

Statement for the Record

The position of FDA Commissioner is critical for the protection of the public's health and safety and for the advancement of science and innovation. Since Dr. Califf's nomination for this position, I have carefully reviewed a significant volume of information, including many of his published articles and work published under his direction, as well as confidential contracts between the Duke Clinical Research Institute and pharmaceutical companies governing the conduct of major clinical trials in which Dr. Califf has participated. In addition, I asked Dr. Califf detailed questions about his work, both in person at his HELP Committee nomination hearing and through subsequent written questions for the record. I have also had multiple meetings with Dr. Califf to discuss his background, his qualifications, and his plans for the agency should he be confirmed by the Senate, and I've had extensive conversations with him about concerns that have been raised about his professional relationship with the drug and medical device industries. Finally, I have consulted with several outside experts in these matters to better understand the materials I have been provided by Dr. Califf. All of this investigation was aimed at better understanding the focus and relative independence of his past work as it gives clues to his willingness, if he is confirmed as head of the FDA, to put the interests of the public first.

After carefully examining Dr. Califf's record and looking closely at his representations both to me and to the Committee generally, I am satisfied that he has conducted himself with integrity as an academic researcher. For example, the language in the confidential contracts I have reviewed is consistent with what independent experts described to me as best practices designed to limit the influence of industry sponsors over academic investigators. Dr. Califf also indicated to me that there are no major trials in which he has participated that were not published, and he noted that he has repeatedly published negative trial results about products under development by the corporate sponsors that funded those trials. Dr. Califf also submitted a comprehensive list of the trials in which he played a major role. This list details the intervention under investigation in each trial and whether the trial resulted in the sponsor's preferred outcome. My staff conducted an independent analysis of the trials presented in this list, and in some instances disagreed with Dr. Califf's conclusions about whether trial results clearly strengthened or undermined the position of a corporate sponsor. Even so, after re-classifying some of the studies, the totality of the data indicate that Dr. Califf has consistently published the results of his research, regardless of whether it ultimately bolstered the interests of that work's sponsor.

My examination of the Califf nomination has raised serious questions about our current clinical trials system. I am particularly concerned with a lack of overall transparency, numerous opportunities for conflicts of interest, and a marked shortage of trials that are designed to determine which products to treat a given condition are the most effective – as well as cost-effective – for various patient populations. My examination has also raised concerns about the FDA's willingness to stand up to industry preferences in the design and conduct of clinical trials. Dr. Califf has indicated his clear and unequivocal commitment to work hard to address these policy issues as Commissioner.

Dr. Califf and I have also discussed in some detail his views regarding other important policies at the FDA, including efforts to move the FDA's blood donation deferral policies to risk-based policies for all blood donors. We have also discussed the importance of reducing antibiotic use in animal agriculture to protect public health, including the development of meaningful metrics to evaluate the effectiveness of FDA's current policies to curb use and the need for strong enforcement of current laws and regulations. In addition, some Senators have raised concerns about the degree to which the FDA is using its current authorities to address the ongoing opioid crisis – and as a Senator from a region that has been hard-hit by this crisis, I expect Dr. Califf and the other relevant agencies to provide full and complete responses to these inquiries if this nomination is to move forward.

The FDA needs a Commissioner who cares more about public health than industry profits or Washington politics. Given that the majority of major clinical trials are sponsored by private industry, it is fair to ask whether anyone with an extensive background in clinical research can be trusted to make decisions that are independent of the industry. On the other hand, there are substantial advantages to having a leader of the FDA who is a serious, front-line researcher who understands the importance of advancing cutting-edge work that will advance the health of millions of Americans – and who is sensitive to the conflicts of interest that can arise in industry-funded research. Based on the information I have reviewed and Dr. Califf’s representations, I am satisfied that he can be a strong leader for the FDA, placing the interests of patients and the American public above all others. Should he be confirmed, I plan to stay closely engaged with Dr. Califf to ensure that he advances the integrity and high standards of the FDA – and I fully intend to hold him accountable for his actions and decisions as the FDA Commissioner.