# Q&A: Firms must share information for massive, rapid vaccine production, says law professor

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As the world rushes to identify safe and effective vaccines and therapeutics to counter the COVID-19 epidemic, attention is turning to the next step: manufacturing these products at enormous scale.

University of Michigan law professor Nicholson Price says companies should share information about manufacturing now so that the pending massive scale-up production can be as smooth as possible. Price, who teaches intellectual property, health law and regulation, co-authored a study with Arti Rai of Duke University and Timo Minssen of the University of Copenhagen that appears in the journal *Science*.

**How receptive have pharmaceutical companies been to sharing their research with other companies? Could you explain what this process would entail?**

It's been a mixed bag. Traditionally, pharma companies have been very reluctant to share their work. Even when they need to share the identity of a drug that works, because they patent the drug and get FDA approval, they're typically very reluctant to share much else, especially information about manufacturing procedures (or other things like which potential candidates don't work out).

Manufacturing information is often kept secret because it helps keep other companies off the market longer, even after patents have expired, and this is especially true for big molecules that are harder to manufacture.

There's been some sharing in the COVID-19 context, both in the context of antibodies (a group of six companies asked the Department of Justice for permission to share information including manufacturing details, and received it) and for vaccines, where some companies have teamed up, though that's more like a traditional licensing deal than sharing between normally competitive companies.

Sharing would involve transferring knowledge about how products are made—in mind-numbing detail. The easier part is that this information is typically already recorded, because the FDA wants exactly that sort of

mind-numbing detail for itself.

## What examples in recent decades have there been with companies partnering their sources and knowledge to solve a global health crisis?

Honestly, the public sector has been much better about knowledge sharing. My favorite example is the World Health Organization's Global Influenza Surveillance and Response Network, which is described in terrific work by professor Amy Kapczynski at Yale, and shares flu samples around the world.

## What would motivate a company to partner with others rather than solely develop the vaccine and sell it worldwide?

Capacity is a big one. We're going to need billions of doses, and scaling up is hard. Partnering lets companies access more capacity than they have—and therefore to sell more doses. The profits might have to be shared, but the pie gets bigger, too.

They also might not have a choice. The U.S. government has talked about using any available capacity to manufacture successful vaccines, and the Defense Production Act gives it authority to mandate production changes for companies.

## When there are multiple companies involved in this process, will there be any challenges with patents?

There might be, but we don't think patents are likely to be a big deal here, at least with respect to manufacturing. What we're really arguing

for is sharing information about how to make vaccines and therapeutics. Often this information is kept secret rather than being patented (which is exactly the problem), and often when manufacturing processes are patented, those patents are invalid (as Professor Rai and I have argued in earlier work published in *Nature Biotechnology*).

## One issue that's likely to arise is who will get the first inoculations among billions of people globally. What will it mean for poor countries if richer countries are likely to get the doses first?

Global access is hugely complicated. Some international efforts are trying to address this; the COVAX initiative is trying to join developed and developing nations to ensure equitable access, but buy-in has been limited. The U.S., for instance, hasn't expressed interest, nor has the U.K., France or Germany. Inequitable distribution seems depressingly likely.

## Another issue could be countries hoarding vaccines. Are there laws against this? If so, what entity would enforce them?

There's been quite a bit of what you might call "vaccine nationalism," in which countries strike billion-dollar deals with vaccine companies and receive promises of many millions of doses—assuming the vaccine pans out.

It's unclear how problematic these deals are; on the one hand they do come across as hoarding; on the other hand, the commitments and funds encourage companies to build up manufacturing capacity even before they know the vaccine is going to work, which they'd normally be

reluctant to do. If that speeds up distribution of a working vaccine, it'll be a huge win. And no laws come to mind that would bar the practice.

## What role can the federal government play in encouraging, or mandating, transparency?

The federal government has a huge role to play. Among other things, it's allocating billions of dollars and could require transparency and active knowledge transfer as a condition of receiving funds. To be fair, it might be doing some of this already—we just don't know, which is its own transparency problem.

The government could also mandate transparency as a condition of approval, but the political economy concerns with transparency mandates are a little more challenging.

## Is there any role for state government?

It's hard to see exactly what state governments could do. Theoretically, state purchasing efforts could require transparency (share how you make a vaccine or we won't buy from you), but realistically, no state would be likely to actually follow through with such a threat, at least not for a first or even second effective vaccine.

## Is there a legal precedent for this kind of transparency or "open source" effort?

Perhaps the best historical example is the SEMATECH consortium, which was a public-private partnership that successfully promoted knowledge sharing in the semiconductor industry. But you could also draw analogies to the recent push for sharing clinical trial data, which has been quite successful, to the extent that the European Medicines

Agency now shares detailed clinical trial data that had previously been kept secret.

Governments can also provide infrastructure for sharing, like the European Open Science Cloud, a digital platform for the scientific community to share information across the research process. This is not an impossible task.

**More information:** W.N. Price at University of Michigan Law School in Ann Arbor, MI el al., "Knowledge transfer for large-scale vaccine manufacturing," *Science* (2020). science.sciencemag.org/lookup/ … 1126/science.abc9588

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