

Attachment—Additional Questions for the Record

**Subcommittee on Health
Hearing on
“Booster Shot: Enhancing Public Health through Vaccine Legislation”
June 15, 2021**

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The Honorable Neal P. Dunn, M.D. (R-FL)

1. Over the past several months, multi-specialty medical groups and integrated delivery systems have expressed frustration around their lack of inclusion in initial vaccine distribution discussions. Multispecialty medical groups and integrated delivery systems (IDSs) are an untapped resource in the national vaccine administration strategy. These organizations play a critical role in the delivery of healthcare in this country and have long standing relationship with their patients and the communities they serve. They also have tools, such as electronic health records to identify patients at higher risk which allows for prioritization for vaccinations and testing. How can we ensure we leverage the expertise and experience multispecialty medical groups have with vaccine administration in any national vaccine distribution strategy and continue to work together on this current pandemic?

I am not able to answer your question regarding multispecialty medical groups and integrated delivery systems as this is not an area of my expertise. However, one of the benefits of an immunization information system (IIS), also known as an immunization registry, is that regardless of where a person receives care, the goal is for that provider to have access to their patient’s comprehensive vaccination record using an IIS.

2. There is a long-standing vaccine distribution process in place involving medical groups and pharmacies. The Influenza vaccine, for example traditionally reaches 45-50% of the US population. What do you think about defaulting to this tried and true process for COVID-19 going forward? This allows the providers who already have vaccine systems in place to best put shots in arms rapidly, instead of sending half the population to non-healthcare locations, and having medical groups competing with other non-providers who received initial batches of COVID shots.

Vaccine distribution is a complex system that relies on both public and private entities. The challenge with any pandemic is getting vaccines to those that need them as quickly as possible. During H1N1, the network of vaccine administrators had to be expanded to vaccinate the population as quickly as possible. The same is true of COVID-19 vaccines and any vaccine that must be distributed broadly and administered quickly. There simply are not enough traditional vaccination providers to manage a surge while also providing routine and emergency healthcare. IIS play an integral role in facilitating the continuity of

vaccination records between traditional and non-traditional providers. Because all COVID-19 vaccines are reported to an IIS, providers can access vaccination records for their patients that received their COVID-19 vaccines outside of their traditional healthcare setting.

3. There is rapidly mounting evidence about the important role of T cells in COVID-19. In fact, a recent study showed that T-cell responses to certain vaccines remain unaffected by common variants, while neutralizing antibodies are significantly diminished. Given the complementary information T-cell testing can provide, should the FDA require T-cell information from vaccine developers when assessing immunogenicity or when determining how frequently booster shots may be needed in different populations? Do you agree it is important for researchers and vaccine developers to incorporate measures of T-cell response when assessing vaccine response and duration and give physicians the tools they need to make appropriate clinical decisions in treating patients?

This is a question for which I do not have the expertise to answer and would be best answered by an immunologist.

4. How can the National Institutes of Health (NIH) support additional research to build on existing evidence on the use of T Cell testing for COVID-19? To assess the long-term effects of COVID infection? To examine the cellular immune response as it studies vaccine efficacy and duration? For other known diseases? To prevent or mitigate future pandemics?

I believe there is an opportunity to leverage data from immunization information systems (IIS) coupled with health systems, payers, and other data sources to examine the long-term efficacy and duration of immunity for COVID-19 vaccines. Establishing a long-term monitoring program would provide real-world indicators that could be used to help determine when booster doses should be added to vaccine schedules, determine breakthrough infection rates, and monitor vaccine efficacy, to name a few. A long-term monitoring program could ultimately be used for all existing and future vaccine-preventable diseases.