Letters

Drugs and FDA: Review Procedures

Elinor Langer's commentary headed "Drug politics: Industry seeks 'Court of Appeals' to challenge FDA rulings on drug safety" (10 July, p. 139) reveals a misunderstanding of proposals for an independent, impartial reviewing mechanism to evaluate the facts when scientific differences arise between the Food and Drug Administration and a pharmaceutical manufacturer over the value of a drug. My own concept, which, as Langer said, has the endorsement of the Greater Philadelphia Committee for Medical-Pharmaceutical Sciences and is supported by growing numbers of academic and practicing physicians, is a simple one. It is to make available to the pharmaceutical industry, by a new regulation, or by an amendment to the Food, Drug, and Cosmetic Act if statutory authority is lacking, the nongovernmental review procedure this same law already accords to manufacturers of color additives and pesticide chemicals in scientific disputes with FDA, and that the Insecticide, Fungicide and Rodenticide Act now accords to manufacturers of pesticides for agricultural use.

Both the 1954 pesticide-chemical provisions and the 1960 color-additive provisions of the Food, Drug, and Cosmetic Act require the Secretary of Health, Education, and Welfare to establish an advisory committee of nongovernment scientists to review scientific issues whenever a qualified person (in other words, the manufacturer of the product) requests such a review. A panel of outside scientists is selected by the National Academy of Sciences–National Research Council, and the Secretary of HEW chooses the committee members from the panel. The conclusions of these committees are not binding on the Secretary but are merely advisory.

No one will question the wisdom of Congress in surrounding the regulatory powers of the Department of HEW and the Department of Agriculture, in the fields of pesticides and colors, with such scientific review procedures. It would be imprudent to suggest that it is less important to have the most qualified scientific judgments brought to bear on matters of drug safety and effectiveness.

Langer observes that an easy answer —"establish a committee"—is being supplied by me and others but wonders whether our "question is 'How can you provide maximum security to the pharmaceutical industry?' or 'How can you best promote drug safety?' " Let me pose a third question. How can you insure that a drug effective in serious illness, but with serious side effects, is not withheld or withdrawn from the physician's armamentarium because either the benefits or the dangers were misjudged?

Langer pointed out that it might take more than a year for FDA to reach a decision if it followed the suggested scientific review procedure. This is quite true. But then she used the example of thalidomide as a reason for rejecting my proposal:

> Suppose, to take an extreme example, the manufacturer had appealed FDA's decision on thalidomide? What would be gained by leaving a dangerous drug on the market for a year while a committee deliberated? If the drug were withdrawn during the committee's study, the manufacturer would be no better off than he is now. If the investigation were quietly handled and the drug remained on the market, the incidence of serious effects could be vastly multiplied.

There are two errors in this comment. Thalidomide was never approved by the FDA for marketing, but was in investigational use only. Thalidomide thus could not have been kept on the market for a year while a committee deliberated. But more important, my proposal would in no way diminish the authority of the Secretary of HEW under present law to remove a drug from the market summarily if he should find "an imminent hazard to the public health." This entirely appropriate provision of the law (Section 505[e]), which I agree with, would be unchanged. The advisory committee's evaluation of a scientific dispute about the drug would *follow* the removal of the drug from the market. Obviously, there would be no hazard to public health.

Langer posed the problem of obtaining impartial scientific advice for FDA, citing the limited supply of clinical pharmacologists and the close ties many of them have with the pharmaceutical industry. This is a very real problem, not just in clinical pharmacology but in all the medical sciences to which FDA would turn for advice. It has troubled many government agencies for many years in relations with many industries, and no doubt will continue to do so. When FDA sees a need, it can and does assemble the same kind of ad hoc advisory committees as are contemplated in my proposal. If this very real problem of possible conflict of interest can be managed when FDA sees a need for outside advice on a scientific issue relating to drug safety or effectiveness, cannot the Secretary of HEW and NAS-NRC manage it just as well when a pharmaceutical house asks for such consultation? Langer referred to FDA's recent efforts to establish links with outside experts and said that FDA established a committee last year, headed by Walter Modell, "to advise the commissioner on general policy." Modell, of Cornell University Medical School's department of pharmacology, heads FDA's Advisory Committee on Investigational Drugs, which advises the Commissioner of Food and Drugs in a much more limited field. The efforts of FDA to upgrade its standing in the scientific community are to be commended and encouraged. FDA's new medical director, Joseph F. Sadusk, Jr., intends to establish a medical advisory board, as well as a number of scientific panels, which, in his words, "will receive from our staff problems of a difficult and controversial nature for which we need guidance." The creation of its own scientific advisory structure by the FDA attests to the desirability of bringing to bear on complex problems of drug safety or effectiveness the best scientific judgments available, in or out of government. Creation of the procedures proposed by me, as a right of the pharmaceutical industry in significant scientific disputes, would be another step toward our common goals. FDA, the pharmaceutical industry, the medical profession, science in general, and—above all—the patient would all reap the benefits.

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