

**Lack of GLP Inspections Leads to Hasty Device Approvals,  
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Political and industry pressure on the FDA may be responsible for fewer good laboratory practice (GLP) inspections and hasty processing of device approvals, an independent watchdog group says.

Critics see the FDA as "frequently bowing to the wishes of the industry it regulates and as susceptible to pressure by politicians ... influenced by industry lobbyists," according to a report released last week by the Project on Government Oversight (POGO).

The group is calling for an investigation into the FDA's dwindling number of GLP inspections for nonclinical testing of high-risk devices. In its report, POGO says such inspections have declined from 33 in 2005 to only one last year. Citing internal sources, POGO says no GLP investigations are expected this year.

The group attributes the decline in part to devicemakers, who have voiced concerns that strict GLP enforcement would add to the expense of devices and cause delays in approval decisions. Industry also is concerned that increased regulation may obstruct innovation and lead to some devices never being developed, according to POGO.

The FDA's GLP program -- which guides the conduct of nonclinical laboratory studies intended to support applications for devices before they are tested in patients -- was established in 1979 after a leading medical lab was found to have fabricated data.

FDA spokeswoman Peper Long confirmed that the FDA has not conducted as many GLP inspections in recent years as it had in the past, entrusting manufacturers to monitor their own testing facilities. "We continue to review our inspectional plans, and CDRH maintains the authority to request additional information on GLP adherence from a manufacturer and inspect any facility for GLP compliance," Long told D&DL.

Pressure on CDRH

POGO is asking the Government Accountability Office (GAO) or the HHS inspector general to examine FDA records to learn when and why the agency started paring back in its early device investigations. The group also is urging lawmakers to give the agency more funding so it can hire and train inspectors to better monitor laboratories before device manufacturers begin clinical trials.

If POGO is successful in its demands, the FDA would have to inspect the possible role of GLP noncompliance whenever a device malfunctions during either clinical testing or after marketing.

The report is the latest to criticize the FDA's device review process, adding to the number of accusations the agency faces of allowing industry and political influences to tamper with evidence that could hinder the safety and efficacy of devices.

Claims from several CDRH scientists that top managers interfered with their scientific reviews and recommendations prompted a congressional investigation late last year into the FDA's approval process for several devices (D&DL, Nov. 24, 2008). The results of that investigation have yet to be released.

Last month, a GAO report said the FDA's approval process for Class III devices was incomplete and recommended that the agency ensure the devices go through a more stringent review (D&DL, Jan. 19). A separate GAO report added the FDA to a list of government operations in need of transformation or at risk for mismanagement, calling on the agency to protect the public more effectively by improving its oversight of devices (D&DL, Jan. 26).

POGO has shared its findings with Rep. Henry Waxman (D-Calif.) and Sen. Edward Kennedy (D-Mass.), and plans on taking the issue to other members of Congress in the coming months, POGO's science advisor Ned Feder told D&DL. Feder hopes that these talks, combined with media attention, will help bring light to what he considers an issue requiring immediate government attention.

#### Congressional Interest

Some congressional members have taken the issue into their own hands. Earlier this month, Rep. Rosa DeLauro (D-Conn.) sent a letter to acting FDA Commissioner Frank Torti requesting information on device and drug approvals made in the final months of the Bush administration.

"I long have been concerned about the influence of industry and political interests in the approval process for drugs and devices at the FDA," DeLauro says in the letter. "I fear that this influence has permeated the culture of the agency and has resulted in the approval of a number of products that later were proven to be unsafe and/or ineffective."

DeLauro asked the agency to provide a list of all medical products that were approved by the FDA last November through January and the dates of when the marketing applications for the products were submitted. The congresswoman requested the FDA respond to her inquiry this week.

POGO's report can be viewed on its website at [www.pogo.org/pogo-files/alerts/public-health/ph-fda-20090218.html](http://www.pogo.org/pogo-files/alerts/public-health/ph-fda-20090218.html).

DeLauro's letter is available at [delauro.house.gov/release.cfm?id=1479](http://delauro.house.gov/release.cfm?id=1479).  
(By subscription Only)