

FDA's Speed to Approve New Drugs Invites Risks

For most of its history, the U.S. Food and Drug Administration approved new prescription medicines at a grudging pace, then in the early 1990s, the demand for AIDS drugs changed the political climate. Congress told the FDA to work closely with pharmaceutical companies in getting new medicines to market more swiftly. President Clinton urged the FDA to trust industry as "partners, not adversaries."

The FDA achieved its new goals, but now the human cost is becoming clear. Seven drugs approved since 1993 have been withdrawn after reports of deaths and severe side effects. A two-year investigation by the Los Angeles Times has found that the FDA approved each of those drugs while disregarding danger signs or blunt warnings from its own specialists.

Then, after learning of significant harm to patients, the agency was slow to seek withdrawal of the products from the market.

According to "adverse-event" reports filed with the FDA, the seven drugs were cited as suspects in 1,002 deaths. Because the deaths are reported by doctors, hospitals and others on a voluntary basis, the true number of deaths could be far higher, according to epidemiologists.

An adverse-event report does not prove that a drug caused a death; other factors, such as preexisting disease, could play a role. But the reports are regarded by public health officials as the most reliable early warnings of danger.

The FDA's performance was tracked through an examination of thousands of pages of government documents, other data obtained under the Freedom of Information Act and interviews with more than 60 present and former agency officials.

The seven drugs were not needed to save lives. One was for heartburn. Another was a diet pill. A third was a painkiller. All told, six of the medicines were never proven to offer lifesaving benefits, and the seventh, an antibiotic, was ultimately judged unnecessary because other, safer antibiotics were available.

