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Risk Assessment and the Credibility of Federal Regulatory Policy: An FDA Perspective*

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FDA's fundamental goals are to protect and promote the public health, using the best possible science and the law. The evolution of food safety policy toward potential carcinogens reflects a conscious decision by the agency and Administration to use risk assessment in carrying out these goals. Examples include FDA policies toward assessing the safety of animal drug residues, setting specifications for constituents of food and color additives, and most recently, a common sense *de minimis* interpretation of the "Delaney clause." While committed to risk assessment as a useful tool, FDA acknowledges that judgments must be made on less than perfect data. In addition, recent history shows that there may be a serious "credibility gap" in public acceptance of regulatory toxicology. To ensure that there is an adequate science base for regulatory decisions, the challenge is twofold: First, the data necessary for sound safety evaluations in individual cases must be developed, based on current knowledge; and, second, the validity of assumptions underlying risk assessment should be tested and refined and scientific consensus achieved. Otherwise, risk management policy will rely on assessments based on extremely conservative assumptions, tending to overestimate risk. Risk assessment assumptions must also be better communicated to policymakers and the public. If these challenges are successfully addressed, public confidence in marketed products, and in science-based regulatory policy, will be enhanced.

FDA's MISSION AND PUBLIC EXPECTATIONS

The evolution of Food and Drug Administration (FDA) regulatory policy represents an important illustration of the Administration's view of risk assessment and risk management. We have made a conscious decision to use, and to work to refine, risk assessment and risk management techniques in carrying out FDA's fundamental goals: protecting and promoting the public health, using the best possible science and the law.

The American people rely on all components of regulated industry as well as FDA to ensure a safe, abundant, and affordable food supply; and safe and effective drugs,

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vaccines, and medical devices. We also regulate veterinary drugs, blood products, cosmetics, and radiation-emitting products. We occupy a critical gatekeeper position in the arena of technology transfer: from the time of discovery of new products, through basic research and clinical testing, to the introduction of products at the consumer level. Our broad mandate also requires us to be involved in educating consumers so that they can act to ensure their own better health and safety.

In a real sense, FDA's mission touches the lives of all Americans and, through our global regulatory leadership, countless others all over the world. Our system is based as much or more on responsible industry behavior as on law and regulation, and it has served us well. We all know the public will not suffer lightly any failures. Their insistence on the highest standards is clearly reflected in the safeguards provided in our laws.

Risk assessment and risk management considerations in the broadest sense have always permeated FDA decisionmaking. In the area of drugs and medical devices, for example, we weigh risks against benefits according to a sliding calculus involving medical judgment (although the process, for the most part, is not what may be termed "classical" risk assessment). Our postmarketing surveillance activities—for drugs, devices, and since 1985 for foods—serve as sentinel systems alerting us to potential adverse effects, a kind of continuing risk assessment that often leads to risk management interventions such as labeling changes. Information and education efforts aimed at arming consumers and health professionals with the knowledge they need to make sound decisions may be viewed as a form of risk management, as are our plant inspections, import surveillance programs, and investigations of foodborne disease outbreaks (often conducted in cooperation with sister Public Health Service agencies).

It would be a daunting if not impossible task to try to address all of these risk assessment and risk management issues. Therefore, this paper will attempt to focus on the broader issues as illustrated by the evolution of food safety policy toward potential carcinogens, one important area of FDA responsibility. As stated above, we at FDA see our mission as putting the best possible science to work in carrying out the laws under our jurisdiction. We are committed to implementing the laws effectively, to serve real public health goals.

In the food safety area, public opinion surveys show some nagging suspicions about direct additives as well as contaminants in foods. Proposition 65 is perhaps the most visible recent evidence of continuing public concern about potential carcinogens and teratogens in water, foods, and other consumer products. At the same time, we see evidence of a degree of skepticism about the proliferation of studies purporting to show new risks even in traditional foods. You do not have to be of a terribly scientific bent to pick this up; a review of the funny papers in our major newspapers shows that "carcinogen of the week" scare stories may be met with somewhat derisive humor. This is where our dedication to the highest scientific standards and testing must come into play on two fronts: to ensure the safety of our food supply against real risks, and to maintain the credibility of regulatory policy. While we must err, responsibly, on the side of safety, we cannot afford to be the boy who cried wolf too many times. FDA is not alone in being the butt of cartoonists, and even editorial writers. Many of you have probably read the *Washington Post's* editorial about the high risk of taking showers, in light of an EPA finding about exposure to chloroform in shower water.

As our scientific sophistication increases, both in terms of exciting new technologies and in terms of our ability to detect potential risks at levels so infinitesimal they stretch the human imagination, it is clear that the challenges of the future will be greater than any we have known in the past. In this Administration, we have made some landmark strides toward meeting these challenges, through such efforts as the Office of Science and Technology Policy (OSTP) state-of-the-science review of chemical carcinogenesis, published in 1984 (1); the Health and Human Services Department's work to define a consistent approach to risk assessment and management, as illustrated by the 1985 report of the Committee to Coordinate Environmental and Related Programs (CCERP) (2); and, of course, the FDA's own Action Plans developed by Commissioner Young to guide the agency into the 21st century (3, 4).

Some of the most relevant parts of the Action Plans and related FDA initiatives are discussed further below. But first, it might be illustrative, if not scientific, to take more of an anecdotal view.

THE SACCHARIN EXPERIENCE

As a green staffer on the Senate Health and Scientific Research Subcommittee, I was first thrown into the fray of risk assessment and risk management with the explosion of the saccharin issue. I remember reading an FDA press release that made me think—Aha, FDA does not like the Delaney clause and wants it repealed. They've written a press release that points out just how ridiculous it is; you'd have to drink hundreds of cans of diet soda before you'd have to worry about cancer. (Later, I was told by people who should know that the real reason for the tone of the release was that FDA officials feared unduly alarming people who had been routinely consuming saccharin.)

Soon after FDA's announcement, calls began to come into the office. We heard from health groups, from parents who wanted their diabetic children to enjoy the normalcy of a soft drink, but at the same time were not willing to expose them to a real risk of cancer for that benefit. We also heard from the parents of children who had had cancer, and who were at high risk for recurrence. All echoed the same questions: Is it true? What level of risk are we talking about? Taking advantage of one of the most important benefits of serving on a Senate Committee staff, I was able to call the National Cancer Institute and get a crash course in why high-dose animal studies were relevant, and to consult with some of the leading experts who had done studies relating to sweetener use and bladder cancer in humans. The subcommittee conducted hearings and heard from some of the best minds in the business.

But in the minds of many, perhaps most Americans, we never got a straight answer to the question of level of risk.

In the end, of course, product-specific legislation was enacted (5). Congress knew there was a larger problem, and so the Saccharin Study and Labeling Act also called for a comprehensive study of our food safety laws and what changes might be necessary to bring them into conformance with consistent policy and state-of-the-art science.

All of this turmoil involved a compound that had been in wide human use for decades, for which human exposure and some epidemiological data were available. Since then, I have learned a lot both formally as well as on the job, and I've lost a lot

of sympathy for the epidemiologist who bemoans the difficulty of extrapolating from high-dose occupational exposures to the lower doses likely to be experienced by most Americans. How much more difficult is the situation facing us when we have to make decisions with only animal data, perhaps conflicting animal data, in premarketing applications for compounds that humans have never been exposed to at all. For FDA at least, that is often the case. We must make policy decisions based on sound science, and scientific judgment, but we must also acknowledge that the judgments we make are based on less than perfect data.

One response to the FDA's announced intentions with respect to popular artificial sweeteners, both cyclamates and saccharin, was panic buying and hoarding of these products. This is hardly a logical reaction if indeed the pronouncements of the Food and Drug Administration are perceived as credible. Even back then, more than a decade ago, the underlying question of scientific and regulatory credibility was more than just a nagging doubt. At least some people *acted* on the assumption that we as scientists and regulators were *not* credible. We were perceived as attempting to deny people a choice they wanted to have, based on our determination that a risk they perceived as acceptable should not even be a matter for informed consumer choice. Similarly, I would be willing to bet that the *Post* editorial writers have not sworn off showers and even continue to use paper towels, despite reported chloroform and dioxin risks.

As it turns out, the public was not wrong to question us about saccharin. At subsequent hearings on extending the saccharin legislation—perhaps appropriately and confusingly known as the moratorium on the ban—Commissioner Young testified that epidemiological evidence developed since the original proposal to take saccharin off the market had tended to allay rather than increase our level of concern (6). But the issue of risk assessment and regulatory credibility goes far beyond Americans' attachment to artificial sweeteners. A quick look at some of the assumptions and extrapolations we commonly make, assumptions which have largely not been tested, indicates that regulatory decisions based on such procedures require something of a leap of faith.

RISK ASSESSMENT ASSUMPTIONS AND THEIR CONSEQUENCES

A couple of years ago, I asked Dr. Ronald Hart, Director of FDA's National Center for Toxicological Research (NCTR), to list some of these assumptions. He was only too glad to do so, and to volunteer that many of them were indeed testable. Although a number of them apply across the boundaries of federal regulatory agencies, I will list just a few that are relevant to FDA. We assume that:

Observed experimental results can be extrapolated across species by use of standard scaling factors, which themselves have not been tested (testable).

A linearized multistage model can be used for low-dose extrapolation (hard, perhaps practically impossible, to test at this point).

Human exposure data from one chemical can be extrapolated to other similar chemicals used in a similar manner (measurable and testable).

Target dose can be assumed to be proportional to administered dose (testable).

Extrapolation across routes of exposure is possible (testable).

Average doses give a reasonable measure of exposure from doses that are not constant in time or rate (not only testable, but in fact probably rarely true).

The risks from multiple exposures and multiple sources of exposure are additive (testable).

Structure–activity correlations can predict human carcinogenicity (or comparable effect for other diseases) (testable).

Levels of unbound and bound residues of metabolites or agents have equivalent carcinogenic potential (testable).

The occurrence of tumors in one species or one sex, perhaps in a single multigenerational animal study is predictive of human susceptibility, despite conflicting test results in other species (testable).

Toxicologically speaking—and I do not claim to be fluent in that tongue—it is quite an array. In each individual instance, it may seem wise, and even prudent, to accept a worst-case scenario. But how far can we go, building worst-case assumption upon worst-case assumption, before we leave the realm of reality, and enter the realm of the, at best, theoretical?

For a long time, particularly in the field of carcinogenesis, it seemed in some cases as if we were adopting an almost antiscientific attitude. There was no point in risk assessment at all, so long as any theoretical risk was unacceptable. Regulatory judgments with broad implications were to be made for the public, without ever even making explicit any of the assumptions upon which they were based.

This attitude, which actually would seem to discourage advances in scientific understanding, has changed. It had to. We had reached a point when regulators were faced with controlling risks that had been described as the equivalent of eating one peanut every 8 or 9 months; or perhaps spending a day in a brick house instead of a wooden one, or taking an uneventful transcontinental airline flight. I am not saying any of these comparisons were necessarily accurate, but we can no longer say that the level of risk does not matter. The science of risk assessment—and it should be a science—is coming into its own as a useful tool for policymakers, and relativity of risk is understood as an important concept by policymakers and the public alike.

Risk assessment has many failings, even apart from the kinds of often hidden assumptions I mentioned. Too frequently, we do not have the data upon which a risk assessment can be based. Perhaps even more often, we have asked risk assessors or scientists to make the kind of policy or societal risk management decisions that are beyond any particular kind of scientific expertise, and some scientists have been willing to take on this role. I am reminded again of a painful scene from the saccharin crisis. At one point, senators asked a panel of scientists to raise their hands and tell us whether saccharin should be banned, restricted, labeled, or what? To their credit, this particular group of scientists had already made their position clear, that such a decision should be made by society, based on the best possible science, and that they had no special qualifications to serve as ultimate arbiters of what risk should or should not be acceptable to society or to individuals within it. Curiously, as I recollect, their "votes" when pressed seemed to correlate with their fields of expertise. Those who had devoted their professional lives to the problem of cancer were far less willing to raise their hands in support of continued unrestricted marketing of saccharin, while those who had concentrated on such fields as obesity and diabetes were more likely

to approve of its continued availability. While the input of such distinguished experts is indispensible, it is not fair for policymakers to place the full burden of risk management regulatory policy upon them, nor is it appropriate for them to take it upon themselves.

This Administration is committed to careful risk assessment, using the best possible techniques we now have, as a guide for regulatory decisionmaking. But at the same time, we recognize the need to take steps to reduce the uncertainty inherent in current techniques.

Reviewing some of the assumptions we often make, I think we can agree that risk assessment as a science is not yet all it should be. For a long time, we could perhaps argue that such assumptions had to be accepted because they could not be tested. Undeniably, some risk assessment principles still fall into that category, but some important ones do not. They can and should be tested. Until they are, risk managers deserve at least to have before them a full discussion of the assumptions that were necessary in arriving at a risk estimate, as well as an analysis of possible substitutes or alternative measures to control exposure and a full exploration of the options—including nonfederal and nonregulatory options—for risk management. In 1985, as I mentioned, CCERP, a Committee representing Public Health Service agencies with primary responsibility for assessing and managing risks, was charged with the task of defining, for the first time, a consistent philosophy of risk; outlining the assumptions upon which risk assessment is based; and developing a problem-solving approach to risk management for the Department of Health and Human Services.

The Committee's report outlined several principles which should form the basis of any risk assessment prepared for decisionmaking purposes, and they deserve mention here. The Committee stressed the need: (i) to gather all pertinent scientific and other information about a product or activity; (ii) to make the data public as early as is responsible and feasible; (iii) to seek outside expert advice and assistance when necessary; and (iv) to develop procedures designed to facilitate *scientific* inquiry into regulatory matters whenever possible, in lieu of formal legal-type procedures (2).

These are the types of guiding principles that Commissioner Young is implementing at the Food and Drug Administration. For example, the report of the expert panel he charged with reviewing the data available on provisionally listed color additives reflected these principles, and served as a notable case study in clearly delineating the assumptions and extrapolations made in risk assessment. Their final report was published in the journal *Risk Analysis* in 1986 (7).

FDA ACTION PLANS

Key elements of both of the Commissioner's Action Plans, a carefully crafted set of initiatives designed to serve as a blueprint for FDA's activities into the 21st century, also highlight both our willingness to employ the best possible risk assessment techniques and our acute awareness of the limitations of those techniques.

In its section on *risk assessment,* Action Plan Phase I pledged FDA to develop a comprehensive program to evaluate and test, where practicable, the assumptions used in risk assessment. Implementation was to involve prioritizing assumptions as to importance and feasibility of testing; defining the measures most relevant to human exposure; evaluating the effects of modulatory factors (such as caloric restriction on

the induction of cancer); and developing models for extrapolating animal test data to humans. Throughout, the value of external peer review, as appropriate, is stressed as a means of both maximizing the scientific quality of the work done and increasing public confidence in the scientific base of FDA actions. I am pleased to report that NCTR, and the Center for Food Safety and Applied Nutrition (CFSAN), as well as researchers at Oak Ridge and in other agencies, have already begun or are planning projects dealing with each of the difficult but testable assumptions I mentioned earlier. When applicable, FDA and other regulatory agencies are already using the results of this work in making regulatory decisions.

FDA is also committed to significant improvements in *risk management,* with particular emphasis on early analysis of options, and utilization of the full range of tools available to us, including education, enforcement, regulation, and cooperative action or voluntary compliance.

Risk assessment was one of the longest term, and potentially most significant, initiatives of Action Plan Phase I. Action Plan Phase II, announced last summer, recognizes that we have not yet reached our goals. Fundamental risk assessment research, while a high priority, cannot be accomplished in a short time frame. Therefore, Action Plan Phase II commits FDA to expanding the "initiatives, begun during Phase I, to improve the peer review/scientific base upon which risk assessments and consequently risk management decisions are made. FDA will develop and implement processes to ensure that its uses of risk assessment techniques in carrying out its regulatory responsibilities contribute to promoting public health in a timely, effective, and efficient manner" (4). Clearly, these are long-term goals.

Another point that appears in both Action Plans is *food safety:* setting priorities based on true public health concerns and bringing food safety policy up-to-date with modern science, utilizing legislative as well as administrative means, if needed.

Examples of the progress we have made that should be brought to fruition under this general rubic include: our policy on *animal drug safety* (formerly known as "sensitivity of method"), relating to the detection of residues in edible tissues of food-producing animals that consume carcinogenic substances (8); as well as our "*constituents*" or "impurities" policy, which allows the agency to set specifications to ensure the safe use of food additives that may contain trace carcinogenic impurities, so long as the additive as a whole is not carcinogenic (9). Last, FDA has enunciated a *de minimis* policy with respect to food safety regulation under the "Delaney clause" of the FFDCA. This legal interpretation is based on the belief that: "If the associated risk is essentially negligible, there is no gain to the public, and the statutory purpose is not implemented" (10) unless the agency has the discretion to interpret the law reasonably.

As I am sure many of you know, last fall the United States Court of Appeals for the District of Columbia dealt our *de minimis* policy a significant setback. The Court decided, in its own words, "with some reluctance," that the Delaney clause did not permit a *de minimis* interpretation (11). On the positive side, for risk assessors and proponents of rational regulatory policy, the court accepted the validity of risk assessment and that "it seems all together correct to characterize . . . as trivial" the risks involved in the use of the two color additives challenged in the case. The court even noted that an absolute interpretation of the Delaney clause could lead to the use of substitute additives that would be "a clear loss for safety." (Conservative risk assessment techniques place the theoretical upperbound lifetime risk of D&C Red No. 19

at between zero and one in 9 million, and D&C Orange No. 17 at between zero and one in 19 billion.) Nonetheless, the Court believed Congress had been "extraordinarily rigid" in adopting the Delaney clause, and that such an absolute standard was "at least a comprehensible policy choice."

SCIENTIFIC CHALLENGES

Although FDA and other regulatory agencies are working hard to grapple with the complex risk assessment and risk management issues, industry and academia cannot afford to sit back and wait for FDA's Action Plan, combined with appropriate legislative initiatives, to move the field forward into the next milennium—nor can the American consumer. Government has no monopoly on scientific expertise or resources, especially in light of the tremendous federal deficit that faces us now. We need to draw on the resources of the academic community and the private sector to work together to make sure that we have the science base needed to make sound regulatory decisions.

The challenge is twofold: First, it is axiomatic that, even in an Administration that is committed to the use of state-of-the-art risk assessment methodology, adequate risk assessments cannot be performed on any substance unless high quality, appropriate testing has been conducted. For example, adequate exposure estimates for externally used products require good skin penetration data. Surprisingly, perhaps, adequate data for risk assessment have sometimes been lacking. For FDA-regulated products, the burden of proving safety rests with sponsors who would market new products to the American consumer. When safety questions are raised, it is up to sponsors to resolve them. So the first challenge is to develop the data necessary for sound risk assessment, based on current knowledge.

The second challenge is still more difficult, yet far more important in the long run. We must test the validity of the assumptions underlying risk assessment, and develop scientific consensus on which require modification or should be discarded. Until this is achieved, it is virtually certain that risk management policy decisions will rely on assessments based on extremely conservative assumptions that will unquestionably tend to overestimate risk, perhaps by many orders of magnitude. The resulting bans or severe use restrictions will undoubtedly be costly, and may unnecessarily deny American producers and consumers the benefits of useful products that more accurate risk assessment would find safe. In order to ensure that the results of this kind of research and testing are perceived as credible rather than as self-serving assaults on currently accepted methodology, this work should ideally be undertaken independently, before questions or problems arise about a particular substance. In the interim, the irreducible uncertainties involved in exercise of even the most rigorous currently available risk assessment procedures must be made explicit by those who undertake to develop risk estimates and those who make policy decisions based on them.

It is a tall order, but at root it is a simple matter of foresight and enlightened self-interest, two qualities that have been essential to the achievement of the American dream of progress since the founding of our nation. In the long run, such research will be a worthwhile investment for industry and for the American people. If we can successfully address the challenges of risk assessment and risk management, we will

both enhance public confidence in marketed products and assure the credibility of science-based regulatory policy. FDA's mission—the goals we all share—will be realized even more effectively.

CONCLUSION

In all of its activities, FDA's mission to protect the public involves assessing risks which pose either a potential or a clear threat to health. Many consumers are confused by conflicting statements of risk and do not understand the relatively large range of uncertainty surrounding risk estimates. And with the number and pervasiveness of chemicals that are now suspected of causing cancer in animals, consumer confidence may understandably be eroding. FDA is working to develop better scientific methodologies to understand and regulate these compounds. As our scientific knowledge increases and we begin to eliminate sources of uncertainty, our policies on levels of such things as unintentional contaminants can be more clearly established upon sound scientific principles.

Having achieved success in developing analytical methods capable of detecting miniscule levels of contaminants, we are now redirecting our scientific resources toward developing improved methods for assessing the risks that may be posed by FDA-regulated products.

The credibility of risk assessment—particularly of substances that are linked to tumors in high-dose animal studies—is still itself at risk. Although FDA's policies (including the *de minimis* policy recently rejected by the court), may reflect the scientific state-of-the-art (and in all probability err on the side of caution), that state-of-the-art could clearly stand some improvement. It behooves all of us to support research aimed at eliminating some of the uncertainties that confront regulators, as well as health professionals and consumers. We must also examine how we can best communicate risk information. FDA and its sister regulatory agencies need the dedicated efforts of scientists in academia and regulated industry to move forward. As it now stands, risk assessment often requires some fundamentally unsatisfying assumptions. Our priorities must be to (i) elucidate, test, and refine them; (ii) make them clear to those who must make the risk management decisions; and (iii) communicate them better to policymakers and to the American people. Otherwise, our credibility, both as regulators and as scientists, will be jeopardized, and our ability to protect and promote public health while maintaining a vigorous economy will lack the public acceptance we need to achieve these goals.

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