December 9, 2024

The Honorable Bernard Sanders
Chair
U.S. Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member
U.S. Senate Committee on Health, Education, Labor and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

CC: Members of the U.S. Senate Committee on Health, Education, Labor and Pensions

Dear Chair Sanders and Ranking Member Cassidy,

Thank you for all the work the Senate HELP Committee has done in the past, and will continue in the future, to fully and thoroughly vet candidates nominated to serve as Commissioner of the U.S. Food and Drug Administration (FDA). We write today to share our criteria for a qualified FDA Commissioner, and our expectations for the vetting and confirmation process. As Dr. Martin (Marty) Makary will soon appear before your committee, we hope you will consider some key attributes and expectations as you consider him to lead the most important regulatory agency for our patients and our clinical practice.

Doctors for America's FDA Task Force was established to ensure accountability and transparency at the FDA, ensuring that the drugs and medical devices approved by the FDA have been proven safe and effective. Since the Task Force's inception, we have worked closely with lawmakers and agency officials to ensure that FDA's primary focus and priority is providing certainty to patients and their doctors around the efficacy and safety of medical products. We are writing to you today to ensure this scientific standard is upheld by the next Commissioner.

As you are aware, the role of the FDA Commissioner is one of the most prestigious and critical positions within the U.S. Department of Health and Human Services (HHS). The individual in charge of the FDA is responsible for overseeing the safety and efficacy of drugs, biologics including vaccines, and medical devices used by hundreds of millions of Americans. Because of this role's immense responsibility and challenges, it is crucial that the individual selected to fill this position is uniquely qualified and has been thoroughly vetted for potential bias or conflicts of interest.

As you work to complete the committee's constitutionally mandated duty to advise the President on the competencies of public servants appointed at this level, we urge you to take the following key criteria into account as you consider the confirmation of the next FDA Commissioner:

Meaningful Clinical Experience: As the Commissioner of the FDA is required to make decisions about the federal regulation of drugs, medical devices, food, and cosmetics, it is crucial they have a clinical background. Nine of the ten last FDA Commissioners held a medical degree. This key understanding of the role of a healthcare professional who prescribes and/or administers FDA-approved medical products to patients is critical for understanding the depth of data and challenges available for clinicians around FDA-approved treatments at the point of care. Additionally, an FDA Commissioner with meaningful clinical experience will help build trust and credibility among healthcare professionals, biomedical researchers, and patients.

Free from Industry Conflicts of Interest: Any individual chosen to serve as Commissioner of the FDA should be free from financial or personal conflicts of interest, especially related to any industries the agency regulates.[1,2] Conflicts including recent employment within or financial ties to any of the industries the FDA regulates or an immediate family member who is employed by or has financial ties to industries regulated by the FDA should be disqualified. In the event an unforeseen conflict arises, any nominee should have committed under oath that he or she will uphold the highest ethical standards of transparency and facilitate the necessary recusals. Financially benefiting in any capacity from FDA regulations undermines the agency's mission and could further exacerbate mistrust in the agency's decision-making.

Committed to Lead with Science: It is crucial that the FDA maintain its gold-standard reputation globally in making regulatory decisions based on scientific evidence. Clinical trials are the backbone of making such evidence-based decisions including authorizing new products onto the market, making them available for patients, and also withdrawing products should safety concerns including a lack of efficacy arise. In approving medical products or allowing them to remain available for patients, FDA is signaling that the product's benefits outweigh its risks. Thus, if the agency decides to not evaluate a product's efficacy or leave efficacy uncertain at the time of market authorization, then this inherently becomes a safety concern for both patients and clinicians who rely on the agency's review to make informed treatment decisions. This also means that the evidence informing FDA decision-making should also be collected among representative and diverse patient populations, including by age, race and ethnicity, and gender. This provides further reassurance to patients and prescribers that the product's benefits and risks have been adequately assessed before being made available.

Recognize Existing Expertise: FDA is composed of thousands of the nation's brightest and most experienced researchers and scientists who provide expertise across disciplines to inform decision-making on novel and emerging health technologies. For over 100 years, men and women from across the U.S. have selflessly chosen to lend their collective talents in public

[1]https://www.statnews.com/2024/11/24/makary-sesame-compounded-weight-loss-drugs-semaglutide-fda-shortage-list/
[2]https://www.pharmavoice.com/news/makary-fda-commissioner-hearings-conflicts-of-interest/734535/

service to our nation through their work at the FDA. The future FDA Commissioner should respect and value the advice of these career civil servants and be committed to weighing, considering, and deferring when necessary to the scientific view of the multiple experts within the agency. Moreover, the FDA Commissioner should also protect this scientific and technical expertise from politics and outside ideological views, including within the administration. Doing so preserves the integrity and independence of the agency as well as trust among patients and doctors.

Uphold Current Regulations: The President and his advisors (many of which have significant financial conflicts of interest) have made it clear that deregulation is imminent across federal agencies.[3] The incoming Commissioner should protect the agency and the American people by ensuring that efficacy and regulations are not rolled back due to political fervor. The recent Supreme Court rulings in the cases of *Loper Bright Enterprises v Raimondo* and *Relentless, Inc v Department of Commerce* are deeply concerning in preventing the agency from using its recognized scientific and technical expertise to address public health challenges. Congress relies on federal agencies to use their specialized expertise to issue regulations intended to protect the public - not judges. The FDA must be committed to protecting patients and sufficiently resourced to address ongoing and imminent legal challenges meant to undermine public health regulations. The Commissioner must push back against executive regulatory actions that are strictly political and be the voice of reason on public health issues. The Commissioner must also ensure that the FDA defends its regulatory authority in the courts. Abandoning ongoing challenges that undermine access to proven treatments or compromise the agency's efforts to ensure rigorous premarket review of medical products to prevent patient harm[4] will also have broader implications on the agency's ability to make regulatory decisions based on rigorous scientific review of products without the undue, unscientific interference of courts motivated by ideology rather than evidence.

Committed to Transparency: The FDA Commissioner must be committed to enhancing transparency in the federal agency to provide physicians and patients with two main assurances: that regulatory decisions including therapeutic approvals and withdrawals are free of conflicts of interest, and based on the highest evidentiary standards for safety and efficacy. While FDA has engaged in "proactive disclosure" around some aspects of its decision-making process, further efforts are needed to provide the public with a clear, evidence-based rationale. Moreover, while the agency does engage outside, independent experts and patients through advisory committees and other public meetings, the agency's primary funding source for its medical product regulatory activities and how it is to be used is negotiated behind closed doors with regulated industries. While this has led to faster approval of novel medical products, it has also led to greater uncertainty for patients and doctors of the products themselves. Removing such non-transparency and allowing for truly independent voices including patients and clinicians to help set an agenda for how the agency should operate rather than regulated industries would further recenter the agency around public health.

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[3]https://www.wsj.com/opinion/musk-and-ramaswamy-the-doge-plan-to-reform-government-supreme-court-guidance-end-executive-power-grab-fa51c020

[4]https://www.statnews.com/2024/12/06/fda-regulation-lab-developed-tests-legal-challenges-political-shift/

When considering the next nominee to serve as FDA Commissioner, please consider the following list of baseline qualities. A competent FDA Commissioner should:

1. Have meaningful clinical experience;
2. Be free from financial conflicts of interest and associations with any industries regulated by the agency;
3. Staunchly support the need for robust clinical trials to support agency decision-making around medical product approvals that measure both safety and efficacy;
4. Maintain the integrity and independence of the agency by transparently following the science in making regulatory decisions;
5. Commit to weighing, considering, and deferring, when necessary, to the scientific view of the multitude of scientific and technical experts within the FDA over their and others' personal opinions or motives;
6. Be willing to uphold, enforce, and defend existing regulations despite political pressures;
7. Commit to enhancing transparency to instill public trust in the FDA.

Doctors for America welcomes the nomination of a physician with meaningful clinical and research experience to lead the FDA. We have also noted Dr. Makary's statements that the agency should not be unduly influenced by industry and the need for strong evidence to support regulatory-decision making. However, it is imperative that Dr. Makary clarifies how he will preserve the integrity and independence of the FDA and his views on the strength of evidence needed to support regulatory decision-making.

Thank you again for the committee's work to thoroughly vet appointees nominated to serve our public health institutions. For decades the FDA has been widely viewed as the global 'gold standard,' an accolade that is both an honor and a responsibility. As you weigh whether a candidate might be qualified to lead such a vital agency, we strongly urge you to ensure that that individual has the qualifications and character necessary to not only lead FDA through the challenges of today but will be prepared to navigate the unknown threats of tomorrow.

Sincerely,
Doctors For America's FDA Task Force