Vaccinate Your Family's Response to Questions for the Record

Degette: Recs for federal government to increase COVID vax uptake

While individual legislators can be trusted messengers within your home states, it is important to recognize that the federal government may not be considered a trusted messenger by those who continue to avoid getting COVID-19 vaccines.

Those holding out getting vaccinated against COVID may not trust the federal government for any number of reasons, or simply just not see the need for it. Instead, we need to be working with local "boots on the ground" groups to identify trusted leaders within those communities, such as faith leaders, teachers, or coaches, and train them to spread the word. The federal government can help by supporting these organizations, providing easily accessible clear, plain language information about vaccines and where to access them.

Fortunately, the Ad Council Collaborative brought together experts in social science and vaccines (including Vaccinate Your Family) to first, get a pulse of the public's opinions on COVID-19 vaccines and to assess vaccination plans and second, to develop toolkits for advocates like VYF to help us reach the 40% of Americans who are considered the "movable middle."

Burgess: difference in hesitancy with COVID vax, compared to other vaccines

Vaccinate Your Family has a long history of educating the public on vaccines and we allow open discourse on our social media platforms (which reach over 3 million people annually). We are seeing three emerging areas of increased hesitancy around the COVID-19 vaccines. One is the current Emergency Use Authorization. People are nervous about something that has not been fully approved by the FDA. Thankfully, both Pfizer and Moderna have applied for full licensure and we expect the FDA to approve these applications shortly. In meantime we need to do a better job communicating the safety of COVID vaccinations, juxtaposed with the severity of COVID.

The second most frequently expressed concern is the speed in which the vaccines were developed. Finally, people are considered about the temporary side effects of the vaccines that protect you against COVID-19 and do not seem to recognize that the long term side effects of contracting the disease are quite unknown and may be much more serious.

Vaccinate Your Family has compiled a list of Frequently Asked Questions and Answers about COVID in both English and Spanish – we urge Members to take a few minutes to review our content and share with your constituents.

The following example of our work to educate the public about the safety of these vaccines is taken from our website at www.vaccinateyourfamily.org.

Just like all other vaccines in the U.S., COVID-19 vaccine candidates are first tested by vaccine manufacturers/researchers in three phases of clinical trials. *The purpose*

of these trials is to see if the vaccine candidates are safe and effective. During the Phase 3 clinical trials, researchers compare the health of those who get the vaccine to that of those who didn't. This helps researchers spot common side effects and see if those in the vaccinated group are less likely to get sick than those who got a placebo. (A placebo is a harmless, "fake" vaccine given to half the people in the clinical trial. People in the vaccine clinical trial are not told whether they received the actual vaccine or the placebo), COVID-19 vaccine trials done so far have generally included tens of thousands of people, including people of color.

Researchers follow everyone in the clinical trials who gets the vaccine for at least two months after their last dose to make sure there aren't any lingering issues or side effects that could be caused by the vaccine.

<u>FDA and their Vaccines and Related Biological Products and Advisory Committee (VRBPAC)</u>

Before being authorized for emergency use in the U.S., the FDA's Vaccines and Related Biological Products and Advisory Committee (VRBPAC) decides if each COVID-19 vaccine meets its safety and effectiveness standard. *If the benefits*

outweighs the risks of the vaccine, the FDA can make the vaccine(s) available for use in the U.S. by approval or emergency use authorization (EUA).

As of February 28, three COVID-19 vaccines (Pfizer-BioNTech, Moderna and Johnson & Johnson) were authorized by the FDA for emergency use authorization in the U.S.

CDC and their Advisory Committee on Immunization Practices (ACIP)

After each COVID-19 vaccine is authorized for emergency use (EUA) or approved by the FDA, the ACIP meets to carefully review the available scientific research and make recommendations for the use of that particular vaccine*. The CDC Director will review ACIP's recommendations and decide whether or not to make them "official".*

As of February 28, the CDC has recommended three COVID vaccines for use in the U.S. (*Pfizer-BioNTech, Moderna* ***and*** *Johnson & Johnson****)***

UPDATE: *On April 13, the FDA and CDC recommended a pause in the use of the Johnson & Johnson (J&J) COVID-19 vaccine due to a possible rare side effect called "thrombosis with thrombocytopenia syndrome" or "TTS" (severe blood clot with low blood platelet counts). On April 23, the Advisory Committee on Immunization Practices (ACIP) – the expert committee that advises the CDC – voted to lift the pause on use of the Johnson &Johnson (Janssen) COVID-19 vaccine.* ***The vaccine is once again recommended for people 18 y.o. and older in the U.S. population. Both the FDA and CDC state that the benefits of the J&J COVID-19 vaccine outweigh the risks.***

Ongoing Vaccine Safety Monitoring Systems in the U.S.

After each COVID-19 vaccine is authorized for emergency use by FDA and recommended by CDC, there are a number of *vaccine safety monitoring systems* ***that are working together to watch for rarer possible side effects that may not have been seen in the vaccine's clinical trials****.*

Some of the vaccine safety monitoring systems have been around for a long time to monitor vaccine safety after being licensed for use in the U.S. population, including:

- *Vaccine Adverse Events Reporting System* ***(VAERS) –****U.S. system for reporting adverse events that happen after vaccination. Anyone can report to VAERS. Reports of side effects that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies.*

- *Vaccine Safety Datalink* ***(VSD) –*** *A network of 9 healthcare organizations that conducts vaccine surveillance and research. VSD is also used to figure out if side effects identified using VAERS are actually related to vaccination.*
- *Clinical Immunization Safety Assessment (CISA) Project* ***–****A collaboration between CDC and 7 medical research centers to provide expert consultation on individual cases and conduct clinical research studies about vaccine safety.*

There are also systems that were recently developed or expanded to add additional safety monitoring, giving the CDC, FDA, and others the ability to evaluate COVID-19 vaccine safety in real-time in order to make sure the vaccines are as safe as possible, including:

- *V-SAFE* ***–*** *A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow up to anyone who reports medically significant (important) adverse events.*
- *National Healthcare Safety Network (NHSN) – An acute care and long-term care facility monitoring system with reporting to VAERS.*
- ***FDA's*** *Biologics Effectiveness and Safety (BEST) System* ***and FDA's*** *Sentinel Initiative****—*** *Systems that contain administrative and claims-based data for surveillance and research.*
- ***Centers for Medicare and Medicaid Services (CMS) Database –*** *FDA and CMS will collaborate to monitor the CMS database (includes approx. 650K nursing home residents).*
- ***Genesis –*** *National Institute on Aging awarded a grant to a team of researchers based at Brown University to design a monitoring system to identify and track adverse health impacts after nursing home residents receive COVID-19 vaccinations.*

If any serious safety issues are detected, immediate action will be taken to find out if the issue is related to the COVID-19 vaccine and determine the best course of action.

Vaccine Safety for Veterans

- ***Department of Veteran Affairs' (VA) Data Warehouse and Electronic Health Records*** *– A system of electronic health record and administrative data for active surveillance and research*
- *VA Adverse Drug Event Reporting System (VA ADERS) – A national reporting system for adverse events following receipt of drugs and immunizations*

Monitoring Vaccine Safety for Members of the Military

- ***Department of Defense (DOD): DOD VAERS data*** *— Adverse event reporting to VAERS for the DOD populations*
- ***DOD's Vaccine Adverse Event Clinical System (VAECS)*** *— A system for case tracking and evaluation of adverse events following immunization in DOD and DOD-affiliated populations*
- ***DOD's Electronic Health Record and Defense Medical Surveillance System*** *— A system of electronic health record and administrative data for active surveillance and research*

Monitoring Vaccine Safety for Tribal Nations

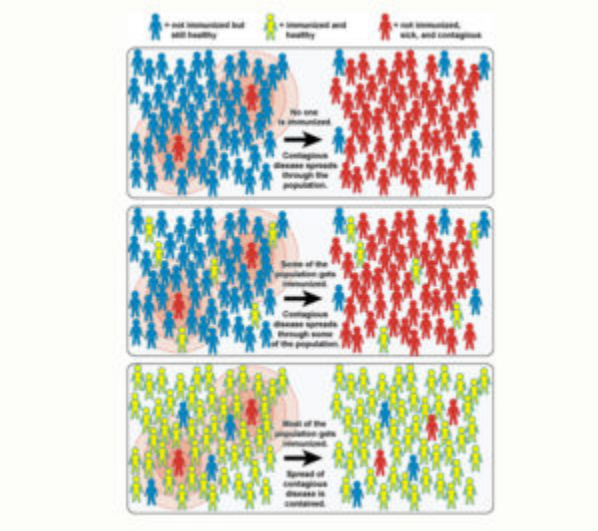
- ***Indian Health Service (IHS): IHS VAERS data*** *— Spontaneous adverse event reporting to VAERS for populations served by IHS and Tribal facilities*

Bilirakis: Is herd immunity the goal?

Herd immunity, or community immunity has thankfully led to the near eradication of polio, and the full eradication of smallpox. And it is crucial to protecting those individuals who cannot be vaccinated against COVID-19 for medical reasons, or are not yet recommended to receive vaccines (children under age 12). Our nation must continue to increase vaccination rates to achieve herd immunity so that we can ensure that the virus has no hosts in which it can continue to spread and mutate. Without a host the virus will no longer be able to develop new strains, which is critical to overcoming the pandemic. We also need to make sure that individuals are caught up on any vaccines they skipped during the pandemic to ensure that we maintain herd immunity for other vaccine preventable diseases like measles. We do not want to end this pandemic with an epidemic. We also discuss this on the VYF website:

Germs can travel quickly through a community and make a lot of people sick. If enough people in your community get a certain disease, it can lead to an outbreak. However, when enough people are vaccinated against a certain disease, the germs can't travel as easily from person to person and the entire community is less likely to get the disease. *Even if a person does get sick, there's less chance of an outbreak*

because it's harder for the disease to spread if a lot of people are vaccinated and therefore immune. Eventually, the disease becomes rare, and sometimes, it can be wiped out altogether, which is what happened with a very serious disease called smallpox. This is known as community immunity or herd immunity.



Community immunity protects everyone, and it is especially important for people who are vulnerable to diseases, but who can't be vaccinated. *This includes children too young to be fully vaccinated, people with serious allergies against certain vaccine ingredients, and people with weakened or failing immune systems (e.g., people with cancer, HIV/AIDS, type 1 diabetes, or other health conditions, and people going through certain medical treatments like chemotherapy.)*

Community immunity is also important for the very small group of people who don't have a strong immune response to vaccines. *These people who cannot get vaccines or who aren't protected from vaccines depend on a high level of immunization in their schools and/or their communities to help protect them against dangerous, and potentially deadly diseases.*

Each vaccine-preventable disease requires a certain percentage of people in a community be vaccinated in order to prevent the disease's spread. The exact percentage depends largely upon how easily a disease can spread from person to person.

Bilirakis: main messages

There are three main messages that need to be communicated about COVID vaccinations:

- First, they are safe.
- Second, they are effective.
- Third, they are necessary. Being vaccinated against COVID does not just protect you, it protects others around you. The only way to get back to normal is through vaccination.