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Regulatory Experts: OMB Memo Could Drastically Slow FDA Guidances

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Sources say a memo by the White House Office of Management and Budget that requires federal agencies submit non-binding guidance to the Office of Information and Regulatory Affairs -- and potentially to Congress -- could throw a wrench in FDA's usual guidance-making process, which could negatively affect both the agency and industry.

The memo, released by OMB Acting Director Russell Vought on Friday (April 12), reaffirms the applicability of the Congressional Review Act (CRA), which requires federal agencies to send rules to OIRA to determine whether they are considered major. If a rule is major, it is sent to be reviewed by Congress, which can then invalidate the rule if lawmakers disapprove of it.

Jim Tozzi, the head of the Center for Regulatory Effectiveness and a former OMB official, said that Executive Order 12866 issued under former President Bill Clinton in 1993 dramatically reduced the number of regulations that OMB reviewed relative to the number reviewed under former President Ronald Reagan.

Though CRA was enacted in 1996, Tozzi said Executive Order 12866 limited the number of rules that OMB reviewed. However, the new OMB memo, which is set to take effect on May 11, would expand considerably the number of regulations reviewed by OMB.

FDA often issues guidances to articulate its policy positions and provide direction for the medical and food product industries. However, the OMB memo points out that the CRA applies to more than just notice-and-comment rules. It also includes guidance documents, general statements of policy and interpretive rules.

Therefore, FDA would have to submit its guidance documents, as well as any other documents that CRA considers to be rules, to OIRA for review.

"Agencies should not publish a rule--major or not major--in the Federal Register, on their websites, or in any other public manner before OIRA has made the major determination and the agency has complied with the requirements of the CRA," the OMB memo says.

Should the OMB memo be enforced, Tozzi said the workload at OIRA, which only has 45 full-time employees, would ramp up quickly.

And sources told *Inside Health Policy* that sending guidances to an overworked OIRA staff and awaiting congressional review could have profound implications on the FDA-regulated industry, since it would slow down FDA's usual process of articulating regulatory policies through guidance.

"I know some folks don't like how FDA uses guidance almost as though it's statute or regulation," Kurt Karst, a director at Hyman Phelps & McNamara, said. "But at the same time, guidance does give FDA the ability to be nimble … and throwing a monkey wrench in a very important process would not do industry a lot of good."

FDA became especially prolific in issuing guidances under the leadership of FDA Commissioner Scott Gottlieb. With Gottlieb at the helm, the agency provided direction to industry on a wide range of new issues, from cybersecurity to regenerative medicine. And even as he left the agency, Gottlieb indicated the agency had plans to issue many more guidances on a variety of topics.

"[Guidances] give a lot of information on what FDA's thinking, which is very important in drug development," Karst said.

Aaron Josephson, a senior director at ML Strategies and former senior policy advisor at FDA's device center, said the OMB memo is likely an effort by the administration to cut down on what he said could be called "administrative legislating."

However, Josephson said he has heard mostly praise from industry about FDA guidances, which he says help lay out what FDA considers to be safe and effective in the immensely complicated world of medical device and human drug development.

Still, he said the effect of the OMB memo on FDA's guidance-making depends on what OIRA decides to flag as a major rule or guidance.

The memo reiterates CRA, which says that a rule is considered major if it has resulted in or is likely to result in: an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, industries, government agencies or geographic regions; or significant adverse effects on competition, employment, investment productivity, innovation or U.S. companies' ability to compete with foreign enterprises.

"I would say the devil will be in the details," Josephson said. "The agency may be able to persuade OIRA that a lot of these things don't meet that threshold [of major]. A device-specific guidance is not necessarily something Congress needs to weigh in as opposed to a sweeping policy change."

Josephson predicted the FDA-regulated industry might push back against the memo.

"I wouldn't be surprised if the medical product trade groups expressed concern about this removing some clarity or uncertainty about certain things," he said. "On the other hand some might applaud a more de-regulatory environment, but with the groups I know and work with, guidance is generally viewed as a positive." -- *David Roza* (droza@iwpnews.com)

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