Science, Not Politics, Must Lead to COVID Vaccine Approvals

Political pressure to speed the introduction of COVID vaccines threatens scientifically proven systems to protect public safety and research integrity.

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COVID-19 has devastated communities and health systems around the world — but it has also created an historic global effort leading to the unprecedented development of more than 165 potential vaccines against COVID-19. Equally impressive innovations are speeding vaccine testing within a rigorous scientific framework, while manufacturing and transportation capacity are being scaled up to distribute millions of doses of future COVID vaccines to those who need them most.

These advances require scientific collaboration and logistical coordination on a scale never seen before, and enormous investments of private and taxpayer money. All of that hard work, innovation and investment is endangered, however, if the public loses faith in a critical step in the process: the independent, unbiased review by regulatory agencies, such as the U.S. Food and Drug Administration (FDA), of data demonstrating that a vaccine is safe and effective.

Vaccines are among the most powerful tools we have to reduce health disparities and advance health equity — but only if they are trusted and used. Government approval of any potential vaccine must be based on a process that is transparent, scientifically rigorous and free from political pressure. This is especially true as misinformation and conspiracy theories about vaccines circulate, and public confidence in vaccines falls. The consequences of any vaccine approval that appears to have been influenced by politics would be particularly grave for Black and Latinx communities, who have real reasons to distrust both politicians and drug testing processes, and who are also at significantly increased risk for COVID infection and illness.

That's why it's particularly worrying that politicians are wading into the vaccine testing and approval process. In the United States, government officials, perhaps with the November election in mind, are discussing granting emergency approval to one or more COVID vaccines as early as October — well ahead of the completion of essential Phase III vaccine testing. Concerns over the potential political manipulation of the vaccine approval process are so grave that last week nine pharmaceutical companies issued an unprecedented public pledge that they would not seek approval of any vaccine without extensive safety and effectiveness data.

How the United States approaches vaccine approval will have global implications. The FDA has

provided a gold standard in the review and approval of drugs and vaccines — so much so that its decisions are often adopted by other countries. The idea that political pressure could lead the FDA to alter its vaccine approval standards should send shockwaves not only through the United States, but through global health systems as well.

The rush-to-approval dynamic is not limited to the FDA, however. The Chinese military began using a COVID vaccine in July, long before advanced testing was complete. And in Russia, the release of a vaccine that has not undergone critically important Phase III testing has produced broad concern, with only 24% of physicians there saying they would give it to their patients.

Large Phase III studies are the only way to determine how well potential vaccines work, including whether they produce side effects unnoticed in smaller studies. To be truly effective, those studies must enroll not only enough people, but also the types of people who are most affected by COVID-19, including older people, people of color, and people with illnesses that may make them particularly susceptible to severe disease.

Any reliable vaccine study must also meet clear criteria, published in advance, for when and how the study is stopped. And all data for any prospective vaccine must be peer-reviewed and published in a transparent process that gives the public unshakable faith that the vaccine is being approved for scientific, and not political reasons.

Global efforts to speed COVID vaccine testing could produce a successful vaccine faster than any previous effort. Testing timelines can only be accelerated to a certain point, however, before we lose vital knowledge about how well a vaccine really works. The Russian example proves that vaccines won't be used if people don't understand or trust the testing and approval process.

That doesn't mean that politicians will stop pressuring researchers and regulators to accelerate testing, sometimes with their own political fortunes in mind. This was most recently evidenced by the U.S. Health and Human Services Secretary's troubling memo which bans the FDA (and other health agencies) from signing new rules regarding medicines. But it does make it more important than ever that researchers, regulators, public health professionals and community advocates raise our voices to prevent the politicization of science.

We've already seen the power of public pressure to compel product developers to publish their data analysis plans, stopping rules, statistical assumptions, and the membership of their independent review boards. Now that same energy should be focused on product developers, the FDA and the Department of Health and Human Services to ensure that Phase III trials are able to accrue adequate safety and efficacy data before any decisions regarding approval are made.

Detailed guidance for COVID vaccine developers, issued by the FDA in June, provides a roadmap for advocates to monitor and evaluate the vaccine approval process. Organizations such as AVAC have produced materials to help advocates and the public understand both the innovations that are helping to speed safe testing of COVID vaccines and the essential steps that must be completed before any COVID vaccines should be approved and licensed.

The rapid development of safe and effective COVID vaccines could help end this pandemic, and strengthen faith in vaccines worldwide. But that can't happen unless we take the signals of diminishing public faith in the process seriously, and eliminate any sign of political interference in vaccine testing or approval. To protect health in the United States and around the world, and advance health equity, we must insist on a COVID vaccine effort that is fast, transparent, thorough and safe, and guided by science, not politics.

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