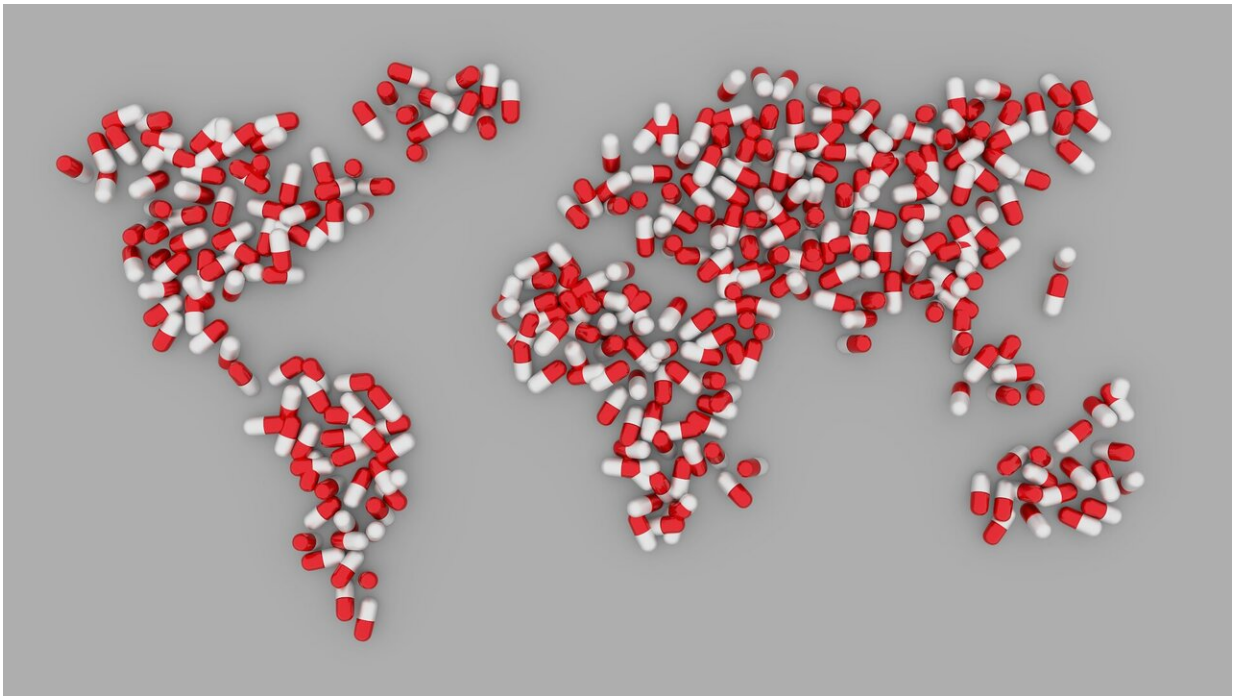
Countries denied access to medicines and vaccines they help develop

May 6 2021, by Mike Cummings



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A Yale-led study reveals that new medicines and vaccines approved for use in the United States are often unavailable in countries that hosted their clinical trials, suggesting that the benefits of drug research are not being shared equitably among populations that participate in testing.

The study, published May 5 in *JAMA Network Open*, covers 34 novel

drugs sponsored by large pharmaceutical companies that the U.S. Food and Drug Administration (FDA) approved between 2012 and 2014. Approvals were made on the basis of a total of 898 trials that were held in the United States and 70 other countries worldwide.

By analyzing the 563 trials for which location data was available, the researchers found that, five years after approval in the United States, only 15% of the drugs (5 of 34) were approved in every country that hosted trials. Among the 70 countries that contributed research participants, 7% (five countries) received market access to the drugs they helped test within a year of FDA approval and 31% (22 countries) did so within five years. Approvals happened faster in high-income countries, such as Germany and Canada, while access was lowest in Africa, where none of the drugs were available anywhere except in South Africa, which had access to just 24% of the drugs after five years.

"We discovered substantial gaps in access to new medications that raise concerns about the equitable distribution of research benefits," said Jennifer Miller, assistant professor at Yale School of Medicine, founder of Bioethics International—a nonprofit advocate for patient-centered medical innovation—and the study's lead author. "Ensuring market access to medicines for the countries helping to develop them can help effectuate a bedrock principle of research ethics: that the benefits and burdens of research should be shared equitably among the people affected by it."

Clinical research for medicines and vaccines seeking FDA approval is largely conducted outside the United States, and increasingly in lower-income countries. While FDA-approval is necessary for drugs to become available in the United States, it does not ensure market access in other countries. Research sponsors, such as pharmaceutical companies, must submit marketing approval applications to make the medicines and vaccines accessible in countries that hosted trials. While marketing

access does not guarantee a patient can afford a medicine or vaccine, or that there is a reasonably sufficient supply of a pharmaceutical product, it is a critical precondition for access to new drugs, the researchers explained.

The 34 drugs were grouped into six treatment areas: infectious disease; cardiovascular disease and diabetes; autoimmune, musculoskeletal, and dermatology; neurology; and psychiatry. The study found that only one of the 34 medications was approved for marketing in all the countries where it was tested a year after FDA approval.

"We found that the typical drug approved by the FDA was tested in 25 different countries," said Dr. Cary Gross, professor of medicine at Yale School of Medicine and a co-author of the paper. "If the citizens of those countries never gain access to the new drug, then one has to ask why are they participating in the research in the first place? Just to see if it's safe for use in the United States and other wealthy countries?"

Even five years after FDA approval, only 5 of 34 of the drugs, or 15%, were approved in all the countries, according to the study.

"Drug research across international boundaries provides U.S. patients access to new medications and vaccines, and could, in theory, maximize benefits for all: The U.S. contributes capital that other countries lack, while those countries contribute human volunteers and a workforce necessary to complete clinical trials expeditiously," said Peter Bach, director of the Center for Health and Policy Outcomes at Memorial Sloan Kettering Cancer Center, and a co-author of the study. "For these partnerships to be truly equitable, then the host countries must benefit from the research by quickly gaining access to the new medications after FDA approval."

To make the process more equitable, the researchers suggest that, as a

condition of running clinical trials, governments of host countries require that pharmaceutical companies commit to submitting a marketing approval application within a designated timeframe after FDA approval. They recommend that companies should consider adopting policies through which they will not test drugs in countries where they do not intend to sell the tested product. The researchers also call for transparent tracking, auditing, and reporting on product registrations in countries that host trials to assist in expanding access to new medicines and vaccines globally.

More information: *JAMA Network Open* (2021). DOI: 10.1001/jamanetworkopen.2021.7075

Provided by Yale University