructions accompanying the sale of the product discharges the duty, providing these are done unambiguously, honestly and in a manner properly calculated to bring these warnings to the reasonably expected user's attention.[22]

That is the objective of seeking compliance with Sections 601 and 602 of the FFDC Act, or in the case of advertising of cosmetics, as with proprietary drugs, with Sections 12, 13, 14 and 15 of the FTC Act.

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[21] See also *U. S. v. "An Article*** *Sudden Change,"* * * * (Hazel Bishop Inc., Claimant) CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 80,229, 409 F. 2d 734 (CA-2 1969) for a similar holding.

[22] 295 F. 2d 292, 244 F. 2d 53.

## Cosmetic Advertising

The advertising of Cosmetics is generally effected by the Wheeler Lea Amendments of 1938, and comes under the special authority, therefore, of the Federal Trade Commission.

Some of the weaponry for compliance available to the FTC are:

1. Temporary injunctions *pendente lite,* actually pending issuance of an administrative complaint and order to cease and desist. These former will issue when immediate, unwarranted danger and/or irreparable harm are threatened to the public. These are addressed to the advertising complained of.

2. Where the advertising relates to a product and either the substance of the product or the advertising claims and recommendations that are made for its use represent probable injury to health, the FTC may initiate criminal action against the parties concerned.

3. For historic and political reasons, the measuring devices given to the FTC in its evaluation are similar to those given the FDA in Section 502 of the Act, so that the usual precepts must govern self-evaluation.

The sponsor must realize an obligation to examine the advertisement to see if it is false and misleading in any particular, or fails to reveal material facts, or contains affirmative advertising claims for safety which are literally false, or indicate disregard for usual determinants of proof; or require special reading on the part of the consumer to use them with safety so that the product is "truly safe when taken in accordance with directions" as the distributor usually says. Does the copy implicitly or patently require special consumer characteristics to use the product with safety which are only apparent to a prudent consumer, after he has read the labeling, after he has made the purchase, in response to an unlimited or deceptively phrased or quoted claim of general safety to all?

Is it violative of FTC's trade regulation reports as they affect particular products or categories of products?

In these reports the commission has been quite specific in limiting the conveyance of ideas as to the safety and efficacy of the product. Such reports give notice in advance, but a review requires prior enforcement action be taken. Some have seen these trade regulations as instrumenting a doctrine of express limitation and affirmative disclosure for products offered for therapeutic purposes. In general, cosmetics are not so offered.

Like the FDA, however, the FTC can insist that intent for use and advertising background show the product is rather a non-prescription drug than a cosmetic and require more affirmative revelation of harmful propensities and contraindications, since they have been successful in this area.

The FTC has the burden of proving that advertising is misleading, deceptive or false. Their Division of Scientific Opinions is generally involved in preparing such evidence. However, the Commission will not hesitate to demand that the advertiser submit special reports. It is authorized to do so under the Act and failure to comply is, like a prohibited act in Chapter 3 of the FFDC Act, subject to penalties. These special reports are evaluated by the FTC, sometimes with help from FDA scientific people, as well. In a sense, they can be small New Drug Applications (NDAs), since the manufacturer or advertiser submits the formula and manufacturing information, data on tests, reports of studies, labeling claim justification, etc.

Neither action of the FDA relative to misbranding, nor that of the FTC relative to false advertising, is an exclusive remedy afforded to the government in a case where both misbranding and false advertising are present. The fact that the FDA may seize an article because it is misbranded does not prevent FTC from issuing a cease and desist order with reference to false advertising concerning that article. However, either government agency should have been victorious a priori. In *U. S. v. Willard Tablet* where Willard had been the victor, the Circuit Court of Appeals upheld the district court in finding that the FDA's seizure and condemnation action was blocked by the FTC defeat on the same labeling issues.[23]

All advertising is within the province of Federal Trade Commission enforcement procedures. However, in the case of prescription drugs, Section 502(n) and its elaborate regulations contemplate FDA scrutiny and enforcement. In general, advertising, whether of prescription drugs or any other, must be derivatory from the labeling and consistent therewith, so the FDA has in the past acted against other than prescription drug advertising on grounds of inappropriate labeling where they claimed the advertising rendered it uncertain or incomplete.

**[To Be Continued in the January Issue]**

[23] *Res judicata* finding, 141 F. 2d 141.

# What's New at FDA?

By PAUL A. PUMPIAN

Mr. Pumpian Is the Director of the Food and Drug Administration's Office of Legislative and Governmental Services.

I AM NOT AWARE of a total presentation having been made concerning the reorganization of the Food and Drug Administration (FDA) from April 1, 1968, to date, so let me first tell you something of the history and philosophy behind the reorganization that began early in 1968.

On April 1, 1968, the Department of Health, Education and Welfare's (HEW's) Assistant Secretary for Health and Scientific Affairs was given "line" responsibility over the Department's health programs. This change from serving in a staff position to the Secretary was the first step in bringing together under one executive, beneath the secretarial level, all the health programs in HEW. These health programs were placed in the Public Health Service, (PHS) and the FDA became a part of PHS at that time. The Commissioner of Food and Drugs then began reporting to the Assistant Secretary of HEW.

The next organizational innovation was the establishment of the Consumer Protection and Environmental Health Service (CPEHS) within HEW. This unit is composed of three administrations, the National Air Pollution Control Administration (NAPCA), the Environmental Control Administration (ECA), and the Food and Drug Administration (FDA).

FDA continues its enforcement and supporting roles in all matters connected with the administration of the Federal Food, Drug, and Cosmetic Act, as well as the six other federal laws it has been enforcing: the Fair Packaging and Labeling Act, the Federal Caustic Poison Act, the Federal Hazardous Substances Act, the Import Milk Act, the Tea Importation Act, and the Filled Milk Act.

One of the results of the organizational change creating the CPEHS was the transfer of some functions to FDA from other units of the Public Health Service. FDA's functions now include:

1. The responsibilities pertaining to the pesticides function and related training functions which were formerly in the National Communicable Disease Center.

2. The functions pertaining to product safety, milk and food protection, shellfish certification, and interstate certification, which were formerly in the National Center for Urban and Industrial Health.

3. The functions pertaining to poison control which were formerly in the Division of District Health Services, Bureau of Health Services and the Health Services and the Mental Health Administration.

## Coordinating State and Federal Activities

With the transfer of the Milk, Food and Interstate Travel Program from the Environmental Control Administration to the FDA, which became effective several months ago, the department's consumer protection programs pertaining to these areas, plus product safety, pesticides, and shellfish have been brought together in one administration for the first time. Since all of these programs are significantly involved with our state counterparts, we feel the placement of these programs within FDA will greatly enhance our efforts to coordinate state-federal cooperation in these critical areas. These new responsibilities will, of course, entail adjustment in resource reallocation within FDA, but we at FDA feel the result will be highly beneficial to the consumer.

Hence, FDA now has the responsibility of insuring that:

1. Foods are safe, pure, and wholesome.
2. Drugs are safe and effective.
3. Cosmetics are harmless.
4. Therapeutic devices are safe and effective.
5. Foods, drugs, cosmetics and devices are honestly and informatively labeled and packaged.
6. Dangerous household products carry adequate warnings for safe use and are properly labeled.
7. Counterfeiting of drugs is stopped.
8. Hazards incident to the various types of consumer products are reduced.

## Organizational Changes

The increasing complexity of FDA's mission has led to our having to be more attentive to the organization and utilization of all

FDA components. The recognition of this necessity by our parent organization, CPEHS, and by our own administrators has resulted in the adoption of some organizational changes and new personnel concepts. More will follow in time, but some that we regard as particularly important already are in effect or are in the process of being implemented.

For example, FDA's field organization has been restructured. There are now in our field organization nine Regional Food and Drug Directors, one in each of the nine regions of the Department of Health, Education, and Welfare. Each of these regional directors is responsible for coordinating the activities of the FDA districts within his particular region. The Regional Food and Drug Directors also serve as directors of the districts in which they are headquartered. The regional directors are headquartered in the following cities: Boston (I), New York (II), Baltimore (III), Atlanta (IV), Chicago (V), Kansas City, (Mo.) (VI), Dallas (VII), Denver (VIII), and Seattle (IX). The remaining eight district directors will report to these regional Food and Drug Directors.

Another new position being established at the regional level is that of the Associate Regional Food and Drug Director. These associate directors will work under the supervision of the Regional Food and Drug Directors and will be physically located at the HEW regional offices in Boston, New York, Charlottesville, Atlanta, Chicago, Kansas City, Dallas, Denver, and San Francisco. You will note that Charlottesville, Virginia and San Francisco, California are in this list, but were not mentioned when the list of locations of the Regional Food and Drug Directors was presented. The difference between these cities and those previously mentioned results from locating the Regional Food and Drug Director in a city other than that in which the HEW Regional Director is located, while the Associate Regional Food and Drug Director is to be in the building housing the HEW Regional Director. Hence, in Region III the Regional Food and Drug Director is located in Baltimore, and the Associate Regional Food and Drug Director will be located in Charlottesville. Likewise, the regional director for Region IX is in Seattle, while the associate regional director will be in San Francisco.

The Associate Regional Food and Drug Directors will participate in facilitating, promoting, and coordinating state-federal cooperative programs. They will collaborate with the Regional Food and Drug Director in developing a cooperative relationship with the executive branches of state governments within their respective regions. They

will also work with other regional elements of CPEHS, and with regional elements of the department on the interrelationship of FDA programs and comprehensive health planning, model cities planning and other regional activities pertaining to environmental health and consumer protection. They will assess the effectiveness of existent state-federal cooperative programs within the regions, summarize weaknesses and significant obstacles to effective state-federal relations, and advise the Regional Food and Drug Director on all of these matters.

The Associate Directors will, as authorized, act for the Regional Food and Drug Director to provide FDA assistance in the event of national disasters or other emergencies. They will compile and analyze "grassroots" reaction to the impact of proposed federal legislation on the states. They will be responsible for maintaining contact with state officials, and for keeping the Regional Food and Drug Directors advised of appropriate news and trends.

## Headquarters Organization

Changes have also been made in the FDA organization at headquarters, which is located in Arlington, Virginia. Early next year, the headquarters units now located in Arlington will be moved to Rockville, Maryland, where FDA will be housed with two other elements of CPEHS.

As for the headquarters organization of FDA, we still have a Commissioner, Dr. Herbert Ley, Jr.; a Deputy Commissioner, Mr. Winton B. Rankin; and an Associate Commissioner for Compliance, Mr. J. Kenneth Kirk. Recently, however, we have had a change in the office of our Associate Commissioner for Science. Dr. Dale Lindsay, formerly Assistant Chancellor for Health Sciences at the University of California at Davis, has succeeded Dr. Daniel Banes as FDA's Associate Commissioner for Science.

In the Office of the Commissioner we have the OLGS, in which has been placed the responsibility for liaison with the Congress and with state officials and their organizations. This unit is responsible for maintaining FDA's cooperative effort with state officials as individuals, as representatives of their state agencies, and with the organizations representing state Food and Drug officials, such as the National Association of State Departments of Agriculture (NASDA), Association of Food and Drug Officials of the United States (AFDOUS) and the Association of States and Territorial Health Officers (ASTHO).

This responsibility was once delegated to the Office of Federal State Relations (FSR), which was merged with the Office of Legislative Services (OLS) to form OLGS. This past December, the Office of International Affairs (OIA) was merged into OLGS so that we now have five units in OLGS: the Office of the Director, and units for Congressional Services, International Affairs, Legislative Services, and State Services.

## Changes in the Bureaus

Another major organizational change has taken place in the headquarters structure of FDA as a result of the merging of the Bureau of Regulatory Compliance (BRC) and the Bureau of Voluntary Compliance (BVC) into what is now known as the Bureau of Compliance. The directors of these two former bureaus, Alfred Barnard and Fred Delmore, are now serving as Associate Directors of the new Bureau of Compliance. The director of this bureau has not yet been named, and the Associate Commissioner for Compliance, Mr. J. Kenneth Kirk, is serving as Acting Director. The Bureau of Compliance will be responsible for the functions previously handled by BRC and BVC, as well as some of the new programs brought into FDA from other parts of the Public Health Service.

The organization of the Bureau of Compliance has not yet been completed, but I understand that it will be divided primarily into units for Operations and Industry Services and for Control and Guidance. In the Operations and Industry Services you will find the responsibility for such things as the development of Good Manufacturing Practices and Industry Self-Certification and Quality Assurance. In the Control and Guidance Unit you will find the Case Guidance functions, the Recall section and those units responsible for Shellfish Sanitation, Milk and Food Service Sanitation and Inter-State Travel Sanitation. I am sure that in the near future a Table of Organization of this Bureau and its constituent units will be published for your guidance.

Many of you, I am sure, are familiar with our Bureau of Medicine, whose Acting Director at the present time is Dr. John Jennings. The bureau, in addition to the Office of the Director, consists of the Office of Marketed Drugs, the Office of Medical Review, the Office of Medical Support and the Office of New Drugs.

The Office of Marketed Drugs has four Divisions: Cardiopulmonary-Renal Drug Surveillance; Metabolic-Endocrine Drug Surveillance; Neuropharmacological Drug Surveillance; and Surgical-Dental Drug Surveillance.

The Surgical-Dental Drug Surveillance Division is responsible for drugs that will be classified as surgical adjuncts, dental, oncology and radiopharmaceutical drugs.

In the Office of Medical Review, we have Divisions of Case Review, Clinical Devices, Hazardous Substances and Medical Devices. In the Office of Medical Support, we have Divisions of Drug Experience, Medical Advertising, Research and Liaison, Scientific Investigations and Statistics. In the Office of New Drugs we have, as in the Office of Marketed Drugs, Divisions based on drug activity. They are the Divisions of Anti-Infective Drugs, Cardiopulmonary and Renal Drugs, Dental and Surgical Adjuncts, Metabolism and Endocrine Drugs, Neuropharmacological Drugs and Oncology and Radiopharmaceuticals.

Also in the Bureaus of Medicine is the Office of Product Safety. The Director of this unit, however, now reports directly to the Commissioner of Food and Drugs rather than to the Director of the Bureau of Medicine, as was done when the Office was originally established. Within the Office of Product Safety, we have the Divisions of Community Study, Hazardous Substances, Pesticide Registration, Poison Control and Safety Services.

In our Bureau of Veterinary Medicine we have, in addition to the Office of the Director, Dr. C. D. Van Houweling, the Divisions of Veterinary Medical Review, Veterinary New Drugs and Veterinary Research. The Medicated Feed Branch is part of the Division of Veterinary Medical Review.

## Eliminating Duplication

At this point, I will tell you a little about what we at FDA are doing to give the consumer more for his tax dollar. I like to think that we are giving the consumer more value for his money by attempting to prevent the duplication of state-FDA activities. Representatives of the regulated industries, as well as taxpayers, should be aware of this effort and its results. For some time now, we in FDA have appreciated the need for eliminating the duplication of resource expenditures in fields of activity common to state agencies and FDA. We feel that there has been a great deal of progress in this direction in a number of ways.

For example, the number of agreements between state agencies and FDA has been most gratifying. During 1968 and 1969, FDA has entered into agreements with agencies in the states of Connecticut, Illinois, Indiana, Kentucky, Maine, Massachusetts, Michigan, New

Jersey, New York, Oklahoma, Oregon, Rhode Island, Texas, Vermont, Virginia, Washington, West Virginia, Wisconsin, and the District of Columbia. Because of the variations in the laws and procedures of the numerous state organizations involved in the different production and distribution problems in different locales and numerous other variables, these agreements vary widely as to areas covered. The subjects of these agreements are in fields dealing with food, soft drinks, medicated feed, dairy products, pesticide residues in various food (or feed) crops, and in food storage surveillance. Other agreements have been made that deal with various aspects of fair packaging and labeling activities. More recently, some landmark agreements have been made in the human drug control area. We believe that these pioneering agreements in the drug field with the states of New York and New Jersey show great promise. We consider these to be pilot programs, and are anxiously awaiting the evaluation of the results of these programs to see if they should be continued and expanded into other states—especially in those states where intrastate drug operations are extensive.

While these formal agreements are both highly effective and highly visible, they most assuredly do not represent all of the increased cooperation and coordination that has taken place between the states and FDA during the past year.

## Resource Data Study

One example of increased interest and effort is our resource data study in ten selected states. Last year a member of my staff, with the assistance of a number of FDA district chief chemists, visited Arizona, California, Connecticut, Florida, Kentucky, Louisiana, Maryland, Virginia, Washington and West Virginia to obtain capability data in areas corresponding to FDA's activity. The purpose of this initial study was two-fold: to compile information for contemplated congressional hearings on states' assistance legislation, and to assist the FDA in formulating and conducting partnership programs with the states.

Since last July, when the survey phase of the project was completed, we have compiled a summary report of the data collected in the ten states. The report contains a number of charts, along with accompanying narrative, summarizing the total resources and capability of each of the states. The type of information obtained is reflected by the charts published in the report:

1. Uniform Provisions of the Food and Drug Laws.
2. State Agencies with FDA Type Regulatory Responsibilities.
3. State Budgets for FDA Type Regulatory Programs.
4. State Manpower Assigned to FDA Type Programs.
5. Priorities Given to Various Food and Drug Programs.
6. Number and Kind of Establishments Inspected.
7. Number and Types of Major Products Analyzed.
8. Facilities and Specialized Equipment of State Laboratories.
9. Formal Education, Experience and Salaries of Employees in Food and Drug Programs.

The report was sent to key officials in each of the ten states and to those FDA directors having a state or states in their territories. To respect the confidentiality of the information obtained, we utilized a code, rather than name the states in the various charts. Each state official received a key which identified only the information pertinent to his state. The FDA districts received a key which identified only those states within their territories.

The response to this summary report has been most gratifying. State officials have responded very favorably on the value of the information contained in the report. In fact, one state, since receiving the report, has introduced legislation for a modern food and drug law.

In view of the success we have had in obtaining the desired information in these ten states and the obvious advantages to the states, as well as to FDA in receiving and maintaining the completed information, we are now planning to extend the project to ten additional states in fiscal 1970, and hopefully an additional ten states each year until all fifty are surveyed.

Since food and drug programs do not remain static for extended periods of time, we believe it important to develop a system to update, on an annual basis, the information received from the states. We hope to have, in the very near future, a questionnaire designed to bring the initial survey up-to-date, and to use in maintaining current information from all the states after they are initially surveyed.

## Conclusion

I will conclude by saying that I have tried to present to you some of "What's New at FDA" in the way of organizational changes and programs with FDA's state counterparts in the belief that you, as legal representatives of the regulated industry, should know *where* to go in FDA with your problems and what your clients should expect from state officials and from FDA when they are working in the same areas. **[The End]**

# Fair Packaging and Labeling

By WALTER R. MOSES

Walter R. Moses Is the FDA's Chief of the Food Case Branch, Division of Case Guidance, Bureau of Compliance.

ON NOVEMBER 3RD OF THIS YEAR, the Fair Packaging and Labeling Act (FPLA) will be three years old. This is a good time to review what has been done and what still needs to be done toward fulfilling the promises of this Truth-in-Packaging Law. When President Johnson signed the bill, he said it was to tell the consumer exactly what is in the package, who made it, just how much it contains, and how much it costs as compared to competitive products. It was also to end the use of labels that lie and packages that confuse. Admittedly, much remains to be done if all these purposes are to be achieved.

The requirements of the FPLA apply in general to packaged consumer commodities. The Food and Drug Administration (FDA) was made responsible for administering only those provisions of the FPLA that apply to foods, drugs, devices, and cosmetics as defined in the Federal Food, Drug, and Cosmetic (FDC) Act. Even with respect to these there were important exceptions, since the FPLA specifically excluded from its provisions the following:

Meat and meat products.

Poultry and poultry products.

Tobacco and tobacco products.

Economic poisons subject to the Federal Insecticide, Fungicide, and Rodenticide Act.

Commodities subject to the Virus-Serum-Toxin Act.

Habit-forming drugs.

Drugs restricted to dispensing by or on the prescription of a physician.

Insulin.

Alcoholic beverages subject to the Federal Alcohol Administration Act.

Commodities subject to the Federal Seed Act.

The Federal Trade Commission administers the provisions of the FPLA with respect to the packaging and labeling of consumer commodities other than foods, drugs, devices, cosmetics, and the exempted commodities listed above. The Department of Commerce is responsible for administering provisions concerning undue proliferation of package sizes and weights.

An FDA proposal published in the *Federal Register* of March 17, 1967, included new regulations to implement the FPLA with respect to label statements for foods and to bring up to date the general regulations issued under the FDC Act more than a quarter of a century earlier. Interested persons were invited to comment. Over 300 comments were submitted by Federal and State officials and industry representatives. These included many constructive comments and helpful suggestions that required careful study. Since the FPLA supersedes state laws regulating label declarations of the quantity of contents on containers of consumer commodities, the FDA felt it was advisable to consult state officials, whose cooperation is essential to effective enforcement of this law. The Committee on Laws and Regulations of the National Conference of Weights and Measures and the Executive Committee of the Association of Food and Drug Officials of the United States were consulted. By the time this could be done and revised regulations drafted, the effective date had passed.

Revised regulations were published on July 21, 1967, and in accord with rulemaking procedures prescribed by law, interested persons were given an opportunity to file objections and request a public hearing. At the same time, the Commissioner of Food and Drugs exercised the option provided in FPLA to permit postponement of the effective date. July 1, 1968, was to be the effective date for all packages introduced into interstate commerce.

It soon became apparent that nearly all food labels needed revision, and that label manufacturers could not make all the new plates, print the labels, and supply these to food packers by the July 1, 1968, deadline. Therefore, the Commissioner published a statement of policy prescribing the conditions under which existing stocks of labels, complying with the FDC Act but not with all FPLA requirements, might be used after July 1, 1968. More than 3,300 firms met the prescribed conditions and were granted permission to use existing labels until new labels could be obtained, but not beyond June 30, 1969.

On September 20, 1967, a final order was published in which the Commissioner ruled on objections and requests for a hearing. Some regulations were revised, and the meaning of others was clarified.

These regulations are intended to further help consumers to know what food is in a package, who packs or distributes it, and how much it contains. However, the FPLA provides that the Secretary may exempt particular commodities from the requirements if he finds that, for good and sufficient reason, full compliance is not necessary to adequately protect consumers. The FDC Act also provides for exempting regulations under certain conditions. Exemptions have been granted for some foods when petitioners submitted proof that the proposed exemption was reasonable, did not impinge on the consumer's right to information essential to value comparisons, would not promote deception or unfair competition, and that full compliance was impracticable or otherwise unnecessary. Individually wrapped pieces of "penny candy" and pieces of candy weighing less than one-half ounce per piece sold in bags or boxes have been exempted from all labeling requirements provided the containers bear the required statements. A proposal published January 17, 1969, and published again in revised form July 10, 1969, would extend this exemption to chewing gum pieces weighing less than one-half ounce.

## Identity Requirements

To tell consumers *what* is in a package, the FPLA requires that commodities be labeled with an identity statement. The regulations for the package require that this be in bold type, on the principal display panel of the package, in a size reasonably related to the most prominent printed matter on such panel, in lines generally parallel to the base on which the package rests. If the food is marketed in various forms, the identity statement must describe the form (such as sliced, diced, minced, whole, etc.), unless the form of the food is visible through the container or is accurately pictured on the label. Soft drinks in bottles are exempted from the required declaration on the principal display panel parallel to the base if the identity appears conspicuously on closures (lids or covers). Multiunit retail packages of such soft drinks (such as six-packs) are exempted if the identity statement on unit container is not obscured by the multiunit package. Continuous label copy wrapping for butter in 4-ounce, 8-ounce, and 1-pound packages need not be parallel to the base provided the statement is not difficult to read as displayed at retail.

To provide purchasers with more information about *what* is in the package, the FPLA authorizes the promulgation of regulations regarding the declaration of ingredients on labels for fabricated consumer commodities other than foods. Foods are subject to the FDC Act, which requires that fabricated foods, other than those for which standards of identity have been established, must be labeled with a listing of ingredients by their common or usual names, but that spices, flavorings, and colorings may be declared as such without naming the specific spice, flavor, or color. The FDA has established identity standards for certain common foods. These prescribe which ingredients must be used, and sometimes how much, as for example, at least 45 parts fruit to 55 parts sugar in jams and jellies. The standards may also prescribe certain labeling statements, including which optional ingredients must be declared.

For other fabricated foods, a new FDA regulation requires that ingredients, including water, be listed in order of decreasing predominance. Furthermore, the proportion of an expensive ingredient must be stated if its presence has a material bearing on price or consumer acceptance, and if the absence of such a declaration may create an erroneous impression that the food contains more of the ingredient than is actually the case. The entire list of ingredients must appear on any appropriate single panel of the label—it need not be on the principal display panel.

The FPLA requires that labels for consumer commodities must bear the name and place of business of the manufacturer, packer, or distributor. The FDC Act has a similar requirement. Regulations require that this include the street address, unless this is listed in a current city or telephone directory. When new labels are printed, the Postal ZIP Code must be included. Regulations also require that the name of the firm, if it is not that of the manufacturer, be qualified to show his relationship, as for example, "Packed for . . . ." or "Distributed by . . . ." This name and place of business must be conspicuous, but the statement need not be placed on the principal display panel. In case of bottled soft drinks, the declaration may appear on the top or side of the closure. It may be omitted on multiunit retail packages for soft drinks (such as a six-pack) provided the declaration on the unit containers is not obscured, or the multiunit package bears an explanation that the name and place of business of the bottler can be found on the unit containers.

## Quantity Requirements

The FPLA requirement that labels tell just *how much* packages contain has had the greatest impact. Most food labels have had to be revised to comply with this provision and the regulations to implement it. The only packages exempted from bearing a declaration of the quantity of contents are:

(1) Food in bulk containers, if at retail outlets it is accurately weighed, measured, or counted within sight of the purchaser or to his order.

(2) Individual serving-size packages containing less than ½ ounce or ½ fluid ounce for use in restaurants, institutions, or passenger carriers.

The quantity-of-contents declaration must be located on the principal display panel (or panels). Except as noted below, it must be positioned in the lower 30 percent of the label panel in lines generally parallel to the base on which the package rests. The following are exempted from the 30 percent placement requirement:

(1) Containers with a principal display panel of 5 square inches or less.

(2) Random food packages and uniform weight packages of cheese products bearing labels stating net weight, price per pound or specified number of pounds, and total price.

(3) Soft drinks packaged in bottles with the other required information only on the closure *and* the quantity of contents declaration blown, formed, or molded into the surface of the bottle near the closure.

(4) Ice cream and certain other frozen desserts and milk, cream, and certain other fluid dairy products in standard ½-pint, 1-pint, ½-gallon, and 1-gallon containers. (A proposal published June 26, 1969, would exempt single strength or undiluted and less than single strength or diluted fruit juice beverages provided the quantity-of-contents declaration appears conspicuously both on the closure and blown, formed, or molded into the glass or plastic container at or above the shoulder.)

(5) Wheat flour products in conventional 2-, 5-, 10-, 25-, 50-, and 100-pound packages.

(6) Corn flour and related products in conventional 5-, 10-, 25-, and 100-pound bags.

(7) Eggs in cartons of one dozen designed to be divided, provided the declaration is on the principal display panel in such position that it will be destroyed when the carton is divided. The divided portions are exempt from labeling requirements.

(8) Margarine in 1-pound rectangular packages, except whipped or soft margarine or packages that contain more than four sticks.

(9) Butter (but not whipped butter) in 8-ounce and 1-pound packages. (Continuous label copy for butter in these sizes and 4-ounce packages is exempted from requirement that the declaration be generally parallel to the base provided it is not difficult to read as displayed at retail.)

The quantity-of-contents declaration must appear in bold face type of specified size as related to the area of the "principal display panel" of the package (not the label), in distinct contrast to the background. It must be separated from other printed information by specified distances. The only foods exempted from the type-size requirements are those in random food packages, and cheese and cheese products bearing labels which declare the net weight, price per pound or per specified number of pounds, and total price.

The quantity-of-contents declaration must be in terms of net weight, net volume, or count, and such combination of these as is needed to tell how much food is in the package. To facilitate comparisons, the number of ounces or fluid ounces must be stated on packages containing less than 4 pounds or 1 gallon. This declaration must include no qualifying terms such as "jumbo quart" or "full gallon." Packages containing 1 pound or more but less than 4 pounds must bear a dual declaration, first in terms of ounces, and then in terms of pounds and ounces or fractions. Such dual declaration is required on packages containing 1 pint or more but less than 1 gallon. For example, a package containing 56 fluid ounces should be labeled: "Net 56 fluid oz. (1 qt. 1½ pt.)" *or* "Net 56 fluid oz. (1 qt. 1 pt. 8 fl. oz.)," *but not* "Net 56 fluid oz. (1 qt. 24 fl. oz.)."

The following exemptions have been granted from the dual declaration requirement:

(1) Ice cream and certain other frozen desserts and milk, cream, and certain other fluid dairy products, if packaged in standard 1-pint, 1-quart, ½-gallon, or 1-gallon containers. Containers of 8 fluid ounces may be labeled simply "½ pint" and 64 fluid ounces as "½ gallon." (A proposal published June 26, 1969, would provide the same exemp-

tions for single strength and less than single strength fruit juice beverages.)

(2) Butter in 1-pound packages may be declared simply as "1 pound" or "1 lb."

(3) Margarine in 1-pound packages may be declared as "1 pound" or "1 lb."

(4) Wheat flour products in 2-pound packages if labeled in terms of pounds.

Neither the FDC Act nor the FPLA requires that labels state the number of servings in a package. Both the FPLA and regulations require, however, that if the label bears any representation as to the number of servings, the net quantity of each serving must be stated. This must be in terms of weight, volume, or count, but need not be in terms of ounces or fluid ounces. It may be stated in such terms as "½ cup," "two tablespoons," or similar terms commonly used by housewives to describe serving sizes.

## Current FPLA Activities

Even a casual survey of items on retail grocery shelves will reveal many labels that do not comply with these regulations. Although foods entering interstate commerce since June 30, 1969, are expected to comply, it may be weeks or months before all foods bearing old labels disappear. Congress made clear its intent that stocks already in channels of commerce when an FPLA regulation becomes effective should not be removed for failure to comply with that regulation, assuming that the labels complied with the rules in effect at the time of shipment.

The number and proportion of items bearing revised labels should increase rapidly. Even those industry members who opposed passage of FPLA have tried diligently to revise their labels by the effective date.

The Label Manufacturers National Association, Inc., after a survey among its labelmaker members, reported that over 100,000 new plates had been made and that as of July 1, 1969, they had supplied 40 billion labels for foods and beverages which were in full compliance. Other billions of revised labels have been printed and are being put into use.

As yet, no regulations have been issued to implement those provisions of the FPLA dealing with such things as "cents-off" pro-

motions and "packages that deceive" because of nonfunctional slack-fill. How soon the FDA can draft and issue such regulations will depend upon how much, if any, money is made available for this purpose.

Regulations covering over-the-counter drugs, devices, and cosmetics are not yet effective. Proposed regulations were published August 22, 1967. Over 50 comments were received. After these were carefully evaluated, an order was published on January 11, 1968. About 25 firms and trade associations filed comments or objections, some accompanied by requests for a public hearing. After studying these, the Commissioner of Food and Drugs concluded that the major issues might best be resolved by canceling the order and publishing a final order to revise and clarify some sections. The new final order was published June 28, 1968, and the effective date was set as July 1, 1969.

Publication of this order was followed by objections and requests for a public hearing from one firm and one trade association. An order ruling on these objections was published by FDA on March 6, 1969. To permit manufacturers time to make label revisions, FDA has changed the effective date to December 31, 1969.

The regulations pertaining to over-the-counter drugs, devices, and cosmetics are similar to the corresponding food regulations with some important exceptions.

The statement of identity for a drug shall be in terms of its established name followed by a statement of its general pharmacological category. If the drug is a mixture with no established name, the requirement may be satisfied by giving its general pharmacological category or principal intended action, as for example, "antacid," "analgesic," or "decongestant."

The statement of identity for a cosmetic shall be in terms of its common or usual name, an appropriately descriptive name, an appropriate illustration representing the intended cosmetic use, or, when the nature of the cosmetic is obvious, a fanciful name understood by the public to identify the cosmetic.

The statement of identity for a device must include its common name followed by a statement of its principal intended action.

The declaration of the quantity of contents for over-the-counter drugs in tablet, capsule, ampule, or other unit form must be expressed in numerical count. If necessary to give accurate information about

the strength of the drug, this should be augmented by some declaration such as "25 tablets, 5 grains each," or "100 capsules, 250 milligrams each."

The quantity-of-contents declaration for devices shall be in terms of numerical count, augmented when necessary with accurate information about weight, measure, or size, as for example, "100 tongue depressors, adult size," or "1 rectal syringe, adult size." Adhesive tape in package form must be labeled in terms of linear measure (length) and width.

Requirements concerning ingredients declarations on drugs are quite involved. In general, the listing of ingredients is intended to supply information needed by users of the drug. Persons who are interested in preparing labels should obtain copies of the Acts and regulations.

As the FPLA enters its fourth year, we may expect its impact on packages and labels to be more visible. State food and drug officials and those responsible for enforcing weights and measures laws will be giving increased attention to the enforcement features. The FDA has prepared a manual to assist these state officials and to promote uniform interpretation of the FPLA and regulations. Consumers can help by reporting suspected violations. Reports may be forwarded to the appropriate state officials or to the nearest FDA district office.

Fulfillment of the promises of the FPLA will depend on the continued active participation and cooperation of the regulated industries, label designers and manufacturers, State and Federal officials, and consumers. **[The End]**

## FDA REORGANIZED

In a government effort to improve the FDA, three top officials of this agency were removed from office on December 11, 1969. The purpose of the reorganization is to strengthen FDA's position within HEW by placing it directly under the authority of Dr. Roger O. Egeberg, HEW's assistant secretary for health and scientific affairs.

Effective February 1, 1970, the new Commissioner of Food and Drugs will be Dr. Charles C. Edwards, a management specialist who has been an assistant to Dr. Egeberg since joining the Department on December 1, 1969.

Further internal changes will replace the present bureaus with a bureau of drugs and a bureau of foods, pesticides and product safety. Robert H. Finch, Secretary of HEW has said that these changes will reorganize FDA "along product rather than functional lines."

# Antitrust Questions in Voluntary Industry Standards

By LIONEL KESTENBAUM

Mr. Kestenbaum, Formerly Chief of the Policy Planning Section, U. S. Department of Justice, Is Now a Member of Bergson, Borkland, Margolis & Adler, a Washington, D. C. Law Firm.

THE SUBJECT OF ANTITRUST QUESTIONS in voluntary industrial standards may strike a discordant note, for I realize that the current trend of public opinion and government pressure is towards more, better and higher standards, towards safer, more reliable and more durable products. Industry is exhorted to show a sense of social consciousness. Antitrust is charged with being out of step with this goal, indeed with being an obstacle to achieving it. In response, at the outset I might question the credibility of these criticisms. The past years have seen a considerable growth of standards-making organizations, and the development of thousands of commercial industrial standards. Curiously, all this activity did not appear, to its proponents, to present antitrust difficulties worth discussing. However, when suggestions for action came from other sources—whether for packaging sizes, quality grading, or safety—antitrust problems quickly took prominence.

Thus, I start with some excusable skepticism about the asserted anxiety. At the same time, I would agree that standards-making activity does present antitrust questions. This is, in part, because some antitrust dogmas need re-examination and restatement in this context—I will come to that later. But it is principally because standards-making can have important competitive consequences. In the midst of the exhortations to industry to get together and do better, we should not forget those consequences. I believe an antitrust analysis can improve the procedures and results of standards-making by illuminating its risks and advantages. I would like, therefore, to discuss: (a) the competitive effects of standards-making,

(b) the development of adequate criteria for antitrust enforcement in this area, and (c) the implications for standards organizations.

## Competitive Effects

What are the possible adverse effects of industrial standards-making? The establishment of a standard often tends to drive the non-standard off the market. This presents the risk, first, that a standard may eliminate options for the consumer, including desired and desirable options. Even an agreement ostensibly to upgrade a product can have the effect of requiring buyers to pay more for quality which they do not need or want. And the ostensible maintaining of quality can be illusory. Notorious examples are standards which specify particular materials and configuration, and which turn out to be obstacles to introduction of new and better or less costly products for the same function.

A second potential effect is that a standard may exclude competition. This would be true of over-rigid specifications, just mentioned. Other illustrations would be standards consistent only with a particular production technique, inspection requirements that are unwarrantedly burdensome for foreign goods, and other conditions that favor certain companies and disadvantage others.

Last, standardization may be associated with illegal restrictive agreements or objectives. Thus, it is sometimes easier to fix prices and divide markets if the diversity of products can be limited. In a famous case, the elimination of "seconds" by plumbing manufacturers was part of just such an illegal program.

For some unduly suspicious types, the process of standards-making inevitably presents the risk that cooperation will go too far. They will point out that standards-making is often the work of persons from a few companies, usually the major ones in the field, who may not adequately consider the interests of others. And they will recall the observation more than a century ago, by Adam Smith, the exponent of free enterprise, that "People of the same trade seldom get together, even for merriment and diversion, but the conversation ends in a conspiracy against the public, or in some contrivance to raise prices." Present company excepted, of course.

After this catalogue of hazards, an antitrust approach might appear to be simple. It is not. The reason, of course, is that standards-making also presents opportunities for important benefits, including competitive benefits. (I can be briefer about these effects, since I assume you will readily concede them.)

Product simplification, such as uniform screw sizes, provides the advantage of interchangeability of parts, and convenience to the user. There is no exclusionary effort since all producers can conform to the standard sizes and, in fact, interchangeability makes it easier for new firms to enter and to supply the market. As to the narrowing of the diversity available to consumers, in this situation diversity would be more of a confusion and a nuisance than an advantage. The formulation of standards can also be a channel for acceptance of new technology, the spread of innovation, the improvement of product quality and so forth. The adoption of standards for size, quality grades and performance criteria can help consumer choice by facilitating product comparison in terms of price, quality and performance. This also can have substantial benefit to competition. Adoption of quality standards, for example, would enable a new entrant to demonstrate that his Brand "X" is as good as anyone else's. Standards can moderate the influence of brand promotion unrelated to actual product differences, and should direct marketing attention to more objective aspects of the article. And quality standards are not necessarily mandatory. In many lines, standard and non-standard products coexist, and any substantial demand for deviation from the standard tends to be readily met.

## Developing Adequate Criteria

It is apparent that, from the standpoint of antitrust policy, any sweeping endorsement—or condemnation—of standards-making would be quite out of place. The problem is to distinguish among standards, and to develop criteria and procedures which would avoid or remedy adverse and unwarranted effects.

Here, it must be acknowledged, some of our favorite traditional antitrust propositions do not prove to be equal to the job. I refer to principles which were developed to cope with restrictive agreements among competitors. The antitrust approach has been to stress single-mindedly the requirement of independent action by companies on important competitive matters. The familiar cases involve pricing practices, allocation of territories, or refusals to deal, but there is language in several cases broadly condemning agreements to limit any kind of independent competitive activity. Agreement, conspiracy, all forms of concerted action are prohibited; and illegal agreement can be inferred from one party's proposal to take certain action and subsequent conduct conforming to the proposal, even without overt expressions of agreement.

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More to the point, in imposing such rules, antitrust has tried to avoid evaluating the quality or effect of proposed concerted action. For example, price fixing is held illegal without consideration of whether the prices arrived at are reasonable or unreasonable. In a famous case, in 1941, the Court struck down a plan in the textile and apparel industry, in which the participants sought to eliminate what they called the "piracy" of designs or styles. They did so by agreeing not to do business with anyone handling such goods, and imposing other sanctions. The Court held that even if the "piracy" was a tort under state law, the antitrust laws prevented the companies from combining to stop it by boycott, exclusion of competitors and other restrictive acts.

## Implications for Standards Organizations

It is disconcerting to consider the possible implications of these doctrines for the basic process of standards-making. The formulation of standards, of course, requires concerted action by representatives of competing companies. The lawyers may assure you that the standards are voluntary, and that there is no problem so long as there is no agreement by the participants actually to follow them. But as I have indicated, if the parties in fact conform to the standard, and stop dealing in non-standard products, that can be enough to prove agreement for antitrust purposes. Furthermore, it is often clearly contemplated, when a standard is adopted, that all members of the industry will follow it, and that the non-standard product will be eliminated. This may, indeed, be inevitable in certain situations, when dealing with standards which are customarily adopted or incorporated in building codes or other law. And as for the plea that the parties were merely working as technicians, with no malicious intent to injure anyone, you may be interested in the well-established antitrust rule that parties are found to have intended the natural and foreseeable consequences of their conduct.

What has been the actual impact of these antitrust propositions on standards making? The answer is, almost none. I referred to a few cases in which standardization was enmeshed in price fixing or other conventional violations, and there were several challenging the arbitrary withholding of certifications or inspections. But in the main, until recently, the inconsistency between standards-making and traditional antitrust principles was ignored. That is, antitrust maintained inviolate its rules demanding independent conduct, while standards-making flourished, and the number of standards proliferated. This had the perhaps regrettable effect of widening the gap between anti-

trust rhetoric and enforcement. But it had the virtue of avoiding the considerable intellectual effort needed to come to grips with the problem.

## Clarification of Policy Needed

Recently, it has become apparent that this advantage would have to be foregone and that antitrust enforcement would have to deal with the standards-making process. Several factors have led to this turn of events. The government has gotten more and more deeply involved in standards-making. In part, this is through the greater use of the government's own procedures for developing voluntary standards, under the aegis of the Department of Commerce. Also, there has been increased interest and participation by federal agencies in private standards organizations. These activities have enlarged the experience and sophistication of government personnel with possible adverse effects of standards, and has caused them to raise issues as to potential antitrust implications.

Moreover, Congress has directed the government to undertake standards-making, such as in automobile safety, tires, and fair packaging. And pressure has been applied, by Congress and others, to stimulate voluntary standards-making in additional areas. In some cases, as I indicated, the response of private parties was to cite the antitrust rules against joint activity as an obstacle. These events, again, have called for clarification of antitrust policy.

Finally, if more were needed, several lower courts, presented with a choice between the *per se* antitrust rules, and deference to standards-making bodies, unhesitatingly chose the latter. This occurred even in cases with clearly exclusionary standards, having very questionable justification, and even though technically a boycott appeared to be involved. The courts seemed to assume that private standards were presumptively reasonable. One judge said he would not "impugn the integrity" of a standards-making organization, which was "dedicated to promote public good"; another thought it bad form even to inquire into the "internal affairs" of such a body. We can attribute these results, at least in part, to the absence of coherent antitrust criteria which distinguish anticompetitive standards practices from others.

Fortunately, antitrust is not utterly without resources to move with the times. In some ways, the standards context is analogous to other situations where it has been recognized that joint, cooperative or concerted action was essential or justified. Examples can be cited from litigation involving such diverse operations as the New York Stock Exchange, a press wire service, a produce market, even a pro-

fessional sports league. In such cases, the antitrust courts did not seek to prevent the joint or concerted operation. But on the basis that this joint or concerted action of competitors gave rise to important economic power, it was held that the antitrust law imposed certain obligations and conditions. The concerted operation was required to provide to others fair and nondiscriminatory access to the market, and it could not impose restrictions on participants or upon others which went beyond the needs justifying the joint endeavor.

## Proposed Guides

This approach can help us formulate a general rule of antitrust policy for standards. I suggest the following proposition: The antitrust laws would be violated by a standard which has substantial effects in excluding competitors or restricting consumer choice, unless justification can be shown. Further, to the increasing extent that a standard has a restrictive or exclusionary character, and is likely to be followed and enforced, the makers of the standard have an increasing burden to show justification and need.

There has been a suggestion that only urgent and unquestionable safety needs would support a standard that was intended to and did have the effect of keeping goods off the market. Others have urged that private mandatory standards may be justified by a context of public regulatory activity, particularly when it is contrary to the parties' economic interests (like the networks agreeing to eliminate cigarette advertising). I believe that the law should be, and is, flexible. But where only efficiency and durability are involved, not safety, especially then should there be consideration of whether less restrictive arrangements could satisfy the need.

Does this mean that standards-making is so beset with pitfalls that it should be avoided? Of course not. But it does mean that there is an antitrust impetus (including treble damages) which should support and encourage the more desirable standards-making activity, the kind that you would prefer to engage in anyway.

Obviously, there is no difficulty about uniform screw sizes, or other standards with no restrictive or exclusionary effect. Also, it is important that the standards are voluntary in fact, and not only in theory, since this would leave room for competitive options and responsiveness to consumer demand. When there are restrictive effects, they must be justified on the ground of technical requirements, or public need. And there is a strong preference among alternatives: in favor of standards framed in terms of performance rather than in

specification of materials and configuration; in favor of standards which provide comparability information and grading levels, rather than a single requirement; in general, in favor of flexibility and adaptability to new technology, and changed circumstances.

I suggest that these are not mere pious hopes, or appeals to your nature. They are guides which are likely to be subject to enforcement by antitrust remedies. Despite the lower court case law, you should not rely upon a general presumption of reasonableness and decent intent. You cannot rely for long upon the alleged dignity and repute of a standards-making body, as putting a heavy burden on any party who has the temerity to challenge a standard. On the contrary, when restrictive or exclusionary effects are involved, the burden is upon those who develop and enforce the standards.

This analysis is intended to signal the direction in which antitrust policy and enforcement can be expected to move. Of course, it also has important implications for the make-up and the procedures of standards-making bodies. For they should be organized in such a way as to avoid unwarranted restrictive or exclusionary effects, and hence the risk of antitrust exposure.

## Essential Considerations

Two points are particularly significant. First, it is important to assure full representation of diverse and conflicting interests in the standards-making process. This should include not only producers of the product, but commercial purchasers, disinterested technical experts, representatives of the general consumer interest, etc. The purpose is to develop standards on the basis of the fullest consideration of all interests. Moreover, it is essential to bring any adverse effects out in the open so that they can be given full weight.

Second, the standards-making process has to provide for weighing the substantive consequences of standards. It just is not adequate to have a standard developed by a limited group, with high-level review only for the purpose of determining whether a consensus existed. The proper approach is indicated by the procedures of the Department of Commerce. Its regulations explicitly provide for a review which looks not only for a consensus, but also for a determination that the standard is technically justified, and that it is consistent with the public interest (which would include the interest in competition). As a corollary, there has to be provision for prompt and efficient amendment, in response to changes in technical knowledge. This is needed to prevent restrictive effects of obsolete standards, and to avoid blocking the introduction of new products.

## Efficacy of Voluntary Standards

The reference to consensus suggests one important point about the efficacy of private standards-making in areas of consumer interest and safety, with which I will close. Modern antitrust policy does not take quite the jaundiced view of business behavior as did Adam Smith in the quotation I cited. But it does assume, with reason, that in the long run business and corporate behavior is governed by economic interests and incentives. This places obvious limitations on the role of voluntary industrial standards.

In some situations, the conflict of economic interests is so great that it is futile to expect private standards-making to resolve important disputes. A recent illustration was the controversy over lumber standards between the green and dry lumber producers, which was finally settled only on the basis of the disinterested technical judgment of the U. S. Forest Products Laboratory and the standards authority of the Commerce Department.

Similar problems may arise in the area of consumer standards. Thus, there is a public interest in quality or grading standards to assist objective comparison of products. But with some products it is difficult to imagine a voluntary consensus on this point, in which manufacturers would cooperate. The difficulties are more critical in the safety field. There can be competitive advantages and incentives in selling safer products, but there may be many situations in which private standards-making would tend to arrive at the lowest common denominator. You have heard of the recent antitrust suit against the automobile companies, involving the joint industry program on anti-smog devices. Here, the Department alleged that the result of the cooperative program was not to advance development, but to retard it and to deter individual initiative. The automobile safety field, also, is one in which standards-making calls for complex balancing of various factors, such as technical feasibility, effect on the accident rate and cost, and in which mandatory standards are an overriding public need. It requires the kind of judgment which we ordinarily expect of a public agency, not a private organization, and it has become, therefore, a government function.

In short, there are significant limitations to private voluntary standards-making. Nevertheless, there will continue to be a large domain in which it will operate, with potential advantages and risks. In that domain, antitrust might cause you some anxiety, but I suggest that it can also be of service. **[The End]**

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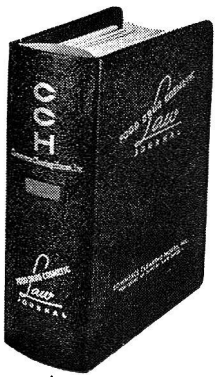


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