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# Food Drug Cosmetic Law JOURNAL

## Additional Papers Presented at the 20th Annual Educational Conference of the Food and Drug Law Institute, Inc. and the Food and Drug Administration

A COMMERCE CLEARING HOUSE PUBLICATION
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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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# FOOD DRUG COSMETIC LAW JOURNAL

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# FOOD DRUG COSMETIC LAW JOURNAL

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## TO THE READER

**Twentieth Annual Educational Conference of the FDLI and the FDA.** The following papers were presented at the 20th Annual Educational Conference of the Food and Drug Law Institute and the Food and Drug Administration, which was held in Washington, D. C. on December 7th and 8th, 1976.

In his article "What the Consumer Should Know About Food and Drugs", *Walter A. Compton* discusses the importance of self-care medication. He states that the Food and Drug Administration has the ability to help insure the public that the quality in this area of medical care is steadily improving. Dr. Compton is Chairman of the Board, Miles Laboratories, Inc. The article begins on page 52.

"Remarks" by *Sherwin Gardner* beginning on page 59 deals with labeling as an instrument of communication with consumers. The article states that labeling should help consumers make informed choices regarding products and that this information should help them more effectively when using products. Mr. Gardner is Acting Commissioner of Food and Drugs of the Food and Drug Administration.

*Monroe E. Trout,* Vice President and Director of Medical Affairs, Sterling Drug, Inc., states in "Drug Licensing" that clinical and toxicological data should be made public in order to prevent an impression of secrecy which would lead to suspicion of the drug industry and the Food and Drug Administration. Dr. Trout also states that if valuable drug study and research, by a research company, should continue and be effective, then generic manufacturers should be required to pay a royalty for manufacturers' licenses to the research company in order to enable further research. The article begins on page 63.

"Some Homework Is Needed" by *Alexander M. Schmidt* states that in order to create beneficial change in the Food and Drug Administration, the single most important thing to do to improve the ability of the Agency is to recruit and retain a professional staff. Dr. Schmidt, former Commissioner of Food and Drugs for the Food and Drug Administration, is Vice Chancellor for Health Services, University of Illinois. The article begins on page 67.

*Richard B. Herzog,* Assistant Director for National Advertising, Federal Trade Commission, deals with whether certain warnings appearing on labels for antacids, should also appear in the advertising for those products. His article "The Antacid Warning—Rulemaking at the FTC" begins on page 76.

*Murray D. Sayer* explores the question of "how safe is safe" with respect to our food supply by examining some of the methods by which the conclusion of safety is arrived at. Mr. Sayer is Assistant General Counsel, General Foods Corporation. His article "How Safe Is Safe—The Legal View" begins on page 85.

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# What the Consumer Should Know About Food and Drugs

By WALTER A. COMPTON, M. D.

Dr. Compton Is Chairman of the Board, Miles Laboratories, Inc.

IT IS A PLEASURE to participate in this session and to discuss the important subject we have before us. There is so much to be said about it that the problem is to be specific within the limits of our time. My experience with the Food and Drug laws of the United States goes back to 1938 with the then new Food, Drug and Cosmetic Act when I listened to the Commissioner, Walter Campbell, address himself to the problems attendant upon a properly regulated use of home medication and especially the "new drug" innovation which arose out of the elixir of sulfanilamide incident. From that time to the present, the succeeding years have been ones of enormous change; with wholly new concepts in drug design, we have seen the face of illness across the land change dramatically, especially in infectious disease where a host of medical problems, at one time nearly always fatal, have substantially disappeared.

## Concept of Antibiosis

With the advent of the concept of antibiosis, the chemical and pharmaceutical industry became the pacesetters with one new "miracle" drug after another largely replacing most of the old "official" remedies of the compendia. Additionally, a medical student of those days was taught that considering the extraordinarily complex process for the development of an infant before its birth, it was not surprising that this would occasionally be faulty, and there was no thought given to the fact that these faults might be caused by extrinsic toxins! We are

soon to learn that indeed they could! Again the notion, which today is taken for granted, that we might he able to pinpoint precipitating agents which could cause malignancy began to get attention, and the word "carcinogenic" suddenly became very important both in research and in food and drug law. These comments are only to put matters in perspective and to emphasize how very much has happened since the passage of that act of 1938.

In that same period, home medications and so-called "over the counter" medication, as distinguished from that mediated by the professional, also began to come of age and with it came an increasing recognition of the important part it can play in the overall management of health care. In London six years ago, a Fellow of the Royal College of General Practitioners, Dr. John Fry, stated:

"Self care is important operationally, and also economically. In developed societies such as Britain, Germany, the United States, Soviet Union, and others, it is not sufficiently appreciated that only one-fourth to one-third of all the people who suffer from any symptoms at any time take the step to seek medical advice. In other words, two-thirds to three-fourths of all ailments are self-managed by the individual and by the family without seeking professional medical advice. This is as it should be because otherwise the whole medical care system would completely collapse."

He brought into contrast a visit to East Africa where, without facilities for good home medication and with a public uninformed and uneducated in the field of self-care, he saw health clinics crowded with all sorts of cases not with the major and exotic tropical diseases that he had anticipated, but with masses of minor ailments which in the British context should have been treated by the people themselves. He then went on to call for further improvement in education, for much better and more accurate knowledge about the medicines used in self-care and the essential collaboration of industry, of government and of the medical profession, together with help of public communication to achieve still better efficiency in this area of medicine.

## Program of Collaboration

Well, we are gathered here as a part of that very program of collaboration. In the United States, the Food and Drug Administration, with its advisory committees and with expert panels to study the efficacy and safety of self-care medication, has within its hands the ability to help insure that the public has a steadily improving quality in this important area of medical care.

While efforts by both government and industry are greatly improving the quality of self-care, I am concerned about some basic

principles which should attend this effort and which too easily may be overlooked. These were well highlighted by the questions asked of the panelists in this session when it was suggested that we speak on "What information consumers *need* to know, what they *want* to know, and what they *don't need* to know— and how best to communicate that information."

To begin with, those who are not medically trained are occasionally apt to overlook what most doctors know—that medicine is still very far from being an exact science, that drugs have great varying degrees of effectiveness under varying circumstances and from one patient to another, or even in the same patient from one time to another; which is to say that *"effective"* is *a relative and not an absolute term.* Secondly, its corollary, which is that the use of an effective drug involves an infinite and changing variety of circumstances of individual biochemistry and personal idiosyncracy, and thus can never be termed wholly safe under all circumstances. Both *"safety"* and *"efficacy"* then are *relative terms* and that very important fact must be kept in focus in writing and administering new law.

Professionals realize that for every benefit in medical care there is and always will have to be a variable degree of attendant risk and, therefore, law and regulations are impossible to write with exact precision; administering the law constantly entails determining whether or not the benefit achieved merits the risk to be taken. Obviously, when dealing with the medical management of an illness, which left untreated involves a high risk of mortality, a high-risk medication which is capable of making a measurable improvement in the comfort and life expectancy of the patient despite that risk well merits being used. At the other end of the spectrum, where the medical problem being attacked is self-terminating or is not one which could be expected to be of long duration or very severe, the degree of acceptable risk becomes much smaller in the choice of the medication used. Both industry and government must constantly address these and like matters in their efforts to serve the public well. Just as the public must continue to have access to and use of well-tested, usually long-known, familiarly beneficial and helpful home medication, at the same time both industry and government must see that such medication has been subjected to adequate research study, that it is as well understood as possible, that its usefulness is clearly described in labeling in such a way that the public can clearly understand it and that if indeed there be limitations on its usefulness, these be defined so the labeling can condition its proper use.

## Labeling

In addition, it is important that the labeling of these home-medication products be couched in such simple terms as to be readily understood not just by the professional, but far more pointedly by that large mass of the public which requires use of straight forward vocabulary and simply understood terms of description. For example, the word "stomach" means vastly different things to the anatomist and to most members of the lay public. The more professional the consultant in this area, the more likely, it seems to me, that he will err without being aware of it. In an effort to be precise, as would be in the case of writing a pharmacology textbook and due to careful intent not to omit some obscure side effect, the professional tends to bring to the problem matters which relate to the professional management of severe illness but which may have little to do with the ordinary circumstances of consumer use or practical considerations of safety and efficacy. For example, this is a plea for the labeling to go directly to the use of such well-understood terms as "the common cold," relying on the public to know well what is meant; to avoid such expressions as "antitussive," when what is meant is relief of cough; "antipyretic" when what is meant is reduction of fever; and "analgesic" when we are simply talking about relief of pain. Also, I see little reason for worrying the public about the relative appropriateness of such common and well-understood terms as "sour stomach," "heartburn," "acid indigestion" or "upset stomach" when it is much more practical to emphasize the fact that if discomfort is severe or not readily relieved, or if it tends to recur frequently, that one should bring it to the attention of the professional before going further. The public might also be advised of the fact that if one is currently being treated for a serious illness by a professional then he should take no medication of any kind without the professional's knowledge and agreement. After a lifetime in this area, I am convinced that the public is not foolish and that it most often is capable of telling the purposes for which a medication is intended, whether or not a medication is helpful, when to discontinue it and to seek elsewhere for relief.

## Professional Medication

The discussion should include the special problems of professional medication, however, it is a subject much too vast for the time available; therefore, I will comment only on an important single recent development. There is an increasing demand that the patient be permitted to look over the shoulder of the professional and to

know much more about how he is being treated, with what he is being treated and the rationale involved. In this area, physicians are in a quandary because every physician knows that there are many areas of illness and many patients with whom too much information is a disservice. It can largely negate the effectiveness of the medication recommended and/or even be dangerous and this could seriously frighten the patient and make him reject essential therapy. There is a current trend to include a rather detailed, technical leaflet in professionally recommended medications which may indiscriminately reach patients and remove that very important opportunity for judgment, or at least an explanatory comment, which should be the professional's prerogative. Perhaps the most important thing that need be said here is that it is essential to go slowly and carefully.

## Nutritional Qualities of Food

Turning to the matter of food, some of the basic considerations that have already been described apply here as well. The public is demanding and beginning to receive more information about the nutritional qualities of foods purchased; there is, however, room for improvement. With the development of urban living, it has become increasingly impossible for the consumer to grow his own food and in turn economics require extended lines of food delivery and techniques of mass production. These altered conditions present additional problems of new compositions of packaging materials and of food preservation against spoilage and against biochemical deterioration. "Food additives", therefore, become essential. Problems attendant upon this are sure to increase rapidly as time goes on and as the raw material base from which food is derived becomes altered. For example, this country is one of the very few in the world in which the consumer can, as a matter of choice, eat such a high proportion of his protein derived from animal sources. But with a more than ten-fold increase in land productivity of food from vegetable sources, it is very evident that even in the United States there is a trend towards field-grown food with vegetable protein taking up a larger proportion of the dietary. With this, there is an important fact that may escape sufficient attention. In the case of drugs, the presence of an impurity of substantial toxicity is not tolerated although it can be of little or no consequence in a medication that is taken in terms of milligrams once or twice a month, a year or never again in a lifetime. But as we move to food products, where a food or a beverage is ingested in a very large quantity daily (or even several times a day), and taken in terms

of ounces or even pounds (instead of milligrams), even very small amounts of such toxic substances can become highly significant throughout the lifetime of the individual. At the same time, with the sheer mass of material being handled, beginning with the raw food product in the field and going through all of the processing steps which are essential in today's requirements for mass production, mass merchandising and extended delivery lines, the problems of quality control with the difficulty of securing adequate representative samples (as, for example, from a warehouse full of sacked grain) becomes evident and quite in contrast to pharmaceutical products where precision quantitative analytical procedures can be applied, both to the raw materials and to the in-process and finished product. Since literally such sampling thoroughness is impossible with most bulk foods and the potential for a variety of contamination is more infinite without precise knowledge of what one is looking for, and since biological testing poses an almost impossible economic problem both in sampling and in experiment design, the attention to the problem, up to now, has principally required an awareness of the more significant toxic adulterants which must be suspected, looked for, prevented from contaminating food and to conduct a careful search when the epidemiologist senses that there is something wrong.

## Polychlorinated Biphenyls

The current inquiry in the case of polychlorinated biphenyls is exhibiting just such a problem in my neighboring state of Michigan. All in all, it is not going to be solved simply by the passage of another law and it is clearly evident that no easy soluton is at hand. The public cannot stop eating while we try to solve the matter in total detail and the most intimate kind of association and dedicated involvement between government, industry, the epidemiologist and the physician becomes important. It is an area of concern which is only just beginning to come sharply into focus and which I believe will have to receive a great deal of increased attention.

## Conclusion

In conclusion, in all the intense activity going on in the subjects we are discussing, certain basic principles seem to me to stand out as having high priority. Both with food and drugs, it seems to me that the public has a right to have clear labeling, that is with the use of simple, commonly used and understood words and phrasing and with the use of *only* those terms which can be genuinely *helpful*, especially in the case of food and home medication where the public is to decide

whether it does or does not want to employ either that food or that medication and how to use it properly. This should be the function of labeling. Secondly, the labeling ought to be kept clean and clear and not confused with matters of promotion. Advertising, on the other hand, should, of course, not be either false or misleading, but neither do I think it should attempt to intervene in the functions of labeling. Outside of this, to tell the public as much as it can about why the product should be used, the circumstances of its use, with perhaps some visual demonstration of its use, and all this without exaggeration or deception becomes its essential requirement for the consumer. A further basic objective and opportunity of both labeling *and* advertising is assistance in education of the consumer in the proper role of home medication and in basic principles of nutrition.

Finally, in labeling particularly, I am often reminded of the analogy of the busy and dangerous intersection protected on the access roads by clearly evident stop signs; but if, in addition to the stop sign, the margins of the highway are cluttered with all sorts of extraneous or even important information, it is all too possible that the most essential piece of information, the adjuration that before entering on that intersection one must come to a complete stop, will not be noticed. It is a real disservice to the public to clutter labeling with less essential information which is not genuinely helpful, which can confuse, which may unnecessarily frighten, and is perhaps of little real use to the consumer in his efforts to choose wisely and use wisely the medication and food which he needs in his home. **[The End]**

# Remarks

By SHERWIN GARDNER

Mr. Gardner Is Acting Commissioner of Food and Drugs of the Food and Drug Administration.

I THINK if someone were to review the recent history of the Food and Drug Administration (FDA)—they would probably find that labeling issues concerning foods, drugs, etc. were preeminent among the matters we have dealt with—and are dealing with. Of course, you might say that is appropriate and is to be expected. After all, the Food, Drug, and Cosmetic Act is built around two principal concepts by which products can be controlled; misbranding and adulteration. Since misbranding connotes the use of information, perhaps, it is reasonable that half of the Agency's efforts should be applied to labeling of the products we regulate.

## Labeling

Labeling is not simply a legal handle for controlling products, but is also an instrument of communication with the consumers. Today, it is not enough that labels tell the truth—they are being called upon "to tell the whole truth" as well.

Thus, labeling issues consume an increasing share of the effort spent by the Agency. So much so that I have the impression that 50 percent of our effort is a conservative estimate of what we allocate to labeling matters. Certainly, that is true in the policymaking area, and also, I suspect, in what occupies the time of our legal staff. That is notwithstanding all the other issues that have been raised requiring our attention and effort—issues concerning ingredient safety, administrative procedure, good manufacturing practice, etc.

## Product Information

Having been exposed for the past six years to this intense interest by virtually everyone about product information, I felt a certain uneasiness in approaching the subject of consumer knowledge about foods, drugs, etc. from the viewpoint of trying to decide what is needed or wanted. What is needed is whatever consumers perceive they need.

Need is a highly subjective factor and is not—or should not be—the issue. I think it is possible to state "needs" in a very general way and obtain universal agreement with such a statement. For example, one "needs" to know the *identity* of a product: Does the package contain chicken soup, applesauce, or macaroni? One also "needs" to know the *quantity* of a product: Is it a ton, a pound, an ounce? Similarly, one "needs" to know the *cost* of a product and *how to use* it: Should it be boiled, broiled, fried or poached?

It is when we get to the next level of definition of need that we run into trouble in agreement on what the consumer should know.

(1) Does *identity* extend to the knowledge of all ingredients and the amounts of those ingredients?

(2) Does knowing *how to use* a product extend to the knowledge of side effects of drugs, and the risks associated with the use of those drugs?

These kinds of questions are the ones we are now grappling with. They are better discussed in terms other than need or want—or even the right to know. Right to know should be a "given", or at least not an issue to debate, in considering what information to provide. I believe it can be far more useful to discuss the subject in terms of the *utility* of information. After all, what is information for?

## Informed Choices Regarding Products

In my view, it should help people make informed choices regarding products. It should help them to act more effectively in their own self-interest when using those products. Thus, I would suggest the most fruitful starting point would be to pose questions in terms of the *purposes* to be achieved by the information:

(1) For what purposes could the consumer use information?

(2) In what ways would information be helpful in identifying what a product is, how much of it there is, and at what cost, and how to use it?

With the answers to these questions, we could then move on to the next step—examining the question of *how* to communicate. This is a question that, in turn, subsumes other very important questions:

(1) How much will it cost to provide the information?

(2) In what format should the information be provided—on labels, or in some other way?

I believe it would be relatively easy to make judgments about most of the widely debated issues of today in this context of their utility for consumer decision-making.

## Nutrition Labeling

People who wish to use nutrition labeling for comparative purchasing decisions or for dietary purposes certainly can do so with the information now provided on many products. People who wish to regulate their consumption of certain ingredients could do so if all foods declared their ingredients. People who need to use prescription medicines would be better able to use and understand the implications of using these products if they had understandable statements on hand concerning precautions, possible side effects and detailed instructions to follow.

It is clear that many people today are saying they want more information about the products they use—"more" meaning either different *kinds* of information or more *detailed* information than that now provided. Of the various items of information that consumers have indicated they want, I think there is little that could not be put to use—in a constructive way by many, if not by most people.

## Product Information

Why, then, is there a debate over providing such product information? Clearly, there are other factors involved that are implied by the title of this session, questions that go beyond "want" or "need" or "how to provide."

Cost is one such factor; obviously, someone is going to have to pay for new labels and for the development of information if it is not already available. There is also a regulatory maintenance cost—if the information is provided, the FDA or the Federal Trade Commission—or somebody—is going to be monitoring the information to be certain it is accurate and not misleading. The provider, too, is faced with new costs resulting from the need to continuously assure that his product is as represented by labeling or advertising. Certainly cost is a legitimate factor that should be considered in reaching decisions over providing product information. There is a cost/benefit evaluation to be made in a number of product information decisions. I believe that evaluation can be made if industry and consumers and government are willing to approach these issues objectively and to explore optional ways of satisfying product information objectives.

I, also, am concerned about other aspects of providing information to the consumer—aspects that are not addressed directly but, again, are implied by the title of this session.

## Vested Interests Issue

I looked for a euphemism, but could not find one, which may be a good thing, since I want this to be a frank discussion of the issue. So, I have called it as I see it—the vested interests issue.

You will find this issue lurking at the fringes of most labeling debates and, sometimes, it is at the very heart of them. It is often obfuscated by using some other aspect of labeling as the reason why to do it or not to do it. It arises when some group does not want to make information available because it may become a competitive disadvantage, or because it is perceived as being beyond the public's ability to deal with it. And sometimes the vested interest issue arises both inside as well as outside government when lawyers, scientists and educators insist on structuring information so that it satisfies their very narrow technical interests, but is of little use to consumers.

I have chosen not to illustrate any of these vested interest issues, for obvious reasons. I thought it useful, however, as the only non-professional labeler here, to make the point that there is some sensitivity to this aspect of the subject within the FDA. I hope that, from time to time, we will all step back from peering at words and phrases under an electron microscope and ask ourselves, "Is this useful information, and is it being provided in a way that it can be understood, and used, by the consumer?"

To summarize:

(1) What consumers need and want to know is what they say they need and want to know;

(2) The costs and feasibility of satisfying those needs, and the trade-offs involved, must be described for consumers by industry;

(3) The difficult task of making judgments about information to be provided falls to government. There are few black-and-white issues here and compromise is not a dirty word but a way of achieving realistic, meaningful results. In this case, it takes three to tango. **[The End]**

# Drug Licensing

By MONROE E. TROUT, M.D.

Dr. Trout Is Vice President and Director of Medical Affairs, Sterling Drug, Inc.

FIRST, LET ME SAY that the following comments are my own and do not necessarily reflect the position of my management or any other group in the pharmaceutical industry.

It is recognized by most that a new drug application (NDA) is a private license to market a drug. It must contain all the animal and human data necessary to show that the drug is safe and effective and such data in the application are considered trade secrets. If the data are not published in the medical literature, obviously they would not be available to another manufacturer in support of an NDA for the same drug.

## Investigational New Drugs

Certainly there are good arguments that such data should be proprietary during the investigational new drugs phase so that competitors cannot use it for comparative purposes in their own research. Also, there is really no great public interest in such data until an NDA is approved. If "the only practical option open to critics of the current system is to suggest ways to improve the system that are clearly recognized by the public as in the health interest of the nation. then one could make the argument that such data be made available when the NDA is approved." There are good public policy reasons why clinical data for an approved NDA should be made public.

First of all, there are only a limited number of clinical investigators in the United States and most of their time should be devoted to totally studying new products. Secondly, the resources of both time and money could be better spent in developing new drugs than repeating work on older products. I might add this same argument applies to the many demands of the government for studies on products which have been in use for decades.

## NDA Concept

It has been stated that the primary problem with the NDA concept is that it does not provide a rational mechanism for generic manufacturers to enter the market when the innovator's product approaches the end of its patent period. Why does the government want generic manufacturers to enter the market? Obviously, for one reason and one reason only, and that is economic.

Now let us get to the nub of the question and be totally pragmatic about the situation.

The FDA states that it makes no decisions with any concern for economics. That is fine. But, there are other groups within the Department of Health, Education and Welfare, such as the maximum allowable cost plan group, which are making economic decisions affecting the industry. And in fact, there are some, although I am quite certain it would be denied, who believe that the reason for the long delays in the FDA approvals for new NDAs is to permit the patent period to run further so that the product will become generic much more quickly.

I have no quarrel with making clinical efficacy data available to anyone after the NDA is approved. As a matter of fact, in the name of science, it should be made available to anyone. Why is this not so? It is purely economic. Why should one company spend seven years of its valuable resource, which is people, spend several million dollars on clinical research and perhaps another half-million to one million on toxicology, only to make it available to any generic manufacturer who wants to use it in order to put out a product at a much lower cost because he does not have to perform the studies himself?

## Drug Monograph

I have no problems with the concept of a drug monograph and a manufacturer's license. However, before a manufacturer is granted a license for a product off patent, he should be required to pay a royalty of a fixed percentage of his total sales to compensate the company which is really providing the innovation and the new research in the industry. That percentage could be as low as one-quarter to one percent of total sales for products off patent. If such a requirement was made and the FDA would not issue a manufacturer's license until the generic manufacturer agreed to pay such a royalty for the other company's data, then I am quite certain that the problem would disappear. Also, in order to stimulate research and to keep manufac-

turers in the research business, I would even suggest that the royalty which is paid by a generic manufacturer for the use of the original company's research must be used by the original company for additional research. In this way the system would stimulate research and not inhibit it as is currently the case.

In addition to this, I believe that the FDA must adopt a single standard both for small generic companies and large manufacturers. How often have I been told by outside contract manufacturers that if they had to comply with the same quality control requirements and manufacturing requirements as our company, they would be out of business tomorrow. It is no wonder that they can sell their products at a much lower cost when their quality control and manufacturing requirements are much less and they have to pay nothing for the research.

## Clinical and Toxicological Data

I also agree with the FDA that clinical and toxicological data should be made public so that there is not an impression of secrecy created which would lead to suspicion of both industry and the FDA. I also think it would have another salutary effect and that is that it would lead to quicker approvals of NDAs which are being held up for pedantic reasons. If the non-publication of such data causes deep resentment among the FDA staff and management, who are obliged under criminal penalties of the law not to reveal the data or the reasons for their decisions whenever a drug is disapproved, then I say open the data to the scientific community and let them decide themselves whether the reasons for refusal are valid on scientific grounds or merely being made on procedural grounds, or because the reviewing officer, due to his lack of expertise, is reluctant to make a positive decision.

Dr. Crout has couched most of his arguments in favor of publication in terms of the health needs of the nation. However, I believe he ignores the economics which creates a two-way street, even for the health needs. If the government is going to require the innovator to give up a property right (which might be unconstitutional) so that another company can come into the business and compete with him at a lower cost because of less expense, then the FDA must be concerned that manufacturers will get out of the business of new drug research. This is not an idle threat and it would benefit no one. It is one that most of us who are in this business on the research side live with on a daily basis. How does one answer management that says, why should I spend ten million dollars on a product which only has a two-year

patent life left because of the tremendous research demands which are time consuming and the long delays in regulatory approval, only to make all of our data available within two years so that another manufacturer can sell at a price which would put me out of business? Why should I support a research operation for that purpose? Can I justify to the stockholders spending that kind of money on research for that kind of return?

It is time that we become pragmatic and look at the real issue instead of couching all of the arguments in terms of platitudes such as the good of society, scientific honesty, no secrecy, etc.

## Service Products

There are many who decry that the industry no longer brings to the market what used to be called service products. There are still many service products provided by industry which were developed a long time ago and which are not profitable to carry in their lines, but are manufactured for sale at a loss because they are needed by a small group of patients. Our company has several of them, and I am quite certain that every other research company in the business has its share. However, it is no secret that such products are not being developed any more because of the tremendous expense of both basic and clinical research. Such resources need to go into areas where the need is greatest, such as arthritis, hypertension, cardiovascular disease, and cancer. I am quite certain, however, if generic manufacturers were required to pay a royalty for manufacturers' licenses and that money was required to be spent on research, that such service medicines again would be studied by the industry. Again, it is a matter of economics, and even though we do not like to talk about the subject, if we are going to continue to be the country which leads the world in innovative new drug research, we must talk about it. We must consider every regulation, every requirement of every regulation and its economic impact and whether the cost/benefit ratio is on the positive side.

There are some who suggest that the government take over all drug research. That has been done in other countries and I can only point to the complete failure of the system in Russia where this is true. If, indeed, we are vitally interested in the health needs of society and not just our own little empires, our own job security, our own power bases, then we must begin to talk openly about the subject which everybody wants to ignore, and that is economics. **[The End]**

# Some Homework Is Needed

By ALEXANDER M. SCHMIDT, M.D.

Dr. Schmidt Is Vice Chancellor for Health Services, University of Illinois.

AS MOST OF YOU KNOW, I have now been a former Commissioner of Food and Drugs for one week, and have been undergoing a transition of my own. The several weeks just passed have been rather difficult for me, for several reasons; although they also have been nice, for many other reasons. The time has been difficult because I tried to get a lot of things done. I visited many people in order to conclude some business and to try to express my appreciation to them for the support they had given the Food and Drug Administration (FDA) and me during the past three and one-half years.

I also had to say "Goodbye", or at least "Auf Wiedersehen" to a lot of people; and goodbyes come hard. In particular, taking leave of the FDA staff was hard for me to do. Among the many people who became my warm friends during my term as Commissioner, and among those who cared deeply about the FDA and the quality of its leadership, the FDA staff has to come first. I owe them more than I can ever repay.

## FDA Staff

But November was kind of nice, too. First of all, thanks again to the FDA staff, we did get a number of things done, some other tasks started and a few difficult items moved along their way.

Secondly, a lot of people said some nice things about how and what the Agency and I have done during the past several years. Some of what was said was undoubtedly ritualistic; but if even 10% of the rest were true, then my time and effort these past few years would be made good many times over.

Among the things frequently said to me were, "I think you're in for a culture shock when you return to Chicago," and "Be certain to let us know what it's like to leave a job like you had."

## Transition Back to Academic Life

Well, my transition back to academic life has gone very smoothly with only one or two small hitches. The first morning back, I was very late to work because I waited at least an hour, but no one came to drive me to work. Finally, in desperation, I drove my own car, narrowly escaping disaster on the Eisenhower Expressway several times when I got too interested in what I was reading.

I did get to work and I liked my new office, even if it is a bit crowded when I take my briefcase in with me. I learned I did not have a private bathroom, so I asked for a key to the Executive Washroom. I then learned that this did not exist either. Actually, once you get the timing down, walking across the street to a bathroom is not bad at all. And there are advantages to my new job. I am getting to use my letter opener, I am typing and I am discovering all sorts of other long lost skills.

While coming back here today, I tried to get on first class, but was told that busses are all one class. There was a bathroom on the bus, however.

I find that I have made a number of other changes. It was 65 degrees when I left Washington, and 3 below zero with a strong wind, in Chicago. When one there refers to the "President", he means of the University. When one refers to the "Boss", he means Mayor Daly. I left Morton Mintz, but gained Mike Rayko; I left Congress, but gained a legislature; and I left regulation, but have become regulated.

All in all, things have gone well and I barely noticed the changes in my life style.

It is nice to return to where I devoted most of my career, the university. And I was greeted warmly by my colleagues. I had suspected to find things very much the same as when I left, but have been surprised by the amount of changes I discovered. Most of the changes relate to new people, new programs and new buildings going up, including a new University Hospital and, inevitably, a new parking garage.

## Minutes of Executive Committee

My habits lead me to try to learn what has happened at the Medical Center during my leave of absence, so I have been reading minutes of executive committee and other meetings and have reviewed a number of reports of special studies on university policy and programs. These documents led me back to others, done five and ten years ago, with which I was already familiar. This is an interesting exercise to go through,

for one finds a pattern, duplicated in many institutions. The pattern goes something like this:

(1) Dissatisfaction is expressed by people inside and/or outside the institution.

(2) A problem is identified.

(3) Solutions are sought.

(4) Some degree of change takes place within the institution.

(5) After a period of time (which has grown shorter recently), it is perceived that the problem is not really solved; and so the process begins again.

Outside experts are usually consulted about problem identification and rational solutions; and reports of *ad hoc* committees, task forces, consulting groups and others, multiply—and often divide.

One rediscovers a couple of great truths when he goes through this exercise.

First, one finds, almost always, that the reason the problem was not solved was because the change in the institution either was not real, or was not sufficient; and subsequent reports of consultants and committees generally repeat previously suggested solutions, with embellishments. The recommended solutions are usually wise and correct, and advocate evolutionary change.

The other great truth is that change in any public institution results only from change on the part of members of that institution. In the case of a university, change occurs only if the students and faculty change—in a bureaucracy, only if bureaucrats change.

And so, at the University of Illinois, what I have discovered so far is that some problems I left have been solved, either by new people and new programs, or by changed people and new programs—and other problems remain to be solved, by carrying out recommendations made many times over. My job will be to discover why the appropriate change has not occurred, and arrange things so it will.

I believe that what I have just described is true for the University of Illinois, and is just as true for the Food and Drug Administration.

## GAO Reports

In 1973, when I joined the FDA, I knew I had a great deal to learn about the Agency; and so, in my ignorance, I asked to see the consultants' reports, General Accounting Office (GAO) reports, man-

agement studies, etc., on the FDA. I later learned to interpret Bob Wetherell's hesitancy to do something; but at the time, when he asked me how many years' worth I wanted to see, I said to go back to 1960, as I wanted to start prior to the 1962 amendment to the Food, Drug and Cosmetic Act. He rolled his eyes heavenward (another important sign), and sometime later delivered several hundred GAO reports and some 160 management studies.

It turned out that out of that mass of material, one could readily identify a relatively few, truly important documents that provided what I wanted—lucid identification of problems, along with sound recommendations for their solution.

As you all know, during the three and one half years just passed, the FDA picked up another 50 or so GAO reports and several other important studies.

Just before I left, Congressman Moss issued his report on the FDA; several Senate Committees are working on important reports and recommendations which will affect the FDA; the Secretary's Review Panel on New Drug Regulation is framing its recommendations; Senator Kennedy's proposals for the Agency will soon be the subject of hearings before him; and the new Administration is getting a bit of advice about how to reorganize the Executive Branch, and particularly the Department of Health, Educational and Welfare (HEW).

This very large volume of material about the FDA, extending back many years, contains a lot of nonsense—but also some important truths, which must not and which cannot be ignored.

Several people have told me that in their view, the last three and a half years have constituted the most troublesome period in the history of FDA—that the amount and volume of criticism received by the Agency was unprecedented. Others have pointed to significant controversies in the Agency's past, and have suggested that since the FDA has been under fire many times, the last few years have not been all that unusual. However that argument might be resolved, one conclusion seems to me to be unavoidable—that because of the recent great critical interest in the FDA, the next year will be critical to the Agency's future.

## Restructure Executive Bureaucracy

President Carter and his staff have been explicit about their intent—or hope—to restructure the Executive bureaucracy, to reduce

the number of agencies, to improve the quality of appointments to regulating agencies and to make the bureaucracy responsive to the people. Their intent, along with the equally explicit recommendations for change in the FDA from both houses of Congress, makes it doubly apparent to me that the next year is an important time for the FDA, for anyone interested in good Food and Drug regulation and, for that matter, the people of this country.

The principal point I would like to make tonight is simply this: that before anyone proceeds to recommend any significant change in the FDA, he or she must be intellectually honest enough to discover what has been recommended in the past, and why; what changes in Agency structure and function have occurred as a result, and what changes have not occurred, and why. It is a simple truth that this has not yet been done. It is time for some homework!

It is obvious to me that if one goes through this necessary exercise, one then has little trouble in deciding what ought to be done with, and to, the FDA, in order to make it perform to current public expectation.

Reviewing most of the truly significant past studies of the FDA has been made relatively easy by the availability of a recent review of such studies and reports on the FDA. This review was performed for the Secretary's Review Panel on New Drug Regulation, and was well done. It ought to be published and distributed by the FDA or the Department, because doing so might well prevent some mistakes of the past being repeated now, or might prevent some other serious mistakes being made.

It is just as ludicrous for anyone to suggest change in the FDA without knowing what has happened as a result of past recommendations, as it is for a scientist to initiate a research project without first reviewing pertinent literature. In either case, it is important to discover what others working in the same field have learned.

## FDA's Problems

There really is nothing mysterious, or even difficult, about most of the FDA's problems. I once analyzed about a year's worth of what I considered major criticisms of the FDA, gleaned from newspapers, from letters written by consumer advocates, from GAO reports and congressional hearings. I discovered that the root cause of a surprisingly large amount of what I thought valid criticism stemmed, not so much from what the Agency did or did not do, but from the slow-

ness—sometimes really incredible slowness—with which we appeared to act. Sometimes we were doing it, whatever it was; sometimes we were about to do it; but if only we had done it, we would not have been vulnerable. Why is the Agency so slow, sometimes? The answer is interesting. First, the Agency has a rapidly growing job to do—increasing both in size and complexity. To plan what to do, to line up the scientific support, to satisfy the General Counsel's office, and then to write it down well, in regulations that will hold up in court, takes time and a surprisingly large number of skilled people at Headquarters.

The FDA is a highly people-intensive organization, and it is only as good as its staff. If someone wants to create beneficial change in the FDA, I think the single most important thing to do is to improve the ability of the Agency to recruit and retain professional staff. The FDA is blessed with having on its staff highly competent, hard working, long-suffering professionals, but in totally inadequate numbers for the jobs given the Agency to do. So, give the FDA the people it needs, help the FDA keep them, or else do not expect so much to be done so fast.

The FDA, and the nation, deserve the best scientists the country can provide to recommend approval or disapproval of drugs, of food additives, of biologicals, and on through the range of the FDA responsibilities. But, top-flight people can go to Universities, to the National Institute of Health (NIH) to industry—and the FDA cannot compete enough of the time for the talent. Count the M. D.'s in the Bureau of Drugs. Count the toxicologists, nutritionists, the ophthalmologists, and the dermatologists. One can count some of the medical specialists in the Agency on one finger.

Scientists are attracted to a situation which provides a reasonable salary, which will provide the opportunity to earn recognition, and which encourages one to grow professionally—to stay at the front of the profession by attending meetings, by doing research, by teaching, and doing clinical work, along with everything else he or she does.

## More Professional Staff

What the FDA really needs is for the Secretary's Panel, and the Senate and House committees, to analyze what the FDA needs in order to recruit and retain more professional staff. What they would find, I suggest, is this:

First, the FDA's present numbers are inadequate to allow anyone much time to pursue research interests, clinical activities, or even to keep up with reading scientific literature. If the FDA is to hire and keep good people, the Agency will have to be able to offer significant time for valid scientific activities other than reviewing petitions. And, to be able to do that implies a larger number of slots for professionals.

Secondly, the FDA must have, in house, in one place, its own scientific laboratories. I am in total disagreement with anyone who says, "NIH can do the research, and the FDA the regulation." Impossible. Read the recommendations of the past—upgrading the scientific capability of the Agency is consistently urged as a top priority.

Third, put the Agency together, out at Beltsville. Build the labs and offices that the FDA needs for the people it needs, give the FDA the people, and then you will see some real improvement, some speeding up.

It is a very real problem that the FDA today must operate from some 23 scattered locations in the Washington area alone.

How can the Commissioner respond to critics who charge the Agency is too slow to act when a simple meeting between the Bureau of Veterinary Medicine and the Bureau of Foods over the uses of diethylstilbestrol in food animals involves a half day's trip between Rockville and downtown Washington?

A mundane problem, certainly. But like another cliche that begins "for want of a nail . . ." it gets to the essence of a problem. And the problem of facilities affects the quality of the talent the FDA is able to recruit, train and retain.

The lack of labs for the FDA is a serious problem. The FDA must have practical answers to many practical questions, and only the FDA is interested in answering some of these questions. Also, there are a great many questions, and it will take all that any of us can do to get the needed research done. The FDA's type of research is not everyone's cup of tea, and many people are not interested in doing research at the request of the FDA. So, either give the FDA the research capability it needs, or let it order up research from the NIH.

Parenthetically, one reason for the FDA's apparent slowness, on occasion, is that no one knows what is best to do—science has not yet provided the information necessary to answer the question. Giving the FDA the scientists and the labs to answer some of the questions will ultimately allow the Agency to be less hesitant.

## Upgrading Organizational Hierarchy

Reorganizing the FDA, particularly to a form discarded in 1970 as unworkable, will not solve any significant Agency problem that I know of. Upgrading the Agency in the organizational hierarchy might solve the problem; and here, let me remind all of you of Peter Hutt's excellent analysis of this problem last year, at this banquet. To his suggestions, I would add one more. I think it important to keep the product-based bureau structure and to upgrade it, as does Peter. But if the idea is to consolidate, then let us put all food regulation in the Bureau of Foods, including meat and poultry inspection. Then, relate the FDA, the Environmental Protection Agency and the Consumer Product Safety Commission more closely than is now the case. All three agencies are concerned with the same kind of regulatory process, and often the same hazardous substances, witness chlorofluro carbons, asbestos, vinyl chloride, etc.

But, do not split science and compliance in the FDA—to quote Sherwin Gardner, that is dumb! Read the December 10, 1969, report to the Secretary of HEW to find out why! That is the report that put them together in 1970!

Sometimes the FDA has been criticized for being slow when in fact, we were hung up in court, or in hearings, or other elements of the process of law. So to anyone wanting to improve the FDA, I say, take a look at the legal hoops the FDA has to jump through. Can improvements in the law be made? In the hearing procedures? In the definition of trade secrets? Some expect the FDA to work its way toward a better definition of imminent hazard, alone. But why not some help from Congress?

## FDA's Educational Role

Lastly, I would make a plea for the importance of the FDA's educational role. One recommendation made by essentially every public group looking at the FDA in the past 20 years is that the FDA has an important role in educating the public, the professions and industry —in order to prevent hazardous products from reaching the market, in order to teach people to avoid risk, in order to teach professionals to use products wisely. Yet, the Agency is criticized by some, including congressional staff, for becoming "soft" on industry by developing educational programs. I hope that Congress will formalize the FDA's educational role by defining it more specifically, and by providing program direction and support.

I have emphasized two main points tonight, directing my remarks to those wishing to remodel the FDA. A thorough study of previous blueprints for change and of recent strengthenings of the structure are properly in order before one takes up hammer and saw. But the main job to be done is to build the professional staff, the scientific milieu and the scientific capability of the Agency. That will not solve all the FDA's problems, but it will solve what to me has been the largest.

None of this is meant to take away from what the FDA is today. It is a strong and good Agency, well managed, knowing its basic mission and performing it well. And the people across this country know it.

The Agency today is more stable than a few years back; it is far less a crisis-to-crisis operation; it relies on orderly process and clearly set out procedures; it has improved its scientific competence and in addition can now rely upon voices other than its own; it has become more responsive to reasonable demands and it conducts its business in the sunshine of public scrutiny.

The FDA is clearly out in front of the entire world in its field, and well deserves to be there. If only reasonable care is taken with the Agency in the next year, as I am sure it will, the FDA will not only survive the present time of hard examination, but will grow even stronger and better. I will watch that development with a great deal of pride and pleasure. **[The End]**

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## NEW GUIDELINE FACILITATES SUBMISSION OF CLINICAL TRIAL DETAILS

The format for reporting details of clinical trials involving the use of an investigational new animal drug in food-producing animals is set forth in a new guideline now available from the Food and Drug Administration. Information on clinical trials is necessary to support an exemption for the investigational use of a new animal drug as part of an investigational new animal drug application. If the sponsor submits appropriate details of each trial, the FDA may permit treated animals to be marketed, when shown to be safe for consumption.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,836

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# The Antacid Warning—Rulemaking at the FTC

By RICHARD B. HERZOG

Mr. Herzog Is Assistant Director for National Advertising, Federal Trade Commission.

UNLIKE MY TALK to you previously on the over-the-counter (OTC) rule, my present topic has not provided me with any dramatic new announcements or interpretations to ignite a lively debate. In this instance, the debate is already ignited. The antacid rulemaking proceeding was commenced in April of 1976, and we expect to go to hearings in early September. As the commencement of the proceeding is no longer news, and as the hearings are still in the future, we might pause and use this occasion for an exercise in perspective.

Before proceeding, I must state that I am speaking here as a member of the staff of the Federal Trade Commission (FTC), and that the views I express are not intended to represent, and should not be construed as representing, the views of the Commission or of any individual Commissioner

A very great constitutional scholar at Harvard, Professor Freund, has said that many of the important questions in public law involve not a choice between right and wrong, but a choice between right and right. That remark comes to mind as one looks at the competing policy considerations that surround the question posed by the antacid warning rulemaking proceeding. The question is, should certain warnings, that must appear in labeling for antacids, also appear in advertising for those products?

## General Scope

The question is formidable. It is noteworthy that the Initial Notice announcing this proceeding does not contain a proposed rule at all. Rather, the Commission set forth the subject matter of the proceeding and a number of questions defining the general scope of the inquiry.

By beginning in this way, without proposing a rule, the Commission was acknowledging the difficulty of the choices and acting so as to keep the proceeding as open-ended as possible for as long as possible. It will be interesting to see whether this approach enhances the proceeding as a means of obtaining thoughtful presentations going to the issues of fact, law and policy involved.

It is possible to see a certain drama in the situation. Here is industry, wanting in its advertising to be bright, positive and healing. And there is the FTC staff—source of darkness, wetness and cold—asking whether people know about cautions, warnings, contraindications and threatening to take precious seconds from thirty-second spots to provide such negative information.

Yet is it not evident that these dualities reflect the fundamental tensions within your industry? As former Commissioner Schmidt recently observed in one of his valedictory interviews, your industry is beset by dual purposes.[1] On the one hand, you are an *industry*—an enterprise that seeks profits through purchase decisions by consumers. On the other hand, you aid people in need; you provide therapy and relief from discomfort and even suffering.

## OTC Drug Advertising

There are tensions in these roles, tensions that present themselves very clearly when we consider OTC drug advertising, and what constraints might be appropriate on it. As Stan Cohen of Advertising Age is fond of saying, advertising is the advertiser's opportunity to present his story in a time, place and manner of his choosing. Your advertising is a method of competition, and it is an effort to persuade and to sell.

But that cannot be the end of it if we are talking about OTC drug advertising. There is an additional measure that we must apply in assessing the role of your advertising. It is not enough that your advertising sells. We must ask the further questions: did it sell the right person? Did it induce a purchase that was right for the person who made the purchase? Did that person have the condition for which the product is intended? Did that person have a condition for which the product is contraindicated?

Those are not questions that the FTC would ask of advertising for automobiles or television sets. To be sure, there are purchases of automobiles or television sets that are unwise for the person making

[1] "Departing FDA Chief Warns of Dangers in Drugs," *Washington Post*, November 15, 1976, at A3.

the purchase. They may not meet his or her needs or even preferences, and they may be financially unsuitable. But such considerations do not have the legal significance that they do when we consider OTC drugs.

## OTC Drug Market

The purpose of the OTC drug market is to provide therapeutic benefits—no more and no less. It is desirable that the marketplace succeed in informing consumers that there is a product available that will relieve their medical problem. At the same time, and unlike virtually any other consumer product, it is public policy that OTC drugs meet actual needs, rather than simply wants; that the choice of product by the consumer be a right choice by objective criteria and that no more of the product than is necessary be used.

## Public Policy

There is also a public policy that the information that is required to be made available about the product actually be used, and used properly, by the consumer. Typically in consumer protection law a requirement of disclosure expresses no more than a policy of information availability. So long as the information is available, there is no particular decision that the consumer must make in order to avoid frustration of the policy. In the Truth-in-Lending laws, for example, the purpose is to inform the consumer of the interest rate; it is entirely a matter of indifference to those laws whether the consumer then decides to borrow any money.

We do not read the requirement in the Food, Drug and Cosmetic Act that there be adequate directions for use and adequate warnings against use[2] as expressing so modest a policy. To us, what that statutory provision expresses is not simply a policy that the information be available. That statute is a public health statute, and the fulfillment of its purpose requires that the information actually be understood and lead to the right decision. As you know, the Food and Drug Administration (FDA) so interprets these provisions in its implementing regulations.[3]

There is little question that the policies bear the utmost seriousness on OTC drug advertising. Your industry spends several hundred million dollars a year on such advertising[4]—a clear statement that individuals of prudence and responsibility consider advertising to be a formidable force in affecting consumer choices of OTC drugs.

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[2] 21 U.S.C. Section 352(f)(1) & (2).

[3] See 21 CFR Section 330.10(a)(4)(v).

[4] *Supra.*

Indeed, the industry recently had occasion to voice that point of view in responding to the so-called Bellotti Petition, in which the Attorneys General of the Commonwealth of Massachusetts and several other states, petitioned the Federal Communications Commission to ban OTC drug advertising on television prior to 9 p.m. Various comments filed by industry representatives emphasized that OTC drug advertising plays a major informational role that facilitates self-medication. Without such advertising, industry pointed out, doctors' offices could be flooded with persons seeking medical advice for problems that OTC advertising enables them to self-diagnose and self-medicate.[5] Industry itself has recognized, in other words, that OTC advertising must be measured, not solely by its contribution to individual and common prosperity, but by its contribution to public health. That is, quite simply, a different league from the one in which most advertising plays.

## Importance of Advertising

There are survey data tending to support the importance of advertising in communicating information about OTC drugs. In a 1973 survey commissioned by the FDA, consumers were asked where, generally, they get their information on OTC drugs.[6] Forty-three percent named advertising—far and away the largest category. Friends and relatives were the next largest source, mentioned by twenty-three percent. Advertising is no doubt reflected as well in that twenty-three percent, because the friends and relatives are themselves getting much of their information from advertising. Only thirteen percent of the survey respondents mentioned the label.

So, here we have advertising that is not like other advertising, playing a major role in the purchase of products that are not like other products. All of which tells us that such advertising should fit comfortably within the public policies that surround the marketing of OTC drug products.

## Warning Information

Now suppose, just suppose, that a major one of those policies was not being sufficiently realized because too many consumers were not

[5] Before the Federal Communications Commission, File Number RM2570: "Supplementary Statement by the Proprietary Association Concerning Panel Discussions on Televised Over-the-Counter Drug Advertising," at 4. (July 21, 1976); and "Supplementary Comments by George E. Davy, Panel C Participant," at 3.

[6] NTIS, "Consumers and Medication," PB232-172 at 52 (May 17, 1974) (13-3 on the Public Record of the Antacid Rulemaking).

getting the word about warning information. It would be, I suggest, both deceptive and unfair under Section 5 of the Federal Trade Commission Act to advertise such products without saying anything about warning information when it is a statistical certainty that a large number of the people who buy the product are not going to consider the warning information for it. Our legal reasoning, in that regard, is contained both in the Initial Notice announcing the warning proceeding,[7] and in the staff statement that we have put in the public record of that proceeding.[8] I, therefore, will not rehearse those arguments here because, after all, what I promised you today was an exercise in policy perspective.

## Legal Analysis

There are two questions, however, that surround the legal analysis. The first one is, are people really not getting the word about warnings? The second question is, if they are not, what might be done about it, and with what costs and benefits?

With respect to the first question—"Are there in fact consumers who are not getting the word?"—your industry and the staff of the FTC have been looking at some of the same data and having what looks like a classic quarrel about whether the bottle is half empty or half full. I am referring to data about label reading habits that were generated in the 1973 consumer survey commissioned by the FDA.[9] The Proprietary Association has proffered such data to emphasize that forty-nine percent of the survey respondents said that they read "almost all" labels.

The perspective that I have been outlining causes us to look at the other half of the data. From that perspective, it matters greatly that thirty-one percent of the survey respondents said that they read either no labels or not very many, and another ten percent said that they read about half of the labels on the OTC drugs that they use. A third of the respondents who were sixty-five and older said that they read no labels.

Those survey respondents who said anything less than that they read almost all labels were asked why they do not read more labels. Forty-two percent of that group said that they were already familiar

[7] 41 *Federal Register* 14535 (Apr. 6, 1976).

[8] Memorandum for the Public Record in re. Proposed Trade Regulation Rulemaking Respecting FDA Required Label Warnings and Drug Interaction Precautions in Advertising for Over-the-Counter Antacids, R611002 (May 20, 1976) (13-1 on the Public Record of the Antacid Rulemaking).

[9] NTIS, "Consumers and Medication," *supra* note 6, at 57.

with the OTC products that they buy, although familiarity was the reason given by a considerably smaller number of those who were sixty-five and older and did not real labels.

## Familiarity with Labels

It may be disputed whether familiarity with labels is a reason not to read them. Labels change, products change and people change, all of which can make prior knowledge inadequate.

In any event, in the survey to which I have referred, it is not clear what people meant when they claimed familiarity. Was it really familiarity from personal use, or from having seen the brand so frequently in advertising that it seemed familiar?

There are in fact other survey data, the import of which is that the claim to actual familiarity with the label is not accurate—in fact, is least accurate with respect to warning information. When the survey respondents were asked what, generally speaking, is included in most OTC labels, many more respondents—in the vicinity of twice as many —mentioned "directions" or "what [the product] is for" than mentioned "side effects" or "cautions."[10]

Those respondents who had cough remedies in their home were asked what, if any, cautions, warnings or side effects were associated with that type of product. The persons who could name a specific example, or who said that the products should not be taken by people of certain ages or with certain ailments, were a very small portion of those surveyed. The results were essentially the same for those who had cold products in their homes.

These and other[11] survey data make us pause before concluding that there is widespread familiarity with the labels of OTC products. Is it not far more plausible that the survey respondents who asserted familiarity were really exhibiting the recognized tendency in survey research to give a socially acceptable answer—one that would tend to enhance self esteem?[12] Knowing that all right thinkers read labels, many of those who had admitted that they did not read labels were

[10] Fifty-six percent mentioned "directions," and 27 percent mentioned "what it is for." By contrast, only 20 percent mentioned "side effects" and 17 percent mentioned "cautions." As respondents could give more than one answer, these numbers cannot be cumulated.

[11] E.g., NTIS, "Consumers and Medication," *supra* note 6, at 46.

[12] See, e.g., P. Green and D. Tull, *Research for Marketing Decisions*, 119 (3rd ed. 1975).

impelled to provide a sensible explanation. It is certainly a fair question whether that is not what explains many of those answers.

## Self-Medication

There is, really, something in the claim of familiarity with labels that does not fit within the entire logic of self-medication. Self-medication is considered to be appropriate for conditions that are self-limiting and of relatively short duration. For almost all OTC drugs, if someone is chronically using a product without the supervision of a doctor, something is wrong. But if the product is used only infrequently and for short periods, then familiarity with the label would require that labels be remembered for long intervals between use. I suggest that labels just lack the zip and zing to be remembered in that way.

If not all people are getting the word about warning information, what might be done about it?

We had a test performed about a year and a half ago in which we inserted two warnings into an actual antacid television commercial.[13] In one version, the warnings were presented in written form only. In another, the disclosure was video and audio. The same ad but without the warnings was used as a control.

The results speak both to the ability of 30 second spots to communicate warning information, and to the effects of such information on the sales persuasiveness of the commercial.

## Aided and Unaided Recall

Of those exposed to the audio plus video disclosure, 63 percent remembered one or both of the warnings with aided recall. With unaided recall, 28 percent recalled one or both of the warnings. This unaided recall figure was actually close to the unaided recall of the selling message, although recall of the selling message was well within expected levels.

Equally pleasing was the news that, as stated by the testing organization, "registration of the correct brand name, and communication of sales-oriented copy points, was almost identical . . . [among] the . . . commercials tested. [T]here is no reason to suspect that the *advertiser's* communication objectives for the commercial were infringed upon by

[13] ASI Audience Reaction Tests Conducted for Federal Trade Commission Bureau of Consumer Protection, April 17-19, 1975, by ASI Market Research, Inc.

inclusion of the warning material." (Emphasis in original.) Brand preference, for example, went up as much in those exposed to the video plus audio warning as in the control group that was exposed to the ad without the warnings.

Now this testing was done using a standard, frequently used commercial procedure. That does not mean that we now know all there is to know about the effects of two warnings in 30 second television spots. But the results are important as we attempt to come to grips with the competing considerations involved in this rulemaking proceeding.

## Warnings in Advertising

I will take this opportunity to respond to one objection to the idea of warnings in advertising, because this objection has already been voiced publicly by an important industry spokesman.[14] The objection is that warning information in an ad will not be recalled at the time of purchase by the consumer. But the specific warning need not be remembered if the warning information consists in an absolute contraindication—a statement that says, "do not take" if you have a particular condition. If the consumer has been told that the product is not for him, he need not remember the specific reason why; all that he need remember is that the product is not for him.

That kind of yes-or-no response is, I suggest, very close to the response that advertising itself frequently elicits. Advertisements frequently induce a favorable attitude or very general belief about a product even though the consumer does not remember the particular commercial or the particular claim about the product. A memory of no more than a brand name can have an evaluative component. If warnings are limited to absolute contraindications, the consumer can draw the right conclusions without having to remember the specific warning. Comparable reasoning might also apply to warnings that are one step removed from an absolute contraindication, namely those telling the consumer who has a certain condition to talk with a doctor before using the product.

## Antacid Warning Rulemaking

These, then, are some of the tensions, some of the policies and some of the data, that will figure in the antacid warning rulemaking.

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[14] See "FTC May Extend Some Label Warnings for Over-the-Counter Antacids to Ads," *Wall Street Journal*, Apr. 6, 1976; 38 FDC Reports ("The Pink Sheet") No. 15, at 6 (1976).

I will leave you with one further word of perspective. Neither the staff nor, I believe, the Commission are eager for a wholesale inclusion of label warning information in advertising. The Initial Notice, therefore, specifically asks whether criteria might be developed so that only the most important warnings need be disclosed in advertising. It also asks whether warnings might be included on a rotating basis, so that only one or two at a time are being included. I mention these parts of the Initial Notice so that the first thing I said today is not forgotten. The Commission did not propose a specific rule. It presented the broadest possible array of options for consideration in the proceeding. It is a proceeding designed, in short, to enhance greatly our understanding of the proper role of OTC advertising. I am sure you will agree that at least in that regard, it is a most important undertaking. **[The End]**

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## SAFETY REVIEW SLATED FOR ALL SUBSTANCES ADDED TO FOOD

A wide-ranging new Food and Drug Administration program of periodically reviewing all substances added to food was announced by Sherwin Gardner, acting FDA Commissioner, at a recent Senate hearing. The review is intended to ensure that the substances are safe by modern scientific standards, he said. To achieve this goal, current toxicological profiles for all food and color additives will be developed. Each profile will then be integrated with a fairly precise estimate of the amount of the additive in the consumer's daily diet. This safety profile of toxicity and exposure will be periodically updated to provide assurance that permitted food additives do not cause disease.

Several ongoing FDA efforts in the food safety field will be incorporated in the program, including the review of additives previously held to be "generally recognized as safe", the development of criteria for evaluating the safety of flavors, and the recently completed evaluation of color additives. Next March, a team of agency scientists will begin to develop a priority action list of the 2,100 substances added directly to foods. In April, the FDA will begin an industry survey to ascertain how much of each additive a consumer might be exposed to. The agency expects to establish profiles for all additives and to make preliminary judgments about their regulatory status within 18 months, Gardner said.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 41,829

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# How Safe Is Safe— The Legal View

By MURRAY D. SAYER

Mr. Sayer is Assistant General Counsel, General Foods Corporation.

ON DECEMBER 28, 1975, the Commissioner of Food and Drugs appeared on a national television show, Face the Nation, to discuss questions of food safety. In response to a series of questions regarding the food color Red No. 2, the Commissioner stated unequivocally that it was safe. Calling Red No. 2 the most studied chemical in the food supply, the Commissioner said studies do not show it to be carcinogenic, mutagenic, or teratogenic. Yet barely three weeks later, the Commissioner banned Red No. 2 on the basis that scientific data had failed to demonstrate the safety of Red No. 2.

## Delisting of Red No. 2

Most of you are fully aware of the circumstances which surrounded the delisting of Red No. 2 and it is not my intent to discuss them. I cite this incident only as an example of the sense of impending crisis and concern felt by consumers, government and industry with respect to our food supply. The Red No. 2 incident is not isolated. It is one of several over the past few years. And every indicator points to a significant reduction in the number of substances permitted in our foods, if we continue to apply the same criteria which we have applied in recent years. While removal of some substances will undoubtedly be appropriate, there is concern among many scientists that a cavalier approach to the food safety issue may result in a more serious hazard to health; that is, a reduction in the kind and quantity of wholesome and nutritious food in a world that will be needing more food, not less.

Putting that issue aside, the main issue today is food safety. My assignment today is to discuss "how safe is safe" from the legal point of view. In one sense, that is a very simple question. Give me the

name of a substance or a food with its various components, and I will go to the law and the regulations and tell you if it is safe—that is, whether it is "legally safe." Of course, "legally safe" or "legally unsafe" does not necessarily have any relationship to whether the product is, in fact, safe or unsafe. Whether a food is safe under the law is merely a conclusion and can be ascertained by figuratively pushing a button and getting a simple answer, either yes or no.

## Conclusion of Safety

Much more complex are the diverse ways under the law by which the conclusion of safety is arrived at. Most people tend to equate questions of safety primarily with food additives. Actually the law in its intent and application goes to all aspects of the food supply. One way in which to explore the question of "how safe is safe" with respect to our food supply would be to examine some of the methods by which the conclusion of safety is arrived at. And what better way to do that than to have a "legally safe" meal and examine how the conclusion of safety is arrived at. So, won't you join me for dinner?

To start off with let us have a drink. Here is a delicious bourbon old fashioned made with a fine bourbon, sugar, juice and garnish.

Is it safe?

Of course, although it does contain maybe one or two thousand parts per million of methanol, or wood alcohol. Yes, wood alcohol can blind you or even kill you if you drink very much, but in these quantities you do not have to worry. After all, that is not much more methanol than you would find in the fruit juice stored in your refrigerator. You see methanol is the natural result of fermentation. So drink up and enjoy.

What? What about the cherry—the red maraschino cherry? Well, yes, the cherry does contain Red No. 4 and it is true that the Food and Drug Administration (FDA) recently removed Red No. 4 from its provisional list of colors. But that does not mean that it is unsafe. Let me explain. There is a provision in the Food and Drug law called the color additives amendment. Under that provision of the law, any substance used to impart color to food makes the food "unsafe" unless that substance is on a permanent or provisional list of colors. For example, if a manufacturer used cocoa to color a brown gravy and not for chocolate flavor, the gravy would be legally unsafe unless cocoa was added to the list of colors.

## Provisional List of Colors

Red No. 4 has been listed on the provisional list of colors since 1962 and was used for many years prior to that. But the FDA felt there was insufficient safety data to permanently list it and has now concluded that it should be removed from the list. However, any food made prior to the delisting can continue to be sold. Since your maraschino cherry was made before Red No. 4 was delisted, it is legally safe. But any cherries made after the delisting of Red No. 4 are unsafe. Now are you satisfied?

Good! Here, have some peanuts—they are delicious.

What is wrong with the peanuts? Why nothing. They are certified to have less than 20 parts per billion of aflatoxin, so they are safe.

What is aflatoxin? Well, aflatoxin is a poison which is produced by a mold called *Aspergillis flavus*. This mold is rather common to peanuts but it now appears it can also be present in other crops such as corn or wheat. Aflatoxin has been demonstrated to be one of the most potent carcinogens in our food supply.

So how come it is safe?

The Food and Drug law contains a provision which says that if any poisonous or deleterious substance is added to a food, such food is unsafe unless it cannot be removed by good manufacturing practice (GMP). In such case, the FDA may establish a tolerance for a safe level of the substance. In this case, the 20 parts per billion is not a formal tolerance. It is really an informal tolerance or what the FDA calls an action level However, the FDA has proposed to set a formal tolerance for aflatoxin at 15 parts per billion.

But, you ask, is 15 parts per billion of aflatoxin safer than 20 parts per billion and if not, why do we permit any?

The answer to the first question is probably no. The reduction in the tolerance merely reflects the smallest possible tolerance without eliminating most peanuts from the food supply. The answer to the second question is best answered in the words of the FDA. In the preamble to the proposed tolerance, the FDA made the following statements:

"Obviously, for complete protection, aflatoxins should be eliminated from food, but this is not presently feasible. Therefore, it is necessary for the Commissioner to weigh the consequences of possible levels above zero.

". . . a move to 5 or 10 parts per billion could result in significant losses to producers, manufacturers, and consumers alike.

"These increased losses of food would result in much higher prices or in unavailability of what is generally considered a highly nutritious and useful food."

So there you have it. Now go ahead and enjoy your peanuts. They are legally safe.

## Sodium Nitrates and Nitrites

Oh, while you are at it, try some of these little cocktail frankfurters. And before you ask, I will tell you what the problem is. They contain sodium nitrates and nitrites at a level of not more than 200 parts per million. Now there is no known potential harm from nitrates and nitrites. However, when ingested, they may combine with certain amines to form nitrosamines and these nitrosamines may, in turn, be carcinogenic.

Sodium nitrates and nitrites are used as curing agents in meat products such as ham, bacon, frankfurters and lunchmeats. They are also used in processing dried fish. In both cases, they are also believed to prevent the growth of *Clostridium botulinum*.

Sodium nitrates and nitrites are classic examples of food additives. They have been approved by both United States Department of Agriculture and the FDA for additions to specified foods. In view of the controversy over these substances, why are they continued in the food supply? At the risk of oversimplifying the issues, essentially it is because the potential harm is speculative, it would seriously affect a significant portion of the food supply as we know it, and the failure to use these substances might result in a very real danger from botulinus poisoning.

But enough of these goodies. Let us adjourn to the dinner table and get on with the meal. We will start things off with a tossed lettuce salad and a delicious roquefort cheese dressing.

Oh yes, these are good natural foods and perfectly safe. There are, of course, a couple of small potential problem areas. For one, like all agricultural commodities, lettuce is treated with pesticides to keep down insect infestation. There is another provision of the Food and Drug law which establishes permissible tolerances for pesticides on crops. If the pesticide residue on the lettuce is within the tolerance, it is safe. If, however, the residue exceeds the tolerance by a couple of parts per million, it is unsafe. As a general rule, the farmers are quite careful about following instructions in applying pesticides so it is appropriate to assume this lettuce is safe.

## High Levels of Nitrates

In addition to the pesticide issue, lettuce and other green leafy vegetables are known to contain high levels of nitrates, often as high

as one to two thousand parts per million. Yes, these are essentially the same nitrates as contained in the frankfurter mentioned above. And if the nitrates in the frankfurter convert to nitrosamines when ingested, so do the nitrates in the lettuce. In any event, no controversy has developed over consumption of lettuce or other green leafy vegetables and it is on the market legally, so it is safe.

As for the roquefort cheese dressing, recent scientific studies have raised some questions. Roquefort, as well as blue cheese and gorgonzola, are made by inoculating cheese with the mold, *Penicillium roqueforti*. Scientists of the Canadian Health Protection Branch have recently reported finding roquefortine at levels as high as 6.8 parts per million in all such cheeses from various parts of the world. Roquefortine is a neurotoxin developed by the mold and can cause convulsive seizures in mice. The scientists at this point do not know the significance of this information and will have to conduct further studies. Until the verdict comes in one way or another, roquefort is safe. So eat and enjoy.

Finally, we get to the pièce de résistance. For this special occasion we are having broiled swordfish. Yes, I know swordfish has been pretty scarce in recent years. However, you can pick it up occasionally now—only $4.75 a pound. But when you can get it, it is safe.

Why is it so hard to get these days? Well, that is a long story but I will try to make it short. Fish is the most likely potential source of mercury poisoning in the food supply. Incidents of mercury poisoning in Japan several years ago demonstrated the very real hazard of mercury poisoning from fish highly contaminated by industrial waste. As a result, the FDA, with the aid of an *ad hoc* scientific committee, established the safe level of mercury in fish at 0.5 parts per million. Since most swordfish on the market contained in excess of 0.5 parts per million of mercury, it was in effect banned from sale. Today, in order for swordfish to be sold on the market, it must contain less than the specified action level. It is also true that some members of the *ad hoc* scientific committee have recently suggested that they revisit the action level but the FDA has declined. So do not worry. This swordfish will not only be delicious, it will be safe.

## Hydrogen Cyanide

To go with the swordfish, I have selected two favorite vegetables, lima beans and baked potato. No problem with these. The lima beans have a safe minimum level of hydrogen cyanide and the potato has a

comfortable safety factor on its solenine content. However, if new varieties of these vegetables are developed which significantly increase the levels of these toxicants, the new varieties would be treated as food additives and would probably be disallowed. In fact, a new variety of white potato was disallowed about six or seven years ago because of its high solenine content.

At this point, I think I will skip dessert and end our legally safe dinner. I hope that in trying to make my point I have not been guilty of overkill. And what is my point? Essentially it is that the issues involved in determining the safety of foods have become too complex for the mechanism which is now used to resolve those issues.

In the 38 years since the present Food and Drug Act was passed, scientific knowledge and technique have increased tremendously. Today we can take a food or food substance composed of hundreds of chemicals and analyze it for its composition. Our analytical methods enable us to measure the presence of a single component in food, not in parts per million, but in parts per billion or even parts per trillion. We can determine the metabolic fate of a substance and its metabolites through the technique of tagging with radioactive isotopes. These and other tests are being conducted by an army of thousands of scientists in government, industry, academia, and private laboratories, each searching for additional information to add to the already over-flowing fount of knowledge. Supporting them is a horde of millions of rats and mice blissfully nibbling away at different levels of substances to determine if they can produce some statistically significant phenomenon.

## New Scientific Methods

Yet with all the new scientific methods available and with the tremendous outpouring of data from those methods, the decision making process is relatively unchanged. It is a process which is subject to much emotion, to undue pressure from whatever direction, and to personal bias. It can lead to seemingly irrational results as in the case of Red No. 2. I cite that as an example not only because it was banned three weeks after a public declaration of its safety, but because every country, except the U. S. and Russia, continue to accept Red No. 2 as safe. Whether one agrees with my views or not, I think all will agree that public confidence in the food supply, in the industry that makes it and in the government agency charged with preserving its safety is at an all time low. That in itself should indicate that something is wrong and that some sort of change is needed.

My point here could be well expressed poetically by four lines from a great old hymn. Those lines are:

"New occasions teach new duties,
Time makes ancient good uncouth;
They must upward still and onward
Who would keep abreast of truth."

It is not my intent to suggest that our present methods of determining safety are either ancient or uncouth since they utilize some of the most advanced scientific techniques. However, it is apparent that new occasions are upon us and we must find new solutions if we are to avoid chaos in the food industry and restore the confidence of the public in both industry and the government.

## Science Court

These new occasions are already beginning to teach new duties. From various directions new efforts are being made to reach that goal of keeping "abreast of truth." One of the most significant of these efforts was held only last September when more than 250 scientists, lawyers, government officials, and businessmen attended a meeting to consider an experiment to establish a science court. In support of the experiment, Secretary of Commerce Richardson made the following observation:

"We are made uncomfortable—indeed, made anxious—by the awareness that the processes by which we now arrive at important decisions are to such a degree nonrational."

This view was further elaborated on by Dr. Arthur Kantrowitz who heads the panel that will study the court idea for a presidential advisory group. He said:

"There are many cases in which technical experts disagree on scientific facts that are relevant to important public decisions. As a result, there is a pressing need to find better methods for resolving factual disputes to provide a sounder basis for public decisions.

"In many of the technical controversies that are conducted in public, technical claims are made but not challenged or answered directly. Instead the proponents make other technical claims, and the escalating process generates enormous confusion in the minds of the public. One purpose of the science court is to create a situation in which the adversaries direct their best arguments at each other and at a panel of sophisticated scientific judges rather than at the general public."

If this idea together with others at the incipient stage can grow and coalesce, we may find at least some of the solutions to the new occasions. But for now, and until that time arrives, the question posed at the start of this discussion, "how safe is safe," will have to remain the unanswered question. **[The End]**

## CLOSING DATES OF PROVISIONALLY LISTED COLOR ADDITIVES POSTPONED

If specific scientific investigations are undertaken to determine the safety of 52 provisionally listed color additives, the additives may continue to be used beyond the previous closing date, the Food and Drug Administration has announced. In conjunction with the postponement of the closing dates, a new regulation has been issued by the FDA to set out the conditions for the provisional listing of the additives and to establish a schedule for the prompt resolution of the status of each of the colors. The FDA said that the closing dates will not be postponed further unless extraordinary circumstances are shown.

### COMMENTS

Some of the commenters on the proposal to postpone closing dates objected to the continued provisional listing of any color additive on the ground that manufacturers and users have had sufficient time since the Color Additive Amendments of 1960 to establish the safety of all other color additives. In response to those comments, the FDA stated that the most important reason for the postponements is that new scientific technology is available for assessing and evaluating the effects of color additives. The agency said it wants to assure that the color additives are evaluated in accordance with contemporary scientific standards before they are permanently listed.

The Certified Color Manufacturers Association commented that the conditions for provisional listing as proposed appeared to require that all co-petitioners agree to perform the steps requisite to satisfy the conditions for continued listing and that all co petitioners actually perform the studies. The FDA agrees with the CCMA's comment that all co-petitioners may not share the same interests, and the final regulation requires only that at least one petitioner for each color agree to perform, and actually undertake and complete, the required studies.

### FINANCING OF STUDIES

The Cosmetic, Toiletry, and Fragrance Association and the Pharmaceutical Manufacturers Association submitted two requests. The FDA rejected the first request that the agency itself conduct the required scientific studies for 25 provisionally listed drug and cosmetic color additives. The agency is asking for comments on the second request, which relates to the financing of the studies. The associations suggested imposition of a research charge on the certification fee for the 25 color additives, stating that the fee would fairly distribute the cost of the testing. The FDA concluded that the request merits consideration and is asking for the views of all interested persons concerning the distribution of costs of required testing.

CCH FOOD DRUG COSMETIC LAW REPORTER, ¶ 41,837, 6801, and 6805

*Pre-Market Toxic-Testing of Chemicals, Defending Their Risk / Benefits*

# TOXIC SUBSTANCES CONTROL ACT

## Law and Explanation

Manufacturers and producers of the 1000-odd new chemicals prepared for he U. S. market each year (as well as those producing old chemicals intended or a significant new use or uses) must now test and submit toxicity data to the Environmental Protection Agency 90 days before sale. After review, the EPA can: *Give* a green light to market it. *Delay* sale and ask for more testing if it feels the data is incomplete. *Ban* it from the market entirely if it determines that the chemical presents an unreasonable risk.

If they disagree with the EPA's decision, manufacturers may challenge the order. The EPA, in turn, can support its judgment through court injunction. With chemicals so important to farmers, processors, industry, importers and exporters, consumer groups and the public as well as to their manufacturers, everyone concerned needs to know these rules and how they work. In cases where risk/benefits ratios are closely balanced, you must also expect litigation.

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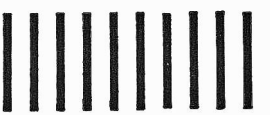

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