

Session 2: Access to Health and Health Services Panel: The COVID-19 Experience

Summary of Proceeding by Maris Hanson and Bryce Neary

Moderator: Dean Annette Clark

Panelists: Wendy Charles, Margaret Chon, Daniel Laster, Ana Santos Rutschman, Madhavi Sunder

Abstract: COVID-19 has had a massive impact on the U.S. and the world in regard to health care and health care access. Improving access has been the topic of scholarship for many years. It took the COVID-19 pandemic to bring these issues to the forefront of public discussion. Inequities in public health access, not only domestically but globally, have become apparent in the light of COVID-19. This expert panel addresses the inequities of vaccines world-wide and the concept of vaccine sharing programs. It also explores the role that intellectual property plays in these equity issues, and some of the risk inherent in using technology and innovation in the exploration of these issues.

I. Introduction

Dean Clark opened the session by stressing the domino effect of health law issues that the COVID-19 pandemic has created. This health crisis forced public and private sectors to innovate, collaborate, and implement healthcare services and systems at breakneck speeds across the world. However, for many people who work in the fields of healthcare law and policy, many of the inherent inequities and disparities of the current healthcare system were not apparent. COVID-19 forced these issues into light of the general public. Dean Clark made a powerful statement to set the stage for the speakers to follow:

I have been doing this work for thirty years, and I have never seen so much discussion about racial and socio-economic health inequity, the existence, the root causes, and the consequences of those inequities; and not just domestically, but also globally, questions about the role of law and regulation have played in creating and maintaining these healthcare systems and outcomes. The pandemic has spotlighted these issues in the context of differential access. To testing and contact tracing, differences in treatment availability and treatment efficacy for those who contracted COVID-19 and now differential access to the vaccine.

This panel's speakers all discussed innovation in health law centering around COVID-19. Professor Rutschman discussed vaccine access, Professor Sunder talked about India's role as the pharmacy of the developing world and the IP structure that allows that, and Professor Chon commented on the prior comments tying them together with IP and Collaborative Innovation. Dr. Charles discussed BurstIQ and the use of blockchain for vaccine passports and contact tracing and

Mr. Laster closed by giving an overview of the successful implementation of Washington's private/public vaccine collaboration.

II. Vaccine Availability, Allocation, and Affordability

COVID-19 has the potential to be used as a unique catalyst for change if we use this experience to drive and inform new approaches to accessibility. The global response to COVID is abnormal and we cannot expect the world to unite to the same degree when facing future events, so it is imperative to use this time to implement improved laws and policies. Equitable access to vaccines and healthcare is an important part of justice, but difficult to define.

Access is a porous word used to mean many things. Professor Anna Santos Rutschmann focused on access through availability, allocation, and affordability. An important aspect of availability is technology policy for both research and manufacture of vaccines. Allocation is affected by advance purchase agreements and vaccine nationalism. Affordability can be negatively impacted by IP factors and by demand. Possible solutions to increase access include contract provisions. Although it is not uncommon for healthcare contracts to include open sharing provisions, companies have begun to drop these clauses. Many of the WHO negotiated contracts for Zika and Ebola did not contain these provisions originally. Technology is another important solution for access. Sharing research and manufacturing capabilities will increase the supply of necessary vaccine and medicines.

COVID-19 has been a catalytic event for long-term legal and policy change. Specifically, intellectual property laws and the equity issues related to vaccine distribution. Intellectual property (IP) law is agnostic to the type of technology it is regulating and controlling. Therefore, vaccine researchers, developers, and manufacturers efforts to quickly produce a vaccine can result in disproportionate distribution and control over it, regardless of good faith efforts otherwise. For example, Moderna and Pfizer each pledged to donate one billion doses of their respective vaccines to mid- and low-income countries, but they won't meet this goal until the end of 2022.⁹ Meanwhile, only 12% of Southeast Asia's adult population is vaccinated; Sub-Saharan Africa is facing its worst COVID-19 death rate yet; and countless other countries are unable to vaccinate even their highest priority groups.¹⁰

This situation has made it clear that reliance on high-income countries who have the infrastructure in place to develop, manufacture, and replicate vaccines is not sufficient. Once low to mid-income countries are given access to the technology, and tech transfer is fully engaged, they should be able to produce enough vaccines to curb the virus in their respective regions. Thus, the countless layers of IP law protecting the market interests of vaccine manufacturers are halting entire populations' chances at herd immunity. Focusing on donations is important, but it won't be anywhere enough with respect to the kinds of numbers necessary to vaccinate the populations of low- and mid--income countries.

⁹ This donation promise was in response to the threat of a WHO waiver of intellectual property rights to COVID-19 vaccines

¹⁰ Statement made by Madhavi Sunder, Associate Dean for Graduate & International Programs and Professor, Georgetown University Law Center

This skewed distribution can also be traced to simple buying power. Many wealthy countries pre-purchased enough vaccine doses to vaccinate their entire population. The UK secured 250 million doses from four suppliers; it has 66 million people.¹¹ While wealthy countries stockpile an incredible number of vaccines, COVID-19 continues to spread, mutate, and adapt in countries who were unable to secure similar quantities. This inequity could be curtailed by creating incentives to vaccinate low- and mid-income countries. Again, diseases don't have borders, and "vaccine nationalism" is counter-intuitive for a long-term global solution.¹²

IP reform can help increase access through affordability. For example, the implementation of patent pools where companies share their information amongst the members through a creative commons license could have the potential to drive research and production for all the members. Professor Rutschman, however, noted a disfavor of patent waivers, concluding that they are an unrealistic solution. COVAX was initially an attempt to create broader access for mid- and low-income countries that was ultimately unsuccessful due to structural problems, unrealized monetary and medical donation pledges and only ever intended to cover 20% of the member country populations. This pooled procurement model shows a lot of process, but the implementation will need to be greatly improved.

Professor Madhavi Sunder emphasized that initially COVAX had a goal to provide enough vaccine to cover 20% of member country populations, however there were never enough donations of either money or vaccine to meet this goal. Additionally, the main supplier, Serum Institute, an Indian company, had the Indian government step in to redirect the vaccine production to local needs within India. The failure of COVAX is a good example of why we should be skeptical of philanthropic solutions and why we need to empower self-sufficiency in developing countries. IP waivers need to be clearly defined both in scope and in duration, but the question remains of how to get the buy-in of the inventors. It is important to remember that a WTO waiver is not a U.S. waiver. While TRIPS allows for a forced waiver of IP protection, this avenue is slow and limited in duration.

Professor Margret Chon made a point that IP and medical science take fundamentally different approaches, which creates tension when IP is applied in the healthcare setting. Medicine is inherently a forecasting, long-range field that uses current crises to learn and plan for the future. Medicine is collaborative in nature and naturally partners with the public sector. Conversely, IP tends to be short-term and is driven to maximize current profits. IP is a necessary evil and can only be part of the solution. It is essential to seek multiple solutions to both push and pull innovation.

III. Public and Private Sector Collaboration

Generally, planning for public health threats is not a priority. There is no monetary incentive to push for research and development of a disease that hasn't affected anyone yet. In the U.S., with free market thinking at the forefront, something like virus preparedness has long been pushed to the wayside. COVID-19 has changed that.

¹¹ *COVID-19 Vaccine Advance Purchases Explained*, HARVARD LAW: BILL OF HEALTH (August 11, 2020), <https://blog.petrieflom.law.harvard.edu/2020/08/11/covid19-vaccine-advance-purchases-explained/>.

¹² *Id.*

The collaboration between public and private sectors has created market incentives for private companies to work with government health care entities. Dr. Wendy Charles gave the example of her employer Burst iQ, which uses their blockchain network to revolutionize the way organizations manage and connect health data. Blockchain provides health data management for health systems that lack central infrastructure and consistent broadband. During the pandemic, the company's blockchain acted as the central nervous system of vaccination and contact tracing data. By streamlining healthcare data management, low- and mid--income countries will be able to surpass many of the outdated systems still used in many high-income countries today. This may be an equalizer of the current gap in technology and accessibility between nations, which would make a critical impact in future health crises.

Dan Laster, the Director of the Washington COVID-19 Vaccine Action Command and Coordination System (VACCS) Center at WA State Department of Health has collaborated with numerous private companies to streamline vaccination processes. Starbucks, Swedish Hospitals, Amazon and Microsoft all worked with the WA State Department of Health to develop solutions the government faced in regard to mass distribution and administration of vaccines.

However, efficiency in vaccine administration is not enough. Availability and accessibility were substantial concerns in getting the Washington public vaccinated. In WA, the VACCS team looked to arguably the best logistics company in the world, Amazon, to overcome these challenges. VACCS was able to partner with Amazon's call centers to make sure that people were able to find vaccination sites easily and answer any additional questions they may have. Over 500,000 calls for vaccination questions were handled by the Amazon call center, and over 42,000 appointments were booked through them directly.

Many people may not live close to a vaccination site, have limited time for extraneous obligations, don't have a car, or can't bear the extra cost of an Uber or Lyft. The VACCS team looked to the private sector to help solve these problems and get people to vaccination sites. Contracts were struck with Uber and Lyft to give people with vaccination appointments rides to their respective sites completely free of charge. In addition, public transit throughout the state of Washington was free for those going to their vaccination appointment. Many of these innovative practices were replicated throughout the U.S.¹³

While interest alignment between public and private sectors was challenging, the collective goal of mass immunization led to mutually beneficial contracts that made Washington state one of the most effective vaccines administrators in the country. In fact, CDC representatives told Mr. Laster that the Lumen Field vaccination site was the most efficient site they had ever seen—with a total vaccination time of only 30 minutes per person. In addition, the WA vaccination information was available in thirty-eight languages both at vaccination sites and on the online information portals. This system worked so well that the VACCS Center later published a “playbook” about how to create efficient vaccination sites.

¹³ *Uber and Lyft Will Give Free Rides to COVID-19 Vaccination Spots, White House Says*, NPR CORONA VIRUS UPDATES (May 11, 2021), <https://www.npr.org/sections/coronavirus-live-updates/2021/05/11/995882805/uber-and-lyft-will-give-free-rides-to-covid-19-vaccination-spots-white-house-say>.

IV. Conclusion

Whether developers receive financial incentives from vaccine patents and other healthcare policies is a separate question from whether consumers face barriers to access; the two are not mutually exclusive. However, a balance must be struck between the public and private sectors on an international scale in order to tackle challenges like COVID-19. By *creating* financial incentives and finding alignments of interests—like many of those utilized in Washington—governments should be able to find better solutions on an international scale.