Opinion

The F.D.A. Is in Trouble. Here's How to Fix It.

Some New Year's resolutions for the incoming boss.

By The Editorial Board
The editorial board is a group of opinion journalists whose views are informed by expertise, research, debate and certain longstanding values. It is separate from the newsroom.

Jan. 11, 2020

Nicholas Konrad

The Food and Drug Administration is in distress. The agency is still the world's leading regulator of food and medical products, responsible for ensuring the safety of some $2.6 trillion in consumer goods each year. That represents 20 cents of every dollar that Americans spend. But critics both inside and outside the sprawling agency say that the F.D.A.'s standards have been slipping for some time.

The effects of that slippage are starting to show. Too many prescription drugs and medical devices are being approved with too little data on how safe or effective they are. And too many other products — like those containing CBD or THC, ingredients found in the marijuana plant — are being sold with no apparent oversight at all.

Part of the problem is that the agency has too few resources and too little power to fulfill its key responsibilities. But it has also become profoundly vulnerable to political interference and other special interests. And a revolving door — F.D.A. staffers frequently go on to lucrative jobs at the very companies they were tasked with policing — has hurt the agency's

credibility.

So too have a string of high-profile public health crises. In just the past few years, the F.D.A. has been faulted for its roles in the opioid epidemic (regulators allowed too many opioids on the market without properly flagging them as addictive or deadly) and a surge in youth vaping (the agency failed to keep untested e-cigarettes off the market or to establish the safety of these products, as millions began using them).

Given all that, it's worrisome that the F.D.A. spent most of 2019 without a permanent commissioner. It's also concerning that the person finally picked to fill the post — Dr. Stephen Hahn, an oncologist and researcher who was sworn in last month — has no significant policy experience nor any real record of his views on the agency he's now in charge of. Dr. Hahn's predecessor, Dr. Scott Gottlieb, came to the F.D.A. with reams of both, and, despite a mere two-year tenure, received bipartisan praise for his efforts to balance the demands of public health under significant public, political and financial pressures.

Dr. Hahn did spend two years as chief medical officer of M.D. Anderson Cancer Center in Houston, where, according to his supporters, he helped the institution recover from several ethical and financial crises. But the scope of that work was vastly different from what awaits Dr. Hahn at the F.D.A. And he assumes this new role at a particularly tumultuous moment. His boss's boss, President Trump, was just impeached; a presidential election is underway; and the agency is facing pressure from companies, politicians and patients to loosen its standards and clear more products for market faster.

Some of that pressure to speed things up is understandable, especially from patients who are frustrated by a lack of treatment options. But several entities — including drug and device companies seeking easier profits and libertarian groups bent on deregulation at any cost — are exploiting those frustrations in an attempt to substantially curtail the F.D.A.'s already diminished powers.

There is a deep tension between groups that want medical products to be proved safe and effective before they are made widely available and those that say that as long as those products pass a bare minimum of safety

testing, patients should be able to decide for themselves. "The F.D.A. has been moving in the latter direction under great political and public pressure," says Dr. Steven Joffe, a bioethicist at the University of Pennsylvania. If that trend continues, the nation may end up with a regulatory agency that's powerless to make any meaningful regulations.

For all its faults and failures, the F.D.A. has traditionally done a great deal to balance access to innovations with protection from danger or fraud. To maintain that balance, the agency needs to be made stronger, not weaker.

Fortunately, options for fortifying the F.D.A. abound. For instance, laws that would make it easier for regulators to police the cosmetics industry and to hold medical device companies to account have been floating through Congress for years. A group of former F.D.A. commissioners last year proposed an even bolder fix: Restore the agency's autonomy by extracting it from the Department of Health and Human Services. The F.D.A.'s decisions used to be final, but for decades now they have been subject to layers of political interference. Making the agency independent, as the Federal Reserve and the Social Security Administration are, could help reverse that trend.

But for these or other worthy ideas to get a fair hearing, Congress will have to step in, and the president — and the electorate — will need to come to terms with the essential role of regulations in protecting the nation's food and drug supply.

In the meantime, the challenge of steering the F.D.A. will fall to Dr. Hahn. He will not have nearly enough resources to carry out the agency's stated mission — no commissioner ever does. But he will not be completely powerless, either. Here are four things Dr. Hahn would do well to keep in mind as he takes the reins.

Stay vocal. Dr. Hahn's predecessor, Dr. Gottlieb, managed to keep a

spotlight on his chosen priorities — namely e-cigarette regulations and generic drug development — with a relentless and multifaceted public messaging campaign. He tweeted, he blogged, he gave speeches and he communicated openly and regularly with the press. Dr. Gottlieb did not achieve all of his goals — in fact his e-cigarette strategy backfired, badly. But he made the F.D.A. less opaque, and he gave the agency an urgently needed voice. Dr. Hahn will have an easier time defending the agency, and keeping it relevant, if he fosters the same transparency.

Slow down on drug and device approvals. The F.D.A. has made several compromises in recent years — such as accepting "real world" or "surrogate" evidence in lieu of traditional clinical trial data — that have enabled increasingly dubious medical products to seep into the marketplace. Dr. Hahn ought to take a fresh look at some of these shifting standards and commit to abandoning the ones that don't work. That will almost certainly mean that the approval process slows down — and that's O.K.

Stand up for science. As reporting from the medical news website Stat and other outlets suggests, the F.D.A. has become too susceptible to outside pressure. Regulators approved a powerful new opioid at the Department of Defense's urging, fast-tracked a dubious antidepressant after President Trump praised it, and reversed its decision to reject a muscular dystrophy drug after patient groups complained loudly. Such kowtowing hardly inspires confidence. Scientific evidence (or the lack thereof) needs to be the deciding factor in any final regulations from the F.D.A. That means saying no to politicians and drug and device makers — as well as patients' groups — when their demands are not supported by the agency's own findings. It also means holding companies to account when they fail to complete postmarket studies, or when their products prove faulty or dangerous.

Follow through on existing commitments. The F.D.A. has yet to issue guidelines for the regulation of increasingly popular CBD products after promising to do so by the end of 2019. E-cigarette makers are supposed to submit their applications for market approval to the agency by May. And a regulatory grace period that the agency granted to so-called stem cell clinics back in 2017 is set to expire this year; when it does, regulators will need to figure out how to police nearly 1,000 businesses selling injections and other treatments that have not proved to work and that have already caused some patients serious harm. Dr. Hahn would build a lot of good will if he showed the F.D.A.'s critics — and the public at

large — that he takes all of these deadlines seriously.

The Times is committed to publishing a diversity of letters to the editor. We'd like to hear what you think about this or any of our articles. Here are some tips. And here's our email: letters@nytimes.com.

Follow The New York Times Opinion section on Facebook, Twitter (@NYTopinion) and Instagram.

Comments 244
The F.D.A. Is in Trouble. Here's How to Fix It.Skip to Comments
The comments section is closed. To submit a letter to the editor for publication, write to letters@nytimes.com.

Celebrate curiosity. Gift subscriptions starting at $25.