Food Dyes Fuel Debate Over Delaney

FDA commissioner Frank Young suggests that relative risk should play a role in banning cancer-causing additives

After 25 years of deliberation by the Food and Drug Administration, agency commissioner Frank Young proposed in June to take another year or more to decide whether to ban several dyes used to tint food and cosmetics, including maraschino cherries, candy, cereal, and lipsticks. The Administration's reluctance to ban these dyes, which cause cancer in animals at high doses, has touched off another debate about the interpretation and enforcement of the Delaney Clause, the law that Congress passed in 1960 banning carcinogenic additives in food, cosmetics, and drugs.

Young's justification for the delay is that complex scientific and policy questions still have not been fully resolved. Young is asking basically three questions: Do the dyes pose a negligible public health risk? If so, should they be banned under the Delaney Clause? Underlying these questions is the more fundamental concern—is Delaney an outmoded law because it does not take relative risk into account?

This is certainly not the first time that these questions have been raised, but in April, Young indicated that he actually might approve the dyes if the agency determines the dyes pose a trivial cancer risk. Such a decision would be a significant change in policy, which Young himself acknowledges. He stated, "It makes no sense at all to brand as illegal, and by doing so to disrupt the marketing of a considerable number of products, additives that present a risk that may be barely more than theoretical. . . ." Using the concept of negligible risk to interpret the Delaney Clause "will be given serious consideration if the scientific issues can be resolved."

The Delaney Clause might not permit such an interpretation, however. It is based on the premise that there is no safe threshold for a cancer-causing substance, and ever since it was passed in 1960, a finding of carcinogenicity alone has triggered a ban of additives without regard to risk, according to FDA scientists and the House Government Operations Committee, which has criticized FDA's handling of the dyes.

Of the 200 dyes on the original 1960 list, 63 have been banned, an action in which Delaney often played a role. FDA has now whittled the list down to ten whose safety is still under review. Six of the ten are animal carcinogens and derivatives of petrochemicals.* In several instances, FDA has gone out of its way and taken the data to outside groups for peer review to confirm its own findings that the dyes are cancer-causing. To the frustration of the staff, Young is now contemplating a shift in criteria.

Members of Congress and consumer groups say Young's attempts to pin down the risk are only a smoke screen and that FDA has succumbed to pressure from the Office of Management and Budget, industry trade groups, and senior officials at the Department of Health and Human Services, of which FDA is a part. They argue that FDA has no room to deviate from a strict interpretation of Delaney, short of legislative change by Congress. The one exception to Delaney is the approval of saccharin, and that was a result of congressional mandate.

Frank Young

Legislators and others charge that the agency succumbed to pressure from OMB and industry.

Critics have demonstrated their frustration and opposition to FDA's protracted deliberations over the dyes in several ways. In June, the House Government Operations Committee voted unanimously that the department Secretary Margaret Heckler had failed to enforce the law by not banning the dyes. On 29 July, Senator William Proxmire (D–Wis.) introduced a bill that gives FDA 2 months after enactment to decide whether to impose a ban. In March, Public Citizen filed suit against FDA in federal district court to compel the government to ban the dyes in question.

For the past 4 years, FDA scientists and the agency's general counsel have locked horns with other government administrators and industry on whether to ban the dyes. Decision-making also has been complicated by the fact that FDA under the Reagan Administration has been headed by three different commissioners—Arthur Hull Hayes, Jr.; Mark Novitch, who became acting chief; and then Young.

Specifically, Young wants to determine whether quantitative risk assessment can show if the dyes pose a negligible risk. Industry does not dispute that the dyes cause cancer in animals at high doses. But the trade groups, such as the Cosmetics, Toiletry, and Fragrance Association, say that, based on their calculations, the cancer risks from exposure to the dyes are insignificant, on the order of one in a million.

FDA scientists reject the industry's calculations because, the staff says, they are based on too many faulty assumptions that may underestimate the risk. More studies, which would take 2 to 4 years, would fill in some of the data gaps, but even then not all the necessary answers would be in hand.

Red No. 3, for example, has been the most problematic dye. It brightens maraschino cherries, other foods, and cosmetics; is among the most widely used of the six dyes at issue; and is the color that food manufacturers and the cosmetics industry have fought the hardest for. Since 1981, FDA has proposed to ban Red No. 3 at least 12 times, but each time the dye has been given a reprieve.

Industry argues that the increased cancer risk from exposure to cosmetics colored with Red No. 3 is at worst one in 31 million. But FDA scientists say that the data are inadequate to undertake a risk assessment. The staff's analysis was confirmed more than a year ago by a committee of academic scientists who advise the federal National Toxicology Program, and also by an ad hoc panel of scientists from Japan, Canada, and the United Kingdom.

* The six dyes are Red No. 3, 8, 9, 19, and 37 and Orange No. 17.

Skirmishing Over the Dyes

For the past 3 years, staff members at the Food and Drug Administration have gone round and round with the commissioners to convince them to ban six food dyes that have been found to cause cancer in test animals. They have had mixed success. All three commissioners and former assistant secretary of health Edward Brandt, Jr., have at one time or another recommended that Margaret Heckler, secretary of the Department of Health and Human Services, ban the dyes. But each official has changed his mind and postponed a decision, citing the need for more study.

According to an extensive number of documents submitted to Representative Ted Weiss (D–N.Y.), chairman of the House Government Operations subcommittee that investigated the matter, every time the agency has been on the verge of a ban, industry representatives have successfully thwarted a ban by taking their case to more senior Administration officials. One of their most forceful advocates has been the cosmetics association and its outside counsel, Peter Barton Hutt, former general counsel at FDA and a partner at the Washington law firm Covington and Burling.

In March 1983, Arthur Hull Hayes, Jr., advised Heckler to ban one of the dyes, a signal to industry that he likely would ban the rest. The next day, the cosmetics association fired off a letter to Heckler calling the FDA position "arbitrary and unreasonable" and asked that she intervene. Over the next month, OMB officials met with Brandt, Hayes, and other FDA staff and raised objections with Heckler's office. The April deadline to ban the dye was postponed.

In the fall of 1983, the agency announced it would postpone the decision to ban Red No. 3 "for the sole purpose" of obtaining the opinions of the panel of the National Toxicology Program. The panel in October concurred with FDA's analysis. Nevertheless, the deadline was extended again. In January 1984, Brandt met with Hutt, who presented him with a list of objections to a ban. Brandt asked FDA to respond. The agency wrote back that the industry memo "makes the same arguments and assertions that [it] has made to FDA over the past couple of years. . . . We see no reason to recommend a different course of action on these six color additives because of [industry's] latest memo."

Shortly afterwards, acting commissioner Mark Novitch recommended a ban on all six dyes. Brandt concurred and on April 11 sent this recommendation to Heckler. But "later that evening," Brandt testified before Weiss, "rethinking the science issues . . . gave me reason to believe I needed to give the issue further thought." The next day, he requested that his memo be withdrawn before Heckler saw it. Brandt explained later that he had changed his mind because he was not convinced that the cancer risk was unachievable..

After Frank Young took office at FDA just over a year ago, OMB's chief of regulatory reform wrote him that they should discuss the issue of food dyes "sooner, rather than later." Last December, Young recommended to Heckler—"after a lengthy and difficult analysis of the data and issues"—that five of the six dyes be banned. FDA could make exceptions for trivial risks, a position that would be legally defensible, he said. "I have concluded, however, that the present circumstances provide a poor context in which to develop such an interpretation." There is no "strong policy reason" to revise the agency's interpretation, he said. Furthermore, FDA "has not defined adequate criteria for determining where a risk is small enough to be considered *de minimis*." But then Young withdrew the recommendation and postponed the decision.

The House committee reported in June that it was divided on whether Delaney should be modified, but concluded unanimously that OMB had improperly interfered with the department's decision-making process and that the department had failed to enforce Delaney as it stands now. The department should "take the necessary steps to enforce the Delaney Clause . . . to ensure that the public will not be exposed to carcinogenic color additives," the committee said.—**M.S.**

Despite his staff's advice, Young now proposes to extend a decision on several of the six dyes for 1 to 2 years, and one of them for up to 5 years in order to evaluate whether the risks can be more precisely figured. He has formed an eight-member committee of government scientists outside FDA to peer-review industry's risk assessments and FDA's analysis. The committee in turn has sent the dye data to 60 other scientists for review. An initial report from the committee is due in September.

The wrestling over risk assessment is irrelevant if the Delaney Clause is interpreted strictly as requiring a ban on any additive that causes cancer at any level, says Ted Weiss (D–N.Y.), chairman of a Government Operations subcommittee that investigated FDA's review of the dyes. The cosmetics association contends, however, that FDA has made allowances under the Delaney Clause in at least two previous cases. It notes that FDA sanctioned the use of a certain type of plastic for soft-drink bottles even though some studies showed that the containers leach minute amounts of a by-product of manufacturing, acrylonitrile, which is an animal carcinogen. In another example, the agency allowed the marketing of a hair dye even though it contains a cancer-causing impurity.

FDA general counsel Thomas Scarlett and others say that the cosmetics association has mischaracterized the agency's position. Neither of those compounds fell under the Delaney Clause, Scarlett says. The plastic bottle contaminant did not meet the definition of a food additive. In the case of the hair dye impurity, a variety of "unique" circumstances caused the agency not to invoke Delaney, that is, the animal feeding studies were deemed irrelevant to determine the safety of the topical use of the hair dye.

Scarlett has advised commissioners that a loose interpretation of Delaney, permitting the use of risk assessment, would be "difficult." The Congressional Research Service, which reviewed the issue of Delaney and the dyes, went so far as to say it would be "legally untenable" to permit the use of the cancer-causing dyes as the clause now stands.

FDA staff has cautioned that for political reasons, too, the agency should not stick its neck out. Agency staff warned that an initiative by the agency to reinterpret Delaney would undercut congressional efforts to do so. For 2 years, Senator Orrin Hatch (R–Utah), chairman of the Labor and Human Resources Committee, with Administration support, has sought to relax Delaney and

allow the marketing of additives posing a "negligible risk." Scarlett also cautioned the department that revisionism by the agency "would provoke a public reaction, quite possibly a strong one."

Peter Barton Hutt, former general counsel at FDA and outside counsel to the Cosmetics, Toiletry, and Fragrance Association, said in an interview that the crux of the matter is, "What is the public health difference [from exposure to the dyes]? This a level of risk that is insignificant." It is "inexplicable" that FDA officials insist that Delaney requires them to ban the dyes, he says.

William Schultz, a Public Citizen attorney, counters that Congress knew what it was doing when it passed Delaney. "No one is saying that we can eliminate all carcinogenic risks. Congress is saying, 'Let's eliminate as many as we can.' There are some carcinogens that are unavoidable, but we can keep out the color additives [which cause cancer] because they're intentionally added."

It's unclear how the debate about Delaney will be resolved. Hatch may reintroduce his bill this fall, but key House Democrats probably will not touch the issue of reform. Passage of the Proxmire bill or the lawsuit brought by Public Citizen may ultimately force the issue. For several months, rumors have been circulating that Young will become the next assistant secretary of health and is expected to be named to the post shortly. If appointed, Young would have even more of a power base to keep deliberating Delaney and the dyes.

So, after 25 years, the fate of the six cancer-causing dyes still hangs in limbo. Gary Flamm, FDA bureau director of toxicology, testified before Weiss, "We are very concerned that there be a consistency and an orderliness in the scientific judgments and decisions that are made." Now, Flamm said in an interview, "no one knows what the guides are. It's not easy to work in this kind of uncertainty."—**MARJORIE SUN**

The Neglected Disease in Medical Education

Medical schools are finally teaching about alcoholism; Johns Hopkins will require basic training for all students and clinicians

It is an old canard in the medical profession that an alcoholic is a fellow who drinks more than his doctor. Physicians have been notoriously deficient when it comes to early diagnosis and intervention with alcoholic patients. And no wonder: they never learned much about the disease in medical school.

Alcoholism afflicts about 10 percent of the drinking population, and alcohol abuse is implicated in at least 20 percent of general hospital admissions. It is said to be the third leading cause of death—although statistics can't tell the story since about 90 percent of alcoholics never see treatment. The early signs of alcoholism are behavioral; yet as recently as a decade ago, instruction in medical schools was confined to organ pathology, and the only alcoholics students knew about were emergency room derelicts. As a result, a 1982 poll by the American Medical Association indicated that only 27 percent of physicians felt competent to deal with an alcoholic patient.

Alcoholism—and addiction in general—is a field fraught with ideological conflict. But more people are now coming to recognize the complexity of the disorder, in which the physical and psychological aspects are absolutely inextricable. Whether or not alcoholism is a "disease" continues to be debated, but the designation (adopted by the AMA in 1956) is almost universally accepted if only to counteract the social stigma and establish the fact that it is treatable and arrestable.

Medical schools are finally coming to reflect the dramatic shift in public attitudes toward alcoholism. The latest development is at the Johns Hopkins Hospital and its School of Medicine, where perhaps the most comprehensive alcoholism initiative in the country is now taking shape. Launched by medical school dean Richard S. Ross and hospital president Robert M. Heyssel, the purpose of the program is to get every medical student and every clinician at the institution acquainted with the early signs of alcoholism and competent to detect and recommend appropriate treatment for the disorder. Emma Stokes, a policy analyst from the Massachusetts Department of Public Health who was hired by Ross and Heyssel to implement the plan, says that at Hopkins as well as other hospitals around the country, alcohol is implicated in 20 to 50 percent of the hospital admissions, but a diagnosis of alcoholism is made in fewer than 5 percent of cases. When she surveyed the medical curriculum on her arrival, she found two elective courses in the psychiatry department and no one had taken either of them for 3 years.

The Hopkins program is unusual in that it has been initiated from top administrative levels. But throughout the country medical schools are developing various strategies that acknowledge the pervasiveness of alcohol as a medical problem. These include the development of new courses, the integration of alcohol information into old ones, seminars, workshops, the establishment of new treatment facilities, and programs for employees, students, and faculty who themselves are addicted to alcohol or drugs.

A vital spur for this activity came from the federally funded Career Teacher Program in the Addictions, which ran from 1971 to 1982. Jointly sponsored by the National Institute on Alcohol Abuse and Alcoholism (NIAAA) and the National Institute on Drug Abuse, this program offered training to a faculty member in each of about 60 institutions. These individuals, most of whom are still in medical education, set about either developing new courses in their own departments, or attempting to broaden the coverage of alcohol and drug-related topics throughout their schools. The career teachers program also led to the establishment of a new Association of Medical Education and Research in Substance Abuse. AMERSA president David Lewis of Brown University's Department of Community Medicine says that membership has been expanding rapidly, with increasing numbers of deans and others concerned with general medical education.

But alcoholism education, coming from almost nowhere, has a long way to go. NIAAA director Robert Niven, a former career teacher, points out that "competition for medical school curriculum is horrendous." Says he, "I would bet the average amount of time devoted to teaching doctors about alcohol and drug issues probably averages 1 percent." Yet, according to a 1983 report