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Risks In Moving Too Quickly, Or Slowly, On COVID-19 Vaccine

By **Richard Manning** (December 11, 2020, 4:31 PM EST)

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A U.S. Food and Drug Administration advisory committee's vote in favor of granting emergency use authorization to Pfizer Inc. and BioNTech SE's COVID-19 vaccine has been greeted with enthusiasm by many people who now perceive a sooner and more certain end to the pandemic.

However, the rapid advancement of this and other COVID-19 vaccines and therapeutics has also been met with concern that the process has moved too quickly.

Some are concerned that perhaps we do not know enough about these new products to be able to rely on their safety and efficacy.

There are pros and cons surrounding the rapid release of a new medicine, and economics offers the important principle of considering all costs and all benefits in decision making about health care and all other areas of choice.

In a famous 1973 article in the Journal of Political Economy, "An Evaluation of Consumer Protection Legislation: The 1962 Drug Amendments," Sam Peltzman of the University of Chicago evaluated the importance of recognizing that there are costs associated both with incorrectly approving an unsafe medicine and with failing to approve a safe one.

This is analogous to the type 1 vs. type 2 error distinction that arises in statistical inference. When an unsafe medicine is inappropriately approved — a type 1 error — some people who use the medicine suffer harms.

However, when an effective medicine is not approved, or is delayed in approval — a type 2 error — those who would benefit from it also experience harms.

Those harms are just as real as those associated with a type 1 error, but they are often underappreciated if not ignored.

Regulators, the courts and even the general public tend not to see these types of errors symmetrically.

When a type 1 error is made and a newly approved medicine is unsafe, it harms identifiable individuals.

If that were to happen, the regulator that approved the medicine would be likely to find him or herself answering difficult questions before congressional committees and would probably face important professional consequences.

In most circumstances, such an error would almost certainly result in litigation against the manufacturing company and media outlets would undoubtedly publicize the harms done to the unfortunate patients.

However, when an effective medicine is not approved or is delayed — a type 2 error — the injured and injuries are far harder to identify and quantify, so they attract less attention from the political process, courts and media.

Suppose, for example, that an effective COVID-19 vaccine or therapy were incorrectly not approved or were delayed in approval.

People would suffer losses from extended suffering to death, job losses and other economic dislocations would continue, but the identity of the people who would have been helped had the medicine been approved in a timely manner is not specifically known.

There is unlikely to be a congressional hearing, there is no lawsuit claiming that a company failed to save a patient's life and there is probably no news story blaming anyone for not acting faster. Because of this imbalance, type 2 errors are more likely to happen.

The HIV/AIDS epidemic illustrated the power of recognizing type 2 errors. In the 1980s, as people were suffering and dying from AIDS, the consequences of the FDA's extended new drug review timelines became obvious.

Because identifiable people were suffering serious harm from a specific disease, Congress changed the rules under which new drugs for critical needs, such as AIDS, were reviewed and approved.

The FDA's Prescription Drug User Fee Act established shorter FDA review periods and required companies to pay user fees with which the FDA hired additional reviewers. This change has resulted in the accelerated assessment of high-priority treatments.

More rapid review generated enormous benefit through the more rapid approval of new AIDS therapies, diminishing the type 2 errors that had been imposing such costs on AIDS patients. This was a great success.

These same changes have also contributed to the more rapid development of COVID-19 vaccines and treatments.

Moreover, the liability protections available in the federal Public Readiness and Emergency Preparedness Act soften the penalty associated with both types of errors in the present pandemic.

The declarations of the secretary of health and human services under the PREP Act provide for immunity from liability to manufacturers, medical practitioners and others, as well as opportunities for compensation to those injured by appropriate countermeasures against COVID-19.

Nevertheless, the asymmetry in our response to these types of errors persists.

These experiences, and these economic principles, offer enduring lessons.

As we consider the speed with which vaccines, therapeutics, and diagnostics for COVID-19 are developed and reviewed, economic analysis argues that policymakers should continue to consider the gains and harms associated with delay as well as the gains and potential harms from more rapid decision making.

Moreover, as judges and juries consider controversies that arise from matters in this arena, those same principles should apply.

Type 2 errors should be given more weight than they typically are. When type 1 errors are punished, but type 2 errors are ignored, or underweighted, we will see outcomes that are not in our collective best interest; too many people continue to suffer losses that could otherwise be avoided.

In the present circumstance, the harms from continuing COVID-19 infections are certain. Hence, we should be willing to tolerate greater uncertainty about the likelihood of type 1 errors in favor of reducing the likelihood of ongoing injuries from type 2 errors.

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