Societal Players that Contributed to COVID-19 Vaccine Trust

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

There is a non-negligible proportion of the population who choose to delay, or even worse, outright reject proper vaccine protocols in the face of severe consequences shown by the COVID-19 pandemic. The World Health Organization (WHO) presents a three C's model for the factors that cause someone to be hesitant towards vaccination: complacency, the ironic effect where the success of vaccinations undermines an individual's motivation to get vaccinated themselves, convenience, where barriers (location, cost, insurance) prevent individuals from getting vaccinated, and confidence, where individuals do not trust the scientific basis behind vaccines, therefore rejecting to comply with vaccination protocols (Sturgis et al., 2021).

In this paper, confidence will be the main factor in the investigation. One key distinction between the vaccine hesitancy issue surrounding COVID-19 and other infectious diseases is the politicization of vaccination. Because the virus and vaccine are now considered a political issue rather than a scientific issue, a clear divide exists in Americans' sentiment on vaccination. This has led to trust in experts breaking down, which was especially seen with the COVID-19 pandemic, where anti-vaccine groups spread misinformation and views that were in direct conflict with what scientific authorities claim. The subject of the paper, then, is to analyze the motivations and interactions of the groups that played a hand in promoting overconfidence in the public, breaking the trust in health experts, and, consequently, a rejection of proper vaccine adoption. The groups that will be analyzed in this paper are anti-vaccine groups, private citizens, pharmaceutical companies, and regulatory agencies.

Background & Context

In 1796, a British physician named Edward Jenner discovered that by inoculating an 8-year-old James Phipps with a strain of the lesser serious cowpox virus, he gained immunity to the more fatal smallpox infection. Summarizing his findings in his paper "*On the Origin of the Vaccine Inoculation,"* Jenner paved the way for an era of vaccine development, the invention of which has been responsible for saving millions of lives every year.

The COVID-19 vaccine is no exception–more than 1 million deaths and 10 million hospitalizations were estimated to be averted because of the vaccine (Schneider et al., 2021). Though the impacts are irrefutable, vaccine hesitancy has always been a barrier to this miracle of science. The COVID-19 vaccine, again, is no exception–although supplies greatly exceed what is required in the U.S., only 63% of eligible adults are fully vaccinated, and an additional 12% are partially vaccinated (Debusmann Jr., 2022). Evidently, there is a growing group of Americans who are wary of the vaccine and refuse to be vaccinated.

The consequences of a society that doesn't fully accept vaccines are dire. First, there is robust support for the assertion that vaccines protect individuals: studies have shown that unvaccinated patients are 100 times more likely to die due to COVID-19 than vaccinated patients (Debusmann Jr., 2022). Second, the full effects of the vaccine are attainable insofar as the majority of the population buys into the technology. A threshold exists for every vaccine, where as long as a certain proportion of the population is vaccinated against an infection, the entire community achieves "herd immunity." When herd immunity is achieved in the population, the spread of the infection drops due to a high number of immune members. This provides protection to not only the vaccinated members of the population, but everyone else, including those who are immunocompromised, young, old, or otherwise unable to be vaccinated due to pre-existing

conditions. In addition, viral variants can emerge within a population lacking broad protection, which can mutate to such a degree that it starts to infect vaccinated individuals (McNamara, 2021). This phenomenon was observed with the Omicron variant, which had such high efficiency and transmissibility that the CDC announced that almost everyone will eventually be infected with it, vaccinated or not (Caldwell et al., 2022).

Methods

The present paper will follow a Social Construct of Technology (SCOT) Framework by first introducing the relevant social groups involved in the vaccine development process and the COVID-19 pandemic, then exploring how stabilization and closure is achieved in this context. The introduction of the groups will be done by drawing on press releases and news reports that covered events during the relevant time period and will help to develop an argument for how each of these groups contributed to the overall confidence in the COVID-19 vaccine.

Relevant Social Groups

Anti-Vaccine Groups

Anti-vaccine groups have the most immediate contribution towards pushing forward the sentiment of rejecting mass vaccination programs and have existed long before the COVID-19 pandemic, even showing opposition to Edward Jenner's smallpox vaccine. This group will be defined in the scope of the paper as those individuals who hold a strong interest in promoting and spreading anti-vaccine beliefs by questioning the safety, efficacy, and validity of the COVID-19 vaccine. They can exist on an organizational level, such as with the Anti-Vaccination Society of America, or by individual activists, ordinary people with strong concerns who spread their controversial viewpoints through online platforms like Facebook and Reddit (Raemdonck, 2019).

Anti-vaccine groups often oppose the counsel given by medical authorities and will spread misinformation that elicits fear and confusion within the rest of the general population. Especially in a time such as the COVID-19 pandemic, when there is a greater deal of uncertainty in the situation than usual and no playbook to go over how to adapt, the impacts of anti-vaccine groups are amplified. Vaccine Adverse Event Reporting System (VAERS), a U.S. public database intended to be used by patients to log adverse health effects following vaccination, was being misused by anti-vaccine activists to stir up fear about the use of the COVID-19 vaccine (Brumfiel, 2019). Activists would falsely claim that the vaccine causes adverse reactions, often citing that the vaccine causes death in patients, which pushes the sentiment of fear for vaccines.

A more recent impact that has come because of the advent of the internet is the accessibility of said misinformation. Unlike in Jenner's time, information spreads in an instant and can be spread by anyone. Systems like VAERS were made a public database during their inception decades ago to increase the transparency of vaccine technologies and combat the arguments made by activists that the government is promoting mass-vaccination programs for ulterior motives (Brumfiel, 2019). The unintended consequence of this, however, is that public databases like this spread misinformation from one wary activist to another, which confirms and solidifies the belief that these vaccines do more harm than good, even when scientific research has time and time again proven that these claims are unfounded.

Private Citizens

Private citizens are defined in this paper as those in the general public, not immediately identified as those in anti-vaccine groups. They represent a large majority of the general population and are made up of those who support vaccination wholeheartedly and those who are uncertain about vaccination.

Those who advocate for vaccination are those who have a strong trust in science and are willing to comply with the counsel provided by medical authorities. Among many factors, a study found that the key which guided an individual's likelihood to vaccinate or not was trust in science (Michaud, 2022). Individuals in this group, who are more likely to be younger in age than those who are anti-vaccine (Michaud, 2022), have an understanding of the requirements for vaccines to have their full effect and will do their part in stopping the spread of infectious diseases. They advocate for others to also take part in complying with medical authorities and trust that they will guide them through the pandemic in good faith.

On the other hand, there was an emerging group of people who fell into another category with the COVID-19 pandemic: those who were uncertain about vaccination. These individuals were not previously anti-vaccine and actually complied with previous vaccination requirements prior to the COVID-19 pandemic. However, this group cites that the never-before-seen global pandemic has given way to technologies that have greater uncertainties and risks, which make them warier of "jumping in line" once a vaccine becomes available.

There are dangers to this mentality. For one, misinformation becomes rampant among other uncertain individuals. An example of an argument presented by these individuals is that they would be more comfortable getting vaccinated once the vaccines are put through more rigorous trials to truly prove human safety and efficacy (Kelen, G., & Maragakis, L., 2022). The assumption from this argument is that the emergency use approval given by the Food & Drug Administration (FDA) compromises the safety of the vaccine relative to a fully approved one and that taking the vaccine can be dangerous. However, the FDA states that vaccines with emergency use approvals are put through rigorous clinical trials, are held to statutory criteria, and are given out during times of public health emergencies to make treatment available in a timely manner

(Center for Biologics Evaluation and Research), making them an appropriate means of treatment in a time such as a global pandemic. This wariness to get vaccinated can also slow the rate of vaccination and increase the rate of transmission, giving way to the formation of more infectious and lethal mutations.

Pharmaceutical Companies

In a capitalist system, where the well-accepted principle is 'winner-take-all', it is inevitable that private businesses feel a sense of competition with one another to bring the most reliable and efficient product to the market in the fastest timeline possible. This is especially true within the pharmaceutical sphere, where one of the numerous hurdles that companies must face for products to reach store shelves is regulatory approval. As soon as a single vaccine candidate receives FDA approval, other candidates in the same competing pool have the added burden of demonstrating improved efficacy and safety compared to the already approved model (Staahl, 2021), making it even more attractive to be the first successful candidate.

With the COVID-19 pandemic, there was increased urgency for a vaccine to hit the market as it served as a beacon of hope that signified the beginning of the end of the global pandemic. Fortunately, this came much sooner than expected when a COVID-19 vaccine was approved for emergency use in December of 2020, first by Pfizer-BioNTech and followed shortly after by Moderna. Before this, typical vaccine rollout time was understood to be a lengthy process (clinical trials, manufacturing, commercialization, and regulation) that took an average of about 10 years–the fastest, before COVID-19, was the Mumps vaccine, which was developed in a record four years. With the two COVID-19 vaccines gaining authorization in less than a year, Pfizer, BioNTech, and Moderna shattered expectations of what was possible within the industry.

Although there are many factors that contributed to the fast success of these vaccines, pharmaceutical companies were responsible in two distinct ways never before seen with other vaccines: the innovative mRNA technology took significantly less time for development compared to previous technologies, and development was carried out in parallel instead of the traditional linear timeline.

Relative to other types such as live-virus or attenuated vaccines, which require long periods to grow viral protein in cells, mRNA vaccines require much less time to create the genetic material responsible for viral protein production (Petri, 2020), an enormous advantage that gave Pfizer and Moderna the edge it had in the race to a vaccine. However, because these were the first mRNA vaccines to receive FDA authorization, as well as international attention, the atmosphere around these vaccines was marked with uncertainty. Clinical trials demonstrated that mRNA vaccines were no riskier or less safe than other vaccines (Petri, 2020), but public acceptance of this new technology was proving to be more difficult than expected. Anti-vaccine groups jumped at this opportunity to discredit the new technology, claiming its lack of maturity in research as a basis for its unsafeness, while some proportion of pro-vaccine private citizens shared a general sense of distrust towards what seemed unfamiliar.

With the urgency of the global pandemic, the development timeline of the COVID-19 vaccine looked vastly different compared to what was normal previously. The development of vaccines is broken into the following phases in order: three clinical phases (Phase I/II/III), regulatory review/approval, manufacturing, and quality control. The vaccine candidates are tested for various qualities across each phase, and because each phase is completed in succession, most candidates never reach later phases like manufacturing. With the launch of Operation Warp Speed, a partnership between the US government and the private sector to

accelerate the development of a COVID-19 vaccine, the former aided much of the work of the latter through financial funds (Petri, 2020), allowing for greater flexibility in how pharmaceutical companies developed manufacturing facilities. At-risk manufacturing, where vaccine doses are filled before Phase III trials are successful, was practiced by most pharmaceutical companies, who could now afford to take this riskier approach with the support of the government, who wanted vaccines to be immediately distributed as soon as a safe and efficacious candidate was found (Petri, 2020). This gave the perception that these phases were completed haphazardly, giving way for concern to grow about the validity of the clinical trials for these vaccine candidates.

Regulatory Agencies

Although there are several federal agencies that have a hand in delivering vaccines to the general public, by far the one with the most regulatory oversight is the FDA. The objective of the FDA is to protect public health by ensuring the safety, efficacy, and security of human drugs, among other medicines (from FDA.gov), which they do by reviewing materials presented by private companies and ensuring the product meets certain specifications. For example, clinical trials conducted during Phases I, II, and III are not conducted by the FDA, but by private groups such as pharmaceutical companies and independent research groups. The FDA simply oversees the manner and results of these clinical trials, checking that they abide by their standard of Good Laboratory Practices, as well as ensuring quality and safety within the products (FDA.gov). During the manufacturing development phase, private companies present to the FDA a Biologics License Application (BLA), a comprehensive submission detailing the whole progress completed thus far, which includes preclinical data, clinical data, manufacturing processes, and facilities.

The BLA is usually the last hurdle that companies must overcome before they are authorized to manufacture and distribute drugs across the states.

As mentioned previously, there are many factors that contributed to the rapid success of the COVID-19 vaccine. Due to the pandemic being a public health emergency, regulatory agencies played a part in this by exercising greater flexibility in their regulatory process. For example, in a press release dated February of 2021, the FDA announced that it would allow frozen vials of the Pfizer-BioNTech vaccines to be transported and stored in temperatures found in common pharmaceutical freezers, where it was previously required to be stored in ultra-low temperature freezers (FDA.gov). This lifted an immense burden off of the pharmaceutical companies producing the vaccines since a drawback to the mighty mRNA vaccine is its sensitivity to temperature. With the relaxed guidelines from the FDA, the pressure was off these companies to develop an appropriate cold supply chain that adequately transported and stored the mRNA vaccines, leading to greater supply.

The reaction of the general public to finding out that the FDA has been relaxing regulatory processes in the pandemic has been mixed. One side believes in the necessity of this strategic move by regulatory agencies, arguing that the pandemic has elevated the need for a vaccine as soon as possible. This group is characterized by having strong confidence in the work that the regulatory agencies conduct, which is to uphold and maintain the safety, quality, and efficacy of the vaccines. On the other hand, some believe that this regulatory flexibility has been a way for pharmaceutical companies to take shortcuts in the development of the vaccine, making them question whether it is a good idea to buy into the product. This group is characterized by having little confidence in the regulatory agencies and uses this argument to further their opposition to vaccines.

A common misconception about the FDA relaxing regulatory requirements is that pharmaceutical companies now had loopholes and shortcuts that allowed them to ease up on certain studies and tests. However, this is not the case. The burden of proof for demonstrating a certain protocol can be relaxed lies with the pharmaceutical companies, meaning it is still up to them to effectively prove to the FDA that the product they are producing is still just as safe, efficacious, and high-quality. For the Pfizer-BioNTech example previously mentioned, the joint companies submitted numerous data and trials to the FDA that demonstrated that their COVID-19 vaccines were still stable and effective after transporting and storing in alternative temperatures (FDA.gov). It was only after the agency reviewed this material that the FDA agreed to relax regulations, allowing for transportation and storage to happen in more flexible conditions.

Closure & Stabilization

The closure and stabilization of vaccines are interesting, because, as mentioned before, vaccines are effective insofar as the majority of the public buys into the technology. Once herd immunity is achieved through mass vaccination programs, protection of the public will be achieved, as enough vaccinated people will act as "buffers" to protect other members who cannot be vaccinated due to predisposing conditions.

An example of vaccines doing wonders for humanity is the polio vaccine. The polio vaccine is the first and only vaccine to have eradicated the disease it treats (CDC.gov). Once a deadly disease that caused paralysis and death across more than 35,000 Americans, after the polio vaccine was released in 1954 and a mass vaccination program was set into motion, polio was wiped off the face of the Earth. No new cases of polio have originated in the U.S. since 1979 (CDC.gov). This tremendous result only came because the general public had widely accepted

the polio vaccine to be the solution they desperately needed to escape this dire situation. The 1950s were marked as a time period where the public had a great deal of trust and confidence in the federal agencies, and local, and state health authorities to deal with the pandemic in an effective and scientific way (Gupta, 2020). It is even more incredible to note that, in the midst of the race to develop the polio vaccine, one of the worst pharmaceutical accidents in the history of the U.S. (Ruane, 2020) occurred – the Cutter Incident. This disaster was responsible for 40,000 cases of serious post-vaccination complications in children after the supposedly inactivated vaccine had been tainted with a live poliovirus (Ruane, 2020). Despite this incident, trust in authorities and science was much higher back then, as the polio vaccine was widely accepted once the proper authorization was released.

With the COVID-19 pandemic, the story has some remarkable differences compared to the polio pandemic. A significant contributor to this difference is the politicization of the virus and the vaccine itself. Back in the 1950s, it was widely accepted that the polio epidemic was a national issue and that the rollout of the vaccine was the only way to retrieve back the "normal days." This time around, the direness of the pandemic is often debated on national TV, as right-leaning political figures will understate the gravity of the situation, often undermining the work of agencies like the CDC (Ruane, 2020). This distracts the general public from trusting these medical authorities, making it even more difficult for vaccines to breakthrough.

Although a COVID-19 vaccine exists (and several others have gained approval from the FDA after Pfizer-BioNTech and Moderna), these vaccines are not the solution to the pandemic. Other vaccine candidates continue to go through clinical trials and FDA approval processes to this day, which means that more candidates will arrive on the market in the future. This can help to bring closure and stabilization to the COVID-19 vaccine, as the availability of wider options

can allow different groups to feel more comfortable and in control of their decision to be vaccinated against COVID-19.

Conclusion

The COVID-19 pandemic united the entire world, bringing every level of government, private companies, and different nations together in the pursuit of formulating a modern-day solution: a COVID-19 vaccine. With every vaccine comes an onslaught of criticism regarding its safety, efficacy, and quality of the vaccine. In the case of the mRNA vaccines produced from Pfizer-BioNTech and Moderna, however, the unique nature in which it was developed, as well as the internet connecting people from all over the world, gave way for it to receive more rejection and hesitancy than other vaccines.

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