In October, Merck & Co announced that its antiviral drug molnupiravir reduced the risk of severe COVID-19 by half, leading to a halt in study enrollment. The company's vice president of research told the news media, "When you see a 50 percent reduction in hospitalization or death, that's a substantial clinical impact."

Less than 2 months later, however, the story had changed. Including several hundred more patients in the study decreased the benefit to a 30% reduction in severe outcomes; the additional study participants who received the medication had fared worse than those who received placebo.

The update raised questions. Why would Merck boldly announce a 50% improvement knowing that substantially more data would soon be available? Did the change in messaging affect public understanding and confidence? And, most fundamentally, where was the voice of leading health officials in explaining this news to the public?

Throughout the pandemic, companies have quickly announced the top-line findings of research involving their drugs, devices, and vaccines, often before making available detailed results on safety and efficacy. The approach has sometimes led to exuberant headlines that need to be tempered on further reflection. The US Food and Drug Administration (FDA) has generally stayed quiet—waiting to see the data, perform its own review, and consult with advisers before making and explaining its regulatory decisions.

This division of labor is not new to the world of medical product regulation. Typically, a product manufacturer is the hare—racing ahead to share results with shareholders and the media. The FDA is the tortoise—carefully reviewing the data and crossing the line with the final judgment. The COVID-19 pandemic, however, has revealed 3 important limitations of this conventional approach.

First, unpredictable and shifting communications may create public confusion, as well as ammunition to those spreading misinformation. The difficulty starts as soon as a pharmaceutical company decides the moment is right to make its announcement, generally with little advance warning to the nation's public health agencies.

"We have learned to find out things based on ... companies' press releases," stated Anne Zink, MD, the chief medical officer for the Alaska Department of Health and Social Services, at a recent National Academies of Sciences, Engineering, and Medicine (NASEM) panel on Emergency Use Authorizations. "Those bits and pieces of information are really hard to message and to implement on the state level," she explained. "Someone sees a press release from a company about a treatment for COVID, the first thing that happens to all of our inboxes is they're filled with 'What day do I get it?' [and] 'When is it going to happen?'"

Second, early company announcements may leave key questions unanswered. There is no standard for how much data companies release or how clinical trial designs are explained. Press statements often come before submission to regulatory agencies or preparation of scientific manuscripts. Frequently, companies refer to their scientific oversight board without quoting from the board's reports directly. It is unusual for companies to explain the timing of additional data that may be forthcoming or to note the critical role of the FDA in reanalyzing and reviewing company research.

At times, disputes have spilled over into public view. In March, after AstraZeneca announced the results of a major vaccine trial, its own data and safety monitoring board rebuked the company for providing "outdated and potentially misleading" data to the public. Soon after, the National
Institute of Allergy and Infectious Diseases took the extraordinary step of issuing a press release
calling on the company to release the “most accurate, up to date efficacy data … as quickly as
possible.”

A third limitation of current practice is that regulators are missing opportunities to build trust.
When critical questions on matters of life and death are in the news, the public should hear more
from the officials responsible for protecting their health.

For example, during fall 2020, before it was known whether vaccines would prove to be safe
and effective against COVID-19, AstraZeneca’s vaccine research was placed on hold in multiple
countries for safety reasons. The company described this step as “routine”; the FDA and other global
regulators provided no public comment. What little information became available came from
comments made by the CEO on an investor phone call. This episode was a lost opportunity for
federal health officials to illustrate the process of clinical trial oversight.

About 1 year later, the media reported that the FDA had required Pfizer and Moderna to add
thousands of patients to pediatric vaccine studies to assess the risk of rare adverse events, delaying
their completion. The news coverage of this action included neither confirmation from the FDA nor a
quote from a responsible agency official explaining the decision to millions of anxious parents.
Instead, sources included the companies and “people familiar with the situation.”

The missed opportunities to enhance public confidence continue today. Many parents of
children younger than 5 years are keenly interested in how vaccine studies are progressing and the
timeline for the results and regulatory submissions. Members of Congress have pressed the FDA to
provide updates. Yet the primary sources of information remain the companies themselves.
Similarly, as company executives speculate about a possible “fourth shot” or Omicron variant
booster, the perspective of the experts who will make key decisions is rarely heard.

It is not too late for both the pharmaceutical industry and the FDA to do better. A recent NASEM
report (that I contributed to as a member of the study committee) recommended that vaccine
manufacturers “adopt a code of conduct for press releases and other communications regarding
vaccine trial results and other matters that emphasizes the critical role of regulatory review.” Such a
voluntary code, for example, could include advance notice to the public health community, release
of key supplemental data and information about the study at the time of top-line results, and a clear
acknowledgment of the next steps in the regulatory review process.

For their part, senior FDA officials do recognize the value of greater transparency about the
development process, while expressing concern about potential legal barriers to sharing more
information with the public. At the recent meeting on Emergency Use Authorizations, Patrizia
Cavazzoni, MD, director of the FDA’s Center for Drug Evaluation and Research, called for “broader
authorities when it comes to communications” and noted that “we have seen a fair bit of
misinformation” about products that the agency has declined to authorize. Jeff Shuren, MD, JD,
director of the FDA’s Center for Devices and Radiological Health, recommended a “common
framework for what people should expect, how the information is provided, [and] what we provide.”

The FDA has the authority to change its rules on confidentiality, including for products that
have not been approved or have been rejected. Moreover, progress need not wait for new
regulations or laws. The agency should move quickly to correct misinformation and ask
manufacturers—publicly, if necessary—to share the microphone when announcing important
information about their products with the public. After all, a key lesson of the pandemic is that trust
is an ingredient that cannot be added to medications and vaccines by manufacturers alone. A more
prominent role for public health leaders in communicating about the tools to fight COVID-19
is overdue.
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Conflict of Interest Disclosures: Dr Sharfstein reported serving as principal deputy commissioner at the US Food and Drug Administration (FDA) from March 2009 to January 2011, where he led the agency's transparency task force, and reported receiving grant funding from Arnold Ventures to work on transparency at the FDA.

Additional Contributions: I thank Peter Lurie, MD, MPH (executive director of the Center for Science in the Public Interest and a former associate commissioner for public health strategy and analysis at the FDA), for helpful comments on a draft of this article.

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