Case #2. Pharmaceutical Supply and Pricing Issues with Antiviral Covid Drugs.

As Poor Nations Seek Covid Pills, Officials Fear Repeat of AIDS Crisis

The antiviral Covid pills, plentiful in the United States, are scarce overseas. **International health groups** and the **U.S. Biden Administration** want to expand access but face obstacles that evoke the H.I.V. epidemic.



Testing for the coronavirus in Montevideo, Uruguay, last year. This week, President Biden will emphasize "global test to treat" at his second international Covid-19 summit in May 2022. Credit...*Matilde Campodonico/Associated Press*

This case has been edited to reflect developments since the article below was published

By Sheryl Gay Stolberg New York Times May 8, 2022

WASHINGTON — A devastating virus was laying waste to nations that lacked medicines available to Americans. The pills were patented and pricey. Poor countries lacked refrigeration to store them, the thinking went, and patients would not be able to follow the complex dosing regimen.

The year was 2002, the virus was H.I.V., and then U.S. president, George W. Bush, secretly sent his top health advisers to Africa to investigate what activists were calling "medical apartheid." In the 20 years since, the United States has led the way in building a global infrastructure for H.I.V. testing and treatment, saving an estimated 21 million lives.

Now, with that history in mind, the **World Health Organization and other global health agencies** and the **Biden Administration** are working to bring coronavirus tests and expensive antiviral pills to low- and middle-income nations. President Biden emphasized "global test to treat" at his second international Covid-19 summit, a virtual gathering of world leaders aimed at injecting new energy into the international pandemic response.

Until now, the response has been focused largely on vaccinations, which remain a high priority. But Mr. Biden, calling on wealthy nations to donate \$2 billion to purchase Covid treatments and \$1 billion to purchase oxygen supplies for low- and middle-income countries.

In the United States, where antiviral pills to combat Covid are widely available, Mr. Biden's "test to treat" initiative lets many patients go to pharmacies, get tested for Covid and receive a free prescription on the spot if they test positive. In low- and middle-income nations, such efforts will most likely be much more limited until generic pills arrive, probably in 2023.

But the global effort faces some of the same obstacles and inequities that existed two decades ago.

Rich nations, including the United States, have gobbled up much of the supply. **Global health agencies** do not have the money to buy the antivirals or tests, which are crucial because the medication needs to be started early in the course of infection. **Drug companies**, trying to protect their patents, are limiting the supply of generic alternatives in many middle-income countries, including an entire swath of Latin America.

With a major new surge from Omicron or a new variant in the global south expected toward the end of 2022, the **ACT Accelerator**, the Geneva-based consortium coordinating the global response and backed by the **WHO**, believes countries are not ready to meet this challenge. "It feels extremely similar — painfully, ironically, tragically similar — to what happened with H.I.V." a spokesperson declared.

One of the biggest hurdles is the rapid decline of Covid testing around the world. The **ACT** recently reported that just 20 percent of the 5.7 billion tests conducted globally have been in low-and middle-income nations. Low-income countries accounted for less than 1 percent of the testing. The reasons are twofold: Countries lack money to buy the tests, and demand has dropped in regions where Covid rates are now low.

Paxlovid, the more powerful of the two Covid antiviral pills approved by the **U.S. Food and Drug Administration**, is so plentiful in the United States that pharmacies are struggling to use up their supplies. The Biden administration has committed to purchasing 20 million treatment courses for Americans.

The W.H.O. recently issued a "strong recommendation" that *Paxlovid*, which is made by US pharmaceutical giant **Pfizer**, be given to patients at high risk of hospitalization and called for its "wide geographic distribution." The W.H.O. has given a far weaker "conditional recommendation" to the other drug, *molnupiravir*, which is made by **Merck** and is not nearly as in demand.

Global health experts say both companies have absorbed the lessons of AIDS — but only to a point.

They have each agreed to allocate several million courses of treatment — a total of seven million courses in all — to UNICEF for distribution in most low- and middle-income countries, which account for more than half the world's population of 7.7 billion. But UNICEF will not be able to buy the drugs unless it can raise the money to do so or countries supply the funds. And seven million courses is hardly enough to address the need, experts say.

The cost to **UNICEF** of Paxlovid — including **Pfizer's** insistence that UNICEF keep how much it pays confidential — remains a sticking point. In announcing its "strong recommendation" for *Paxlovid*, the W.H.O. took the highly unusual step of publicly scolding **Pfizer** for a "lack of transparency," which makes it difficult to know which countries have the drug and what they are paying.

Pharmaceutical Manufacturers often prefer that the details of their sales agreements be secret so as not to weaken their hand with other potential buyers. *Paxlovid* had been a "key growth driver" for **Pfizer**, which is using a "tiered pricing approach" in which low- and lower-middle-income countries will get *Paxlovid* at a not-for-profit price.

In response to an inquiry from The New York Times, **Pfizer** issued a statement saying that it was "deeply disappointed by the sentiment expressed by our partners," adding, "We have in good faith heard and responded to many of their concerns."

Both **Pfizer** and **Merck** have also taken steps to make inexpensive generic versions of their pills available, signing licensing agreements with the **Medicines Patent Pool**, which was created during the global AIDS crisis to bring drugs to low- and middle-income nations at low cost. It took years, and bitter fights between activists and companies, to reach such agreements for H.I.V. drugs.

But the agreements for Covid antivirals do not apply to many middle-income nations, including much of Latin America and parts of northern Africa and Asia. The result, experts say, is that both poor and rich nations will have access, but countries in the middle will have to negotiate with the companies — or force the drugmakers to turn over their intellectual property.

So far, 36 companies from 12 countries have signed up to make generic Paxlovid. Companies in India are already making generic versions of both Paxlovid and molnupiravir. The expectation is that both drugs will ultimately be available in about 100 low- and middle-income countries, covering about half the world's population. **Pfizer** and **Merck** will not receive royalties from the

sales while the W.H.O.'s declaration of the pandemic as a global health emergency remains in effect.

"Given the severity of the pandemic and given the fact that vaccines had a very uneven penetration rate, we felt that this was a very important contribution the company could make," said Paul Schaper, executive director for global public policy at **Merck**.

But those generics will not be available until 2023. In the meantime, doctors and activists around the world say vulnerable patients are dying as antiviral pills, monoclonal antibodies and even oxygen remain out of reach. In countries with low vaccination rates, the need is especially urgent...

"Paxlovid will be the game changer," Dr. Kitaka said. That is especially true "for patients who become critically ill and end up in the I.C.U.," she added.

In the Dominican Republic, **Pfizer** is fighting a petition for the government to compel the company to share its patents for Paxlovid with generic makers. Similar petitions have been filed in Colombia, Chile and Peru.

"Both **Merck** and **Pfizer** have reserved for themselves all the high-income countries and virtually all of the upper-middle-income countries and even some lower-middle-income countries," said Brook Baker, a law professor at Northeastern University...



Receiving a Covid vaccine in Kathantha Yimbo, Sierra Leone, in February. In countries with low vaccination rates, the need for antiviral pills and tests is especially urgent. *Credit...Finbarr O'Reilly for The New York Times*

The **ACT Accelerator consortium** has plans to expand rapid testing in 20 "priority countries," mostly in Africa, and to run pilot "test to treat" programs in 10 nations. But both initiatives are stalled because of a lack of money and a separate reason that officials find even more troubling: a sense of "pandemic fatigue" in nations whose leaders have other pressing priorities...

CASE QUESTIONS

- 1. Create a supporting argument for and against each of the following assertion:
- a. (2) Pharmaceutical companies should make antiviral Covid drugs available to low-income countries at the cost of production and no more.
- b. (2) Pharmaceutical companies should make public the price they charge various buying entities for their antiviral Covid drugs.

In effect, you will be making 2 arguments for each question—"for" and "against." Be sure to explain the basis for your positions.

(total maximum words for two answers-- 250 words)