



following the science to protect public health in pandemic

We are committed to making decisions guided by the best evidence. Our approach has been and must remain the gold standard that all can rely upon.

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A lot has been said and written recently about the Food and Drug Administration. The integrity and independence of the agency have been called into question.

We are the senior career civil servants who direct the work of the various centers at the FDA. Together we are responsible for over 17,000 employees, and among us we have over 100 years of experience at FDA. We care deeply about our agency, its mission and its people.

The current FDA was created about a decade before the 1918 pandemic. Congress established our predecessor, then in the Department of Agriculture's Bureau of Chemistry, to protect the public from unsafe foods and remedies. Since then, the scope of our work has increased to address emerging public health issues, promoting innovation while ensuring safety for the products that we regulate. The foundational and fundamental principles of the FDA, however, remain steadfast: to protect and promote the health and well-being of the American public, and to base our decisions in support of our public health mission on sound science.

COVID challenges for FDA

Over the years, the FDA has encountered numerous challenges and criticisms. We understand that — it comes with the territory. It is not possible for an agency with the impact and reach of the FDA to do its job without inviting controversy and disagreement, particularly when health or even life is at risk. Nevertheless, when protecting the public health is our beacon, and sound science is our guide to navigate controversial waters, we stay true to our mission as we fulfill our duty to the public.

The current pandemic presents new challenges for our country, for the entire health care community and all levels of government, including the FDA. We continue to make decisions



scientific information can be openly debated. The FDA is at its best when its scientific, clinical and other experts are free to do what they do best — follow the science to address the public health issues and revise policy if the understanding of the science changes.

We absolutely understand that the FDA, like other federal executive agencies, operates in a political environment. That is a reality that we must navigate adeptly while maintaining our independence to ensure the best possible outcomes for public health. When it comes to decisions to authorize or approve the products we regulate, or to take appropriate action when we uncover safety issues, we and our career staff do the best by public health when we are the decision-makers, arriving at those decisions based on our unbiased evaluation of the scientific evidence.

***An apolitical process:** Secretary Alex Azar on how HHS is developing a COVID-19 vaccine at 'Warp Speed'*

Maintaining the American public's trust in the FDA is vital. If the agency's credibility is lost because of real or perceived interference, people will not rely on the agency's safety warnings. Erosion of public trust will leave consumers and patients doubting our recommendations, less likely to enroll in clinical studies or to use FDA-regulated products when they should to maintain or improve their health. This is problematic under normal circumstances but especially if we are to ultimately overcome COVID-19. Protecting the FDA's independence is essential if we are to do the best possible job of protecting public health and saving lives.

Health of Americans is our beacon

The FDA staff is dedicated to advancing public health. We are physicians, pharmacists, nurses, engineers, veterinarians, nutritional scientists, microbiologists, chemists, toxicologists, and many other professionals and support staff who share a common mission. All of us have dedicated our professional lives to public health. Over the years we have encountered opinions or ideas brought forward by our stakeholders that have initially seemed promising, only to be found flawed once subjected to sound scientific review. It is why we are always learning and innovating, be it in the regulation of medical products, foods, or tobacco products. It's why we have a scientific method. And it's why we have the FDA.

***Coronavirus journey:** Don't count on herd immunity for COVID-19 yet. A vaccine is the best way to get there.*



the FDA's 17,000 plus career staff will continue to work to the best of our ability on their behalf, and with their health and well-being as our beacon.

The co-authors of this column are the senior career executives at FDA who oversee all the work of the agency's centers and field operations. The views expressed here are exclusively their own and do not represent the position of the FDA, the Department of Health and Human Services or the U.S. government.

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