Drug Agency Vigilance Key to Protecting Life

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To the Food and Drug Administration falls the heaviest responsibility of any government agency—that of protecting the health and life of every American. A major function of FDA is to keep ineffective and harmful drugs from reaching the public, and to make certain that drugs with life-saving potential but deadly effects if prescribed indiscriminately, are clearly labeled with warnings. Yet on occasion FDA has been dangerously lax.

Drug testing by manufacturers is a multi-stage operation, with FDA approval required in all but the first stage. After a pharmaceutical company tries a new compound on animals, it must obtain permission to test the product on humans. Here, as Dr. Goddard revealed in a national news magazine, lies a critical weakness — staff shortages in the agency enable it to "make only a quick review"; in the absence of negative indication, the manufacturer is free to proceed. If no toxicity is discovered, the number of human volunteers is broadened. Then the drug is released to private physicians and clinics for controlled but very extensive testing. At last the manufacturer applies for marketing permission. Continued vigilance is still required by law. Side-effects noted after public sales are to be reported to FDA.

THE DRUG agency, in its monitoring, must rely largely upon information in reports and applications. Even after a drug is marketed, FDA relies upon manufacturer's information in noting adverse long-term reactions. Honest reporting by experimenters and FDA are both crucial in arriving at just evaluations. Both at times have failed.

FDA has admitted its carelessness in handling of a "cure-all" but potentially dangerous drug, DMSO. Between 20,000 and 50,000 persons were using it as opposed to the usual 100 persons at the clinical investigatory stage. FDA finally halted testing, but not soon enough to prevent at least 24 cases of eye damage and several deaths possibly linked to DMSO, according to "Washington Post."

Some pharmaceutical companies, endangering public safety, have misrepresented or withheld critical facts: They have falsified or withheld information about newly-tested compounds; they have, during the investigatory stage, covered an area broader than that permitted; they have withheld information on side-effects encountered after marketing of the drug; and some have failed to submit to physicians information necessary for prescribing potent drugs with minimum risk.

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SEVERAL MONTHS ago, a long-acting sulfa drug was ordered off the market and manufacturers of similar drugs were ordered to put sharp warnings on labels as to possible fatal irritation of the skin and mucous membrane. Reminiscent of the thalidomide tragedy was the discovery and warning to two manufacturers to clearly label products containing any of three antihistamines indicating possible linkage to birth defects. At about the same time, approximately 250 brands of antibiotic throat lozenges were banned; Safety was not an issue, but for more than $25 million annually, consumers were buying ineffective remedies.

FDA Commissioner Dr. James L. Goddard, who took office in January, has made clear his intentions of enforcing strict standards. The Food and Drug Administration has an awesome responsibility; as protector of the public, it may be going in the right direction now in assuring safety. But the same congressional oversight and scrutiny that has enforced vigilance is needed for its continuation. Otherwise the lives of 197 million Americans will be endangered.

"Folks who know least seem to know it fluently!"