

White House is split over how to vaccinate the world

A proposal to waive drugmakers' patents to enable developing countries to make generic vaccines wins some backers in the Biden administration

By [Dan Diamond](#) and [Jeff Stein](#)

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A high-stakes fight over drug companies' response to the [coronavirus](#) pandemic has split the Biden administration, with activists and progressives urging the White House to back an international petition to waive the companies' patents — and some senior officials privately signaling they're open to the idea.

The debate has reignited decades-old tensions in global health, pitting such influential figures as Pope Francis, who backs the patent-waiver proposal, against philanthropist Bill Gates, who's opposed. It has also challenged U.S. officials who have prioritized this nation's coronavirus response but know that the virus's continued spread and mutation overseas will eventually pose risks to Americans.

The proposal was discussed last week by Anthony S. Fauci, a top coronavirus adviser to President Biden, and Katherine Tai, the U.S. trade representative, who spoke about ways to help the developing world as it reels from a worsening crisis.

Fauci briefed Tai on the benefits of sharing technologies from companies that hold vaccine patents — a position that he supports, arguing that it would allow developing countries to rapidly produce their own vaccines, said people with knowledge of White House deliberations who spoke on the condition of anonymity because of the conversations' sensitivity. Tai separately told colleagues that she's considered advocating to lift some patent protections but is still gathering information, said two of those people.

But other officials in the Commerce Department and the coronavirus task force warn that waiving the patents could backfire, including by handing intellectual property to international rivals. They also say that allowing new manufacturers to compete for scarce vaccine ingredients and expertise could hinder existing production, and that donating doses to countries in need would be more efficient.

The patent fight centers on a [proposal](#) in front of the World Trade Organization, which would allow the global trade body's 164 member nations to stop enforcing a group of coronavirus-related patents for the duration of the pandemic.

That proposal has been spearheaded by India and South Africa, which argue that relaxing the patents would allow more countries to produce or import generic versions of coronavirus vaccines, rather than wait months or years for enough doses to immunize their populations. Dozens of developing countries have signed on to the seven-month-old effort, which has attracted renewed attention as the virus ravages India, causing thousands of deaths per day and the rationing of health services.

But the United States and other wealthy nations, including Britain and Canada, have helped block the petition, with officials worried that it would throw global vaccine production into disarray, prompting advocates to complain that the White House is prioritizing drug companies' billion-dollar profits rather than the billions of people still waiting for their first shots.

“We’re putting a lot of pressure on the Biden administration because the U.S. public actually co-funded a lot of this research through Operation Warp Speed,” said Fatima Hassan, who leads South Africa’s Health Justice Initiative and is among the activists calling for a “people’s vaccine.”

Hassan said the companies have treated the vaccines as a “commodity” rather than a public good, and she appealed to Biden to pressure the companies to voluntarily share their scientific discoveries — or face the temporary loss of their patents. “It’s really amazing to me that you have one of the most powerful countries in the world, and it can’t take on four CEOs,” Hassan added, charging that the leaders of Moderna, Johnson & Johnson, Pfizer and AstraZeneca have not done enough to make their coronavirus vaccines available to developing countries.

Pharmaceutical companies counter that they’ve taken dramatic steps to aid the global response, such as collaborating on vaccine development to produce as many as 10 billion doses this year, with more than 1.5 billion of those reserved for poorer countries. Industry officials say accelerating vaccine production would provide more rapid assistance to hard-hit nations.

“We could hand them the patents, and we could say, ‘These are the types of quality-control measures that have to be in place.’ But you know, it can take us five to 10 years to stand up a brand-new manufacturing facility,” said Anne McDonald Pritchett, a senior vice president at the Pharmaceutical Research and Manufacturers of America, the industry’s trade association.

The drug industry, along with other businesses and outside intellectual-property experts, also has warned the White House that loosening the patents would create a thicket of legal challenges and could backfire when the pandemic is over. For instance, rival nations such as China and Russia are eager to learn the secrets of the technology behind vaccines supported by billions of dollars in U.S. taxpayer funds.

Waiving the patent protections would be “disastrous for innovation. It would be very bad for the United States in the long term and short term,” argued Andrei Iancu, who was undersecretary of commerce for intellectual property and director of the U.S. Patent and Trademark Office during the Trump administration.

Inside the White House, officials have wrestled with how to proceed, with some teams pushing to use the patent issue as leverage with the pharmaceutical industry to ramp up its global efforts and others worried that it would subvert the United States’ own coronavirus response.

Indian Prime Minister Narendra Modi raised the patent issue in a call Monday with Biden, according to a statement from Modi’s office. White House officials declined to comment on the conversation and the administration’s broader deliberations. While Biden did not directly address the issue in his speech to Congress on Wednesday night, he vowed that the United States “will become an arsenal of vaccines for other countries, just as America was the arsenal of democracy for the world.” Officials are debating how many millions of stockpiled doses to donate.

The patent fight has intensified as public health experts warn that the coronavirus pandemic is worsening in India and other parts of the world, even as it recedes in the United States. The World Health Organization reported 5.7 million new global cases last week, an 8 percent weekly jump and the highest level on record, driven by the explosion of infections in India.

“In light of this growing humanitarian crisis, I urge you to leverage all tools and resources available to the United States to provide relief to India,” Sen. Elizabeth Warren (D-Mass.) wrote Biden on Wednesday, laying out possible steps such as using the waiver to compel companies to share their “know-how” with the World Health Organization.

‘We have ... an artificial scarcity’

For some global health experts, the coronavirus fight has fueled an old accusation: that wealthy nations and deep-pocketed companies are hoarding expertise and treatments, while less-fortunate nations wait and suffer.

It’s also evoked comparisons to a 1990s-era battle that pitted drugmakers with patented HIV medicines against health officials in developing countries trying to manufacture cheaper generics. That fight culminated in former South African president Nelson Mandela accusing the companies of using patents to try to profit off the spreading outbreak in his country, prompting drugmakers to back down.

The renewed tensions have spilled out in public, including in a briefing Wednesday by the ONE Campaign, a global health advocacy organization.

“It’s a very divisive issue, let’s be honest about this,” said José Manuel Barroso, a former prime minister of Portugal and chair of a global vaccine alliance known as Gavi, which is backed by pharmaceutical companies. Barroso said that in his personal capacity, he had supported the temporary waiver of vaccine patents. “But frankly, now [in] 2021, this will not solve our problem,” he added, calling instead for more sharing and production of doses that he argued would lead to quicker results.

“I respectfully disagree,” countered Winnie Byanyima, the executive director of the Joint United Nations Program on HIV/AIDS, which is part of a pro-waiver coalition. “Just a handful of companies actually can decide who gets the vaccine, who gets to buy and who gets to be vaccinated. Yes, we can talk about donations but surely cannot donate what is not there — we have a scarcity. And it’s an artificial scarcity.”

While the White House has touted its decision to share millions of doses and supplies with India this week, advocates also say it puts a spotlight on what Biden didn’t do. “This piecemeal response and using exceptional measures and charity to respond to a situation of a grave public health crisis is not a sustainable way to move forward,” said Hassan, the South African advocate.

Hassan also noted that under South Africa’s plan, vaccines will not be widely available until late 2021 and she may not be immunized until February 2022. “I’m under 65, I have no comorbidities, so I’ll rightly be last in line,” she said.

About 0.5 percent of South Africans and 9 percent of Indians have been vaccinated against the coronavirus so far, compared with more than 43 percent of Americans, according to data tracked by the Our World in Data project at the University of Oxford.

White House divisions

Within the Biden administration, the patent-protection debate has split the White House along multiple political and policy factions, said three officials with knowledge of the discussions. Progressives have argued with centrists about

whether the administration is wrongly siding with the pharmaceutical industry, which has lobbied to preserve its patent protections. International aid experts have wrangled with the officials focused on domestic virus response, who have worried that efforts to shake up global supply chains could undercut efforts to help Americans now.

“The people whose job it is to protect the property of U.S. businesses are up in arms that it’s a bad idea,” said one official involved in the patent discussions who spoke on the condition of anonymity. “The people whose job is to defeat the pandemic are much more receptive to it.”

[Perspective | Waiving vaccine patents won't help inoculate poorer nations]

The growing pressure over patent protections has emerged as an early test for Tai, the new U.S. trade representative, who is expected to soon make a recommendation to the White House about whether to support waiving some of the requirements overseen by the World Trade Organization’s Council for Trade-Related Aspects of Intellectual Property Rights, or TRIPS.

Tai told a World Trade Organization virtual conference this month that “the highest standards of courage and sacrifice are demanded of us in times of crisis. The same needs to be demanded of industry” — a comment widely interpreted as a signal that drugmakers should brace for a waiver recommendation.

But officials familiar with Tai’s thinking said the trade representative was committed to hearing all sides, noting that she held conversations this week with leaders of companies that hold patents on vaccines as well as with experts like Gates. Tai also is exploring whether there might be ways to boost global vaccine production without waiving the requirements altogether, such as by having WTO member nations use emergency powers to produce patent-protected products.

Some of the health officials who helped develop the coronavirus vaccines being deployed across the United States have argued that more can be done to speed vaccine production. Barney Graham, deputy director at the Vaccine Research Center at the National Institutes of Health, said the U.S. government has “some leverage,” having developed some of the technology used in Moderna’s vaccine.

“I think everyone is in agreement that working as fast as we can to provide vaccines for the world is in the best interests of everyone since we are all in this together, and the faster we vaccinate, the less likely new variants will emerge,” Graham said.

‘A wake-up call’

Drug industry leaders share that assessment but contend that they’ve taken appropriate steps to vaccinate the world, pointing to arrangements with Covax, an initiative set up to distribute billions of coronavirus vaccines globally. The administration’s priority, they say, should be to help source supplies to make the vaccines, which can have hundreds of proprietary components.

“One of our biggest challenges is, simply, the access to some of the critical raw materials that we need,” said PhRMA’s McDonald Pritchett, noting that phospholipids, one key ingredient in the mRNA vaccines, are produced by just four manufacturers, including one that is attempting to ramp up its production about 100-fold since last year. “We need to identify additional ways to further expand capacity.”

Progressives' rallying cry is that the crisis is a test of the nation's moral authority in the world.

"The Biden administration has an obligation to reverse the damage done by the Trump administration and reestablish our nation's global reputation as a public health leader," Rep. Rosa L. DeLauro (D-Conn.), chair of the House Appropriations Committee, said last month, calling for the waiver.

But other lawmakers who oppose the waiver warn that loosening the protections would harm the nation on the global stage. Sen. Christopher A. Coons (D-Del.), a close ally of Biden, has even invoked the Jan. 6 storming of the Capitol among the reasons to protect patents, saying it revealed the need to unite the country.

"All of this is a wake-up call for us that we need to have another Sputnik-like moment of reinvestment in American innovation and competitiveness," Coons added at a think tank event last week. "A central part of being successful in this competition is continuing with our constitutionally created protected-property right of a patent."

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