

# Groups urge FDA to release info on rejected drugs

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By [Susan Heavey](#)

WASHINGTON (Reuters) - The U.S. Food and Drug Administration should make more information available to the public, even on drugs and devices that never make it to the U.S. market, consumer advocates told the health agency on Wednesday.

But industry representatives cautioned that findings or data containing confidential company information could harm competition if made widely available.

While the FDA often provides public details on products that win its approval, doctors and consumers could benefit from similar disclosure on those it rejects, several advocates and former FDA staff reviewers said at a public meeting to discuss ways the agency can make its regulatory decisions clearer.

Details on why it declines a new use for a drug already on the market could help protect patients from possible side effects if doctors are already prescribing it for so-called "off-label" use or as rival drugs are developed, said the Pew Prescription Project's Allan Coukell.

"Lives might have been saved," Coukell, director of the nonpartisan consumer safety group, told the panel of eight top FDA officials.

The FDA, which regulates a wide-range of foods, drugs and devices that make up about 25 percent of the U.S. economy, has ultimate say on whether medications can be sold or whether certain foods must be recalled. It also monitors manufacturing sites and monitors drug risks, among other duties.

But it has come under fire amid a number of scandals involving a variety of products including painkillers, contaminated peppers and peanut butter.

Some critics said the agency, which gets much of its funding from company fees, is too cozy with the industries it regulates.

FDA has adopted a "corporate culture" and focuses too much on company interests instead of science, said Public Citizen Health Research Group Deputy Director Peter Lurie, whose advocacy group has long-challenged many FDA decisions.

Dr. Joshua Sharfstein, deputy commissioner of the FDA and head of the panel, defended the fees earlier this year, saying agency staff make decisions based on evidence.

U.S. lawmakers only recently boosted the FDA's budget.

Industry groups said the FDA could do a better helping consumers understand its actions but warned that too much public detail on products or manufacturing may tip off rivals.

"To provide that type of information before approval would provide competitors with insights ... those types of insights come at a cost, a competitive cost," said Pharmaceutical Research and Manufacturers of America lawyer Jeffrey Francer.

Mark Leahey, president of the Medical Device Manufacturers Association, said it could also scare off potential venture capitalists crucial to many smaller companies.

"Investments ... will dry up," he told the panel.

The panel is set to meet again this autumn and will deliver its recommendations to FDA Commissioner Margaret Hamburg in six months.

*(Reporting by Susan Heavey, editing by Leslie Gevirtz)*