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Food Drug Cosmetic Law JOURNAL

FDA–Social Trend and Regulatory Reform

. . . . . ALEXANDER M. SCHMIDT

Are Food Additives Overregulated?

. . . . . BERNARD L. OSER

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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

Balanced Government Regulation of Consumer Products

By PETER BARTON HUTT

Mr. Hutt Is a Partner in the Law Firm of Covington & Burling.

THIS PAPER will deal broadly with the question of how government regulation of consumer products can be controlled to prevent either indifference to genuine problems or unnecessary overregulation. It will briefly examine the rationale for and mechanisms of government regulation and review possible ways of achieving control of agencies in order to assure balanced regulatory activities.

Rationale for Government Regulation

The rationale customarily given for government regulation of consumer products (and now almost universally accepted) is that, in a complex society, individual consumers are no longer able to protect their own interests—government, therefore, must do it for them. Implicit in this well-recognized principle is the assumption that there is something from which the public does, in fact, need protection. It means that, without this protection, consumer products would be marketed without adequate assurance of safety and, where appropriate, effectiveness.

If one examines historical developments in the field of government regulation, it is readily apparent that this implicit assumption has, in fact, been the activating force behind all federal legislation enacted to regulate the safety and effectiveness of consumer products. The history of government regulation in this field is the history of the perceived failure of business to regulate itself. Time and again,

Congress has acted in response to what it believed to be a demonstrated danger.

In some instances, this danger has indeed existed, and was well documented. Regulatory legislation has not always been, as some would like to believe, the irrational product of mischievous gadflies who have exploited public ignorance and emotion. In other instances, however, the danger has been largely speculative or has involved only economic issues where governmental intervention might reasonably be viewed as having worse effects than the problems it is designed to solve. It is not the purpose of this paper to debate the relative merits of these arguments with respect to any particular legislation, much less the field of consumer product legislation as a whole. Suffice it to say that an enormous amount of legislation has been enacted and is unlikely to be repealed.

The manufacturers of consumer products have generally opposed legislation which increased government regulation of their products, while consumer groups generally favored such legislation. This does not mean, as others argue, that the manufacturers of consumer products are evil people. The people who work in business are no more evil than those who work in government, or Congress, or consumer organizations Their level of competence, integrity and concern for the public is about equal. It is a far more subtle matter. Any advocate (whether a businessman, a consumer advocate or a government employee) will inevitably become convinced of the soundness of his position, and be less likely than an independent observer to perceive the full ramifications and potential dangers of that position from a broad societal perspective. The purpose of all government regulation, which admittedly is not always achieved in practice, is to make certain that broad public objectives are not only kept in mind, but indeed are used to shape daily business decisions.

Mechanisms of Government Regulation

The specific form of government regulation chosen to deal with a particular situation will depend, of course, upon the nature of the subject being regulated and societal priorities. In spite of all the talk about new forms of regulation and innovative regulatory controls, there really is no such thing as a new regulatory concept. Rather, there is just an infinite number or variations of three basic concepts that were invented centuries ago. These three basic concepts involve governmental action taken to police requirements imposed by statute

or regulations on products after they are marketed, a requirement of governmental review or approval prior to marketing, and private legal action undertaken pursuant to common law or statute.

There is, of course, no uniformity whatever among the numerous statutes which impose government regulation on particular consumer products. The details of each piece of legislation have been fought out in thousands of minor skirmishes and major battles—often, as it later turns out when the statute is in fact implemented, over the wrong issues.

Major issues are often left unresolved in this legislation—sometimes because they are not recognized, but quite often because Congress is unwilling or unable to resolve them. Where specific issues are addressed directly to legislation, the language used is often sufficiently imprecise to permit wide latitude in interpretation. Thus, the implementation of these regulatory enactments is largely left to the administrative agency to which the statute is delegated.

In spite of all the current political rhetoric about regulatory reform, it is unrealistic to believe that health and safety legislation will be repealed, diluted, or made more specific in the future. Thus, the real issue facing the country today, and on which some regulatory reform is feasible, relates to the various mechanisms that might be used for keeping government regulation within reasonable bounds, that is, neither too loose nor too strict, but sufficient enough to accomplish its intended and well-accepted objectives.

Control of Regulatory Agencies by the Executive Branch

In theory, the President controls the Executive Branch. He issues orders to the Cabinet which in turn executes them throughout the government. The Office of Management and Budget (OMB) acts as a second check by assuring that the budget of each regulatory agency reflects the President's views. Thus, it is set up just like the Army, and should run with the same precision and control.

In practice, however, we all know that this is nonsense. Most of the federal government runs wholly independent of the President or his Cabinet. Indeed, the views of the incumbent President are largely irrelevant to the day-to-day operations of regulatory agencies. There is simply no substance to the myth that the President and his Cabinet exert significant control over any regulatory agency, although they may wish to do so.

The reason for this situation can be understood by analyzing why the analogy to the Army is so grossly misplaced. The Army is run under a single military code that requires complete and unquestioned obedience to any command. In contrast, each governmental agency has its own independent, and frequently different, governing objectives and requirements as set out in the laws enacted by Congress. In effect, each regulatory agency—and frequently, different groups within a single regulatory agency—is its own separate army. The same situation would exist if each division or battalion or company in the military were to have its own separate governing laws, regulations and objectives.

A useful example of the limitations that result may be seen in the President's recent attempt to require the entire Executive Branch to consider the inflationary impact of all major federal action. The regulatory agencies have either given limited lip service to this Executive Order, or have ignored it completely, on the ground that the President has no authority to amend or overrule the laws and regulations governing specific agency action. The Food and Drug Administration (FDA) has declined to submit draft regulations to OMB for review, on the same ground.

More important, however, is the readily apparent fact that the White House and OMB could not conceivably undertake a meaningful job of control over the vast number of policies adopted and actions taken by regulatory agencies even if it had the authority and will to do so. The issues are too many and too complex. Neither the White House or OMB has the expertise to understand or resolve them. And in any event, all but a very few have insufficient national priority and importance to justify such high level consideration. One shudders at the thought of what would happen to the White House or OMB, and thus to more important issues of national policy, if either attempted to read, much less evaluate, all or even a representative sample of the notices appearing in the *Federal Register* every day.

Another layer of review of this type, moreover, would further delay and confuse rational development of public policy, rather than encouraging it. Issues would be considered not because of their broad public impact, but because of their political importance. Certainly, a high-level review of this type could add little value to the difficult scientific judgments that usually are involved in controversial decisions relating to the public health and safety.

Control of Regulatory Agencies by Congress

In theory, of course, Congress sets policies in legislation and then conducts broad oversight to make certain that those policies are adequately pursued. Thus, Congress itself should be exercising effective control over the regulatory agencies. But what happens in actual practice is no better, and potentially far more dangerous, than what happens in the Executive Branch.

The concept of Congressional oversight is very important to our form of government. Congress should act at the very cutting edge of national policies, providing a forum for all viewpoints and seeking a consensus on national priorities. It should lead the way in candid analysis of the very difficult public issues and choices the country increasingly faces.

We all know that this is not happening. It would be comforting to conclude that this is because the current Congressional leadership is simply inadequate for the task, and that new and better leaders could replace them. But there are also deeper problems that are undermining the system.

Congressmen and Senators are, of course, major public figures. Their time is in demand for many causes. Even more so than in the Executive Branch, they have very limited time and resources available to research and understand the complex and subtle issues involved in even the most important regulatory policies.

Moreover, the basic job of any politician is to satisfy enough of his constituents so that he will be reelected. In this day of instant communications, a member of Congress must constantly keep his name before the public to assure them that he is, in fact, doing his job on their behalf. The kind of tedious and dull policy analysis which is so badly needed in Congress is obviously ill-suited to the more important task of assuring reelection.

In my four years at the FDA, during which I testified before Congress about 80 times, I can recall no oversight hearing that even purported to be a balanced and objective analysis of an issue, and was constructively intended to help the Agency do a better job in the future. They were, instead, uniformly prosecutorial in nature, and designed to embarrass, harass and intimidate Agency personnel. Their basic purpose was publicity. Most made no attempt to conceal the preconceived conclusions, which were backed up by witnesses and documents carefully culled to present a single viewpoint. Not in-

frequently, at the end of a hearing, the Chairman read a typed summation which was prepared well in advance and prior to listening to any of the testimony. They were nothing short of staged plays. If any regulatory agency acted that way, it would be reversed summarily and reprimanded severely by the courts. But there is no appeal from a Congressional hearing.

Moreover, not one dealt with broad issues of policy. Each was concerned with a specific regulatory matter, usually dealing with the safety of a particular product that would be certain to produce the desired publicity, even though it usually represented a trivial matter when compared with other problems facing the agency. If broader policy questions were involved, it was merely fortuitous.

Even more discouraging, none dealt with the most important question now facing the FDA and all other regulatory agencies, the difficult priority choices among competing needs. No regulatory agency today can do all that it is called upon and expected to do. But Congress cannot admit that, or explore priorities in balanced and constructive oversight hearings, without turning off the fountain of publicity that it has discovered. The news media would soon tire of hearings that explored only the resource needs of the agencies and the work that can and cannot be done under various alternative budgets.

Because members of Congress have such little time or knowledge of regulatory matters, they rely heavily on their staffs. It is these unelected Congressional staff members who shape the hearings and the resulting publicity. Thus, both in their daily interaction with agency personnel and in the hearings themselves, they have an increasingly and disproportionately large potential for influence over the activities of regulatory agencies. These people are no better or worse than the staff of the regulatory agencies themselves, but certainly far less familiar with all of the facts and issues involved and subject to none of the same restraints.

Indeed, there is no longer any question but that the members of Congress and their staffs have much greater potential for influence and power over the activities of regulatory agencies than the Executive Branch. That potential does not stem from their authority to enact legislation or an agency's budget. Rather, it stems from the enormous impact of the publicity that they can generate. Repeated accusations by prominent Congressional figures, whether justified or unjustified, can ultimately damage an agency and an individual far more than any threat of legislative action.

The potential power wielded by these people, down to the lowest staff member on a Congressional committee, represents a very serious threat to the fair administration of justice by regulatory agencies in this country. It is a far greater danger than any threat of improper interference by the Executive Branch. Insulation of regulatory agencies from improper Congressional influence represents perhaps the single most important issue for regulatory reform, but obviously one that Congress is not likely to acknowledge, much less pursue.

Fortunately, this potential for improper influence has seldom resulted in serious problems. Congressional inquiries and hearings have for the most part accelerated or slowed down regulatory action that would otherwise have occurred anyway, but have not changed the ultimate course of events. Nonetheless, this danger persists and must be watched carefully.

There are, of course, exceptional members of Congress and Congressional staff members who both understand the difficulty of the issues and try their best to contribute rather than just criticize. It is not the purpose of this paper to deal in specific personalities. Suffice it to say that, at this time, Congress as a whole does not present a useful and constructive means of controlling the agencies to assure balanced regulatory activities.

Many doubt that Congress will be able to change its current atmosphere in the near future. To do so, it must be willing to forego the attraction of sensational hearings on trivial examples of close judgments, televised accusations about the motives and integrity of our public officials, and similar ego-building and vote-getting public displays. It must be willing to discuss in cold and sober detail the various alternatives faced by the agencies, their public cost and benefit, the difficulty in making the subtle judgments that must be made every day, and the problem of educating the public to the fact that all of our modern life presents inescapable risks and trade-offs that cannot be avoided no matter how hard we try. It also involves closing the gap between public expectations, which have been led to unrealistic heights, and the agencies' resources and ability to meet those expectations. It will take a very courageous leadership.

Control of Regulatory Agencies by the Top Management of the Agencies

Regardless of the inappropriateness of control over regulatory agencies by the Executive Branch or Congress, one should at least

assume that the top management of an agency would have both the incentive and the power to establish and maintain effective control. In practice, however, this can also fall short of the theoretical model, and is usually less effective than in private organizations.

For the same reason that the Executive Branch often cannot control the regulatory activities of a regulatory agency, the agency's top officials themselves often cannot effectively exert such control. Not only is it difficult to know all that is going on in any particular agency but, just as in business or any other large organization, the lower level staff employees who control the basic structuring and rationalization of any matter, and who know most about the facts, very frequently can marshall sufficient information and argumentation to prevail. Top management usually has neither the time nor the detailed knowledge to review most agency decisions. Existing laws, regulations, manuals and other precedents limit the government administrator's options to a far greater extent than his counterpart in the private sector. And by the time that a proposed regulatory decision reaches the top level of a regulatory agency, with full and enthusiastic staff support behind it—and often with the press or interested persons outside the agency already informed—it can be very difficult indeed, although certainly not impossible, to turn it around. Moreover, any direct overruling of lower level employees carries with it a substantial possibility of Congressional investigation, adverse publicity or court challenge. Thus, the "technocrats" (as John Kenneth Galbraith termed them) exert the same dominant influence in the government that they do in any private organization.

Top management of a regulatory agency may, moreover, have independent reasons for concluding not to attempt to exert major control over the daily regulatory activities of an agency. The motives of a government administrator, after all, are no more pure, or less pragmatic, than the leaders in other segments of our society. He will undoubtedly wish to escape major criticism, to take action that will be viewed favorably in the media, to increase the size and importance of his agency, and to avoid obviously unpopular positions and action wherever humanly possible, while also protecting the public and otherwise performing his statutory duties. He is, in short, subject to the same human strengths and weaknesses as leaders in business, Congress and consumer organizations.

There are, moreover, more severe limitations applicable to a high government official. The government administrator must carry out

his responsibilities in a far more open and public manner than any member of Congress or any person in the private sector. The Freedom of Information Act, daily leaks by agency staff members, judicial requirements for explaining decisions, detailed investigations by the General Accounting Office and Congressional staff members, and public hearings on Congressional committees provide assurance that very little, if anything, that is at all controversial will long escape public scrutiny. These safeguards provide major assurance that improper activity will not take place, and for that reason alone the need for openness in government should receive widespread public support. But the price that unquestionably is paid for these safeguards is a substantial limitation upon the flexibility and authority of a government administrator to exert even legitimate control over his agency's regulatory activities.

The Civil Service Commission laws and regulations also drastically limit the ability of government officials to discipline, transfer or discharge staff employees. There are sound policy reasons behind these rules. It would be tragic if government employees could be penalized for political reasons, or because they failed to carry out improper orders. At the same time, a price is paid in terms of insulating government employees against proper attempts by higher officials to implement policy choices which the law authorizes them to make.

Control of Regulatory Agencies by Private Parties

At first blush, it seems unlikely that private action affords any real possibility for meaningful control over governmental agencies to assure balanced regulatory action. Yet today it is the only significant control exerted other than by agency personnel, and its promise for the future is very bright indeed.

The weakness of and hindrance to Executive Branch and Congressional control over regulatory agencies are far less likely to exist with respect to interested private parties. Those persons in the private sector who are directly involved in a particular matter—consumer organizations, professional groups, trade associations and other interested persons—usually know most about it. They have the interest and tenacity to pursue both the specific details and the broader policy implications. They have both a constitutional and a statutory right to initiate and participate in the development of the matter and to challenge the result in the courts. Those who believe that agency action should be instituted or intensified, and those who believe it should

be abandoned or modified, have equal access and opportunity to press their respective positions. It is this fundamental right of initiation, participation and challenge that provides, today and in the future, the most meaningful substantive control over regulatory agency activities.

For the most part, the participation of private parties in regulatory decisions has been intelligent and helpful. To be sure, there has been an unnecessary amount of rhetoric, hyperbole, and frivolous questions, but real issues have usually been debated in real terms.

Some fine tuning of the procedural rules governing the right of initiation, participation and challenge is undoubtedly still necessary. That has, indeed, been a major objective of the FDA for the past five years, culminating in publication of its procedural regulations in 1975. Those regulations are designed to assure that all citizens have the right to submit petitions to the Agency which must be considered and acted upon responsibly, that public policy will be developed through publication of proposed regulations, that all interested segments of the public will be permitted to offer their comments on them, that each of those comments must be specifically answered on the merits, and that any person can challenge the end result in court. All sides are given a fair opportunity to participate, and none have any unfair advantage.

There remains the popular belief, of course, that one private group or another unfairly "dominates" regulatory agencies. Consumer groups have argued that the FDA is dominated by the food industry, and the food industry has responded with equal vehemence that consumer advocates have undue influence over the Agency. Any objective analysis would rapidly show that both arguments are equally false. Neither group is as effective as the other believes, or even as the group itself believes. It would be refreshing, even though unexpected, if both agreed to a truce on this relatively trivial issue, and instead dealt with the important and difficult matters pending before the Agency on their merits. Hopefully, the openness that has been exhibited by the FDA in the past few years, as codified in the procedural regulations, will lay to rest some of these shibboleths. Nonetheless, one must expect that they will continue to be used in the future by some who, disappointed that their position did not prevail, are simply unwilling to accept the fact that the decision made was nonetheless reasonable.

Procedural fairness will work in controlling agency action to assure that it is balanced, and thus neither too stringent nor too lenient,

only to the extent that court review rigorously enforces it. I have stated both during my government service and my private practice of law that all FDA action (including the failure to act when requested) should be subject to close court review on the merits, when challenged, and should be upheld only where there is substantial evidence to support it. It should no longer be sufficient that agency action merely be determined not to be arbitrary and capricious. If a government decision cannot withstand this more rigorous review, it should not be allowed to stand. And if the courts are not willing to review each matter closely, and to demand high standards from the agencies, the agencies will inevitably relax those standards. Thus, detailed and conscientious judicial review is the keystone to any effective control over regulatory agencies.

Recruitment and Retention of High Quality Personnel

Ultimately, the only guarantee for fair and reasonable balance in any regulatory agency lies in the recruitment and retention of high quality personnel. It is far better to have a bad law administered by good people than to have a good law administered by bad people.

The old aphorism that we have "a government of laws, not of men" has often been misinterpreted and misunderstood. Surely, no person is or should be above the law. But all law is administered by mere mortals, and thus we will always have a government of men. The same law interpreted and applied by two different people may result in two enormously different consequences.

Unfortunately, far too little attention has been focused on the basic question of how to recruit and retain able personnel in regulatory agencies. Without attempting to be definitive, the following possibilities must surely be explored. First, it is important that Congress retreat from its current penchant for vitriolic criticism, and instead recognize the difficulties inherent in many regulatory judgments. Repeated Congressional attacks substantially undermine the possibility that able people will be willing to undertake responsible government positions. Second, the public must similarly be educated to understand the limitations in any regulatory judgment, and particularly those that involve the public health and safety. No one can satisfy the demands of those who advocate absolute safety from consumer products. Third, higher pay, commensurate with that available outside the government, is essential for any recruitment and retention program. Fourth, better working conditions, including office facilities

and administrative support, must be provided. It is unrealistic to expect that people will continue to make major personal sacrifices for their entire careers in order to pursue government service.

A final change, which is badly needed but difficult to achieve, is to instill in government service the best aspects of the spirit of competition that prevails in the private sector. It is unrealistic to believe that the profit motive, which is the driving force in a free economy, can be translated directly to government service. More meaningful rewards and other "profits" must, however, be found for government service if it is to attract the most able personnel. And surely, it is far more important that the government attract personnel of the highest caliber than it is for any other segment of our society, since we are all dependent upon government for our future well-being.

It is, moreover, apparent that even these considerations will be insufficient to guarantee that all of the expertise and experience relevant to resolving the difficult and complex issues faced by the regulatory agencies every day will in fact receive the benefit of the best judgment available in the country. The use of outside independent advisory committees is thus essential to the regulatory process. Indeed, in the short term, this is the only real hope for obtaining the kind of expertise appropriate for the difficult scientific issues that currently characterize most regulatory agency issues. The question is not whether a regulatory agency can come to some conclusion without the use of advisory committees; rather, the question is whether the use of advisory committees will substantially enhance those decisions in terms of substance, credibility and public acceptance. There is no doubt whatever but that, in all regulatory agencies today, advisory committees are essential for sound scientific decisions.

Contrary to the allegations of some, the use of advisory committees in no way denigrates or undermines an agency's full-time scientific staff. In the FDA, the Agency's best scientists have warmly welcomed the use of advisory committees, since it provides an opportunity for continuous interchange on scientific developments with some of the outstanding experts in the country and the same type of peer review that is accepted throughout the scientific community. Indeed, the use of expert advisory committees allows an agency to attract higher quality scientific personnel on a full-time basis than would otherwise be true.

Conclusion

For all of its pitfalls and problems, the rewards of government service are enormous. Any person who has the opportunity for government service owes it to himself, as well as his country, to pursue it. If all of us are not willing to enter into that service, and to do our best to improve our government, then we certainly can have no complaint about what happens as a result. There is a great potential for good in the government, as well as a great potential for evil, and it is our individual and collective duty to do everything we can to make certain that the former prevails. **[The End]**

FDA SEEKS NOMINEES FOR UPCOMING ADVISORY COMMITTEE VACANCIES

Nominations for persons to serve as voting members on a number of Bureau of Drugs' public advisory committees have been requested by the Food and Drug Administration (FDA). The nominations are for vacancies which will occur at various times during the year. Those selected for membership must have adequately diversified specialized training and experience related to the work of the committee, such as experience in medical practice, teaching and/or research. Terms of office are four years. Committees having openings as of December 31, 1976 are those dealing with dermatology and ophthalmic drugs. There will be openings on the following committees as of June 30, 1977: anesthesiology; anti-infective agents; cardiovascular and renal; dental drug products; endocrinology and metabolism; obstetrics and gynecology; oncologic; psychopharmacological agents; pulmonary-allergy and clinical immunology; radiopharmaceutical; surgical drugs; biometric and epidemiological methodology; and FDA/NIDA drug research. Vacancies on advisory committees for controlled substances and arthritis will occur on January 31, 1977 and September 30, 1977, respectively.

CCH Food Drug Cosmetic Law Reporter, ¶ 41,744

FDA—Social Trend and Regulatory Reform

By ALEXANDER M. SCHMIDT, M.D.

Dr. Schmidt Is the Commissioner of Food and Drugs of the Food and Drug Administration.

I WOULD LIKE TO EXPRESS my appreciation for the invitation to join you here today, and for this opportunity to explore matters of mutual interest and concern.

Jim Mack thoughtfully sent me a copy of the *Association Bulletin* indicating your interest in the rationale behind Food and Drug Administration (FDA) actions generally, and he also told me of your interest in certain specific FDA policies that directly affect your industry.

In considering how to respond to your dual interest, I thought perhaps the best way would be to consider some basic social trends affecting the evolution of the FDA, in the general context of our nation's intense and legitimate concern for regulatory reform.

Less Intrusive Government

Behind all the tumult regarding regulatory reform is an elemental desire of the American people: the desire for less intrusive government. I might add that this Bicentennial year marks the anniversary of a somewhat more insistent assertion by the American people for less intrusive government. It is worth remembering in this regard that the tenth general item on the bill of particulars drawn up by Thomas Jefferson and submitted to a restive world was that a remote government had "erected a multitude of new offices, and sent hither swarms of officers to harass our people, and eat out their substance."

Of course, in the early 1770's, the government in question was not so remote, being located only in London, not in Washington. But the irritation caused by swarms of officers, regulating activities that people felt they could handle better themselves, was remarkably similar to

the irritation felt now, except that filling out government forms may well be more frustrating than heavily taxed tea. After all, if you dress up like Indians and throw government forms in Boston Harbor, you will just be sent more forms, and then probably be cited for not filing an environmental impact statement!

So, I believe that today President Ford is articulating a traditional American desire to declare our independence from overregulation of our activities.

Role of the Food and Drug Administration

Where does the FDA fit into this picture of people weary of overregulation, suspicious of pervasive, intrusive government? Should the FDA turn its back to the American consumer, adopt *caveat emptor* as its motto, and leave the consumer to make his or her own determination of safety and efficacy? No, of course not. Given the realities of modern drug and food technology and distribution, the individual consumer simply cannot, unaided, make those kinds of determinations. When toxicity is measured, as it often must be today, in complex biological test systems employing detection methods sensitive to parts per billion, the consumer needs the protection of a regulatory agency capable of assuring that sensitive and accurate test systems are in fact being applied.

If I am not suggesting a gradual withering away of the FDA in response to the public agitation against regulatory agencies, what then am I suggesting?

I am suggesting that there is a legitimate, as well as an illegitimate, basis for the role, function and level of support accorded the FDA.

Perhaps the best way to illustrate what I mean by an "illegitimate basis" is by quoting from an essay written by Dr. Harvey Wiley in 1890. Dr. Wiley, as many of you know, was the "Father" of food and drug regulation in this country. The title of Wiley's essay is, "What I eat and why."

In it, he says,

"I have no use for fads and fancies in diet, but I grant to all persons who have, full privilege to enjoy them. If a man wants to live on nuts, I make no objection; if he prefers to eat raw foods alone, he has my permission; if he eschews meat I never object; if he uses some alcoholic beverage with his food I do not abuse him; if he eats five times a day, I consider him fortunate; if he eats late at night my prayer is that he sleeps well."

In short, we can see in Wiley a man who managed to combine a passionate commitment to safety, with a rare aversion to imposing his personal view on others.

So, an illegitimate basis for regulation is the arbitrary imposition of preconceived and unsupported views. That is bad! Unnecessary regulation is bad; and excessive regulation is bad—as is inefficient, slow, unfair or dishonest regulation. I think everyone could agree to this. The problems start when one begins to define those adjectives—"unnecessary," "excessive," "inefficient."

Color Additives

Let me illustrate this by responding to a direct question asked by Jim Mack. What are we going to do about colors now on the provisional list?

While some of you may think that every time I make a statement about the provisional list, I make an off-color remark, I want to assure you I am really not prejudiced against color, per se (and, obviously, neither is the consuming public). There is still a tendency to want margarine to say "butter" to the eye as well as to the ear. Such habits are hard to break.

But herein lies an important point. The FDA is not in the business of deciding whose habits, or what habits, should be changed. We have not declared war on colors, nor do we believe the addition of colors to food is necessarily immoral or out of step with proper thinking. It is not the FDA's business to be making this kind of a determination.

In regard to colors, this means that our policy and our decisions are to be based on the clear mandates of law and science, and nothing else. There are presently 82 color additives on the provisional list, of which only five are food colors: FD&C Green No. 3, Yellow No. 6, Red No. 4, Blue No. 2 and carbon black. We are committed to ruling up or down on the safety of these colors by September 30 of this year, using the scientific data we have on hand. Unless justification for continuing, provisionally, to list a color, in the form of ongoing, relevant scientific studies, exists, no further extension of provisional status can be provided.

I cannot now tell you the current status of each of these colors, because the evaluation of the accumulated safety data is still under way. I can tell you, though, that our decisions will be made on the basis of science, and not out of a need to assure tidy management or to gain public applause.

If an arbitrary and thoughtless exercise of regulatory power is an illegitimate form of food and drug regulation, what then do I re-

gard as our legitimate role? I wish I could give you a quick and easy answer to that question. Unfortunately, we do not enjoy the luxury of marching to an unequivocal beat, and this is responsible for a great many of our difficulties with industry, with consumers, with Congress, and even with our own professionals inside the Agency. This confusion about our proper role is, to me, a major challenge to regulatory reform and to reformers.

What I would suggest is that this nation needs to engage in an open debate about the proper role, function and level of support for the FDA.

The message I am getting from my mail, from Congress, from the news media, and from consumers all across the country, is that the primary concern with overregulation has to do with regulation of commerce, not protection of health and safety. If you fly a lot, you might favor doing away with the Civil Aeronautics Board, but not the Federal Aviation Administration.

Public Concern

The public is becoming increasingly concerned, not less concerned, about the safety of food and drugs. People want to know if a chemical is safe, that is, whether they can use it safely, and if not, what is the risk. They also want to be able to choose whether or not to accept any risk, and this explains, in part, the current emphasis on full disclosure labeling of food, a subject to which I will return.

One of the first steps in regulatory reform as it pertains to the FDA, then, ought to be a systematic and scholarly examination of our laws as they express public policy, the purpose being to clarify our role—what it is that we are and are not to do.

It is now already our job to evaluate food colors (to return to that example) to be certain they can be used safely. Whether or not any food colors ought to be used at all is a public policy question and not ours to answer arbitrarily.

To turn to another example, it is now public policy, expressed in law, that drugs, prior to marketing in this country, must be shown to be safe and effective for the purposes claimed, by substantial evidence derived from sound scientific studies performed by experts. Is that good public policy, and sound law? I think so, but others do not. The first step in regulatory reform, though, is not to criticize the FDA for carrying out the law, but rather to debate openly the wisdom of the law.

And when I say "open debate," I mean debate wherein everyone's cards are face up on the table. If people want the FDA to do less, in the sense of washing its hands of certain questions relevant to the public health, then let them come out and propose this, rather than try to cloak their antiregulatory stance in some vague and tired rhetoric about separation of powers, budgetary niceties or pointy-headed regulators of oppressive regulations.

Let us debate, but let us debate issues rather than shadows or surrogates of issues.

Drug Lag

For example, we often hear about a so-called "drug lag," in which the stringent requirements imposed by law on drug companies seeking approval for a new drug purportedly make the emergence of important new drugs in this country lag behind their emergence overseas. If that is indeed currently an important issue, then let us debate the public policy and the alternatives. Is anyone seriously proposing that we eliminate or substantially reduce our drug safety or efficacy requirements, or that we seek less scientific evidence or evidence of a quality lower than that which we now demand? Is someone suggesting that we close one eye to risk and concentrate singly on benefit? If that is what is being proposed, then let us examine it. But if that is not what is being proposed, then what is?

If what is being proposed is an examination of the FDA to see whether it is inefficient, slow, wasteful or dishonest, then let us examine those questions.

If what is being proposed is some way to maintain, indeed, to strengthen safety assurance, while getting drugs more quickly to those who need them, then the FDA, Senator Kennedy and others have all made proposals to do exactly that, and the merit of these proposals would seem to qualify as a subject worthy of legitimate and dispassionate debate.

Delaney Clause

In this regard, let us turn away from drugs to something more germane to your own industry, and a subject obviously appropriate for debate, the Delaney Clause. The definition—"No substance can be added to food if it has been found to cause cancer when fed to animals"—is an amendment to the Federal Food, Drug and Cosmetic Act. Jim Mack has asked me, "Where do you stand on the Delaney Clause?"

Well, the Delaney Clause is the law of the land, and we exist to enforce the law. Further, the Delaney Clause still seems to be the most practical and workable substitute we now have for the needed definitive scientific knowledge in the area it addresses. By definitive scientific knowledge, I mean the data that can provide answers about whether or not there is a "safe" level of human exposure to any animal carcinogen.

Someday, the FDA will be able to respond to questions of carcinogenicity in precise quantitative terms. We will know that below a certain quantity of "x," the chemical is safely metabolized or excreted; above this quantity of "x," there is an increasing, but known, probability of cancer. But we do not yet often have data that permit such quantification.

But some people, including some scientists, feel that we now know enough to allow Congress to eliminate the absolute nature of the Delaney Clause, and substitute some method of assessment of risk—so let this, too, be a matter of open debate, and examination of public policy.

Further, let the debate take place in the arena that fashions public policy, the Congress. For when it comes to this kind of basic policy question, I believe that you and all who deal with the FDA should perceive the FDA for what it is: an instrument of public policy, not its creator.

Proper Role of a Regulatory Agency

If all I had to say to you today is that we are anxious to secure a unified judgment about the proper role of the FDA and the proper policies we should follow in regard to your concerns, I am afraid these remarks might seem somewhat negative.

But I think there is a more positive way to look at this question of the proper role of a regulatory agency such as the FDA. That way involves the question of how we can do our job, without becoming increasingly more intrusive.

I feel personally that intrusive regulation is not necessary, and that, to be even more positive, the recent evolution of the FDA is leading in the direction of less intrusiveness.

In fact, I think a good case can be made of the fact that the best way to regulate also happens to be the least intrusive—by seeking to have informed individuals and institutions making their own rational choices. This, of course, is the essence of education—to provide an individual with knowledge and attitudes sufficient to allow that person

to make rational choices, so he or she does not need an external regulator.

In this connection, one way to look at the question raised in your *Bulletin*—the rationale behind the FDA actions in general—is to trace the evolution of the FDA as we have developed in the direction of regulation that is both less intrusive and more effective. There have been at least two major phases to the evolution of our current regulatory philosophy.

The first phase persisted for the longest period, and was characterized by a "case-by-case" approach to regulation. While this approach continues to be important, it is no longer the almost exclusive focus of FDA activity, as it was for the first 60 years of our existence. The "case-by-case" approach educated by means of bad example. A violation occurred, and we prosecuted, the obvious purpose being not only to punish the guilty but, by means of the example, to deter the not-so-innocent, as well. This was intrusive regulation, and was sometimes unfairly selective. It was very effective in certain areas, totally ineffective in others, but it was essentially all that was available.

The second phase involved a gentler, generally fairer, but yet effective process of education through the cooperative development of regulations. I say "cooperative development," because our regulations are increasingly being written by a process that takes into account the legitimate consumer, industry, and professional points of view.

Implementation of Medical Devices Legislation

One current and highly illuminating example of this is our effort to implement the new medical devices legislation in the most effective and least intrusive manner. To achieve this we are, for example, sending our medical device staff to ten cities across the country, where they will meet with manufacturers and users of medical devices. Our aim is not only to explain what we are seeking to accomplish, but we also want to learn ways to do it without unnecessarily burdening those who make medical devices, without hindering those who develop them, and without interfering unnecessarily with those who use them.

Our current process of securing comment and advice on proposed regulations is only one element of their educational potential. Equally important is that the final regulations seek to tell those affected by them, "Look world, here's what we require, here's why we require it, and here's how you can avoid the unpleasantness of falling out of step with your colleagues." As befits an educational document, we have

sought to squeeze out as much of the gobbledygook and bureaucratese as possible. Each significant new proposed regulation comes complete with a preamble which provides readable information about the background and purposes of the proposal. In addition, the final regulation is accompanied by a preamble that also reflects important comments and the reasons why they were or were not adopted. The important point about the education and value of regulations is that they are prospective to the same degree that criminal and civil penalities are retrospective. They inform, they educate, about the future.

Good Manufacturing Practices

Since 1963, we have extended our use of regulations to define good manufacturing practices (GMPs), as well as safe products. Through current GMPs, we are shifting our attention from diagnosing disease, to preventive medicine. The intent of GMP regulations is to determine those processes which, if followed, will assure that a faulty product is unlikely, or indeed impossible, to result from the manufacturing practices.

Now, I realize that GMPs are not universally viewed as a good example of less intrusive government. This certainly came out strongly in the first "road show" set up to get the reaction of device manufacturers to our draft medical devices GMPs. As one outraged and highly articulate device manufacturer put it: Your GMPs are "a blatant obscene effort by the FDA to not only run our everyday business, but even to structure its day-to-day activities and prescribe its very planning. It is an unbelievable document. I cannot believe that you people are sane, let alone serious."

Perhaps some of your membership shared this view when you took umbrage at the GMP Regulations for Cacao Products and Confectionary. You took more than umbrage, come to think about it, you took us to court! The process of seeking redress through the courts is, of course, vital to our system of due process, and it also serves as an important mechanism by which public policy gets clarified. In this instance, the court confirmed that the FDA does indeed have the authority to issue substantive regulations, including GMP regulations.

Once again, though, we were not acting as free agents, but as an instrument of public policy. But the major point here is not the court decision, but rather to look at the GMPs as a way of working together to devise manufacturing guidelines that effectively prevent unsafe products from being made. These GMPs are not created in a back room by persons unfamiliar with your industry, intent on driving you out of

business. They are intended to express that state of the manufacturing art that will do a job in your interest as well as in the interest of the consumer. They are educational documents, based on industry and other sources educating us about what is possible, and what is necessary to achieve excellence, and educating those making a particular product about what the current state of the art dictates.

Once these practice standards are revised as experience dictates, I would not think GMPs were as intrusive or oppressive as our suddenly bringing a legal action stemming from a violation, or asking for a recall or seizure of a product that we determine is violative. At the very least, GMPs set out the ground rules in advance.

Current Regulatory Philosophy

Finally, I would like to mention a last point about our current regulatory philosophy. We are starting to educate not only those who make products, but also those who use or consume them. Let me pause a moment to put this into context. I said earlier that one of the theses of the form of government whose Bicentennial we celebrate, is that an educated citizenry has the capacity and the will to make its own decisions about how it will be governed. It is actually this principle, and not a musket fired in Massachusetts, that was the "shot heard round the world."

Today, the American public is far better educated and far more sophisticated about its universe than was all but a small stratum of society 200 years ago. And it takes only a quick glance at your daily paper to see that Americans are today asserting as never before a right to be heard and a right to be informed about decisions affecting their lives. The consumer movement is but one instance of this desire to know. Television specials, talk shows, books and magazines all reflect this trend.

Though the FDA is subject to sustained, and often unfair, criticism from consumer groups, we welcome this insistence on knowing—whether it involves a particular product or the way in which we reach our decisions about products.

To repeat something I said earlier, the members of the consuming public want to have several kinds of information.

They want to know if a product is safe to use, and if any risk is involved, they want to know how much; they want to have sufficient information to be able to choose wisely whether to use a product or which product, among many, to use.

For example, in the drug field, increasing numbers of women now want to know what drug is being prescribed for them, why, and what it will do to their bodies, minds and future children. Women are learning that estrogens relieve menopausal symptoms, but at the cost of an increased risk of uterine cancer.

I believe women should be provided with sufficient information about drugs to allow them to participate in the decisions made in their behalf. They should be able to decide whether or not they wish to take a drug, or which drug, among many, they might prefer. We are now experimenting with patient package inserts, leaflets containing information about drugs, and have been giving them to women taking oral contraceptives for the past several years, with good acceptance of the practice.

The idea of providing specific drug information to patients offends some physicians, who fear that patients will make bad decisions. Our limited experience with the oral contraceptive patient information leaflets would not bear this out.

Other physicians, recognizing that they have too little time to instruct their patients carefully about drug hazards, favor the idea of patient package inserts. Some even believe that an educated and understanding patient will be less apt to sue for malpractice!

An increasing number of the public and of Congress feels that our current food labeling, also, is not informative enough to allow consumers to make wise choices among products, or to choose whether to use a product at all.

In particular, the exemption from label declaration of mandatory ingredients in standardized foods, the general absence of declaration of names of colors and fragrances and the lack of quantitative ingredient labeling are all currently being debated. I fully expect legislation will be passed—affecting each of these areas—sometime in the next few years.

The FDA has received formal petitions asking that we mandate percentage ingredient labeling for at least baby food. I have directed the Bureau of Foods to recommend to me the best type of fully informative labeling for baby, infant or junior foods, and any other foods prepared from more than one ingredient and put up in pureed, blended, strained, bite-size or cereal form. We will examine the advisability of declaring the percentage of characterizing ingredients in those foods, as part of the label.

Uniform Format for Voluntary Disclosure

We will also prepare a regulation which will provide a uniform format for the voluntary disclosure by manufacturers of the percentage of any or all ingredients listed on the label. The need to prepare this guide is made clear by the several food companies and chains which wish to start voluntarily a quantitative labeling program.

Anything we might wish to do, we will do by means of discussions, public debate, proposed regulations, analysis of comments on the proposals and a final ordering if the proposal is finalized.

You must do at least these several things: (a) decide honestly and openly what you think ought to be done, and why; (b) talk to us—in spite of what you may hear, we are accessible, and we try to listen; (c) work through this association—the group action is efficient; and (d) work through your Congressmen, particularly those on the policy making committees. All too often, what happens in Congressional committees depends on a very few active and articulate people who want something done. Be certain your Congressmen know your thoughts. If the subject at hand is whether or not to pass a law, it is better to talk to Congress before the law is passed than to criticize the FDA afterwards, as we implement the law.

Basically, we all want the same things, and we should work together to get them. The FDA's primary job is to protect the public, but in doing so, we obviously protect you. I welcome your support, your help and your constructive criticism. Last but not least, I appreciate your kind attention to these remarks. **[The End]**

A Violation of the Federal Food, Drug and Cosmetic Act— A Crime in Search of a Criminal

By ROGER M. RODWIN

Mr. Rodwin Is Vice-President of Legal Affairs of Winthrop Laboratories, Inc., a Division of Sterling Drug, Inc.

I. Criminal Law—Generally

Historically, criminal law was founded upon the proposition that the public interests of the community required protection against injuries caused by an individual who wrongfully committed a prohibited act, which was punishable by the state. Generally, unless otherwise provided by statute, an overt act constitutes a crime only if it is accompanied by a criminal intent or by such negligence as is regarded by law as equivalent to criminal intent. "*Actus non facit reum, nisi mens sit rea.*"[1] An act does not make guilt, unless the mind is guilty. And similarly, *scienter*, the knowledge of the actor, is an indispensable element of a crime, unless otherwise provided by statute. Lastly, ignorance of what the law requires or prohibits has been said to be "No excuse." Together these principles lay one foundation for the criminal law of the United States, which provides at the outset, "Whoever commits an offense against the United States or aids, abets, counsels, commands, induces or procures its commission, is punishable as a principal." Indeed, derivative or vicarious criminal liability is imposed as well. "Whoever willfully causes an act to be done which if directly performed by him or another would be an of-

[1] See *Corpus Juris Secundum*, Secs. 1—29.

fense against the United States, is punishable as a principal."[2] Thus, the crime of arson requires the willful and malicious setting fire to or burning.[3] All crimes involving fraud or deception require as a fundamental element not only knowledge of the act but also the *intention* to deceive.

II. The Federal Food, Drug and Cosmetic Act

Section 303 of the Federal Food, Drug and Cosmetic Act, on the other hand, provides that: "Any person who violates a provision of Section 301 (the prohibited acts such as misbranding, adulteration, etc.) shall be imprisoned for not more than one year or fined not more than $1,000 or both." In addition, "if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000 or both." Thus, the initial violation of a provision of the Food, Drug and Cosmetic Act can lead to a criminal penalty in the absence of the accused's intention to commit a violation of the Act and even without knowledge or the ability to know of the commission of an act, for which he is held "responsible."

III. The Case Law Under Section 303

Dotterweich

The initial case interpreting and defining the scope of the criminal provisions of the Act was the landmark decision in 1943, *United States v. Dotterweich*.[4] The case involved a prosecution against the Buffalo Pharmacal Company and its president, Joseph H. Dotterweich, for violations of Section 301(a) of the Act. The company had purchased drugs from a manufacturer, repackaged them under its own label and shipped the products in interstate commerce. There was no question with respect to the facts that the product was misbranded, adulterated and shipped in interstate commerce. The jury found Mr. Dotterweich guilty on all three counts but disagreed as to the corporation. Thus, the question presented for review in the United States Supreme Court was whether the manager of a corporation, as well as the corporation itself, may be criminally prosecuted under the Act of 1938 for the introduction of misbranded and adulterated articles into interstate commerce. In deciding against Mr. Dotterweich, and reinstating his conviction, the Supreme Court analyzed the purposes of the Act which

[2] 18 U. S. C. Sec. 2, 62 Stat. 684.
[3] 18 U. S. C. Sec. 81.
[4] *United States v. Dotterweich*, 320 U. S. 277, 64 S. Ct. 134 (1943).

". . . touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection . . . the prosecution to which Dotterweich was subjected is based on a now familiar type of legislation whereby penalties serve as effective means of regulation. Such legislation dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing. In the interest of the larger good it puts the burden of acting at hazard upon a person otherwise innocent but standing in responsible relation to a public danger."[5]

The Supreme Court decided that the term "person" as used in the statute included an individual in addition to a corporation, which term was specifically included in the statutory definition. The Supreme Court reinstated the conviction against Mr. Dotterweich holding that he aided and abetted the *commission* of an offense in that he ". . . *shared* a *responsibility* in the business process *resulting* in the unlawful distribution of misbranded and adulterated drugs . . . The offense is committed . . . by all who have a responsible *share* in the *furtherance* of the *transaction* which the statute outlaws, namely, to put into the stream of interstate commerce adulterated or misbranded drugs."[6] (Emphasis supplied.) The Court did not, however, decide whether this rule would apply to a corporate officer who had not supervised the violative act, had no reason to believe that a violation had occurred, was assured that a pending violation had been corrected, or who demonstrated that it was impossible to prevent the violation. Some of these questions have now been answered.

Wiesenfeld

In 1964, a prosecution of a public storage warehouseman under Section 301(k) came before the Supreme Court in *United States v. Wiesenfeld Warehouse Company*.[7] The principal issue before the Supreme Court in the *Wiesenfeld* case involved the question of whether or not a criminal violation had occurred under Section 301(k), where the food in question is simply *held*, after interstate shipment before ultimate sale, under insanitary conditions whereby it might have become contaminated with filth. The Court concluded that a criminal offense had occurred under such circumstances, and reiterated the established policy in food and drug regulation:

". . . guilty intent is not a prerequisite to the imposition of criminal sanctions. Food and drug legislation, concerned as it is with protecting the lives and the health of human beings, under circumstances in which they might be un-

[5] 320 U. S. at 280—281. For a thorough analysis of the *"Dotterweich* Doctrine," see O'Keefe and Shapiro, "Personal Criminal Liability Under the Federal Food, Drug and Cosmetic Act—The *Dotterweich* Doctrine," 30 Food Drug Cosmetic Law Journal 5—78 (Jan., 1975).

[6] 320 U. S. at 284.

[7] *United States v. Wiesenfeld Warehouse Company*, 376 U. S. 88, 84 S. Ct., 559 (1964).

able to protect themselves, often dispenses with the conventional requirement for criminal conduct—awareness of some wrongdoing."[8]

It observed, however, that the government in this case may be

". . . seeking to impose criminal sanctions upon one who is by the very nature of his business *powerless* to protect against this kind of contamination however high the standard of care exercised."[9]

Such a defense is appropriate under the Act and requires factual proof to be raised defensively at a trial on the merits. The statute was held to apply to such a situation but a defense could be based upon the accused's lack of power to avoid the violation in question.

Park

Last year, the Supreme Court decided the case of *United States v. John R. Park*[10] in a decision well known through the industry. John R. Park was the president of a large, national foodstore chain, Acme Markets Inc., and was charged with violating Section 301(k) of the Act. The charge alleged that the corporation and its president had caused interstate food shipments being held in Acme's Baltimore warehouse to be exposed to rodent contamination. The company pleaded guilty but the president defended and was convicted after a trial.

The facts are not in dispute. In April of 1970, the Food and Drug Administration (FDA) advised Mr. Park by letter of insanitary conditions at one of the company's 12 warehouses located in Philadelphia. In 1971, the FDA found that similar conditions existed in the company's Baltimore warehouse. Several months later there was a second inspection in the Baltimore warehouse revealing some improvement but continuing evidence of rodent activity in the building. The FDA had written to Mr. Park with respect to the conditions at the Baltimore warehouse after the first inspection. The Baltimore Division Vice-President had responded to the letter and described the steps taken to remedy the condition. Mr. Park testified, in his own behalf, that he had delegated various responsibilities to "dependable subordinates." He identified those individuals responsible for sanitation and argued that he was assured that the Baltimore Division Vice-President was investigating the situation immediately and was taking corrective action. He stated that he did not believe that there was anything more he could have done and maintained that he should not be personally liable for the failures of his subordinates. He did, however, admit that he was "responsible for the entire operation of the company" and ultimately admitted

[8] 376 U. S. at 91.
[9] *Ibid.*
[10] *United States v. John R. Park*, 421 U. S. 658, 95 S. Ct. 1903 (1975).

that he was aware of the original Philadelphia warehouse incident and thus the fact that his sanitation ". . . system . . . 'wasn't working perfectly' and that as Acme's chief executive officer he was responsible for 'any result which occurs in our company.' "[11] The Supreme Court concluded that *Dotterweich* should be followed and held that these sanctions of the Federal Food, Drug and Cosmetic Act impose

"not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur. The requirements of foresight and vigilance imposed on responsible corporate agents are beyond question demanding, and perhaps onerous, but they are no more stringent than the public has a right to expect of those who voluntarily assume positions of authority in business enterprises whose services and products affect the health and well-being of the public that supports them."[12]

The Court added,

"The theory upon which responsible corporate agents are held criminally accountable for causing violations of the Act permits a claim that a defendant was powerless to prevent or correct the violations to be 'raised defensively at a trial on the merits.' *United States v. Wiesenfeld Warehouse*, 376 U. S. 86, 91, 84 S. Ct. 559, 563 (1964)."

The Court concluded that: "The concept of a 'responsible relationship' to, or a 'responsible share' in, a violation of the Act indeed imports some measure of blameworthiness; but it is equally clear that the Government establishes a *prima facie* case when it . . . (demonstrates) that the defendant had by reason of his position in the corporation, responsibility and authority either to prevent in the first instance or promptly to correct, the violation complained of, and that he failed to do so."[13]

Y. Hata

During the pendency of the appeal from the Supreme Court in *Park*, another case was on appeal from a U. S. District Court in Hawaii to the Ninth Circuit Court of Appeals, *United States v. Y. Hata and Company, Ltd.*[14] In the *Hata* appeal from convictions of a corporation and its president under Section 301 *et seq.* of the Act, the issue of the individual's "objective impossibility" in preventing the violation was squarely raised. The indictment was originally based upon inspections in the spring of 1972 of a multi-food storage warehouse owned by the corporation in Hawaii. The FDA discovered during those inspections that birds were flying in and out of the

[11] 95 S. Ct. at 1908.
[12] 95 S. Ct. at 1911.
[13] 95 S. Ct. at 1912.
[14] *United States v. Y. Hata and Company, Ltd.*, CCH Food Drug Cosmetic Law Reporter ¶ 38,065, 535 F. 2d 508 (CA-9, 1976).

warehouse, perching on overhead sprinkler pipes and on bags of rice, and eating from rice bags. They also found bird excreta on some rice bags.

The Ninth Circuit concluded that *Park* controlled the appeal. In the *Hata* case, unlike *Park*, defendants specifically requested an instruction on "objective impossibility" or lack of "power or capacity" to avoid the violation. The Court decided that in *Hata* the defendants were not entitled to receive that instruction from the Court, since there was no proof or offer to prove that the defendants were powerless to remedy or prevent the violations. The elements of the defense of "objective impossibility" had not been offered in evidence and thus the trial judge was not bound to submit the issue to the jury. The appellate court emphasized that the defendants were aware of the bird infestation for several years and, though they tried numerous devices to prevent birds from entering the warehouse, none were successful. They were planning to enclose the food storage area of the warehouse in a huge wire cage when the FDA inspectors arrived. It was clear, however, that the defendants had not seriously considered the wire-cage scheme until the spring of 1972 at the time of the inspection. The Court observed that a wire cage was scarcely a novel, preventive device. Such a "system would substantially, if not completely, prevent access by thieving and untidy birds." The "objective impossibility" argument asserted by the individual defendant in *Hata* was apparently created after trial to fit the rule just enunciated in *Park*.

It should be noted that during the *Hata* proceedings, the defendants contended that the government abused the informal hearing process by introducing, during trial, "self-incriminating evidence obtained unfairly from the (preliminary) hearing." Unfortunately, this contention was not made in a motion to suppress prior to trial and was, therefore, waived. A last ditch attempt was made to dismiss the indictment on the ground of pre-trial publicity. The Court dismissed this contention by stating that pre-trial publicity pertains to the ultimate fairness of the trial, not to the conduct of the government in promoting the prosecution. Citing *United States v. Abbott Laboratories, Inc.*,[15] the defendants conceded the jury was impartial and, thus, any pretrial publicity did not negate the fairness of the trial.

Starr

Lastly, the case of *United States v. Dean Starr*[16] was decided by the Ninth Circuit Court of Appeals on the same day as the *Hata*

[15] *United States v. Abbott Laboratories, Inc.*, 505 F. 2d 565 (CA-4, 1974).

[16] *United States v. Dean Starr*, CCH FOOD DRUG COSMETIC LAW REPORTER ¶ 38,066, 535 F. 2d 512 (CA-9, 1976).

decision. In this case, the Cheney Brothers Food Corporation and its Secretary-Treasurer, Dean Starr, were charged with violating the Act by allowing contamination of food stored in a company warehouse. The individual, Starr, appealed. The charge was based upon an infestation of mice which occurred in 1972 after an adjoining field was plowed for farming. The corporation and Mr. Starr, who was charged with handling sanitation problems, knew of the problem and took some corrective action. In the presence of the FDA inspector, the warehouse janitor was ordered to make corrections but did not do so for a month. When the inspector returned, the janitor told him that mice were still in the warehouse and that he had not taken the corrective steps as ordered. The janitor also falsely suggested to the FDA the existence of additional violations.

The Court found that Mr. Starr had the responsibility of the actual operation of the warehouse and, thus, had the responsibility "out of which the violation grew." Starr argued that it was "objectively impossible" to avoid the violation, since the contamination was caused by a "natural phenomenon"—the plowing of a nearby field, which in turn resulted in mice fleeing that sanctuary and infesting the warehouse. The Court dismissed this position and declared that the duty of "foresight and vigilance" requires a defendant to anticipate and prepare for such an occurrence whether it be deemed "natural" or "artificial." Secondly, it was argued that the janitor sabotaged the company, refused to comply with the officer's clean-up instructions and allegedly brought new violations to the attention of the FDA inspector. The Court determined that the defendant still had the responsibility and cannot delegate it. The janitor's frustration of the company's effort to correct the violations would mitigate the penalty, but the passage of a month indicated that the Secretary-Treasurer failed to "devise whatever measures are necessary to insure compliance with the Act."[17] The Secretary-Treasurer, Starr, clearly could have taken additional steps to cure the violative conditions by the time of the second inspection. "Objective impossibility" as a defense to the charge was not supported in this case. Note, that in each of these leading cases following and expanding upon *Dotterweich*, the violation was obvious, related to food contamination and involved lack of sanitation.

[17] *United States v. Park*, 421 U. S. 672.

IV. Current Regulatory and Legislative Crosscurrents

A. The New Current Good Manufacturing Practices

On Friday, the 13th of February, the FDA published proposed regulations with respect to Current Good Manufacturing Practices in the Manufacture, Processing, Packing or Holding of Drugs. Section 211.180 of the regulations requires in Subdivision (e) that:

"Procedures shall be established to assure that the responsible corporate officials of the firm are notified in writing of any investigations conducted under . . . these regulations, of any recalls, reports of inspectional observations issued by the Food and Drug Administration, or any regulatory actions relating to Good Manufacturing Practices brought by the Food and Drug Administration. These procedures shall specify among other things, that a routine written report shall be issued at least quarterly summarizing all such matters and the status of corporate actions being taken to resolve outstanding problems."

In this manner, the FDA hopes to dispose of one element in fixing personal responsibility by requiring notice to be given to specific corporate officials of the firm. This regulatory requirement lays the foundation for a criminal proceeding in accordance with *Park*, insofar as the government thereby establishes "a responsible relationship" to a violation of the law.

B. Proposed Amendments to the Act

Shortly after the publication of the Current Good Manufacturing Practice regulations, there was a proposal to amend the Act, in order to blunt the impact of the *Park* decision on top corporate executives. The amendment would limit the government's basis for criminal prosecutions against top corporate executives by requiring proof that the violation was committed *knowingly, willfully or negligently.* Congressional leaders have indicated that they are not prepared to accept such a restriction of criminal liability at this time.

On July 30th, the Senate passed the Eagleton Cosmetic Bill, but at the last moment the language in the bill, which would have required a negligence standard or at least knowledge of the violation, was replaced by the so-called Hathaway amendment, which imposed a "prudent man" standard for criminal liability. Thus, the Eagleton Cosmetic Bill, with the Hathaway amendment, now provides criminal penalties with respect to anyone who acts knowingly, willfully or without the care, skill, prudence and diligence under the circumstances then prevailing that a *prudent man* acting in a like capacity and familiar with such matters would use in the conduct of an enterprise of a like character.

C. The Medical Device Amendments

The Medical Device Amendments of 1976 were followed by proposed regulatory procedures published in the September 3rd edition of the *Federal Register*. Among the requirements set forth in the Establishment Registration Section is one which requires each registered establishment to designate an individual within the organization to serve as liaison between the organization and the FDA in matters relating to registration. The term "official correspondent" is defined in Section 807.3(d) as the person designated by the owner as responsible for performing the duties described therein. The FDA is quick to warn, however, that:

"The use of an official correspondent is intended only to expedite communication between the agency and persons required to register. Therefore, the designation of an individual as the official correspondent for device registration and device listing purposes in no way exempts the owner or operator, or *other legally responsible individuals*, from compliance with all applicable provisions of the act."[18] (Emphasis supplied.)

V. The Criteria for Criminal Prosecution Under Section 303

It seems clear, therefore, that individuals who hold any responsible position of authority in such a manufacturing enterprise are exposed to the very real hazard of criminal prosecution for an unintended violation of the law about which they may have no knowledge or, assuming awareness of the act or circumstance in its broadest sense, are without the scientific knowledge or technical capacity to comprehend its significance as a violation of the Act. The real question then becomes what criteria are considered by those who review such situations and ultimately authorize criminal prosecutions by representatives of the FDA.[19] It would appear that the following factors would be regarded by the government as important in determining whether or not to institute criminal prosecution against an individual:

(1) Any willful, intentional violation of the Act or deliberate conduct which constitutes a violation of the Act.

(2) Gross negligence or reckless disregard for the requirements of the law which results in a violation of the Act.

(3) Any conduct which results in a violation of the Act and creates a dangerous condition or health hazard to the public.

(4) Any act or failure to act in a situation which is obvious and results in a violation of the Act.

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[18] 41 *F. R.* 37458 (Sept. 3, 1976).

[19] See Pfeifer, "Section 305 Hearings and Criminal Prosecutions," 31 FOOD DRUG COSMETIC LAW JOURNAL 376 (July, 1976); also see Fine, "The Philosophy of Enforcement," 31 FOOD DRUG COSMETIC LAW JOURNAL 324 (June, 1976).

(5) Any repetitive, recurrent or persisting violation which evidences an attempt to meet only minimum requirements. This may be the most typical situation where the FDA discovers a recurrent, uncorrected violation after notice to the responsible employees.

(6) Any conduct, or failure to act, which is related to a quality control system which could have prevented the violation. This is the kind of situation present in the *Park* case when Mr. Park admitted that his maintenance system was not working perfectly.

(7) When the result of the violation causes substantial economic damage to the public even though there may be no health hazard or other personal damage.

(8) The last criteria relates to who would be chosen as the individuals to prosecute in such situations. Generally speaking, any individual who knew or should have known of the circumstances, conditions, or actions surrounding a violation and who occupied a position with the power and/or authority to prevent, detect or correct the violation, *whether directly or indirectly.*

VI. Conclusion

A. Don't Overlook the Obvious

It is important to remember that the individual who actually failed to act properly and whose failure (or conduct) is the cause of the violation, is certainly within the ambit of prospective defendants. The janitor in the *Starr* case who purposely failed to maintain the premises is criminally and civilly responsible as the initial, violative person. Beyond that individual, his superior, the supervisor, the manager, the manager's corporate director and ultimately the executive officers of the corporation, including the appropriate Vice-President, President and/or Chairman, would be the individuals caught within the net of the criminal provisions of the Act. The Supreme Court emphasized in *Park* that the sanctions imposed upon responsible corporate officials is ". . . by no means necessarily confined to a single corporate agent or employee . . . ."

The FDA is convinced that prosecution of a business without including an individual or individuals as defendants would rarely serve to impart the deterrent effect that a prosecution should have. Prosecution, in this area, must include those individuals who are responsible for the conduct of the business and have the power or authority to correct and prevent violations. Certainly, we can

expect the FDA to recommend criminal prosecution without warning or notice where there is evidence of: (1) intentional fraudulent or deceptive conduct (including economic fraud, that is, short weight, etc.); (2) obvious hazards to public health; (3) serious sanitation deficiencies; (4) a cover-up of serious violations.

B. . . . Or The Not So Obvious

On December 18, 1975, the FDA published new regulations concerning Prescription Drug Consumer Price Listing under Section 200.200. Subdivision (c) of these regulations provides that:

"Any reminder advertisement or reminder labeling intended to provide consumers with prescription price information which is not in compliance with this section shall be the subject of appropriate regulatory action. *Such action may be taken against the product and/or the responsible person.*"[20] (Emphasis supplied.)

Even Drug Efficacy Study Implementation notices are raising the spectre of criminal prosecution. In a recent publication (September 8, 1976) of the *Federal Register* relating to the marketing status of isoproterenol hydrochloride, the FDA warned that:

". . . approval of an abbreviated new drug application . . . must be obtained prior to marketing such product. Marketing prior to approval of a new drug application will subject such products, and *those persons who caused the products to be marketed, to regulatory action.*"[21] (Emphasis supplied.)

While a corporation's civil and criminal liability is directly related to the conduct of its agents and employees, I would emphasize that the relative responsibilities of the various individual defendants may differ substantially. In fact, the basic problem may have been created by the failure or refusal of one to do what another directed or requested. Remember the janitor in *Starr* who failed to act in accordance with direct orders. On the other hand, what about the corporate officer who fails to implement a responsible recommendation by an operator, his supervisor or manager?

The cases and developments subsequent to *Dotterweich* would appear to have gone beyond the original intentions of Congress and rationale of the *Dotterweich* situation. The *Park* rule may be treading dangerously close to depriving "responsible individuals" of their Constitutional rights by criminal convictions in the absence of proof of *wrongful conduct*. Presumably, the Supreme Court will review the *Hata* and *Starr* cases and ultimately determine whether they are "alien to fundamental principles of our law."[22] **[The End]**

[20] 40 *F. R.* 58799 (Dec. 18, 1975).
[21] 41 *F. R.* 37837 (Sept. 8, 1976).
[22] *Park* dissent at 1917.

Are Food Additives Overregulated?

By BERNARD L. OSER, Ph.D.

Dr. Oser, of Bernard L. Oser Associates, Inc., Is Scientific Editor of the FOOD DRUG COSMETIC LAW JOURNAL.

I AM NOT SUPPORTING POLITICAL CANDIDATES at present, but will quote President Ford's recent remarks on the subject of overregulation. In attacking excessive government regulation, President Ford said, "The Mulligan stew of rules and government regulations often conflicting with one and another, has created a nightmare of red tape, paper shuffling, and new heights of counterproductivity."

Government agencies, including the Food and Drug Administration (FDA), responsible for administration of laws regulating health and safety, are not exempt from this charge of President Ford's. Nevertheless, it cannot be denied that Congressional mandates in the areas as complex and technical as foods and drugs, which include sanitation, nutrition, safety and health, demand a high degree of regulation. But the question is, how much? Does overregulation refer to too many regulations, too broad regulations, or too detailed regulations? The claim has been made that overregulation is costly to industry, and consequently to the consumer as well; that it retards innovation by reducing the incentive to develop potential new products or new uses for existing products. Commissioner Alexander Schmidt has recently stated the reverse, that technological developments generate new regulatory problems.

The multiplicity of regulations, which are often couched in vague legalistic jargon, makes it virtually incumbent on all food companies to retain legal as well as scientific counsel. This places a burden, especially on smaller companies which constitute the vast majority of food producers and processors.

The regulations on food additives are divided into a series of subparts, running from A through H. The first is general and relates to procedural and interpretative matters. The second covers the provi-

sions for exemption from food additive regulations, and includes the so-called GRAS (generally recognized as safe) substances. The legal definition of food includes feed for animals, so Subpart C refers to additives permitted in the feed and drinking water of animals, particularly food-producing animals. Subpart D covers the regulations issued for direct additives permitted to be used in food for human consumption. Next is a short subpart dealing with prior sanctions, substances which are exempt from the definition of food additives. Subpart F relates to the indirect additives such as migrants from containers and packaging materials and equipment. Then there is a small group of regulations concerned with radiation and radiation sources which concludes the principal sections dealing with permitted food additives.

In Subpart B, there are about 250 substances. Subpart B (e) (1) and (2) comprise natural spices and flavors, the largest single category of exempt additives in the FDA's so-called white list. Altogether there are approximately 663 substances in Subpart B, about half in the category of natural flavors and spices, the rest being various functional additives, *viz.* a number of trace minerals used in animal feeds, a very small group of synthetic flavoring substances, and migrants from paper and cotton packaging materials.

Some regulations covering direct or indirect additives include large numbers of substances. They are often called omnibus regulations. For example, under Sections 121.1163 and 121.1164 are the groups of flavoring substances which were originally evaluated as GRAS by the expert panel of the flavor industry and were later incorporated into regulations by the FDA. There are, in that particular list, over 800 flavoring substances, although in actuality there are now well over 1200 generally recognized as safe.

Incidentally, in connection with natural and so-called synthetic flavoring substances, it should be mentioned that it does not follow that the natural substances, including spices, are necessarily safer than the synthetic. We certainly know less about them because there have been fewer toxicological studies of natural substances, and they are of very complex composition. Moreover, what are called synthetic substances are in many cases chemical analogues or counterparts of naturally-occurring substances and indeed may be derived from natural sources.

The chemical industry, which is the principal source of research and development leading to the production of food additives and pesticides, has become rather disenchanted with the complexities, not to mention the time and cost of getting regulatory approval of new food colors, sweetening agents or antibiotics which might have widespread use.

This was illustrated by the difficulty of securing the regulation on whole fish-protein concentrate. Now there are similar problems with texturized-vegetable proteins and with recycled animal waste for use in feed. The potential market for many useful products may be too limited to justify the cost of obtaining clearance from the FDA and other regulatory agencies that may be involved. Dr. Harvey W. Wiley, who fathered our first Food and Drug Act in 1906, disclaimed being an alarmist. He believed that chemicals ought not to be added to foods unless it could be shown that they bestowed qualities to the benefit of the "health, prosperity, and honesty of the community." Describing the problem as mainly ethical, he said, "Injury to public health . . . is the least important question in the subject of food adulteration, and it is the one which should be considered last of all. The real evil of food adulteration is deception of the consumer." Under the present law, no food additive can be approved if its use is construed to be deceptive.

Laws Regulating Food Safety

That new and unanticipated difficulties are often encountered in the administration of Congressional mandates is abundantly illustrated in the implementation of laws regulating food safety. Experience has shown that more attention has had to be devoted by both the FDA and the food industry to substances which past experience indicated to be safe, and to incidental additives present in hitherto undetectable amounts, than to direct or newly introduced additives. This has been the combined result of several factors, namely: (1) the application of new analytical methodology of exquisite refinement and sensitivity, capable of revealing the presence of substances in the parts per billion and lower ranges; (2) advances in toxicological procedures which multiply and intensify the critical parameters of adverse biological effects, for example, longer test periods, more animals, more clinical observations, and mutagenic, teratogenic, and multigeneration reproduction tests; and finally (3) the lack of an official policy which formally recognizes that minute amounts of acutely or chronically toxic chemicals can be inconsequential from the standpoint of safety under conditions of normal use. Thus much to the concern of industry and the embarrassment of the FDA, many "no residue" substances which were formerly permitted to be used have been proscribed because they can now be detected by more highly sensitive analytical methods.

Despite all the attention devoted to food additives from a regulatory standpoint, they play a relatively minor role in terms of public health hazards. This is reflected in the list of priorities developed by

the FDA's Bureau of Foods. Heading the list are food-borne infections which are generally transitory and of low morbidity. Food poisoning results not so much from food production or from the ingredients used as from improper handling or storage both in the home and food-service establishments. At the bottom of the order are the functional ingredients whose safety in use is covered by the Food Additives and Color Additives Amendments. That outbreaks of illness caused by the normal presence of additives in food are virtually nonexistent is indicated by the fact that they are not even reported by the Communicable Disease Center. As reported by Dr. Howard Roberts, the present Director of the Bureau of Foods, food-borne infections continue to have top billing on the FDA's program while food additives trail far behind in terms of potential hazard to health.

Sensitivity Scale

On the other hand, Dr. Roberts' "sensitivity" scale based on consumer reaction is the result of unwarranted apprehension concerning food safety generated in the public media and by misinformed or biased alarmists. Consumer concern influences both regulatory and legislative activity to a degree out of all proportion to real public health hazard.

The food industry also reacts to public concern. It will be recalled that the universally used food color amaranth (Red No. 2), safrole (the main-flavor constituent of root beer) and recently trichlorethylene (a solvent used to decaffeinate coffee) were removed by industry before they were banned by the government. Hypersensitivity as related to food additives is more of a reaction of industry and government than a human affliction.

On the other hand, the exploitation of the alleged absence of food additives—"contains no artificial color," "contains no artificial flavor," "no cyclamates"—has become a commercially profitable maneuver, which, even if true, could be misleading. This type of exploitation has given rise to the organic food myth, which, from a nutritional viewpoint, is an economic fraud on the American community. Furthermore, it is not warranted by the evidence that organic foods are free from filth or pesticide residues, or that they are more wholesome than foods produced with the help of chemical fertilizer and pesticides.

The standard of safety of foods consumed by the American public is higher by many orders of magnitude than was the case a century ago. At the recently celebrated centennial of the American Chemical Society, several speakers drew attention to the quality of food and the

prevalence of truly hazardous adulteration years ago, compared with today. Nevertheless, we have no hard evidence that public health has been enhanced since the enactment of the Food Additives Amendment—because it was protection rather than correction of a hazard that prompted passage of the amendment. Public awareness of the extent of use of chemicals in food production and processing became pronounced after World War II through food standards hearings and the discovery of antibiotics and new organic pesticides. As contrasted with foods of the pre-Wiley era, it is not the threat of acute poisoning that concerns the regulatory agency but the suspicion of subtle, cumulative or chronic toxicity which is difficult, if not impossible, to correlate epidemiologically with the etiology of disease. It is well known that highly toxic substances occur naturally in a great variety of foods, not to mention the contaminants formed by molds in grains, nuts and fruits before and after harvest. The toxic nature of oxalates, hemagglutinins, goitrogens, cyanogenetic glycosides, solanine, shellfish and mushroom poisons were discovered largely through human experience long before toxicological studies were conducted in laboratory animals. The low incidence of food poisoning from the presence of these substances in plant and animal foods is due to the fact that the levels generally present are so low that they are tolerated without apparent harm. However, were these natural toxicants first discovered today it is doubtful that the foods could stand the tests for safety. It will be recalled that several natural sources of food flavors, *viz.* the tonka bean, whose major constituent is coumarin, and oil of sassafras, whose major constituent is safrole, were banned on toxicological grounds.

Prior Approval of Safety

In sharp contrast with the way the law regulates the presence of naturally-occurring poisonous substances in food, added substances are subject to prior approval of safety unless qualified scientists regard the conditions under which they are used to be safe, as judged by common experience or by "scientific procedures." Many problems were created by the provisions for exemption contained in the statutory definition of food additives, especially when it became necessary to arrive at the GRAS status of natural as well as synthetic substances. It was not long before it was realized that natural occurrence does not *ipso factor* confer safety on food components.

Recently, the FDA has become preoccupied with developing guidelines, partly at the urging of industry. Some food processors have wanted clarification concerning the Agency's expectations in relation to good

manufacturing practice (GMP) as specified in the Federal Food, Drug and Cosmetic Act particularly with regard to sanitation. It was thought to be useful and educational to develop operational guidelines. It turns out that industry had not bargained for as much as it has gotten because these guidelines have actually become equivalent to regulations with the force and effect of law. In a recent decision dealing with guidelines proposed for the cacao and the confectionery products industry, the court said, "In reviewing the promulgation of regulations which are the product of an informal rule-making procedure, the Court's function is limited to a determination that the regulations are reasonable and within the statutory scope of authority, that they have been formulated in the manner prescribed, and that individuals opposing the promulgation have had an opportunity to make their views known." There are those in industry that would contend that they have not had sufficient opportunity nor have their views been given adequate weight. The responses to objections given in the preambles to these GMP regulations are not sufficient in the view of many commentators. In any case, this illustrates the need for those responsible for food production and quality assurance to keep abreast of FDA releases in the *Federal Register* and take cognizance of the dates for filing comments on proposals and of the effectiveness of orders. The FDA has thus far issued "umbrella" GMP's which cover in a broad sense the sanitary provisions for the maintenance and operation of food plants and are now developing more specific regulations applicable to particular branches of the food industries. Included are cacao and confectionery products, low-acid canned foods, smoked fish, bottled drinking water, and in the offing are frozen foods, baked goods, fermented foods, and so on. The concern of these industries is that GMP recommendations are likely to become so detailed that they will become technological straitjackets.

On the horizon now is a new proposal of special interest to food scientists and technologists, namely, that there be developed "guidelines" for good laboratory practice (GLP). Among other things these would apply to qualification of personnel, adequacy of facilities, maintenance of records, etc. and provide for regular FDA inspection. GLP regulations would not be objectionable if they were couched in general and clearly understandable terms but they could cause unnecessary difficulty for industrial control and testing laboratories if they were to be too specific. (In the light of the recent Red No. 2 debacle, one might ask whether the FDA itself could stand detailed scrutiny of its

own laboratory operations.) With respect to the safety evaluation of food additives, it is necessary to point out that toxicology is neither an exact nor a static science. New developments are constantly occurring and new criteria are being introduced. We do blood enzyme tests for which suitable methods did not exist 20 years ago. We are examining for mutagenic and teratogenic effects by newly developed procedures. Electron microscopy has come into use as a histopathologic tool. Computer technology has facilitated statistical evaluation of data.

Complexity of Toxicology

Toxicologists do not object to guidelines if indeed they are guidelines. They prefer to retain the prerogatives of professionals in the conduct of their investigations, letting the chips fall where they may, rather than having to conform to inflexible cookbook procedures. The complexity of toxicology from the design of protocols, to the selection and performance of the tests and the biological and statistical interpretation of findings in relation to the conditions of use or exposure, all require the application of a high degree of scientific judgment too difficult to spell out in rigid terms. Safety evaluation is based fundamentally on the demonstration, under appropriate conditions, of no toxic or otherwise adverse effect. There are many reasons why informed judgment rather than objective measurement must be applied. First of all, there is an intrinsic lack of precision in the determination of quantitative no-adverse effect dosage levels in animals. This is a gray zone depending upon what is regarded as an adverse effect and the methods used to determine it. Secondly, various, yet arbitrary, safety factors are used in extrapolating from "no-adverse effect" levels to permissible dietary intakes and tolerances in food. Thirdly, pathologists differ in their reading of histopathologic responses under the grossly exaggerated conditions employed in feeding studies. The understandable absence of complete unanimity among qualified scientists on these issues is compounded by the bureaucratic interpretations of ill-defined or ambiguous concepts embodied in the law.

Compliance with food additive regulations is further complicated by the not infrequent efforts to redefine terms such as "substance" in the definition of food additives which are GRAS, "no residue" by reference to analytical methods of "appropriate" sensitivity, "carcinogens" to embrace promoters of benign as well as malignant tumors, and "imminent hazard" in relation to both time and severity.

The Senate Bill, S. 641, providing for surveillance of food processors, requires that every company develop safety assurance standards. These

are to be formulated and implemented so as to provide "reasonable assurance that food does not present an unreasonable risk of adulteration." Can anything be more vague than that?

These are some of the difficulties associated with regulations in pursuit of the illusory goal of achieving absolute safety. On the subject of excessive regulation, it is worth quoting from an interesting letter that appeared in *C & E News* (October 6, 1975): "The combined hysteria of politicians, consumerists, and regulators seems to have convinced much of the press and some reasonable part of the public that the answer to the bad effect of too much regulation is still more regulation, that more laws will correct the evils of laws that are already too complex and involved and the way to free a cumbered body politic is to wind still more red tape around the corpse."

Congressional Mandates

The responsibility of the FDA as the Agency charged with enforcing Congressional mandates in the area of food and drug safety is not an enviable one. In an address at the University of Georgia, John T. Walden, Assistant Commissioner for Public Affairs, recently stated that the FDA faces "opposition and controversy in all we do. In nearly all our actions the critics on the one hand yell that we've gone too far too fast, that we are interfering with human freedom and economic progress. Simultaneously, the critics at the other extreme are shouting that what we do is too little and too late, that we have sold out to the industries we regulate and failed our major obligations to protect the public from unsafe products and unscrupulous businessmen."

Senator Edward M. Kennedy, one of the harshest critics of the FDA, has stated that: "Congress has given it an extraordinarily wide range of responsibilities," "staggering" enforcement responsibilities coupled with a budget that is "ridiculously low." In support of his bill (S. 2696) to reorganize the FDA into two separate and independent units (a drug and devices administration and a food and cosmetic administration), he acknowledges the need for increasing the scientific competence of the Agency. Pending proposals will still further widen the range of enforcement activities and extend the FDA's burden. For example, to implement proposed regulations defining GLP and to monitor industrial and independent laboratories, the FDA requested an appropriation of $25 million. This is in addition to the authorized budget of over $200 million for the next fiscal year.

It is interesting to examine how the FDA has grown, in both size of staff and budget, in the past quarter century during which our major laws regulating food and drug safety were enacted. The annual appropriations have risen over 37-fold since the early 1950's while the number of personnel has multiplied almost seven times. In spite of the relatively greater rise in appropriations (which of course includes inflationary factors, the cost of facilities, etc.), the FDA is still not able to attract the caliber of high level administrative, scientific and technical personnel essential for the proper fulfillment of its obligations. At present, recruitment for top level positions is limited by the maximum salaries permitted under civil service regulations. Scientists of outstanding competence who would be willing to assume such responsibilities at salaries incommensurate with the task, and to withstand the criticism and at times the abuse that goes with the job, are few and far between.

The proposal to split the FDA into two agencies, as mentioned above, would inevitably involve overlapping responsibilities, multiple jurisdiction, and costly duplication of which there is already too much. For example, USDA, FDA, EPA and OSHA have authority over various aspects of pesticides and are not infrequently in conflict. Other proposed legislation would give Congress authority to revoke regulations of administrative agencies or at least require that they be reconsidered. One wonders what effect this might have on a decision of the FDA which was based not on scientific facts but on the wish to allay public concern, as was said to be the case with the Red No. 2 decision.

In concluding this discussion of the plethora of regulations applicable to food safety and the relative roles of the FDA and Congress, it is apropos to quote from a recent editorial in the journal, *Science:* "Congress is perhaps the branch of government least suited to receive, process and use scientific information, not because of intellectual incapacity, but because of its organization and protocol and the nature of the legislative process." **[The End]**

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