PROGRESS REPORT FOR: Food and Drug Safety

ON SEPTEMBER 26, 1995, the Public Health Service (PHS) conducted a review of progress on HEALTHY PEOPLE 2000 objectives in the Food and Drug Safety priority area.

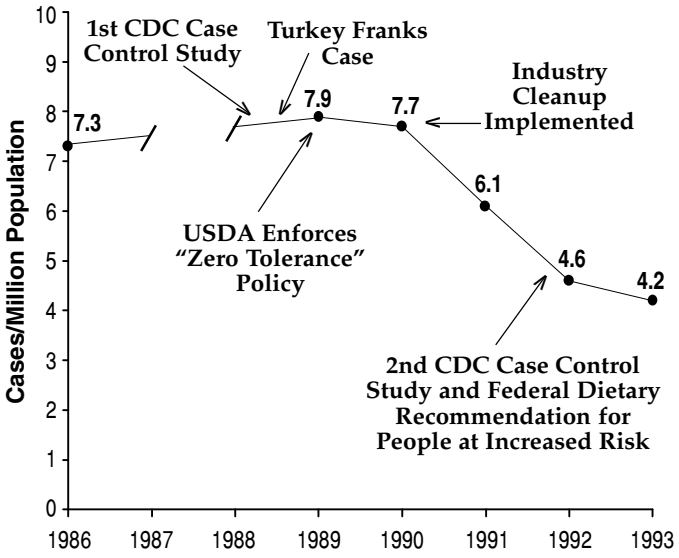
The Food and Drug Administration (FDA) is the designated PHS lead agency for the Food and Drug Safety priority area. The Deputy Administrator of the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) participated in the Progress Review. The National Institutes of Health (NIH), Indian Health Service (IHS), Centers for Disease Control and Prevention (CDC), Agency for Health Care Policy and Research (AHCPR), and Health Care Financing Administration (HCFA) were also represented. Guests included the American Medical Association, American Nurses Association, Conference for Food Protection, National Council on Patient Information and Education, and National Association of Boards of Pharmacy.

The progress review focused attention on the importance of FDA's Hazard Analysis Critical Control Point (HACCP) approach to food safety and efforts underway to make this food safety system standard in the U.S. food supply. HACCP employs a science-based analysis of potential hazards, determining where problems can occur and instituting measures to prevent or correct such occurrences.

Objectives 12.1-4 relate to reducing the incidence of foodborne illnesses, encouraging safe food preparation practices, and extending the adoption of model food codes. As reported in the April 12, 1995, issue of the *Journal of the American Medical Association*, there was a reduction in the observed incidence of listeriosis between 1989 and 1993, largely as a result of industry, regulatory, and educational efforts conducted by public and private sector organizations working together. Replication of this success for other pathogens may not be possible, owing to the changing epidemiology of foodborne diseases, increased consumer demand for fresh foods year-round, and the appearance of emerging pathogens in new products. In addition, current surveillance systems may not be able to detect changes in incidence. For example, not all States require the reporting of *E. coli 0157* and *Campylobacter* infections.

A decreasing trend in the number of *Salmonella enteritidis* outbreaks has also been detected and may be associated with the adoption of quality assurance programs by egg producers. Because the elderly and the immunocompromised are more susceptible to salmonellosis, FDA has worked with HCFA to encourage safe food preparation practices and the use of pasteurized eggs in nursing homes.

Incidence of Listeriosis from Selected Surveillance Areas



Source: *JAMA* April 12, 1993, Vol. 273(14):1118

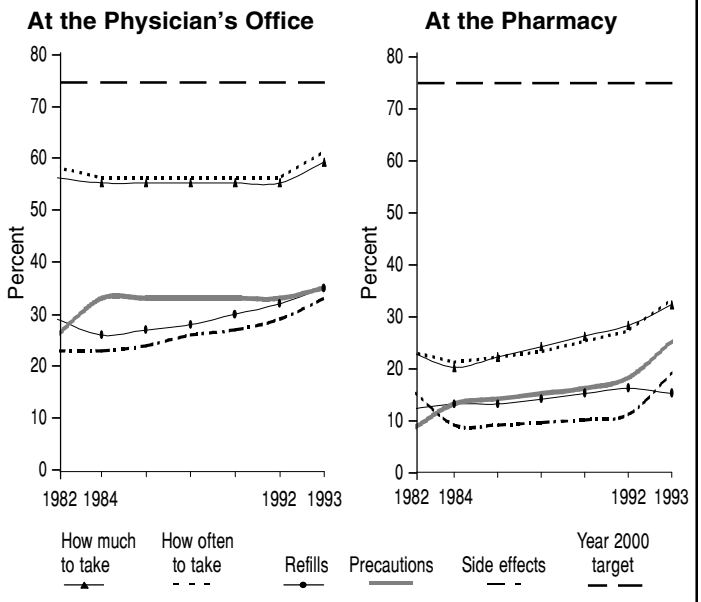
FDA and USDA/FSIS issued regulatory proposals that would require seafood processing plants and federally inspected meat and poultry plants to adopt HACCP systems for documenting production of safe products. FDA has approved irradiation for use with poultry products. A petition for use of irradiation in other meat products is now under review.

On the basis of a Memorandum of Understanding between FDA and the conference for Food Protection, the *Food Code* is being reviewed by the conference. FDA plans to revise the *Food Code* every 2 years. To promote adoption of the *Code* by States and professional and trade groups, FDA initiated regional training programs in 1994, made presentations before more than 50 audiences that year and, with USDA, conducted four video satellite teleconferences directed at State and local officials. To assist in implementing the *Code*, the agency has completed development of its Electronic Inspection System (EIS), which provides findings to food establishment operators more efficiently. The IHS representative noted that the incidence of gastrointestinal illnesses had declined by 81 percent since 1974 among American Indians and Alaska Natives, reflecting to a large degree the success of educational efforts directed at foodhandlers.

Participants in the progress review then turned to drug safety issues. It was noted that 98 percent of all pharmacies are now computerized and have the capacity to be linked to centralized databases. Efforts to implement computerized patient records and potential impacts that this technological advance will have on the interaction between health professionals and their patients were discussed.

Objective 12.6 was expanded in the *1995 Midcourse Review* to include drug profile reviews by dispensers of medication. In 1992, the Primary Care Providers Survey indicated that 84 percent of internists and 70 percent of family physicians surveyed maintained a current medication list for 81–100 percent of their patients 65 and older. A survey conducted in 1993 by the National Association of Retail Druggists, while not specifically focusing on the age group targeted in objective 12.6, showed that 92 percent of pharmacists queried reported that they provided printed patient drug information. A 1994 study by the National Association of Boards of Pharmacy found that 64 percent of consumers stated that they had received printed material about their medications from the pharmacy. While it was acknowledged that this upward trend in pharmacy-provided information may be due in part to implementation of requirements of the Omnibus Budget Reconciliation Act of 1990, representatives for the profession of pharmacy stressed that this observation is consistent with current shifts in the practice of pharmacy toward a concept of patient advocacy and total care.

Verbal Information for New Prescriptions*



*This is received spontaneously and not in response to a question
Source: FDA, 1982, 1984, 1992, 1994

In 1993, the FDA MedWatch program was launched to inform health professionals about the importance of monitoring for adverse events and product problems and to facilitate voluntary reporting of such events directly to the agency. The *FDA Desk Guide for Adverse Event and Product Problem Reporting*, which contains reporting forms and instructions for health professionals, can be requested by calling 1-800-FDA-1088. There was an initial mailing of the *Desk Guide* to approximately one-half of all internists in the United States during 1993. The MedWatch reporting form has been published in many widely used drug information sources, such as the *Physicians' Desk Reference*, American Medical Association (AMA) *Drug Evaluations*, and U.S. Pharmacopoeia *Dispensing Information*. For 1994, FDA estimates that 71.6 percent of the adverse drug event reports received by the agency were interpreted as serious. FDA reported that over 100 organizations representing both health professionals and industry have joined as partners to promote the effective use of the MedWatch program.

The discussion focused on the need to ensure the consistent quality and usefulness of printed information being provided to patients concerning the medications they take. It was noted that AHCPR has an initiative in progress designed to acquaint beneficiaries with the types and scope of information they should expect to receive during encounters with physicians and pharmacists. AHCPR noted that we are faced with a significant technical challenge by the increasing need to share information about patients while preserving the patient's right to confidentiality.

The progress review concluded with a call for greater efforts in the areas of both consumer and provider education. There is, as well, a need to strengthen collaboration among Federal agencies (Administration on Aging, for example) and between the Federal sector and professional and patient organizations. Several issues could be brought into sharper focus by research, including how information provided to patients can lead to better health outcomes.

Public Health Service Agencies

Agency for Health Care Policy and Research
Agency for Toxic Substances and Disease Registry
Centers for Disease Control and Prevention
Food and Drug Administration
Health Resources and Services Administration
Indian Health Service
National Institutes of Health
Substance Abuse and Mental Health Services Administration
Office of the Surgeon General

HEALTHY PEOPLE 2000 Coordinator

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