

FDA initiative may crack wall of secrecy

Much of the information gathered by the US Food and Drug Administration (FDA) from pharmaceutical companies is ultimately not published. But this data can provide insight into drug efficacy and safety, and thus many people have called for greater access to it. The agency is now mulling over whether to release more information from unpublished clinical trials as part of its ‘Transparency Initiative’, the first phase of which was unveiled on 12 January.

FDA commissioner Margaret Hamburg launched the initiative in June 2009 in response to a call from the Obama administration to increase government transparency. The centerpiece of the first phase is a website, ‘FDA Basics’ (<http://www.fda.gov/aboutFDA/basics/>), designed to better explain the inner workings of the agency.

But, for the second phase, an FDA taskforce will make recommendations to Hamburg on potentially more contentious issues. Measures to open up data given to the FDA by drug companies are “on the table” according to Afia Asamoah, who spearheads the FDA initiative.

As *Nature Medicine* went to press, the taskforce was expected to release draft recommendations in late February or early March that will address how to make information at the agency more transparent. The release will be followed by a 60-day public comment period. Asamoah says it is too early to say when and whether the FDA might implement such recommendations—that

depends in part on the response of the FDA leadership.

With this initiative, say researchers and patient advocacy groups, the FDA has an opportunity to radically improve the evaluation of drugs by offering researchers access to more data.

The agency currently posts online FDA summaries of clinical data on drugs approved from 1998 onward. But a 6 January analysis by the Washington, DC-based Sunlight Foundation concluded that of the 25 most prescribed drugs, information was not available online for nine drugs approved before 1998. Moreover, the FDA does not routinely post information on old drugs approved for a new condition, nor does it release information on drugs that did not meet the bar for approval.

Trade secrets

The agency has a mandate to protect trade secrets and confidential commercial information. But many researchers and advocacy groups say these protections currently extend too far.

“Once people are participating in a clinical trial, the data become a public health issue, not a company’s private domain,” says Diana Zuckerman, president of the National Research Center for Women & Families in Washington, DC.

Erick Turner, a researcher at Oregon Health and Science University in Portland and a former FDA employee, has grappled firsthand with

the FDA drug databases. He and his colleagues made a splash with a 2008 analysis examining 74 FDA-registered studies of 12 popular antidepressants. Although almost all studies with positive results were published, they found that 22 out of 36 studies with results that the FDA viewed as negative or questionable were not. Turner and his colleagues concluded that the drugs do not work as well as the published literature suggests (*N. Engl. J. Med.* 358, 252–260, 2008).

Getting the data was not easy. To evaluate drugs approved prior to 1998, Turner had to rely on documents obtained by a Freedom of Information Act request, which can take years to process. The data are not in a format compatible with search engines, so he “killed more than a few trees,” he says. “I would print out the whole damn thing and create these huge piles.”

What’s more, the documents that are available often contain redacted portions, using criteria that researchers say are opaque.

“We have seen documents where the adverse events have been redacted,” says Lisa Bero, a researcher at the University of California–San Francisco who studies the FDA databases.

Such barriers have stood in the way of analyses of a range of drugs, say Bero and Turner. They would also like to see more information on drugs prescribed ‘off label’ for unapproved conditions. As an example, Turner cites atypical antipsychotics, such as Abilify, which is widely prescribed off label for children with autism. He says that at present it’s impossible to know whether such drugs have been tested on this group. “I think a doctor who prescribed drugs for autism would want to know that,” says Turner.

Although advocacy groups have asked the FDA to release such data, they may be up for a fight with industry. The industry group Pharmaceutical Research and Manufacturers of America (PhRMA) welcomes the new FDA initiative, according to assistant general counsel Jeffrey Francer, and the Washington, DC-based organization also looks forward to the third phase of the initiative, which will focus on increasing transparency of the FDA process to companies. But increasing transparency must proceed in a way that does not stifle innovation or jeopardize confidential commercial information, says Francer. For instance, PhRMA favors release of data on compounds denied approval—but only after a company has discontinued work on that compound.



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