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Whistleblowers at FDA May Be Stifled, Grassley Says (Update3)

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March 24 (Bloomberg) -- Government employees who think public safety is being compromised may be deterred from speaking out because of a <u>memorandum</u> from the acting head of the U.S. Food and Drug Administration, Senator <u>Charles Grassley</u> said.

The memo from the FDA official, <u>Frank M. Torti</u>, dated March 13 and sent to agency employees, warned that those who disclose confidential information may face "disciplinary sanctions and/or individual criminal liability." An FDA spokeswoman described the memo, <u>posted</u> on Internet Web sites, as "routine" and a "prudent reminder" to employees.

<u>Grassley</u>, the senior Republican on the Senate Finance Committee, has been investigating drug-company payments to doctors and whether lobbying influenced FDA decisions. In a letter to Torti, he defended FDA employees who released information, hailing them as "patriotic" and "whistle- blowers."

"I have serious concerns that your memorandum goes beyond legitimate privacy concerns and appears to run contrary to many statutes protecting executive branch communications with members of Congress," Grassley said in his letter to Torti, which was dated today and distributed by e-mail.

"Denying or interfering with employees' rights to furnish information to Congress is also against the law," Grassley said in his letter.

Privileged Communications

Torti's memo lists trade secrets, confidential commercial files, and personal data such as the names of patients taking part in clinical trials as among the kinds of information that shouldn't be disclosed. Documents such as inspection reports prepared for enforcement purposes and privileged interoffice correspondence, including e-mail, also should be kept confidential, according to Torti's memo. The memo was intended to remind employees that while it is "committed to greater transparency," the agency also handles several kinds of information that must be held confidential, said <u>Judy</u> <u>Leon</u>, the FDA spokeswoman, in a telephone interview today.

"It's important to be aware of that to protect patient confidentiality and commercial confidential information," she said. "There was nothing other than that intended by the memo and its timing."

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