AN AUDIENCE WITH…

From pandemic preparedness to public–private partnerships

Julie Gerberding — incoming CEO of the Foundation for the NIH (FNIH), and former Director of the CDC and executive at Merck & Co. — discusses COVID-19 learnings, centralized clinical trials and trust in science.

Credit: Merck & Co.

Julie Gerberding has seen her share of pandemics. As an internal medicine resident at UCSF in the 1980s, she treated some of the first AIDS patients in San Francisco. Within months of being promoted to lead the CDC in 2002, the first cases of SARS cropped up. And 10 years into her tenure at Merck & Co., as the company's Chief Patient Officer, she had an insider's view of industry's response to COVID.

Each pandemic played out differently, but for Gerberding the similarities between them were striking. "There's a sense of helplessness — not knowing how to provide effective medical care to very ill people, and the tremendous sadness at the loss of lives." In the case of AIDS, this transformed Gerberding's mental model of medicine. "I recognized that we had no cures and, in the early days, no treatments. What we did have was humanity, and an ability to help patients cope."

With COVID, the chase for treatments also sparked a broader interest in a more centralized approach to clinical trials. The Foundation for the NIH (FNIH) — the non-profit charity that manages public–private partnerships between the NIH and industry partners — coordinated ACTIV, a set of clinical trials that has assessed 33 potential COVID drugs in over 20,000 patients.

Gerberding, as the FNIH's incoming CEO, will now help steward ACTIV and the rest of the foundation's US$500 million of biomedical research to keep delivering. Another one of the FNIH's biggest pre-competitive projects, the Accelerating Medicines Partnership, is hunting for targets and biomarkers for various diseases.

"The FNIH is the mouse that roared," says Gerberding. Partnerships are key to addressing both future pandemic preparedness and to re-building trust in science, she adds.

You've seen pandemics start from the viewpoint of a frontline doctor, as the director of the CDC and as an industry leader. What's your takeaway from these different perspectives?

The overarching lesson is that these outbreaks and pandemics happen and will continue to happen. It's extremely frustrating to have that left-brain recognition, and then to see how poorly we prepare and respond to these events. These are predictable surprises. And yet each time we see a new outbreak, our policymakers seem to forget that we've been here and done this before. We start the engine all over again. Then we look back and say, "Oh my goodness, how come we weren't prepared?". Then as soon as we get past the crisis, we go back into a state of complacency.

Where are we now, on the spectrum between crisis mode and complacency? And when is the right time to cement changes?

This coronavirus has been full of surprises, and we are still in the pandemic, with the BA.4 and BA.5 variants now taking hold in the USA.

I think the time to learn during any public health crisis is while it's happening on a continuing basis. I'm not in favour of waiting until it's over and then looking back on it. We need to have an adaptive response and to some extent, we've done that — because we were forced to.

But it's also important, when it is all over, to do a thorough and comprehensive after-action review of what we did right, what didn't go well and what we have learned so that we can position ourselves to better detect and respond the next time something emerges. It's not an either/or situation; the learning needs to be continuous and we need to do a comprehensive deep dive — with all sectors involved — to truly translate our findings into actionable remediation and preparedness steps.

The exemplar of this is the 9/11 Commission, which was a very thorough evaluation of the attacks on 9/11. Many of those recommendations, but unfortunately not all of them, were hardened into policy and structural changes in our government and budgets, and these have had fairly durable impacts on our national security pillar. But we haven't been able to accomplish the same thing with the biothreat pillar. This is where we see the biggest swings between crisis mode and complacency — we get emergency funding, and then that money goes away. Without sustained structural increases in funding, commensurate with the threat that we face, we will never get ahead of the curve in the biothreat department.

Which big policy change would you make?

The broadest change, from the US perspective, is that we need to create permanent Federal accountability for biosecurity.

If we had that, then it would be somewhat easier to go to Congress and get sustained funding for pandemic preparedness. The thing that people don't really understand is that in the USA, biopreparedness is funded on an annual basis. We get emergency funding when a threat is upon us, and then that evaporates. We can't build sustained capability on one-time funding.

What about on the industry side? Companies delivered safe and effective vaccines and drugs at unprecedented speed. But many trials were poorly designed and executed — exacerbating some of the challenges. What needs to change there?

One really important success story in that context was Operation Warp Speed, which coordinated decisions about procurement and supply chains to accelerate the availability and use of products. Another success story is ACTIV — a partnership between the NIH,

industry and nonprofit organizations to run coordinated clinical trials of vaccines, antivirals, antibodies and other classes of drugs. This was organized by the FNIH, to get past the scattershot approach of people doing small trials with no power, which diluted our ability to really do the definitive studies that needed to be done.

The lesson we've learned in this is that central coordination of critical countermeasure development is absolutely essential. When everyone runs off in their own direction, that really dilutes that effort.

We could have done more and done it faster. But this was a mechanism that did not exist before: we've never had such a big, collaborative drug development effort. If only we'd had such a thing at the beginning of the AIDS epidemic, we probably would have had antivirals a lot faster than we did.

What is the future of ACTIV?

In the short run, ACTIV is alive because we still need it. We have ongoing trials, and hopefully we'll have more trials of next-generation countermeasures. The broader outlook is that we need to build on this type of collaborative research. My first question when I got to the FNIH was: what can we learn from ACTIV? If we can bring the same sense of agility and urgency to other areas of discovery and pre-competitive clinical science, that can really help us.

Industry has embraced pre-competitive collaborations, but clinical trials are still typically considered as part of the competitive domain. What challenges does this present?

We're in the middle of an unprecedented pandemic, so there was a suspension of the usual competitive interests. When we talk about opportunities in other spaces, there will be a reorientation of some of the priorities. That's understandable and predictable. But I have certainly seen through my industry experiences that the scientists who work at Merck & Co. are really no different than the scientists working at UCSF or in the NIH. We want the same thing: we want faster access to better drugs that are affordable and help patients. That's a unifying principle.

But Merck & Co. didn't use ACTIV to develop molnupiravir. The same is true of Pfizer and Paxlovid, and Regeneron and REGEN-COV — and the list goes on. What lesson do we take from that?

One of the overarching concerns was speed, and collaboration has a very high transactional cost. And in some cases, companies had trial networks that were ready to roll. If you want to go fast, you go alone. If you want to go far, you go together. I think there's room for both, and I wouldn't be critical of those who went alone.

But there are some settings — say for interventions in patients in intensive care units, where not many subjects will meet the enrollment criteria — where you really benefit from a collaborative approach. Those are things that we'll learn and think about when we do the deep dive on ACTIV.

What's also been impressive to me is the ongoing spirit that we're all in this together. It's a really good feeling to see that folks stick to it, even when it gets hard. Some people would like to put this pandemic in the rearview mirror, and I'm so glad that the people who are still searching for better countermeasures aren't among them. They are working hard to develop even better next-generation interventions.

What other priorities do you have?

I feel like I'm in the candy store of biomedical science right now. One of the first things I want to understand is how to define our impact, so that people can see why these public–private partnerships are so powerful. And, how do we use these partnerships to most effectively accelerate solutions to the unsolved medical challenges we face?

Another area that I'm interested in is mental illness, and whether there are collaborative ways in which we can identify targets or biomarkers for mental illness.

Do you expect to collaborate with the FDA and CDC?

I don't want to speculate on that right now because it is still early days, but the FDA and the CDC both also have foundations and we will be comparing notes across the foundations.

But one area that I will say that I'm very interested in is the issue of trust in science.

The NIH obviously has a great deal of credibility as the broker of good science, but the pandemic has chipped away at some of that trust. The CDC and the FDA have their own issues. And we are dealing with a society that is plagued with misinformation and disinformation. Respected community leaders and thought leaders will need to come together — really, over a long arc of time, I'm afraid to say — to begin to tackle the trust and confidence that people have in the integrity and credibility of the science that supports our health decisions. The erosion of that trust is probably my biggest worry.

What is industry's role in that rebuild?

I have only the perspective of one company. But I found that building allies and listening

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are really helpful attributes. We need to meet with different patient-focused organizations and really listen to what we can learn from these people.

I have a strong faith in the alignment between what patient advocacy and caregiving organizations need from industry, what industry needs, and what our society needs. What is it that we all have in common? We want faster, affordable access to better drugs and medicines and vaccines that solve our really important, challenging health issues.

We're not a healthy society, but we have the best science anyone could imagine. How do we fill that gap? If we don't approach it from the patient experience, it probably doesn't matter how good our medicines are. I think that's ultimately the way to build trust.

Some drug developers made massive windfalls with COVID. Do you think that impacted trust in biomedical innovation?

Let's just be really clear: only a few companies experienced windfalls from the pandemic. Most of us worked hard, and did not create drugs that were proven to be highly useful against COVID. I can point for example to Merck & Co.'s failed vaccine efforts: neither of our vaccines were good enough to be helpful in the pandemic. Those were sunk costs. Of the 800 or more products that were in various stages of clinical development by the end of 2020, very few of these created windfalls.

That's something that people don't really understand about this industry. It's easy to point out when there's a big winner, but no one really talks about the companies that make failed investments. Look at the many failures in the anti-infective antibiotic resistance world. As a result, we're in a crisis there, and we can't treat some of the complicated superbug infections that are actually killing people during this coronavirus pandemic.

I don't think that the payment system should be structured so that there's grandiose profitability in a pandemic to a company that is the so-called winner. But at the same time, industry as a whole did not win. Most of us lost.

Interviewed by Asher Mullard

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