The New York Times
nytimes.com

September 28, 2006
Editorial

Prescription for a Stronger F.D.A.

A prestigious advisory group has put its weight behind criticism that the Food and Drug Administration is pitifully weak when it comes to removing dangerous prescription drugs from the market. Last week, a panel appointed by the Institute of Medicine, part of the National Academy of Sciences, issued a slew of recommendations to strengthen the beleaguered F.D.A. as it struggles to regulate a huge array of medications whose ill effects sometimes show up only after years of wide use.

The institute's report, which was requested by the F.D.A., deplores the big imbalance between the money and staff devoted to approving new drugs and the much smaller resources for monitoring drugs after they are on the market. The imbalance results in part from the pharmaceutical industry's providing user fees that pay for expediting the approval process, but not for monitoring the aftereffects. Worse yet, even when it spots a problem, the agency has very little power to regulate drugs on the market unless there is overwhelming evidence that they are unsafe, which is seldom the case.

Although the nation is mired in budget deficits, the institute was wise to call for a large increase in financing and personnel for this crucially important regulator of public health. If Congress is too stingy to ante up more money, it should at least divert some of the drug industry's user fees to surveillance after a drug's approval.

The panel calls for the F.D.A. to evaluate the safety and effectiveness of drugs that are truly new, not just copycats, at least once every five years. It wants the agency to be given explicit power to compel post-marketing studies and to impose fines, injunctions and withdrawals to enforce its decisions. In a departure from conventional wisdom, the panel also urges the F.D.A. to require that a substantial majority of the members of each of its advisory panels be free of significant financial involvement with companies whose interests might be affected. That undercuts the agency's claims that there are not enough experts without ties to the drug industry.

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