Faster FDA Action Asked in Lawsuit

The Food and Drug Administration (FDA) last week came under increased pressure to act more rapidly against unsafe and ineffective drugs. The American Public Health Association (APHA) and the National Council of Senior Citizens (NCSC) filed a lawsuit in the U.S. District Court in Washington, D.C., charging the FDA with violation of the 1962 Kefauver-Harris Drug Act. The act, passed in the wake of the thalidomide scandal, required the FDA to certify all drugs on the market as safe and effective. To implement the act, the agency commissioned a study of all drugs by the National Academy of Sciences–National Research Council (NAS-NRC). The massive study was finished in July 1969, but the FDA has so far released only about 15 percent of the results.

The FDA is charged with delaying 8 years in implementing the act, with failure to release immediately the NAS-NRC report, and with failure to follow proper steps for the swift removal of substandard drugs from the market.

The main controversy centers around the definition of "imminent hazard." By labeling a drug an imminent hazard to public health, the FDA can force its immediate removal from the market. FDA spokesmen claim that no drug now on the market is an imminent hazard. FDA Commissioner Charles C. Edwards said, "When we find an imminent hazard to public health we will not hesitate to invoke the procedure." But the exact definition of what constitutes an imminent hazard has never been delineated.

The lawsuit charges that an imminent hazard labeling should have been issued for a category of diuretics—the potassium thiazide combinations—and 50 anti-infection mixtures, including combinations of penicillin and streptomycin (pen-streps). The NAS-NRC study showed that the indiscriminate use of pen-streps has led to a proliferation of resistant organisms, which threaten worldwide epidemics.

The FDA, however, has chosen to avoid using the imminent hazard labeling and instead has used the phrase "serious hazard for some users." This semantic difference has permitted the drugs to remain on the market while their manufacturer fought the FDA ruling in court.

According to Edwards, the NAS-NRC reports cannot be released immediately because "they are subject to interpretation and, unless guidance is provided as to labeling revisions and other changes required, a chaotic situation could result." He added that the FDA is working as fast as possible to produce the needed guidelines and that he expects all the reports to be released by the end of this year.

The decision to file a suit represents a major escalation in the years-long battle to make the FDA act more rapidly. The idea for the suit originated with Dr. Robert McCleery, a former member of the FDA and currently a consultant to Ralph Nader's Center for Responsive Law. McCleery enlisted the support of the APHA and the NCSC in December.

McCleery called the suit a "last resort, taken because administrative procedures such as congressional hearings and letters to the FDA have failed to produce any change." He charged that the real reason behind the FDA's failure to act more quickly against unsafe drugs is that "it fears political and economic consequences if a large group of drugs were rapidly removed from the market." The FDA denied the charge and blamed delays on involved court fights with drug manufacturers (*Science*, 29 August 1969).

The suit also marks a significant change in policy by the APHA and the NCSC. Neither group has ever before filed suit against a federal agency.

Nelson Cruikshank, president of the NCSC, said that the suit opens the way for similar actions by his group against other federal agencies.

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being funded, but the last few to receive NASA funds will finish up next year. NASA will, however, still provide indirect support of graduate students through research assistantships financed under the $75 million in research grants to universities.

The NIH announcement that predoctoral fellowships would be phased out actually made official what had been foreshadowed by cuts in fellowships in recent years. Training grants are the chosen NIH instrument for support of predoctoral students, and some 5000 are now being supported through the program. The variety of NIH programs and the peculiarities of the agency's financing and record-keeping make it difficult to pull together exact quantitative data, but the decline in NIH support of postgraduate education and training is indicated in broad outline by the fact that there were an estimated 15,000 NIH training grants of various kinds in 1968, perhaps 10,000 of them supporting predoctoral students, while this year the total is about 11,000, with about 5000 of them supporting predoctoral students. In addition to phasing out predoctoral fellowships, NIH has been under instructions from departmental headquarters to examine the teaching mission of NIH. The implications at first were that grant programs were to be converted to loan programs, but now NIH planners say emphasis is on relating its training grant programs to concrete needs for the people trained.

The National Institute of Mental Health (NIMH) this year is absorbing a sharp curtailment of its predoctoral fellowship program, with the number of new and competing fellowships cut from 105 in fiscal 1970 to 53 in fiscal 1971. This means a drop in predoctoral fellowships from 750 in the current year to 491 next year. Postdoctoral fellowships will be more than halved, dropping from the current 105 to 53, as new and competing awards are reduced from the 73 made in the current year to 44.

In absolute numbers, the biggest single federal predoctoral fellowship program is operated under the National Defense Education Act (NDEA). In fiscal 1968 some 6000 new fellowships were awarded, and the total number of individuals being financed was 15,000. In the current fiscal year (1970) which ends on 30 June, new fellowships dropped to 2370 and the number in fiscal year 1971 is scheduled to be 2200; thus the total number supported under