

Unfortunately, many medical school investigators whose research programs are funded by NIH also receive personal honoraria from the drug industry. While federal funds are paid only to the medical school and can be used as prescribed in strict budgets, the industry funds may be received as personal income outside the framework of medical school salary scales. Some of these investigators seem far more concerned about the welfare of the pharmaceutical industry than they do about the tax-paying public, even though the public actually provides most of their support. The industry has every right to pay their consultants as they see fit, but publicly-supported investigators should not be permitted to be involved in serious conflict of interest.

The FDA is the only real organization solely devoted to protecting the American public. This agency is the stepchild of two great drug catastrophes: the Food, Drug and Cosmetic Act of 1938 was passed as a result of the elixir of sulfanilamide catastrophe in which 108 children died, and the 1962 Harris-Kefauver amendments were enacted because of the thalidomide catastrophe. The powers of this agency are limited by law and the officials are subject to political pressure. If anyone in the medical profession wishes to criticize or belittle the FDA, he can find an immediate audience in almost any medical journal and his efforts will bring him rich rewards from the pharmaceutical industry. Claims are continually being made that the agency is interfering with research and depriving the public of life-saving drugs. The truth, more likely than not, is that the agency has prevented doctors from poisoning patients with some new, expensive drug of questionable merit.

This agency has a long way to go. Under Commissioner James Goddard many improvements came about. Officials gradually began to insist on better quality trials, and a crackdown on false advertising was begun. Although Goddard was overly frank, and the drug industry capitalized by both misquoting him and exploiting his candor, the public owes him a great debt for improving the Administration. There is every expectation that his successor, Dr. Herbert Ley, will continue to serve the public interest, and see that the FDA becomes even more effective in its mission.

FUTURE THERAPEUTIC CATASTROPHES

Over the past 30 years, this country has experienced several major therapeutic disasters. Many patients were needlessly killed or badly injured by indiscriminate use of certain new drugs. It is said that this is a price we must pay for progress. If a good scientist examined the records of these disasters, he would have to conclude that if testing were conducted in a totally impartial, highly scientific manner, all of these catastrophes could have been avoided. But the Pollyannas of the drug industry assure us that new disasters are impossible.

A few Cassandras, however, prophesy even worse calamities. Pharmaceutical companies are producing new and highly toxic compounds at a startling rate and the number of new drugs being introduced for clinical testing is rapidly increasing. What are the possibilities of another major drug disaster? Dr. H. Friedman, in a letter to *Science* magazine, stated:

"Let us assume that a drug (such as a combination psychic energizer and diuretic) with no known side effects is aggressively promoted and very widely used throughout North America and Europe. Some 16 years after its adoption, the first hints of unexpected side effects begin to appear and several more years are required before they are confirmed. All children born to mothers using this drug during the first three months of pregnancy (effective as it is for morning sickness) are found to be sterile. The use of the drug for 20 years has affected the larger proportion of an entire generation so that populations of countries effected will drop sharply for several decades and require several additional decades to recover if given the opportunity.

"The effects of thalidomide were relatively easy to discover and limit, but how readily can we detect more subtle effects in time to prevent the possibility of a history-changing catastrophe? In contrast to such a situation, the individual tragedies attributed to past and present drugs would seem rather tolerable."

All the elements for vast future catastrophes are present: lots of new, highly toxic drugs, sloppy and dishonest testing, and hard-sell, dishonest advertising campaigns, to which the average doctor is highly susceptible.