

group which they named SAVE (Scientists Allied to Veto Extinction) and began a process of lobbying local representative Paul Tsongas (D-Mass.) and the Massachusetts senators. As the significance of CRL to the technical and university communities in the Boston area was made clear, the Massachusetts congressmen joined their New York counterparts in protesting the reorganization plans. By

now the entire New York congressional delegation was united (something rarely achieved) in opposition to the RADC move. Even the White House is known to have let the Pentagon know of its concern.

As a result of these efforts, the Air Force backed off implementing the establishment of the C<sup>3</sup> center last March. Instead, two additional studies were commissioned by the Secretary of the Air Force to look at

how best to accomplish the mission the C<sup>3</sup> center was designed to carry out, and to look at the impact of moving the geophysics laboratory. The two studies were completed in late May.

On 31 July of this year, McLucas announced his decisions to Congress. Citing such factors as economic impact and personnel turbulence to be weighed against management efficiency and geographical collocation, McLucas concluded that the Air Force could accomplish many of its C<sup>3</sup> objectives without disrupting RADC, although certain manpower reductions may be effected in the future. As the Rome center would now stay put, the proposed move of the geophysics portion of CRL to New Mexico would no longer be cost effective, and would not be carried out. About 200 jobs at CRL are also still in jeopardy.

Nonetheless, some changes were made. An effective C<sup>3</sup> center is being established on a managerial, if not a physical, level by having RADC report to AFSC's Electronic Systems Division (ESD is the organization responsible for developing and acquiring C<sup>3</sup> related systems for the Air Force). Similarly, CRL may in the future also be managerially restructured, so that the portion of CRL that is relevant to C<sup>3</sup> would report to ESD, and the geophysics portion would be separate.

While the situations in New York and Massachusetts were held up by politics, the implementation of the laboratory restructuring at Wright-Patterson has proceeded on schedule. Last winter, the Dayton chapter of the American Chemical Society managed to rally some support from local congressmen and the governor of Ohio for a proposal to preserve ARL by having it transferred to the Energy Research and Development Administration. But when the Air Force peremptorily said, "No, we have other plans for the building," the proposal quietly died.

Air Force officials say that about three-fourths of ARL scientists have been or will be offered places in the development laboratories at Wright-Patterson. The remaining one-fourth will be held in a transitional status for a year, during which they will continue to draw salaries and be free to look for new jobs elsewhere. Many of the jobs in the laboratories, however, are far from continuations of the research that was done in ARL, not being research at all in some cases. Moreover, a majority of the highest-grade civilians apparently are not being offered permanent slots, in part perhaps in an effort to address the problem of civil service grade inflation referred to earlier.

Contrary to the fears expressed early on, the physical facilities of ARL are not fall-

## FDA Rapped for Delay on New Drugs

Two University of Rochester pharmacology professors have produced a report that contributes to the ongoing debate over regulation of new drugs by the Food and Drug Administration (FDA).

In their study, "Regulation and Drug Development," William M. Wardell and Louis Lasagna say the FDA's rigid interpretation of the 1962 amendments to the Food, Drug and Cosmetic Act—which were passed in reaction to the thalidomide disaster in Europe—is inhibiting the agency from filling its responsibility to encourage the development and use of new and better drugs. As a result, they say, American patients are being deprived of therapeutic agents that are already in use in other countries.

Supporting evidence is drawn from a comparison of British and American regulatory systems. Of 180 new drugs introduced in the two countries in the decade beginning in 1962, they say, 98 are exclusively available in Britain, compared with 21 available only in the United States. A survey of British physicians also revealed that "certain drugs then unavailable in the United States had made a great impact on the prescribing habits of British experts."

The authors argue that new drugs "contribute minimally" to the problem of drug toxicity, and conclude that "it appears that the United States has lost more than it has gained from adopting a more conservative approach than did Britain in the post-thalidomide era."

The chief theme of the report is the need for more flexibility in the interpretation of regulations, and the need to allow qualified professionals more discretion in the therapeutic use of new drugs. To this end, the authors propose the creation of a distinction between the therapeutic and the investigational use of yet unmarketed drugs, such as exists in Sweden. They believe that recognized medical centers and teaching hospitals should be allowed to use investigational drugs for therapy at their own discretion: "if a respectable minority of professional opinion believes in the utility of a drug, then it ought at least to be available for those who believe in it."

The authors express concern about the "drug lag"—the long time it takes for an investigational new drug (IND) to be approved for marketing. In Britain, new drugs are approved earlier and subjected to more rigorous post marketing surveillance. In the United States, the study observes, the emphasis is on pre-marketing trials, and postmarketing monitoring is inadequate to measure whether the total benefits of a new drug outweigh possible adverse effects.

The report says things at FDA have improved in recent years—foreign data on new drugs are being accepted, for example, and a large backlog of new drugs finally has been cleared for marketing—but warns that the FDA is still "under intense pressure from Congress, from consumer groups, and from factions inside the agency to abandon its medically more realistic attitude."

The Wardell and Lasagna study, published by the American Enterprise Institute for Public Policy Research, concurs with many conclusions in a study by economist Sam Peltzman, who said the 1962 amendments had caused costs of new drug development to rise without noticeably enhancing their safety and efficacy. In rebuttal (*Science*, 23 February 1973), the FDA claimed the regulations had prevented many ineffective drugs from reaching the market; that a number of drugs available in Europe but not in the United States had proved to be unsafe, and that the decline in the introduction of new drugs was a worldwide phenomenon unrelated to the stricter U.S. regulations.—C.H.