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### The Thalidomide Lesson

The thalidomide case has given the nation a lesson on the work of the Food and Drug Administration and a demonstration of the merit of caution in approving new drugs. Dr. Frances Kelsey, the heroine of the case, has received from President Kennedy the gold medal Award for Distinguished Civilian Service, and is the deserved recipient of the nation's gratitude.

It is already clear that the case will be used to support efforts to secure tighter controls over the release of new drugs. The President has written to Senator Eastland, chairman of the Senate Judiciary Committee, recommending action "to protect the American people against unsafe and worthless drugs." The President had earlier made such recommendations, in his consumer message to Congress, and so had Senator Kefauver, following his three-year inquiry into practices of the drug industry (Science, 14 July, 27 October, and 15 December 1961). But these had been shelved by the Judiciary Committee in favor of what Secretary Ribicoff called a "mere shadow" of the original. What is now being considered comes close to the original.

Whatever happens on the legislative scene, it also seems likely that pharmaceutical manufacturers will be more careful about the evaluation of new drugs. A new Commission on Drug Safety has been appointed by the Pharmaceutical Manufacturers Association (see page 516).

In short, Dr. Kelsey's caution has prevented much heartache, and it appears that the thalidomide case may be useful in improving the procedures used in evaluating and appraising new drugs.

But this happy outcome is not assured, for the reaction against what we have escaped could inspire restrictions severe enough to impede the development and use of new and beneficial drugs. The effect of delays in making new drugs available could be as detrimental as the effect of putting them into use too hastily. In the situation of knowing poignantly the dangers of commission and having to guess at the dangers of omission, we could adopt practices more harmful than those we seek to correct.

None of the principal issues of the Kefauver hearings—pricing policies, patent rights, generic vs. trade names, or proof of efficacy—were involved in this case, but only the old and fundamental matter of proof of safety. Nevertheless, if emotion over charges of giving dangerous drugs to pregnant young women, the universal pity aroused by horribly malformed babies, the publicity resources of a congressional inquiry, and the publicity and influence of organized medicine and the pharmaceutical industry are allowed to result in jangling clashes, the final result could be a bitter stalemate, or restrictions so severe as to enforce an unhealthy timidity on everyone involved in the testing, development, and approval of new drugs.

The moral is trite, but nonetheless important: moderation is required. Is it reasonable to hope that the thalidomide scare will bring all of the principals together for constructive planning of improvements in the always difficult business of screening, testing, and approving new drugs?—D.W.