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RSV Vaccines and the Pharma Playbook

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Introduction

In recent months public announcements have boldly proclaimed,

- **What to know about RSV, a virus surging among young children in Canada.**
- **Surge in RSV adds to pediatric hospital pressures.**
- **"This is Our COVID" – What Physicians Need to Know About the Pediatric RSV Surge.**

Whether or not these assertions regarding the Respiratory Syncytial Virus (RSV) are true, they are similar to the doom and gloom headlines that are fundamental to the promotion of any vaccine. They are the basic elements of a vaccine marketing campaign designed to elevate levels of dread, uncertainty, and despair, creating a sense of urgency leading to the approval and rollout of a vaccine candidate. This series of tactics, known to some as "The Playbook" were used flawlessly for the COVID-19 mRNA vaccines. Months of dire headlines regarding COVID-19 deaths and the upending of everyday life convinced most that a novel genetic injection developed at warp speed was indeed "the only way back to normal." Now that the effectiveness and safety of these COVID-19 mRNA shots are in question, it is reasonable to wonder how much of the recent panic regarding severe respiratory syncytial virus (RSV) infections in children is simply marketing hype leading to the release of phase 3 clinical trial data for Pfizer's new RSV candidate vaccine. The question is particularly pertinent because society has continued to survive and thrive without such a vaccine for the past sixty years.

Prior to discussing if The Playbook is being employed to justify RSV vaccines, details about RSV infections are relevant.

Respiratory Syncytial Virus Infections

RSV causes infections of the respiratory tract and lungs usually on a seasonal basis beginning in Canada in late fall and extending into early spring. RSV infections share similar signs and symptoms as the common cold, and their highly contagious nature ensures that 95% of children have had at least one infection by age 2.

A 2020 article in the Canadian Communicable Disease Report notes that surveillance studies are being conducted to assess the country wide impact of RSV infections. Until such investigations are completed it is not possible to determine what would constitute a surge in RSV infections.

RSV infections in healthy children are for the most part clinically uneventful. By using home supportive treatments for a cold, most RSV infections resolve within 10-14 days. For most sufferers, RSV infections are a common, relatively mild health nuisance associated with winter. Recurrences throughout a lifetime, and even within a single RSV season, are common.

However, some medically compromised children might be at greater risk of serious consequences from RSV infection. According to Public Health Canada, the risk of severe outcomes from RSV infection is higher among:

- Infants and young children under the age of 2.
- Children with chronic lung disease, congenital heart disease, compromised immune systems or neuromuscular disorders.

In these children, initial RSV infections can manifest as an influenza - like illness leading to symptomatic lower respiratory tract infections including pneumonia. While only a minority of overall cases of RSV infection require hospitalization, RSV is the single most common cause of respiratory hospitalization in infants.

In Canada, infants at risk of serious RSV infections have access to preventive treatment in the form of RSV neutralizing monoclonal antibody therapy from late fall to early spring which reduces by more than 50%, hospital admissions related to lower respiratory tract infections. A 2019 investigation noted that in Canada

during 2003 -2013, a total of 79 RSV associated infant deaths were recorded with 32 of these being attributable solely to an RSV infection. Given that RSV infections are mild, treatable, and very rarely fatal it is questionable if the created panic is truly warranted.

RSV and Vaccines

There are two major antigenic subtypes or groups of RSV, namely RSV/A and RSV/B. During an RSV infection season, viruses of both antigenic groups might be present, or one group might dominate to a lesser or greater degree. The viral variability of RSV infections and their tendency to involve immature immune systems are why developing RSV vaccines has been fraught with difficulties. More significantly, in the 1960s, an RSV vaccine given to children who had not been infected with RSV resulted in enhanced respiratory disease leading to serious illness and death. This legacy of vaccine - induced illness and a corresponding **acute need for vaccine safety have justifiably influenced and unquestionably delayed the development and launch of an RSV vaccine.**

That said, vaccines are among the "Holy Grail" of pharmaceutical products as their use in the healthy has been justified to protect the few who are at actual risk of serious illness. Vaccines are so lucrative that Bill Gates- a shareholder in vaccine manufacturing companies- through the Bill and Malinda Gates Foundation pledged $127.5 million dollars in 2019 to help develop maternal vaccines. By the mid 2019s- nine months before the declaration of the COVID-19 crisis- phase 3 clinical trials of various vaccine candidates for pregnant women, infants and children were undertaken including multiple RSV vaccine candidates.

Under normal circumstances, vaccine development requires 5 to 10 years of study to firmly establish safety prior to regulatory approval and widespread rollout. However, if a pharmaceutical company can convince regulators that there is an emergency by inducing "RSV hysteria" it is much more likely to secure conditional approval of its drug based on preliminary safety data.

The Playbook

The Playbook is a series of tactics employed at various stages of vaccine development to increase the chances of vaccine approval and adoption. These could include but are not limited to the following:

- Raise the general awareness of a virus having potentially lethal consequences in anticipation of releasing data on a new vaccine.
- Vigorously support the initial morbidity and mortality associated with the virus using anecdotal evidence.
- Exaggerate the frequency of infections by minimizing the importance of clinical symptoms and relying on non-validated tests.
- Encourage activism by funding special interest groups to raise disease awareness.
- Declare the vaccine as "safe and effective" based on preliminary data and encourage its use as a new standard of care.
- Unblind randomized trials as quickly as possible to prevent detection of long-term safety issues.
- Pressure governments to accelerate the vaccine's approval based on a perceived emergency.
- Encourage media, public health, health care professionals and academics to focus on vaccine equity instead of vaccine safety and informed consent.
- Develop charged words such as "anti-vaxxer" or "purveyor of misinformation" to neutralize those who question vaccine safety.

The manufacturers of the unique m-RNA vaccines have profited handsomely from many of these tactics. Determining if similar strategies are being used to promote the Pfizer RSV vaccine is therefore a necessary exercise.

RSV Vaccines and The Playbook

Unlike SARS-CoV-2, RSV is not a new virus. Its clinical signs and symptoms, mode of transmission, contagious nature and at-risk patients are well established. For

most patients, it is a relatively mild, seasonal, self- limiting virus, usually associated with uneventful infections prone to frequent recurrences. Under such circumstances, people would be justifiably hesitant about receiving a vaccine of questionable utility.

Headlines such as, **"Surge in RSV adds to pediatric hospital pressure"** and "**Kids are getting hit hard by respiratory viruses. Here's what scientists know-and what they don't know."**, although alarming are being given without supporting numbers, provide limited context and are based on low level evidence. They are tactics typical of The Playbook as they subtly distort and exaggerate the traditional disease burden of RSV infections among infants.

Timing of the headlines is also highly suspicious as there was little to no news of an RSV surge in the fall of 2021 when social restrictions were first lifted. However, RSV alarmism curiously peaked weeks prior to Pfizer announcing that its phase 3 clinical trials of the bivalent syncytial virus vaccine candidate of pregnant women successfully prevented serious RSV infections in infants up to 6 months of age.

While the possibility of an unprecedented surge in severe RSV infections prior to the release of the trial data cannot be ruled out, this type of media hype was favourable to Pfizer justifying expedited approval of its first in class vaccine candidate. It is most likely that the marked reduction in RSV and influenza cases in the first two years of the covid-19 pandemic due to social distancing, lockdowns, and other measures merely delayed infants and toddlers from contracting RSV, resulting in the reported apparent "surge" of cases.

Precautionary Principle and Prenatal Care

Pfizer will surely claim that this new vaccine is, "safe and effective" and will encourage pregnant women to receive the vaccine to protect their unborn children since- **it is better to be safe than sorry.** The painful awful experiences of

thalidomide and diethystilbestrol illustrated the dire consequences of adopting shortcuts to prenatal care by foregoing decades of careful study of drug safety.

A fundamental tenet of health care is- **First, do no harm.** This principle must never be compromised when caring for pregnant mothers. Traditionally, women have been encouraged to avoid medications during pregnancy. It is an ethical and moral imperative that drugs administered during pregnancy **must** have an established safety record and be of proven therapeutic value.

Conclusion

The Playbook has been a long-standing tool used by pharma to promote vaccine products. It has yielded tremendous financial success, especially through the COVID-19 crisis. In Canada, despite the hyperbole of headlines, there is insufficient evidence confirming a surge in RSV infections. It is more likely that the surge in exaggerated headlines has helped Pfizer develop a case for expedited vaccine approval.

The rush to develop RSV vaccines with their inevitable but unknown side effects and potential serious impacts on fetal development, must be balanced against the minimal inconveniences associated with mild RSV infections in children and the use of monoclonal antibody therapy to reduce frequency and severity of such infections among high-risk patients.

This exposure of the insidious nature of the Pharma Playbook should allow pregnant mothers and their health care providers to critically assess the need for, and safety of RSV vaccines. They must not permit the appeal of sophisticated advertising and media campaigns to jeopardize their health and, more importantly, that of their unborn child.