

## EDITORIAL

# Pursuit of the Whistle-Blowers

FEBRUARY 15, 2012

A federal lawsuit filed against the Food and Drug Administration raises disturbing questions about whether the agency retaliated against whistle-blowers for trying to warn Congress that medical devices were being pushed toward approval despite safety concerns.

The suit was filed by six scientists and physicians who are former or current employees and contractors. They contend that the agency monitored their computers and e-mail accounts to learn how they planned to convey concerns to Congress or other authorities. The F.D.A. tried but failed to have criminal charges brought against several employees and then ended their employment.

The plaintiffs had challenged the safety and effectiveness of devices used in detecting colon cancer, breast cancer or other medical problems. Virtually all of the devices were approved by supervisors who disagreed with their judgments. Based on material found on the computers, the F.D.A. concluded the employees violated federal law by disclosing confidential information submitted by manufacturers in the agency's premarket review process. However, the inspector general's office for the Department of Health and Human Services twice concluded that there was no evidence of criminal misconduct, and the Justice Department declined to prosecute. The federal Office of Special Counsel, in reviewing one case, found reasonable grounds to believe that

the individual was fired in retaliation for constitutionally protected speech.

Senator Charles Grassley, the ranking member of the Senate Judiciary Committee, complained in a letter to the F.D.A. last month that an e-mail to his staff had been intercepted. He warned agency officials that interfering with a Congressional inquiry is against the law. If the court finds that the F.D.A. acted improperly, the agency should punish the managers responsible. ■