CENTER FOR Science IN THE Public Interest

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Dr. Robert M. Califf
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

The Center for Science in the Public Interest[1] congratulates you on your recent confirmation and return to the role of Food and Drug Administration (FDA) Commissioner. At this moment in its long history, the FDA's single biggest challenge is restoring public trust after the unfortunate politicization of the agency under the Trump administration. Some of the agency's own decisions have exacerbated this loss of trust, notably with the Alzheimer's disease drug Aduhelm and more recently the agency's slow response in recalling hazardous infant formula. First and foremost, the agency must restore both the rigor of its decision-making and its reputation to boost confidence in an all-too-leery public reluctant to follow government public health recommendations. Indeed the lack of trust in government agencies, which is not restricted to the FDA, is a root cause of the COVID vaccine hesitancy that has cost tens of thousands of lives.

The FDA is in a unique position to address public health issues in the United States, and the Commissioner is instrumental in setting agency priorities. As a cardiologist, you know much better than most that the leading causes of death in our country are due to preventable diet-related diseases.[2] Yet only two percent of FDA's staff budget for food goes toward promoting healthy eating patterns.[3] Overall, we recommend that you increase investment and staffing in the Center for Food Safety and Applied Nutrition (CFSAN) for work on nutrition and support a National Institute of Nutrition to answer critical questions in the field. Beyond nutrition, there are other food system-related public health issues that deserve additional attention and these are identified below. Furthermore, the agency is grappling with an array of extremely challenging problems ranging from the pandemic to opioids that need to be effectively addressed.

We would like to offer our assistance as you confront these problems. Our specific recommendations are laid out below.

Ensure that the food environment is healthier.

1. **Monitor industry progress toward meeting the 2.5-year short-term sodium reduction targets and establish interim and longer-term targets.** While we were pleased to see the FDA release its short-term voluntary sodium reduction targets for industry, first proposed during your

[1] CSPI has worked since 1971 to improve the public's health through better nutrition and safer food. It is a non-profit consumer education and advocacy organization, supported by donations from individuals and foundations and its members and subscribers to its *Nutrition Action* magazine.
[2] Centers for Disease Control and Prevention. Mortality in the United States, 2020. December 2021. Accessed at https://www.cdc.gov/nchs/data/databriefs/db427.pdf.
[3] Government Accountability Office. Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities. GAO-18-174. January 2018. Accessed at https://www.gao.gov/products/gao-18-174.

first term in 2016 in response to CSPI's 2005 petition and subsequent litigation, the FDA must now work with industry to ensure robust implementation of the 2.5-year short-term targets. We urge the agency to develop an overall sodium monitoring plan that details how industry progress will be monitored and to establish longer-term targets that would fully achieve safe levels of sodium in the food supply. Further, we recommend that the agency identify a subset of categories representing the top sources of average sodium consumption and prioritize industry progress in the reduction of sodium in those foods.

2. **Establish voluntary added sugar reduction guidance, similar to the guidance set for sodium.** Intake of added sugar is associated with increased risk of excess weight, type 2 diabetes, hypertension, stroke, heart disease, and cavities. We urge the FDA to set gradual added sugar reduction targets for packaged and restaurant foods and beverages using methodologies developed for the sodium guidance.
3. **Improve food labeling to support consumer health.**
    a. Establish a mandatory front-of-package labeling system that effectively and conveniently signals to the consumer the nutritional quality of the food.
    b. Increase the availability and transparency of nutrition information for restaurant foods by including disclosure of added sugar as part of menu labeling in the additional nutrition information available and ensure calories are posted on restaurant menus on third-party platforms.
    c. Resume enforcement, deferred during the pandemic, of menu labeling,[4] Nutrition Facts,[5] and other nutrition labeling.[6]

Ensure that the food supply is safer.

1. **Complete critical food safety rules still not implemented more than ten years after the agency was directed to create these rules under the Food Safety Modernization Act (FSMA).** Two proposed rules still not yet finalized will help address recurring outbreaks: the first will enhance product traceability and the second will help ensure the safety of water used in produce production.
2. **Set limits for opiate contamination in poppy seeds.** CSPI has asked FDA to take action on a petition submitted a year ago to set a maximum threshold for opiates in poppy seeds, which have been tied to at least 20 non-fatal overdoses and 19 deaths in the US.
3. **Improve adverse event reporting.** CFSAN leadership has told CSPI that it intends to update its system for reporting adverse food events, with plans to launch the new portal in fall 2022. This portal is important, as there is no separate reporting system for foods so consumers have to use MedWatch, which is designed for drugs and devices.
4. **The FDA should use its authority to require allergen labeling for additional allergens not already required to be labeled.** Congress recently added sesame to the list of allergens required to be labeled, and has directed the FDA to report on a science-based process for designating new allergens. The agency recently sent a guidance to OMB on this topic.
5. **Close the Generally Recognized as Safe, or GRAS, loophole.** CSPI has urged the FDA to close the GRAS loophole that allows food manufacturers to make secret safety determinations themselves for chemicals that they add to food, without notifying the FDA or the public.

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[4] Temporary Policy Regarding Nutrition Labeling of Standard Menu Items in Chain Restaurants and Similar Retail Food Establishments During the COVID-19 Public Health Emergency. Guidance for Industry. April 2020. https://www.fda.gov/media/136597/download

[5] Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency: Guidance for Industry. March 2020. https://www.fda.gov/media/136469/download

[6] Temporary Policy Regarding Certain Food Labeling Requirements During the COVID-19 Public Health Emergency: Minor Formulation Changes and Vending Machines: Guidance for Industry. May 2020. https://www.fda.gov/media/138315/download

6. **Crack down on illegal dietary supplements.** The marketplace for dietary supplements has continued to explode in the years since you left the FDA, and we hope as Commissioner you will support comprehensive reform of the weak 1994 law governing supplements. Bills are under development, including requiring a mandatory list of all products on the market.
7. **Improve regulation of synthetic color additives.** The FDA convened an advisory committee in 2011 that acknowledged problem behaviors may be exacerbated in susceptible children by exposure to synthetic color additives. However, the agency declined to ban the dyes and has not taken any action on dyes since.
8. **Advance plans to reduce inappropriate antibiotic use in agriculture.** The FDA should advance and update its 5-year plan to reduce inappropriate antibiotics use, including by creating a more comprehensive antibiotic use monitoring program for agriculture to prevent the development of antimicrobial resistant bacteria. The agency should publish usage data adjusted for the estimated biomass of the domestic livestock populations to allow for better comparisons of year over year usage. Furthermore, the FDA should require all drug sponsors to expeditiously establish scientifically justified durations of use for their products, as without these the antibiotics may be used for longer than necessary.
9. **Take action on CSPI's petition to ban phthalates.** The FDA has failed to protect the public from phthalates, the ubiquitous and harmful chemicals used in food packaging and processing equipment. CSPI petitioned the agency in 2016 to ban the chemicals, but received no response. This led to delay lawsuits against the agency last year that are currently stayed. We urge the agency to grant the petition.

Additional public health considerations.

1. **Regulate laboratory-developed tests (LDTs).** The FDA failed to follow through on its proposal for a tiered approach to regulating LDTs when you were previously Commissioner. Yet this sector has continued to grow, and the lack of LDT regulation resulted in many substandard tests coming to market during the COVID-19 pandemic. One such solution is the Verifying Accurate Leading-edge IVCT Development Act of 2021, or VALID Act, which aims to reform the federal oversight for LDTs but which, in its current form, risks exempting large numbers of tests from significant regulation. The agency has provided technical assistance on the Act, which will require additional work to assure the safety and effectiveness of the most significant tests. Absent passage of the legislation, the FDA should proactively use its existing authority over medical devices to ensure the effectiveness of these tests.
2. **Incorporate population health considerations in product approvals.** Previously, as Commissioner, you requested a National Academy of Medicine study on population health considerations in opioid approvals. This led to a newly announced policy in a draft guidance in which the FDA said it would consider population health in its reviews of drugs of abuse, antibiotics, and potentially other products. Josh Sharfstein and I recently wrote an article in JAMA that provides some ideas for future action.
3. **Revisit the Emergency Use Authorization (EUA) process.** As you and I discussed during the National Academy of Medicine meeting on this topic, this provision has brought life-saving vaccines expeditiously to market during the pandemic. However, I believe that the EUA standard provides too much flexibility and has not always adequately protected consumers. I urge the agency to conduct an assessment of the performance of the EUA provisions during the pandemic and to suggest any needed improvements in the authorization standard, transparency, and timelines for submission of approval applications.
4. **Agency transparency.** The agency response to COVID-19 was most effective when it was most transparent. I urge you to revisit agency policy on the disclosure of Complete Response Letters,[7]

[7] Lurie P, et al. Comparison of Content of FDA Letters not Approving Applications for New Drugs and Associated Public Announcements from Sponsors: Cross Sectional Study. *BMJ*. 2015 Jun 10;350:h2758.

the filing of New Drug Applications,[8] and Refuse to File letters[9] based on research published by me and my FDA colleagues.

Sincerely,

Peter Lurie, MD, MPH
President
Center for Science in the Public Interest

[8] Chahal HS, et al. Public Disclosure of the Filing of New Drug and Therapeutic Biologics Applications with the US Food and Drug Administration. *JAMA Intern Med.* 2019 Aug 1;179(8):1144-1146.
[9] Chahal HS, et al. Contents of US Food and Drug Administration Refuse-to-File Letters for New Drug Applications and Efficacy Supplements and Their Public Disclosure by Applicants. *JAMA Intern Med*. 2021 Apr 1;181(4):522-529.