Suit against Fast Breeder Reactor

The national Scientists' Institute for Public Information (SIPI) has filed suit against the Atomic Energy Commission (AEC) for failing to submit an environmental impact statement on the effects of the development of the liquid metal cooled, fast breeder reactor and its eventual commercial use in power plants.

The suit charges AEC with violation of the National Environmental Protection Act (NEPA) and asks that the AEC meet legal requirements by issuing a statement describing alternatives to the reactor and the potential impact of the program on the environment.

The AEC has announced it will circulate environmental impact statements on individual fast breeder nuclear reactors as they are built. SIPI's demand for submission of an impact statement early in the development stage is viewed as a departure from current practice. Such legal action in the past has been taken only against specific reactor projects. A precedent for the action, cited by SIPI, was the filing last year of a similar suit against the supersonic transport.

SIPI was particularly critical of the use of plutonium as a fuel for the fast breeder reactors and, in a statement issued when the suit was filed, the organization said that "By the year 2000, the AEC predicts that hundreds of these fast breeder reactors would be located throughout the United States. Such a situation would pose the risks of explosion, accidents, sabotage, and a plutonium black market, all of which might lead to radiation contamination of the environment."

SIPI is an organization of 15 distinguished American scientists established to provide the public with understandable scientific information on important public issues. Some 15 local scientific information committees are affiliated with the national organization.

The suit was filed in U.S. District Court in the District of Columbia by the Natural Resources Defense Council, a public interest law firm, on behalf of SIPI. It is the first such legal action undertaken by the national SIPI group.

drugs as effective; they found the majority of drugs lacking evidence of effectiveness as defined by the 1962 amendments.

As soon as FDA issued its first orders against ineffective drugs back in 1968, it was deluged with hearing requests, lawsuits, and other legal obstacles presented by the pharmaceutical manufacturers. These obstacles were finally removed by a 20 October 1970 court decision declaring that FDA could force the antibiotic product Panalba off the market (*Science*, 29 August 1969). The FDA was thus given a green light by the courts to proceed against those drugs ruled less than effective by the NAS–NRC panels.

Now, however, the FDA is facing a new wave of opposition. In the past several weeks, both Congress and the FDA have received hundreds of letters from irate physicians protesting the impending regulatory actions. During recent congressional hearings, FDA representatives charged that many of these letters resulted from drug company detailmen (salesmen) misinforming the doctors as to FDA's intentions and urging the doctors to write in protest.

Most of this protest focused on the FDA's policy regarding fixed combination drugs—that is, mixtures of prescription products. And it is in regard to fixed combination drugs that FDA has given in to the pressure.

The NAS–NRC panels established the designation of "ineffective as a fixed combination" because these drugs present a special problem in determining whether the product is effective as claimed. Usually, each component of the mixture is effective for some purpose when taken as a separate entity. Thus, each combination drug is bound to cure something. This was the case with Panalba, which was a mixture of two antibiotics, tetracycline and novobiocin. But the NAS–NRC panelists decided that a combination drug had to be more effective than either of its components taken alone. The NAS–NRC panel evaluating Panalba conceded that it cured everything that tetracycline alone would cure, but the panel declared the drug to be ineffective as a fixed combination because the presence of the second drug appeared not to enhance this process.

The NAS–NRC panelists generally came down very hard on fixed combinations. They rated as effective only 45 combinations out of some 1200 studied. The panel's overall attitude toward the fixed combinations threatens a good deal of the potential sales of the pharmaceutical industry. Combination drugs now account for over half of the products sold nationwide and some 40 percent of the best-selling drugs. In addition, they represent a large percentage of future markets, since selling combinations greatly expands a drug company's potential range of products.

Convenience and economy generally form the basis of the arguments offered in favor of retaining the combination drugs. The Pharmaceutical Manufacturers Association commissioned a study which concluded that prescription drug costs would somehow rise 59 percent if combination drugs were eliminated. And some practicing physicians believe that a patient is more likely to take multiple drugs if they are contained in one pill.

On the other hand, the panelists feared that the risk of a patient's receiving a drug he doesn't really need or taking an improper dose of a drug far outweighs considerations of convenience and economy. Nevertheless, the FDA seems to be moving much closer to the industry viewpoint regarding the combination drugs. In recent hearings before the House Health and Environment Subcommittee, Commissioner Edwards made it clear that the agency doesn't feel bound by the Academy's decisions on combination drugs and is preparing to further modify a proposed FDA statement governing the effectiveness of such products. This prompted the Pharmaceutical Manufacturers Association to declare that "Industry and FDA now appear to be in agreement that if a combination benefits a few patients but not most it should be kept."

This distinction between a "few" and "most" is critical to the entire efficacy review. The Kefauver-Harris amendments defined efficacy as "substantial evidence" based on "adequate and well-controlled investigations, including clinical investigations." In arguing against enactment of the Kefauver-Harris amendments in 1962, a rep-