DAILY NEWS

Again and again, the FDA fails American patients

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Last week, the United Kingdom approved a new antiviral pill (molnupiravir). Studies show the drug reduces the risk of hospitalization and death among high-risk COVID patients by half. U.S. taxpayers funded molnupiravir's development. Yet the U.S. Food and Drug Administration isn't even meeting to consider approval until Nov. 30.

Molnupiravir is the latest example of the FDA denying patients their most important health care right — the right to make their own health decisions — by prohibiting them from getting drugs that have received approval in other advanced countries.

In the 1980s, an HIV-AIDS diagnosis was a death sentence. Patients were dying by the tens of thousands. Yet the FDA infamously denied AIDS patients access to treatments that were available in China, Israel, Japan, Mexico and Sweden.
In the 1990s, Kathy Gogolak consulted specialists at home and abroad, desperate for a treatment that could control her son Tommy's seizures. No matter how many grand mal seizures you witness, she explains, you never get over them — especially when it's your child.

With the help of Dr. Orrin Devinsky, now director of NYU Langone's Comprehensive Epilepsy Center, she identified clobazam. The drug had been available in Europe since 1974. By 2007, it would be available in more than 100 countries. Yet the FDA would not approve it until 2011.

Gogolak's best option was to obtain the drug, illegally, from a Canadian pharmacy. When the U.S. government seized her son's medication at the border, she kept placing orders and spending money until she got the medicine her son needed. It worked. With clobazam, Tommy has been seizure-free for decades.

Between 2000 and 2010, the FDA blocked U.S. patients from accessing a total of 37 novel drugs available in Canada and Europe. In each case, "no other FDA-approved prescription medicine had the same mechanism of action." Ten of the drugs treated diseases "for which no alternative therapy was available in the USA."

The FDA has blocked life-saving vaccines. In 2013, Australia, Canada and the European Union approved a novel vaccine for a strain of meningitis with a case fatality rate of 10%. That year, multiple American universities suffered fatal outbreaks. University officials had to beg the FDA for permission to use the vaccine to protect their students. The FDA relented — in 2015.

The FDA continues to violate this right in the era of COVID. It has likely cost thousands of lives since the pandemic began by blocking safe and effective diagnostic tests available in other countries. Molnupiravir is saving lives in the United Kingdom; the FDA is blocking it here.

If clinical trial results are accurate, another antiviral pill (ritonavir) reduces the risk of hospitalization and death among high-risk COVID patients by 89%. If other countries approve it first, patients will again lose precious time as the FDA denies them the right to access the drug on the strength of those approvals.

Some members of Congress propose freeing Americans to purchase some medicines, from some countries, in limited circumstances. That might be a good first step. Yet all patients have a fundamental human right to make their own medical decisions.

Congress can restore that right by outright eliminating barriers to purchasing drugs available in other countries. Doing so would have allowed U.S. patients to access those 37 novel drugs a median of 13.6 months earlier. It would allow COVID patients to access molnupiravir today.

Tommy Gogolak was lucky. His father Peter is the all-time leading scorer for the New York Giants. Like the late basketball star Kobe Bryant, who traveled to Germany for a treatment the FDA has not approved, the Gogolaks had the means to circumvent the FDA. Patients who don't have a professional athlete in the family should have the same right to access drugs available in other countries.

They would not be flying blind. Just as wealthy patients do when they purchase drugs abroad, all patients can obtain guidance from their doctors, foreign regulatory agencies, insurers who evaluate drugs as part of their coverage decisions, and other knowledgeable sources.

There would be risks, just as there are with drugs the has FDA approved. As the late AIDS activist Martin Delaney explained in 1988, the question is, "Who gets to decide what risks are acceptable: the bureaucracy in Washington or the patient whose life is on the line?"

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