

April 26, 2022: FDA User Fees Agreements: Advancing Medical Product Regulation

Senator Maggie Hassan: Well, I want to thank you, Madam Chair and Ranking Member Burr, for having this hearing, and thank you for the witnesses for being here today. Dr. Cavazzoni, last summer, I led a bipartisan letter to the FDA raising concerns about the apparent conflicts of interests surrounding the consulting firm McKinsey. The firm worked for the agency on opioid-related projects, while also simultaneously working for opioid manufacturers like Purdue Pharma. The FDA's response to the letter indicated that McKinsey failed to disclose any potential conflicts of interest when applying for FDA contracts. And earlier this month, Chair Murray and I led a letter asking the HHS Inspector General to investigate further. What actions is the FDA now taking against McKinsey based on the firm's failures to disclose apparent conflicts of interest? For example, is the FDA suspending current and future contracts with McKinsey and referring this case to the Department of Justice for potential violations of the False Claims Act?

Dr. Patrizia Cavazzoni: Thank you, Senator, for that question. It is very important to establish that while McKinsey have worked with FDA under contracts over several years, their work did not entail specific regulatory work or a scientific review work pertaining to products or product classes.

MWH: But my question is, what are you all doing to make sure that we don't come to a place like this again and to hold McKinsey accountable for failure to disclose what is an apparent conflict of interest?

PC: So, FDA follows the U.S. government contracting rules, and those rules require contractors to disclose any conflict of interest, and we expect contractors to do so. So, this is the framework under which we operate. And we will continue to set those expectations.

MWH: So, I'm going to follow up with you, additionally, because I am still interested in wanting an answer to whether you're going to suspend contracts, current or future contracts with McKinsey, whether there is a case for referring this to DOJ, and I'll continue to follow up on the issue, including with the HHS Inspector.

PC: The answer to that...the Center for Drugs currently have a contract with McKinsey and across FDA, there is we anticipate that further contracts will not be issued pending the outcome of the investigations. And I can defer to my colleagues, Dr. Marks, to speak.

MWH: Well, I'm going to hold off on that because I have a few other questions and limited time, but I will follow up with you, Dr. Marks. I have another question, Dr. Cavazzoni. In the FDA's response to my original letter, the agency claimed that it first became aware that McKinsey had taken on opioid manufacturers as clients in early 2021. However, the *New York Times* reported on

McKinsey's representation of Purdue Pharma in February 2019. Contracting databases show that from February 2019 to January 2021, McKinsey received more than \$20 million dollars in new contracts from the FDA. How did the FDA fail to notice McKinsey's apparent conflicts of interest until almost two years after they were public knowledge printed in the *New York Times*?

PC: As I mentioned earlier, we rely on government contracting rules, which set the expectations for contractors to disclose conflicts of interest. And it is also very important to highlight that the work that McKinsey did at FDA was about general process, concept of operations, organizational design, and did not entail involvement, direct involvement in product regulation or scientific review.

MWH: That may or may not be true. But the reality is that when somebody who is bragging to drug manufacturers that they know what questions to ask and have influence at the FDA, that should be of concern. And it strains credulity to think that nobody at the FDA involved with McKinsey between 2019 and 2021 had any idea that the company had major potential conflicts of interest based on news reports in major publications. How is the FDA adjusting its contracting processes going forward to ensure that it is aware of publicly reported information about apparent conflicts of interest with major companies to which it is awarding tens of millions of dollars in contracts?

PC: As I indicated earlier, we follow contracting regulations that apply across the entire U.S. government, including other agencies. And we rely on contractors to follow those rules and to inform us of any conflicts of interest.

MWH: I appreciate that answer. I think it is not sufficient for us to rely on self-reporting anymore, and I look forward to working with members of committees on whether we should exclusively rely on self-reporting from contractors, given what we have seen from McKinsey. Thank you, Madam Chair.