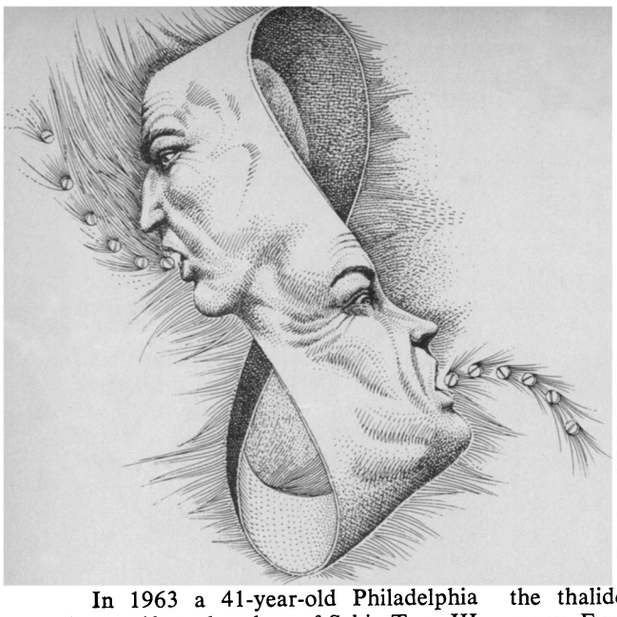

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Agonizing over food and drugs: How safe?

Are drugs and food additives policed too little or too much? Consumer inputs will probably not ease decisions.

by Joan Arehart-Treichel

In 1963 a 41-year-old Philadelphia housewife took a dose of Sabin Type III polio vaccine and contracted polio from the vaccine. She became a permanent quadriplegic. The Federal District Court in Philadelphia ruled that the vaccine lots had been released negligently by the Division of Biologics Standards of the National Institutes of Health, then the nation's vaccine regulators. The FDC awarded the woman more than $1 million in damages.

In 1972 a Lancaster, Pa., woman suffered a severe reaction to BHT, an additive widely used to extend the shelf life of oil-containing foods. A physician had to rush to her home to give her hormonal treatment. At the 1972 Senate hearings into food additives, Michael Jacobson, a microbiologist and co-director of the Center for Science in the Public Interest, charged that "As with the preservative BHT, the uncontrolled use of food colorings exposes the entire population to unnecessary possibilities of allergic reactions."

Obviously American Government surveillance of drugs and food additives is not above reproach. On the other hand the U.S. Food and Drug Administration has come under increasing criticism during the past decade for imposing too stringent requirements for testing the safety of new drugs.

Medications are reaching the market today at a much slower rate, and at much greater expense to drug companies, than 10 years ago. Many people think it is because of the FDA's rigorous testing requirements. In a February Senate hearing, Charles Edwards, former FDA commissioner and now assistant secretary for health of Health, Education and Welfare, rebuked charges that Americans are being deprived of important new safe and effective drugs available in other countries. Edwards stressed that the FDA is safeguarding Americans from some hazardous drugs. Because of FDA surveillance, for example, American children were spared the thalidomide tragedy that afflicted many European babies a decade ago. The FDA also blocked a weight-reducing drug before it was linked with fatal lung diseases in Austria, Germany and Switzerland. A drug for lowering blood pressure was banned by the FDA and later caused liver disorders in users in other countries. An asthma drug marketed in Europe but not in the United States caused a number of deaths.

So how far should the FDA or any other American regulatory agency go to make sure that American drugs and food additives are safe?

The heart of the question is whether it is possible to have no-risk food additives and drugs. In May at a National Academy of Sciences forum on the Design of Policy on Drugs and Food Additives, W. Clarke Wescoe, vice chairman of the board and director of Sterling Drug, Inc., asserted that it is not possible. "We strive in our preoccupation . . . for a circumstance that man has never enjoyed and a Utopian existence most probably beyond his reach. Man has always been at risk in his world, and he always will be."

Drugs and food additives, by their nature, are chemicals foreign to the body. Foreign chemicals can help the body; they can also harm it. No drug or additive is without side effects, and whether a chemical is beneficial or harmful is circumscribed by an individual's particular reaction to it. Pharmacological research is revealing more and more individual reactions to drugs (SN: 12/30/72, p. 422). Each person's response is determined partly by the efficiency of his or her drug-metabolizing enzymes.

If there is no such thing as a no-risk drug or food additive, how should their safety be determined? Benefits of an agent must be weighed against its risks. But what benefits and what risks? Jacqueline Verrett and Jean Carper, who played major roles in the FDA ban of the artificial sweeteners cyclamates, ask: "When industry tosses around the term 'benefit-risk' what does it mean? Consumer health benefits weighed against consumer health risk? Consumer economic benefits weighed against consumer health risk? Or some kind of consumer social benefit (such as time-saving) against consumer health risk? On the other hand, does it mean industry economic benefit against consumer health risk?"

More crucial, what criterion does the FDA use to weigh benefits against risks? James S. Turner, lawyer and co-director of Consumer Action for Improved Food and Drugs, declares that "no generally accepted definition of benefits and risks has been agreed upon." The Delaney Amendment, for example, requires that if any food additive in any amount is found to cause cancer in animals or humans, it must be removed from the market. "There is more scientific discretion in the amendment," Turner believes, "than has been generally admitted." The banning of cyclamates, he asserts, included unnecessary references to the Delaney Amendment.

If the FDA has no set way of weighing benefits and risks, it is further hampered in its decision-making by the data it deals with. In spite of sophisticated analytical techniques, scientists are not sure that drug or additive reactions observed in laboratory animals will be experienced by people, nor whether all people will react in the same way to an agent. FDA safety decisions will probably become more, rather than less, complex as analytical techniques become more refined and pharmacologists discover more and more substances in tissues in ever smaller amounts.

The Delaney Amendment was recently called into play to prohibit the use of diethylstilbestrol (DES) as a feed additive for cattle. That particular decision was a triumph of superior, sophisticated analytical technique that permitted the measurement of 120 parts

per trillion of DES in cattle liver. A New York Times editorial said "such sensitivity in measuring infinitesimal quantities is a respectable scientific feat. But how meaningful," it asked, "is it as a guide to the public? Is there a significant, even an appreciable risk of anyone getting cancer from eating meat containing so tiny a quantity of DES?"

Shortly after he became FDA commissioner in 1969, Edwards declared, ". . . We must have greater consumer participation in the governmental process so we can be assured that what we are doing is truly in response to the desires and expectations of the consumer." Peter B. Hutt, general counsel for the FDA, avowed at the NAS forum: "Public and Congressional confidence in the ability of the FDA to carry out its statutory responsibilities has unquestionably been undermined. It has thus become apparent that the agency must meet this challenge or face potential destruction."

The FDA is now seeking greater public scrutiny and participation in safety decisions. It is developing new mechanisms to guarantee that interested persons have access to the FDA before important decisions are made. During the past 18 months it has developed procedures for review of nonprescription drugs. Anyone may submit written information or make oral presentations to the reviewing panel at its frequent meetings. New procedures permit the FDA, for the first time, to impose additional safety testing for already marketed food ingredients. This move encourages petitions by any person who wishes to request specific testing for a particular substance. The FDA has just announced a public hearing to consider internal guidelines to govern the formulation and labeling of a class of prescription drugs. This is the first such hearing in the agency's history.

Consumer involvement may improve the FDA's decision-making process. But it won't necessarily make the weighing of benefits and risks easier since such questions are laden with ethical considerations. Should a drug be released that is life-saving for some people yet harmful to others?

"Regulation of the safety of food and drugs should be an extremely simple and perfunctory task," says Hutt. "Unfortunately this does not occur in the real world. In the 20 months that I have held my current position, I cannot recall one major safety decision by the FDA—regardless which way it was resolved—that has failed to provoke prolonged, and at times, bitter public dispute. . . . Public policy design and execution with respect to the safety of food and drugs is highly, and perhaps irretrievably, controversial."

"The decision to release a medicine for use in man," Wescoe concurs, "has always been an agonizing one." □

films OF THE WEEK

CHILD BEHAVIOR-YOU. 16mm, color, sound, 15 min. To modify child behavior from infancy through adolescence, the simple principle is to reward and reinforce the desired behavior—whereas in practice, it is often the undesirable actions which receive the attention. By using humorous animation to show what parent-child relations during those years could be like, children and parents are not threatened or offended. Parents and children can also be encouraged to recall and explore feelings about themselves and about each other. Audience: parents, children. Purchase $225 or rental $25 from Benchmark Films, Dept. SN, 145 Scarborough Rd., Briarcliff Manor, N. Y. 10510.

THE EVERGLADES. 16mm, color, sound, 7 min. The Everglades is a swampy wilderness of exceptional beauty inhabited by uncountable varieties of plants and animals. The importance of clean air and clean water is paramount in maintaining the delicate balance of nature here. Water replenishes the Everglades by a system of natural sloughs and manmade canals. In recent years the human population of south Florida has increased to a point of concern, and water has been diverted to the fast-growing population centers. The water now flowing into the Everglades has been polluted and the entire ecosystem is threatened by this alteration. The list of endangered species of birds, plant life and animals grows longer every year. The serious pollution problem has produced a crisis and presents an immediate challenge to man's inventiveness and to the awakening of his ecological awareness. Audience: all ages. Purchase $120 from ACI Films, Dept. SN, 35 W. 45th St., New York, N. Y. 10036.

THE SIFAKA. 16mm, b&w, sound, 12 min. This film is about the sifaka, one of the Malagasy lemurs. It was made in the arid forests of southern Madagascar. In this region, groups live in well-defined and largely exclusive "territories." Encounters take place along the "borders" of these territories. The vocal repertoire of this species contains several calls. The "spat" call was associated with submissive behavior and the wailing call was given by animals that had lost contact with the group. Characteristically, the sifakas are peaceful animals, but during the one week of the year when mating occurred, males fought fiercely. The film shows locomotion, grooming, dominance, marking behavior and infant-parent relationships. Audience: behaviorists, particularly primatologists. Purchase $60 or rental $15 from the Rockefeller University, Dept. SN, Box 72, Film Service, 1230 York Ave., New York, N. Y. 10021.

SURVEILLANCE: WHO'S WATCHING? 16mm, b&w, sound, 60 min. This documentary presents a detailed and on-the-scene investigation of political surveillance and harassment of individuals with a major focus on the activities of the Chicago Police Department's "Red Squad." Interviews are conducted with persons who have been affected by surveillance, government officials and former FBI agents. The dissemination of information about private citizens by the FBI, city police departments and other agencies is examined. Members of the film crew give an account of their own harassment and jailing by the Chicago Police Department. Audience: secondary, college, adult. Purchase $265 or rental $13.50 from Audio-Visual Center, Dept. SN, Indiana University, Bloomington, Ind. 47401.

Listing is for readers' information of new 16mm and agriculture for professional, student and gen- and 8mm films on science, engineering, medicine eral audiences. For further information on purchase, rental or free loan, write to distributor or