Old drug standards delay new drug approvals
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During the next year, the Food and Drug Administration will review many new drug applications for preventing and treating the new coronavirus. But early approvals could get delayed by the standards the agency used for older drugs, according to new research from the McCombs School of Business at The University of Texas at Austin.

In a forthcoming paper published online in advance by the Strategic Management Journal, Associate Management Professor Francisco Polidoro Jr. reviewed 291 drugs approved over 35 years. He found that the more information the FDA had about existing drugs, the longer it took to OK new ones for the same conditions.

When there was more information about older drugs, more than half the newer drugs in the study took more than 20 months to win approval. By contrast, only 20% of new drugs took that long to get approved when less information was available about older drugs. Delays in drug approvals cost their creators an average of $1 million a day.

"Sometimes knowledge can become a hindrance, and too much of a good thing can become a bad thing," Polidoro said.

But his findings also contain hopeful news for potential COVID-19 treatments. When the agency had to review several innovative drugs in a relatively short time—three years—delays got shorter. Polidoro defines an innovative drug as one that uses a new mechanism of action to attack a disease.

"As it struggles with innovations, the organization becomes better able to deal with them," he said. "It gets more used to breaking routines and creating new ones."

Although his topic is timely for the pandemic, Polidoro has been curious about the subject for a decade as he has researched pharmaceutical companies and organizational learning.

In minutes of FDA meetings, he found regulators debating whether to apply old standards to innovative drugs for treating dementia, HIV and macular degeneration. He reasoned that the more information regulators had on existing drugs, the greater the variety of outcomes related to efficacy and safety that they need to ponder—and the longer approval would take.

To test his theory, he used a variety of data sources, including the Freedom of Information Act, to get data on drug approvals from 1980 to 2014. He divided the drugs into 18 therapeutic classes, from controlling blood pressure to fighting viruses, and he singled out the innovative drugs in each class.

To quantify regulators' embedded knowledge, Polidoro counted the number of papers on existing drugs that were published in top medical journals. The number of publications varied greatly from case to case—they averaged about 150 but sometimes totaled more than 1,000.
He found that the more papers there were for a class of drugs, the longer it took for innovative drugs in that class to win approval. When the measure of papers increased by 32% beyond the average, the result was a 75% longer approval time.

A lesson for COVID-19 therapies, Polidoro said, is that regulators should be thinking ahead about new standards by which to judge them. Different drugs might require different criteria to measure their effectiveness, such as how tocilizumab prevents inflammation of lung tissue while remdesivir blocks the virus from reproducing.

"It will be difficult to compare these solutions with each other because they have different safety and efficacy profiles," he said. "They're not like apples to apples. Recognition of these differences can help ensure timely approvals."


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