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Biden's FDA Commissioner Playbook: Build On COVID Innovations To Modernize Agency

by Nancy Bradish Myers

Unintended silver lining of pandemic-generated innovation has brought the agency to an opportunistic fork in the road, and the commissioner choice will be consequential in determining the path forward.

As stakeholders await the nomination of the next US Food and Drug Administration commissioner, the incoming Biden administration has a unique opportunity to choose a leader with the skills and vision to build boldly upon the innovations of the agency's COVID-19 response in order to advance a comprehensive modernization of the agency.

To date, FDA has laudably risen to the challenge of the pandemic by rapidly empowering its public health experts to find novel and streamlined ways to fulfill its mission.

A few of these innovations include initiatives to facilitate the identification of COVID vaccine and treatment candidates, allow for the rapid recruitment of clinical trial participants for COVID-related clinical trials, and incorporate new tools such as telemedicine, digital health and real-world data to keep ongoing clinical studies moving forward. The agency also has adopted improved internal and external communication methods to speed the advancement of new ideas and practices.

This unintended silver lining of pandemic-generated innovation has brought the agency to an opportunistic fork in the road, and the commissioner choice will be consequential in determining the path forward.

The FDA needs a leader who will not only hit the ground running to meet the continued demands of the pandemic, but also seize the opportunity to leverage the agency's COVID innovations to

meet the challenges of 21st century health care.

The goal should not be just to adopt certain COVID programs in a piecemeal fashion. Rather, the FDA should set out to harness the learnings of the *de facto* pilots and new processes necessitated by COVID and weave them together to chart a new course of dramatic reform that will lead to the rapid but safe advancement of new technologies and, in the process, burnish the FDA's gold standard reputation.

Moving in this direction will not be easy and will require a very talented leader who will bring to bear certain key skills and characteristics. For example, the commissioner nominee should be:

- A seasoned executive who has built and managed a large and evolving organization. The 17,000-person-plus FDA workforce has been put through the wringer in 2020. Isolated at home and juggling family/community responsibilities, many FDAers have worked tirelessly to meet the multifaceted challenges of the pandemic. The agency workforce needs a leader who can find ways to permit the staff recharge without losing the momentum that COVID and other regulatory priorities demand;
- An innovative leader who can balance both immediate management needs with a next-generation vision for the future that encourages the development and implementation of significant new processes and organizational shifts to address changing scientific demands and environments;
- A trustworthy and collaborative scientist and physician who without effort conveys both competence and empathy. The importance of credibility and willingness to work collaboratively with all relevant parties cannot be understated;
- An FDA supporter who is already intimately familiar with the workings of the agency, its broad portfolio and associated stakeholders, and its critical leadership role not only in the US but throughout the world. This time around, there will be little time for on-the-job training;
- A leader with a strong global reputation. With a worldwide pandemic raging, international cooperation is essential because the interactions that accompany global travel, commerce and aid programs mean that the US is only as safe as the least protected country. The FDA also needs a commissioner who can assure its international regulatory partners that it is focused on following the science and has not weakened its standards;
- A skilled and trusted communicator. The next FDA commissioner must be able to communicate comfortably and persuasively both internally with staff and externally using all tools available, including social media;
- A person who is politic but not necessarily political. The FDA will need a commissioner who can share the agency's stories and effectively describe its direction and champion its resource needs. The nominee will need to be able to credibly engage and work productively

with a bipartisan group of Senate and House members, including agency friends and critics, as well as an new administration that may be highly critical of key industries the agency regulates due to access and affordability issues.

- Someone with the fortitude to fearlessly juggle chainsaws with a smile but also the willingness to take the time to thoughtfully reach out to the FDA's wide range of stakeholders – especially patient, consumer, and scientific organizations – to build and maintain relationships and engender trust.

FDA has a shining opportunity to make some bold reforms that will prepare it for the future of medicine. Leveraging its COVID-inspired pilots and re-envisioned processes could leapfrog the development and regulation of medical products and foods into a new era. Hopefully, President-elect Biden will choose a candidate who can carry the agency into an era of renewed credibility and regulatory innovation.

Biden and his team also need to be mindful of the stakes at hand in choosing a confirmable FDA commissioner. A speedy nomination and confirmation will be important to reassure internal and external stakeholders, as will fresh ideas and impeccable credentials.

Let's hope we hear from the Biden team soon because the challenges and silver-lining opportunities generated by COVID-19 are not going to wait.

Nancy Bradish Myers is president and CEO of Catalyst Healthcare Consulting.