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EDITORIAL

The Pogo-ization of Post-Pandemic Vaccine Policy

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"*We can draw lessons from the past, but we cannot live in it—Lyndon Johnson*

1 Introduction: "Post-Modern" Immunization Platforms

Currently, we have a post-pandemic window of opportunity for the public health community to take the plunge and lead the USA towards embracing immunizations or be bogged down in politics. As FDA Commissioner Dr. Robert Califf has pointed out, the battle over vaccines and other interventions is asymmetrical—between knowledge and ignorance [1]. There are many fronts and many players. The FDA has a bully pulpit, but talk is cheap, resources are scarce, and the unrestrained and well-resourced purveyors of misinformation and disinformation can play fast and loose with the truth, using social media as their mouthpiece. However, for America's public health community, there must be one goal – to have more people immunized. However, "moving the needle" can't just be about COVID-19 vaccinations.

COVID-19 was an opportunity, and the tip of the iceberg of an important public health teaching moment. In addition to ensuring any new immunization is safe, effective, and urgent, America's health care leadership has a golden opportunity to update our government systems—simplifying reviewing, approving, scheduling, and reimbursing vaccines and other immunizing agents. These and other updates are critical to inform public health policy, keep pace with evolving viruses, and re-tool systems to ensure access, and to incentivize health care providers.

In addition to keeping pace with evolving viruses and updating our reimbursement and implementation systems to ensure broad access to vulnerable populations, we must also keep pace with rapidly evolving non-traditional preventatives that can significantly reduce hospitalizations and serious outcomes. This means we must improve and adapt our scientific communication beyond the boundaries of professional journals and lobbyists—to barbershops, pulpits, pediatricians, and parent-teacher associations across America.

We do not want vaccination rates to return to their pre-pandemic levels—we want to improve upon those numbers. This is not about returning to the status quo—it's about changing public health behavior to fully, and enthusiastically, embrace the value of immunization. In the words of Edmund Burke, *"He who wrestles with us strengthens our nerves and sharpens our skill. Our antagonist is our helper."*

According to Dr. Peter Marks, Director of the FDA's Center for Biologics Evaluation and Research (CBER), "we have to do a better job communicating the best possible science supported by the best possible data." Through that basic formula, we can (i) restore high standards of science for all immunizations and (ii) devise and actively communicate twenty-first century scientific standards and guidance on innovative technologies (e.g., monoclonal "immunizing agents" to fight respiratory syncytial virus [RSV] in children). "Success" doesn't mean returning to pre-pandemic immunization rates, it means surpassing them. This is especially true when it comes to childhood vaccination rates.

2 Death by 1000 Cuts: The Penalty of Process Fouls

During the pandemic, the American public was introduced to many phrases unknown to the vast majority of people, with one of the most important being "emergency use authorization" (EUA) [2]. The "emergency" was clear—a deadly pandemic. Less clear was the distinction between an "authorization" and an "approval." This distinction-with-a-difference was especially contentious when it came

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to the two mRNA vaccines (and, shortly afterwards, their boosters). Mixed in with another term from the COVID-19 lexicon, "vaccine mandates," rhetorical regulatory precision, rather than clarifying and reassuring, resulted in confusion and suspicion that the FDA was using the general population as lab rats—even though nothing could be further from the truth.

The fact that we were able to field large placebo-controlled trials for all the COVID-19 vaccines (both mRNA and traditional technologies) should have been a terrific story of the health care ecosystem coming together in a time of crisis. But the reverse was the reality. The lack of basic social science and communication skills from (among others) U.S. Health and Human Services Secretary Xavier Becerra, the FDA, CDA, NIH, White House, and state public health authorities, was an inexcusable process foul. Sound science and solid partnerships were negatively impacted by poor communication. The FDA must embrace the necessity of social science and build the agency's capacity for it—and this cannot wait until the next PDUFA reauthorization in 2032.

In the shark-infested waters of post-pandemic health care policy, the FDA needs to "build a bigger boat."

Another process foul was the way in which both the FDA's Vaccines and Related Biological Products Advisory Committee [3] (VRBPAC) and the Centers for Disease Control's (CDC) Advisory Committee on Immunization Practices [4] (ACIP) publicly dickered and dithered over the appropriate population designations for both the initial vaccine roll-out and then proceeded to repeat the mistake with booster schedules, frustrating vaccine advocates and empowering vaccine antagonists. The result? Low booster rates. A smaller but significant process foul was the way that the Moderna bivalent booster data were presented to both FDA and CDC advisory committees. A self-inflicted wound among vaccine advocates that has been allowed to fester [5].

Another process botch came after a July 4th, 2021, Independence Day "super-spreader" event in Barnstable County, Massachusetts, where 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town during July 3–17; 346 cased (74 %) occurred in fully vaccinated persons [6]. The CDC introduced the term "breakthrough infection" into the COVID-19 vocabulary but buried the lead. The media headline from this story was that existing vaccines were ineffective. But the actual story was the complete opposite. Of the infected revelers, five patients were hospitalized, and no deaths were reported. This was real-world proof that the vaccines work—not by providing total immunity, but by radically mitigating the symptoms.

But that wasn't the published story. "Breakthrough infections" became the story. This self-inflicted social science wound was further exacerbated by President Biden who told the American public on July 21, 2021 that, "people who get their COVID-19 vaccines are completely protected from infection, sickness, and death from the coronavirus" [7]. While his statement was retracted by the White House and "clarified" by public health authorities, the story was in the public domain, resulting in a further erosion of trust in vaccine effectiveness, and reinforcing in the minds of many Americans that Uncle Sam's right hand didn't know what the left hand was doing.

After his election, President Biden regularly said that "science is back." Unfortunately, "following the science," didn't always happen. Before either the FDA's VRBPAC or the CDC's ACIP even voted on the Moderna bivalent booster, the White House was publicizing a national roll-out strategy. That strategy didn't work, and the reasons why Americans did not roll up their sleeves are attributable the above-mentioned process botches. The most common reasons for not receiving the bivalent booster dose were lack of awareness of both the eligibility for vaccination (23.2%) or the availability of the vaccine (19.3%), followed by the perceived lack of immunity against infection (18.9%) [8]. "Following the science" cannot be the chosen path only when it is politically convenient. According to one VRBPAC member, "The train had left the station before we voted."

3 "Populations" Versus "People"

Preventative programs work when they are adopted by "populations." A valuable lessons learned from the COVID-19 experience is that America's health literacy needs to be improved [9]. "Success" does not just refer to "how many people have been vaccinated," but what that looks like from the perspective of various at-risk populations. Our new national focus on issues such as health equity [10] is an opportunity to address this important public health priority. This is particularly germane when it comes to exciting new advances in treating RSV, the third leg of the current "tripledemic [11]. We must advance America's health literacy, for example, in recognizing the distinction-with-a-difference between "vaccines" and immunization "interventions" such as the new monoclonal antibody treatments that (just like vaccines) can significantly reduce hospitalizations and serious outcomes for at-risk populations [12]. This played out "live" at the February 23, 2022 meeting of CDC's ACIP where advisors and experts valiantly struggled with a myriad of implementation and reimbursement issues of adding a monoclonal for RSV into systems that were developed over 50 years ago; this in turn raised the specter of possible access and first-dollar coverage issues for underserved patients [13].

Technology and innovation need to be embraced for what they do (not what they are defined as) and implementation systems should be made flexible in order to ensure uptake

of any new preventive interventions in our public health toolbox.

4 The "Next Normal" of Immunizations

When it comes to vaccine development and public immunization strategies, the American health care ecosystem should not be chasing the "new normal," but rather the "next" normal because, when it comes to health care in general and immunizations in particular, there will never be a revised static "new" normal. What will always be just around the corner is *the next normal*. Stasis isn't always good, especially if you believe in the power of innovation. If we have learned nothing else from COVID-19 we should remember and embrace the warning of management guru W. Edwards Deming, who said, "it is not necessary to change. Survival is not mandatory."

5 Our Public Health Goal

For a host of childhood diseases from COVID-19 to annual influenza and RSV, immunization remains the foundation of our public health. We cannot define "victory" as returning to the pre-pandemic normal. Immunization rates for childhood diseases are abysmally low [14]. Many people inside the public health community believe that aggressively pursuing a more robust immunization education initiative is too risky because of the political environment [15]. Further, the public health potential of future interventions is also threatened as experts struggle with the integration of newer technologies (e.g., immunizing monoclonals) into outdated systems. A shift in our thinking from the effects of a preventive action versus its definition (i.e., immunizing monoclonals) is sorely needed if we are to keep pace with new viral threats.

Politics and outdated implementation systems aren't the "real" problems—pertussis, measles, mumps, and rubella are the problems and, frighteningly, polio is the problem. We don't have a moment to lose. In the words of Abraham Lincoln, "You cannot escape the responsibility of tomorrow by evading it today." Or, in the famous words of Pogo, "We have met the enemy and he is us."

Declarations

Conflict of Interest Statement The author reports no conflicts of interest.

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