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THE FOOD & DRUG ADMINISTRATION'S REAL PROBLEM: DRUG UNAVAILABILITY

(Updating *Backgrounder* No. 644, "Red Tape for the Dying: The Food & Drug Administration and AIDS," April 8, 1988.

A series of disclosures in recent weeks revealed fraud and bribery in the Food and Drug Administration's (FDA) generic drug approval programs. Some lawmakers have reacted to these disturbing developments by calling for stricter FDA review of new drug approvals. FDA's real problem, however, remains a drug approval process that moves too slowly, not too quickly. Over the past year, the FDA has taken several significant steps toward making new drugs available more quickly to those who need them most, such as sufferers of potentially fatal diseases, including AIDS. Only last week, for example, the FDA approved wide distribution of the anti-AIDS drug DDI, even though tests of the drug's effectiveness and side effects have not yet been completed. The recent scandals should not be used as an excuse to halt or slow these actions.

Among the important steps taken by the FDA since last year:

◆◆ Expanded use of the "treatment IND" (investigative new drug) program. Under this program, drugs are made available more readily to physicians before they are approved by the FDA for general distribution by pharmacists on prescription. It is through this program that DDI will now be distributed. The FDA is currently considering a concept known as "parallel tracking" – by which even more widespread distribution would occur while clinical testing is still going on.

◆◆ Permission for individuals to import unapproved drugs from abroad, in limited quantities for personal use. This could help reduce the many instances of physicians and their desperate patients smuggling drugs into the country.

◆◆ Acceptance of test data from community-based clinical programs. This is a dramatic departure from the centralized clinical trials that previously had been the only acceptable means for investigating new drugs.

What triggered the changes was the AIDS crisis; thousands of Americans with a terminal illness found themselves denied new drugs that might treat or cure their condition. Reform has been given a further boost by the work of the President's National Committee to Review New Drug Approval Procedures headed by Dr. Louis Lasagna of Tufts University, one of the nation's foremost experts on the drug approval process. This committee heard the FDA's approval process sharply criticized by physicians, researchers, and government officials.

Deadly Delays. The recent reforms may lessen the problem of "drug-lag" – the delay in making new drugs available caused by FDA approval procedures for new drugs. This delay can be deadly. Last December, for example, the FDA approved misoprostol as the first drug for

controlling the dangerous gastric ulcers that commonly afflict arthritis sufferers taking nonsteroidal anti-inflammatory medication. Although FDA's high-priority review of misoprostol took "only" nine months – a relatively short time for FDA review – more than 7,000 Americans died of gastric ulcer bleeding during this period. Almost all of these probably would have been saved by the drug.

While FDA's recent reforms are to be applauded, true reform has a long way to go. The FDA still refuses to seriously examine the issue of how many lives are lost because of its approval procedures. Only by knowing this can the risks of releasing a drug too soon be compared with the harm of delaying approval of a drug. So far, the agency, and the press, focus mainly on the dangers of approving drugs too quickly.

Respecting Good Science and Human Dignity. The only policy that can balance these risks is one based on the principle that a new drug's suitability should be determined by individual patients and their physicians, not by an across-the-board ruling from a federal agency. The FDA's role in reviewing new drugs should be solely advisory. The agency should continue to evaluate the safety and effectiveness of new drugs and make current information available to physicians and the American people, but it should not be able to prevent the use of drugs that physicians and patients believe to be beneficial. This more limited FDA role, in contrast to its current function, would respect good science, informed choice, and human dignity.

The FDA has over the last year begun to reduce the problem of drug lag by making drugs available more quickly to those who need them most. Further reform is essential if needless deaths and suffering are to be avoided. Lawmakers thus should not allow the recent revelations of fraud and abuse in the FDA's generic drug program to be used as an excuse to slow down the approval process, thereby adding to the drug lag problem.

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