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Latest mRNA Vaccine for RSV Wins Expedited Review

Analysis by Dr. Joseph Mercola Fact Checked | February 09, 2023

STORY AT-A-GLANCE

- Moderna just moved one step closer to bringing mRNA-1345, an RSV shot, to market
- The U.S. Food and Drug Administration granted the experimental shot fast-track designation in August 2021
- Now, Moderna's mRNA RSV shot has been given Breakthrough Therapy Designation, which allows for faster development and an expedited review period
- RSV is usually not serious; most people experience only mild, cold-like symptoms and recover on their own in a week or two
- Moderna plans to file for FDA approval of mRNA-1345 in the first half of 2023
- Along with Moderna's mRNA RSV shot, Pfizer and GSK have also developed RSV vaccines that are awaiting regulatory approval

Get ready. A new mRNA shot is barreling down the runway and may be available as soon as fall 2023. This time, it's not to target SARS-CoV-2 but, rather, respiratory syncytial virus (RSV), a pathogen that typically causes mild cold-like symptoms.

Pfizer and Moderna are racing to bring their RSV shots to market, and Moderna just moved one step closer with its mRNA-1345. The U.S. Food and Drug Administration (FDA) granted the experimental shot fast-track designation in August 2021. Now, Moderna's mRNA RSV shot has been given Breakthrough Therapy Designation, which allows for faster development and an expedited review period.[1]

WEF Warns of RSV 'Tripledemic'

You may have seen RSV making headlines more often than usual this winter — in lock-step with the mRNA shots soon to be released to save us all from it. In November 2022, the World Economic Forum (WEF) warned RSV could cause a "tripledemic" along with COVID-19 and flu.[2]

It reported case numbers of RSV rising in the U.S. and Canada, because children weren't exposed to this and other common infections during COVID-19 lockdowns.[3] The U.S. Centers for Disease Control and Prevention also warned:[4]

> *"CDC surveillance has shown an increase in RSV detections and RSV-associated emergency department visits and hospitalizations in multiple U.S. regions, with some regions nearing seasonal peak levels. Clinicians and public health professionals should be aware of increases in respiratory viruses, including RSV."*

Still, RSV is usually not serious; most people recover on their own in a week or two. While it can lead to severe illness, including bronchiolitis and pneumonia, in infants younger than 1 year and older adults, almost all children have had an RSV infection by their second birthday[5] — and most recover from it just fine.

We saw from Operation Warp Speed how pharmaceutical companies and governments have bragged about the speed with which they can approve new shots, however. And the RSV shot is no different. At this point, the obligatory RSV propaganda seems perfectly timed to ramp up with the coming release of a new RSV jab.

Moderna's mRNA RSV Shot Is on the Way

The FDA granted Moderna's mRNA-1345 Breakthrough Therapy Designation based on a Phase 3 trial involving 37,000 adults aged 60 years and older.[6] The mRNA RSV shot had a reported efficacy of 83.7% against RSV-associated lower respiratory tract disease. Moderna plans to file for FDA approval of mRNA-1345 in the first half of 2023.[7]

The shot initially would be intended for adults aged 60 and over, but Moderna is also testing its mRNA RSV shot in children via an ongoing Phase 1 trial.[8] "With this designation, we look forward to productive conversations with the FDA in the hopes of bringing our RSV vaccine candidate for older adults to the market safely and quickly," Moderna CEO Stéphane Bancel said.[9]

Moderna's RSV shot uses the same lipid nanoparticle as its COVID-19 injection. The primary difference between the two shots is the coding of the mRNA. In the RSV shot, the mRNA encodes for a prefusion F glycoprotein. Prefusion F protein is a protein that mediates the RSV virus' entry into your cells and is known to elicit a neutralizing antibody response.[10]

Under normal circumstances, it's hard to imagine an RSV vaccine built on a novel mRNA platform getting fast-tracked, but we're no longer in normal times. The rollout of mRNA COVID-19 shots has, as predicted, paved the way for any number of new mRNA-based injections going straight to human trials. RSV is just the beginning.

Moderna Has 48 mRNA Shot Programs Underway

At the WEF's Davos Agenda 2022, at a session titled "COVID-19: What's Next?"[11] Bancel was open about Moderna's plans to combine multiple shots, such as a COVID-19 shot, a flu shot and RSV shot, into one injection — coming in 2023 — to avoid "compliance issues." He said:[12]

> *"The other piece we're working on is for 2023, is how do we make it possible from a societal standpoint that people want to be vaccinated?*
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> *And we're going to do this by preparing combinations, we're working on the flu vaccine, we're working on an RSV vaccine, and our goal is to be able to have a single annual booster, so that we don't have compliance issues, where people don't want to get two to three shots a winter, but they get one dose, where they get a booster for corona, and a booster for flu and RSV, to make sure that people get their vaccine."*

When asked how soon this would occur, he continued:[13,14]

> *"So the RSV program is now in Phase 3, the flu program is in Phase 2 and soon in Phase 3, I hope as soon as second quarter of this year. So the best case scenario would be the fall of 2023, as a best case scenario …"*

At the 2023 WEF meeting in Davos, Bancel again spoke about mRNA shots, this time stating he'd "like to have mRNA capacity on every continent."[15] It seems they're well on their way.

As of January 2023, Moderna has 48 programs in development, including "36 programs in clinical trials encompassing investigational mRNA infectious disease vaccine candidates and mRNA therapeutic candidates spanning seven different modalities."[16] In a news release, Bancel reported:[17]

> *"Applying our experience and using our mRNA platform, we are developing vaccine candidates that we believe could one day help prevent hospitalizations and deaths from some of the most prevalent respiratory viruses.*
>
> *We are also progressing several respiratory vaccine candidates, including combination vaccines against multiple respiratory viruses, and are committed to building our respiratory franchise.*
>
> *By pursuing combination products to protect against a range of diseases, we believe that we can potentially help decrease morbidity and mortality from respiratory disease, lower healthcare costs and increase health security globally."*

Moderna Made mRNA 'Breakthrough' Right Before Pandemic

The Pentagon's secretive Defense Advanced Research Projects Agency (DARPA) has been working for years to develop an antibody to any virus within 60 days of collecting blood from a survivor.[18]

Its Pandemic Prevention Platform program, known as P3, "aims specifically to develop a scalable, adaptable, rapid response platform capable of producing relevant numbers of doses against any known or previously unknown infectious threat within 60 days of identification of such a threat in order to keep the outbreak from escalating and decrease disruptions to the military and homeland."[19]

DARPA also lunched ADEPT:PROTECT (Autonomous Diagnostics to Enable Prevention and Therapeutics: Prophylactic Options to Environmental and Contagious Threats) to develop technologies — like mRNA — that can be rapidly deployed against emerging infectious diseases and biological weapons.[20]

It was September 2019 when Moderna announced it had developed mRNA-1944 — the first systemic mRNA therapeutic to show production of a secreted protein in humans — courtesy of financial support from DARPA's ADEPT:PROTECT program.[21] Months later, the COVID-19 pandemic would result in the development of the first experimental mRNA gene therapy, which has been distributed among the masses. The Highwire reported:[22]

> *"With uncanny foresight, Moderna's expeditious mRNA endeavor … had immediate manufacturing support from the Coalition for Epidemic Preparedness Innovations (CEPI) to ensure the pandemic's gene-editing jabs traversed the globe. Significantly, CEPI was founded in 2017 by the WEF, the Bill & Melinda Gates Foundation, the Wellcome Trust, and the governments of Norway and India.*
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> *Aligned with the same goals as DARPA, CEPI is a global syndicate of public-private organizations whose mission is to highlight pandemic threats, continuously prepare for the next "Disease X," and advance vaccines.*
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> *Presently, over 13 billion doses of COVID-19 vaccines have been administered worldwide. With vaccine manufacturers protected from liability, evidence increasingly indicates that mRNA injections are not just failing but, more significantly, are causing many serious adverse events, including myocarditis, increased risk of cancer and stroke, and death."*

Will mRNA RSV Shots Trigger a Public Health Disaster?

Past attempts to develop RSV vaccines have ended in tragedy, particularly in the 1960s. In a trial on infants, two babies died after first appearing to tolerate the shot. The problem occurred during the following cold and flu season, when 80% of those vaccinated caught RSV and had to be hospitalized. Only 5% of those who received the placebo shot were hospitalized for RSV.[23]

The issue is antibody-dependent enhancement (ADE), a problem that's also occurred in the development of coronavirus shots. In 2020, Timothy Cardozo of NYU Langone Health and Ronald Veazey with the Tulane University School of Medicine set out to determine if enough research existed to require clinicians to disclose the specific risk that COVID-19 shots could worsen disease if the recipient is exposed to circulating virus — similar to what occurred in the RSV trial.

They reviewed preclinical and clinical evidence, which revealed that ADE is a significant concern, noting:[24]

> *"COVID-19 vaccines designed to elicit neutralizing antibodies may sensitize vaccine recipients to more severe disease than if they were not vaccinated. Vaccines for SARS, MERS and RSV have never been approved, and the data generated in the development and testing of these vaccines suggest a serious mechanistic concern:*
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> *… that vaccines designed empirically using the traditional approach (consisting of the unmodified or minimally modified coronavirus viral spike to elicit neutralizing antibodies), be they composed of protein, viral vector, DNA or RNA and irrespective of delivery method, may worsen COVID-19 disease via antibody-dependent enhancement (ADE)."*

They concluded that, in order to meet medical ethics standards of informed consent, people who receive COVID-19 shots should be clearly warned of the "specific and significant COVID-19 risk of ADE."[25] This didn't happen, and it likely won't for RSV shots, either.

More RSV Shots in the Pipeline

Along with Moderna's mRNA RSV shot, Pfizer and GSK have also developed RSV vaccines that are awaiting regulatory approval. Pfizer is even targeting its RSV shot to pregnant women, claiming it can help prevent RSV in newborns. While Moderna is also planning trials in pregnant women, GSK stopped its pregnancy trial in 2022 due to safety concerns.[26]

But no matter which pharmaceutical company ends up being first to bring it to market, the RSV vaccine is clearly on the way. It could potentially be available by fall 2023, and the way RSV was hyped over the winter, it likely won't be long before this shot moves beyond the older people target and expands to infants and children, becoming another requirement on the official vaccine schedule.

But considering the multitude of problems associated with the mRNA COVID-19 shots, I'm not optimistic about the development of a fast-tracked mRNA shot against RSV. The risks of these experimental, fast-tracked shots are serious, while, in most cases, RSV is not.