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Memo to FDA Staff: Don't Leak This



President Obama's call for open government and transparency is all fine and good, but the FDA has delivered a warning shot to anyone thinking of disclosing information the agency doesn't want leaked.

In a staff [memo](#) Friday, FDA Deputy Commissioner Frank Torti outlined prohibitions on disclosure of commercial information that "can result in disciplinary sanctions and/or individual criminal liability" or could cause the FDA to be sued for damages. Concern over keeping trade secrets is routine in government.

But Torti, who is also the FDA's science officer, went on to say that the release of intra- and interagency documents with protected information was also covered, including "internal memoranda, letters, and e-mail to and from employees within within FDA" and between government agencies. The memo, first aired in the [In Vivo blog](#) on Monday, continues:

Examples of documents that might contain this kind of information include drafts of policymaking documents, draft notices of proposed and final rules, drafts of other Federal Register documents, recommendations to take (or not to take) some regulatory or enforcement action, requests for legal opinions and the opinions themselves, etc.

The FDA has been under attack in Congress in recent years, with a parade of whistle blowers carting those kind of papers. They have found their way to the Senate Finance Committee — including one [big critic](#) of the FDA, Republican Chuck Grassley of Iowa — as well as to the House Energy and Commerce Committee.

The FDA tells the Health Blog that Torti's missive was nothing unusual. "This 'all hands memo' was simply a prudent reminder to staff that while we are committed to the president's principles of transparency, as a regulatory agency we also need to be mindful of several categories of confidential information we need to respect every single day.... Fairly obvious stuff," said agency spokeswoman Judy Leon.

Steve Nissen disagrees. The Cleveland Clinic cardiologist who frequently advises members of Congress and their staffs about pharmaceutical problems and the FDA, has urged that a [main priority](#) of a new FDA commissioner should be "transparency."

In an interview this week, Nissen said the agency allows companies too much leeway in branding important material on safety and efficacy as commercial or proprietary information, and that agency leaders disclose too little about their interactions with industry lobbyists and lawyers. "I'm a little stunned that the FDA would send this [memo] out at this time," Nissen said. "I wonder what some of the people on the Hill think."

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