Health

Resources diverted

COVID impeded global efforts on fighting AIDS

UNITED NATIONS, Dec 1, (AP): **Dr. Anthony Fauci**, the top US infectious disease expert, said Tuesday the COVID-19 pandemic has diverted scientific and financial resources from the fight against AIDS, seriously impeding global efforts to achieve the UN goal of ending AIDS by 2030.

Fauci told the UN General Assembly that tackling COVID-19 has also disrupted supply chains and increased the risk for people with HIV, the virus that causes AIDS, of being infected with another deadly virus.

"To confront these challenges, we must intensify our collaborative research efforts and unclog supply chains through investment and regulatory action," he said. "We also must assure that people with HIV in all countries have early access to effective COVID-19 vaccines and therapeutics while their supply of anti- HIV drugs also is maintained."


Fauci

The director of the National Institute of Allergy and Infectious Diseases and the chief medical advisor to President Joe Biden spoke at the assembly's commemoration of World AIDS Day, which is Wednesday. The 40th anniversary of the first report that brought AIDS to the attention of the public was on June 5 .

Fauci said he has been "deeply engaged" in responding to both the HIV/AIDS and COVID-19 pandemics, and "they have stimulated responses we all can be proud of including remarkable scientific progress, global cooperation and widespread compassion, particularly in the distribution of life-saving AIDS medications."

"On the other hand," he said, "they also reveal that as a global society, we still are struggling with long-standing inequities in health care access, and very real health communication challenges linked in some countries to waning trust in core institutions."

Fauci said in a recorded speech that much of what scientists and public health experts learned from their long investment in HIV/AIDS research "has been successfully applied to the COVID-19 pandemic." He pointed to the design of drugs and the potential impact on survival of monoclonal antibodies, which can fight infections.

Progress

"Important discoveries stimulated by COVID-19 may also help us make progress against HIV/AIDS," he said, singling out messenger RNA vaccines and the pool of substances that are effective in vaccines.

MRNA vaccines work by using a piece of genetic code from the spike protein of the coronavirus to train the immune system to generate a response. Both the Pfizer-BioNTech and the Moderna vaccines rely on mRNA.

Fauci said COVID-19 also showed how quickly scientists and public health officials can respond to counter a pandemic when there is substantial and sustained financial investment, "and perhaps most importantly, when governments and the private sector work together" and provide incentives for production.

Now, he said, the challenge for scientists, funders, and supporters of research "is to apply these lessons to fight against HIV/AIDS."

UNAIDS, the U.N. agency leading the global effort to end the AIDS pandemic, issued a report Monday saying new HIV infections are not falling fast enough globally to stop the pandemic, with 1.5 million new HIV infections in 2020. It warned that the world could face 7.7 million AIDS-related deaths over the next 10 years if leaders don't tackle the inequalities in the availability of drugs and treatment.

COVID-19 is also undercutting the AIDS response in many places, UNAIDS said, pointing to a decline in HIV testing, and fewer people with HIV initiating treatment in 2020 in 40 of 50 countries it surveyed. The U.N. agency said HIV prevention services were also impacted.

UNAIDS Executive Director Winnie Byanyima told the General Assembly on Tuesday that "progress on AIDS, which was already off track before COVID, is now under even greater strain as the COVID crisis continues to rage, disrupting HIV prevention and treatment services, disrupting schooling, disrupting violence prevention programs and much more."

In June, the General Assembly overwhelmingly approved a declaration calling for urgent action to end AIDS by 2030. It commits the assembly's 193 member nations to implement the 18-page document, including reducing annual new HIV infections to under 370,000 and annual AIDS-related deaths to under 250,000 by 2025. It also calls for progress toward eliminating all forms of HIV-related stigma and discrimination, and for urgent work toward an HIV vaccine and a cure for AIDS.

Byanyima called the plan "exciting" but warned in a recorded speech that "only by moving fast to end the inequalities which drive the pandemic can we overcome it."

This undated file image provided by Merck & Co. shows their new antiviral medication molnupiravir. (AP)

Coronavirus

Merck antiviral drug's benefits outweigh its risks

US panel backs first-of-a-kind COVID pill

WASHINGTON, Dec 1, (AP): A panel of US health advisers on Tuesday narrowly backed a closely watched COVID-19 pill from Merck, setting the stage for a likely authorization of the first drug that Americans could take at home to treat the coronavirus.

The Food and Drug Administration panel voted 13-10 that the antiviral drug's benefits outweigh its risks, including potential birth defects if used during pregnancy.

"I see this as an incredibly difficult decision with many more questions than answers," said panel chair Dr. Lindsey Baden of Harvard Medical School, who voted in favor of the drug. He said FDA would have to carefully tailor the drug's use for patients who stand to benefit most.

The recommendation came after hours of debate about the drug's modest benefits and potential safety issues. Most experts backing the treatment stressed that it should not be used by anyone who is pregnant and called on FDA to recommend extra precautions before the drug is prescribed, such as pregnancy tests for women of child-bearing age.

The vote specifically backed the drug for adults with mild-to-moderate COVID-19 who face the greatest risks, including older people and those with conditions like obesity and asthma. Most experts also said the drug shouldn't be used in vaccinated people, who weren't part of Merck's research and haven't been shown to benefit.

The FDA isn't bound by the panel's recommendation and is expected to make its own decision before year's end. The antiviral is already authorized in the UK.

The drug, molnupiravir, could provide a much-needed weapon against the virus as colder weather pushes case counts higher and US officials brace for the arrival of the new omicron variant.

Merck hasn't specifically tested its drug against the new variant but said it should have some potency based on its effectiveness against other strains of coronavirus.

That uncertainty frustrated many panelists as they grappled with whether to back the treatment for millions of Americans.

Effectiveness

"With no data saying it works with new variants, I really think we need to be careful about saying that this is the way to go," said Dr. David Hardy of Charles Drew University School of Medicine and Science, who ultimately voted to back the drug.

On Friday, Merck released updated data that paint a less compelling picture of the drug's effectiveness than just a few weeks earlier.

Merck said final study results showed molnupiravir reduced hospitalization and death by 30% among adults infected with the coronavirus, when compared with adults taking a placebo. That effect was significantly less than the 50% reduction it first announced based on incomplete results.

For many panelists, the modest effect wasn't enough to outweigh the drug's potential toxicity to human fetuses.

"Given the large potential population affected, the risk of widespread effects on potential birth defects has not been adequately studied," said Dr. Sankar Swaminathan of the University of Utah School of Medicine, who voted against the drug.

FDA scientists told the panelists earlier Tuesday that company studies in rats showed the drug caused birth defects when given at very high doses. FDA staffers concluded the data "suggest that molnupiravir may cause fetal harm when administered to pregnant individuals."

The agency is weighing a blanket restriction against any use in pregnant women or allowing doctors to use the drug in rare cases. Some panelists said that option should be left open for pregnant mothers who have high-risk COVID-19 and may have few other treatment options.

Dr. Janet Cragan, who backed the drug, said that even with tight restrictions some pregnant women would inevitably take the antiviral.

"I don't think you can ethically tell a woman with COVID-19 that she can't have the drug if she's decided that's what she needs," said Cragan, a panel member and staffer with the Centers for Disease Control and Prevention. "I think the final decision has to come down to the individual woman and her provider."

Merck's drug uses a novel approach to fight COVID-19: It inserts tiny errors into the coronavirus' genetic code to stop it from reproducing. That genetic effect has raised concerns that the drug could spur more virulent strains of the virus. FDA regulators said Tuesday that risk is theoretical but many panelists said it should be carefully tracked in follow-up studies.

Advance

Antiviral pills have long been seen as a key advance beyond currently used antibody drugs, which must be injected or infused by health professionals. But given the shortcomings of Merck's data, several experts said they would prioritize patients to receive the older drugs.

While Merck and its partner Ridgeback Biotherapeutics were the first to submit their COVID-19 pill to the FDA, rival drugmaker Pfizer is close behind with its own pill under review.

Pfizer's drug is part of a decades-old family of antiviral pills known as protease inhibitors, a standard treatment for HIV and hepatitis C. They work differently than Merck's pill and haven't been linked to the kind of mutation concerns raised with Merck's drug.

Pfizer said this week that its drug shouldn't be affected by the omicron variant's mutations.

Both drugs require patients to take multiple pills, twice a day for five days.

The US government has agreed to purchase 10 million treatment courses of Pfizer's drug, if it's authorized. That's more than three times the government's purchase agreement with Merck for 3.1 million courses of molnupiravir.

FDA scientists said Tuesday that company studies in rats showed the drug caused toxicity and birth defects in the skeleton, eyes and kidneys. Taken together, FDA staffers concluded the data "suggest that molnupiravir may cause fetal harm when administered to pregnant individuals."

Regulators said they are considering barring molnupiravir's use during pregnancy or warning against it but leaving it as an option in rare cases. The FDA also proposed that doctors verify patients are not pregnant before starting treatment and recommend contraceptives to certain patients.

Merck scientists said they believe their drug will be effective against the new omicron variant. They said the drug worked against other variants, including the prevailing delta strain.

Panelists also weighed whether the pills should be offered to patients who have been vaccinated or previously had COVID-19. Merck didn't study the drug in vaccinated people, but data from a handful of patients with prior infections suggested it had little benefit. Still, it may be impractical for doctors to screen out those patients. The Merck drug works best when given within five days of first COVID-19 symptoms, underscoring the need for speedy treatment.

Merck tested the drug in adults with mild-to-moderate COVID-19 who were considered higher risk due to health problems like obesity, diabetes or heart disease.