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The Honorable Julie VanOrden

Chair, Senate Health & Welfare Committee
Idaho State Senate
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Dear Chair VanOrden and Committee Members,

On behalf of the Alliance for mRNA Medicines (AMM), thank you for the opportunity to offer our perspective on SB 1346, a bill to establish a moratorium on mRNA products in the state of Idaho.

Opposition to SB 1346

SB 1346 would place a two-year moratorium on the administration of “human gene therapy products for any infectious disease indication to a child under eighteen (18) years of age or a woman who is pregnant, regardless of whether such administration is termed an immunization, vaccine, or any other term.”

The Alliance for mRNA Medicines (AMM)¹ opposes SB 1346, as the legislation would:

- 1) Restrict the ability of Idahoans to choose mRNA-based medicines and interfere in the doctor-patient relationship**
- 2) Incorrectly classify mRNA vaccines as “human gene therapy products”**
- 3) Adversely impact individuals seeking innovative treatments and harm the broad community of companies and academic researchers driving mRNA research and development in Idaho and across the nation**
- 4) Require Idaho to create a “shadow FDA”, at great cost to taxpayers, to evaluate whether products should be exempted from the moratorium**
- 5) Harm national security by limiting access to lifesaving mRNA medicines**
- 6) Undermine the legacy of President Trump’s leadership in Operation Warp Speed**

¹ ***About the Alliance for mRNA Medicines:*** The Alliance for mRNA Medicines (AMM)¹ is the leading global organization dedicated to advancing and advocating for mRNA and next-generation encoding RNA therapeutics and vaccines for the benefit of patients, public health, and society. Our mission is to propel the future of mRNA medicine, improve patients’ lives, and advance scientific knowledge by convening and empowering mRNA industry leaders, innovators, scientists, and other key stakeholders. AMM’s membership, which is composed of over 90 organizations, consists of biotechnology companies, biopharmaceutical companies, contract development and manufacturing organizations (CDMOs), suppliers, raw material providers, and academic researchers.



Further explanation of AMM's concerns about SB 1346:

1. *SB 1346 would restrict the ability of Idahoans to choose mRNA-based medicines and interfere in the doctor-patient relationship*

As noted earlier, this legislation would take away choices from patients particularly vulnerable to infectious diseases, including pregnant women, immunocompromised individuals, and the elderly. National research published in the *Journal of General Internal Medicine* found that during the Delta and Omicron waves, a significant portion of the more than 599,000 excess deaths recorded nationwide could have been averted with higher vaccination rates — with states that had lower vaccination rates, like Idaho, faring considerably worse than those with higher rates [1]. Idaho's 13 confirmed measles cases in 2025 — all in unvaccinated or unverified children — with new cases continuing into 2026 [2], drives home the importance of giving people the option to vaccinate themselves and their families against infectious disease.

The bill's moratorium encompasses “all products that mediate their effects by transcription or translation of transferred genetic material.” This extends far beyond COVID-19 vaccines to capture virtually every nucleic acid-based medical product for infectious disease. Its practical effect is not to protect Idaho families but to remove their freedom to choose:

- **mRNA vaccines for RSV.** Respiratory syncytial virus is the leading cause of infant hospitalization in the United States [3]. Multiple mRNA-based RSV vaccines are in advanced clinical trials for pediatric populations. If these vaccines receive FDA approval and this bill is law, Idaho parents, unlike parents in every other state, will not have the option to protect their infants with the best available medicine.
- **Next-generation mRNA influenza vaccines** that promise faster, more effective protection for children [4]. Idaho families would be denied access to these products regardless of their own assessment of risk and benefit.
- **Viral-vector vaccines** for diseases like Ebola, and an entire frontier of nucleic acid-based therapeutics for antibiotic-resistant infections and emerging pathogens [5].

The bill exempts cancer and genetic disorder treatments but draws no parallel carve-out for serious or life-threatening infectious diseases. A child with a devastating infectious disease who could benefit from an advanced nucleic acid-based therapeutic would be denied access, not because the treatment is unsafe, but because the disease is classified as infectious rather than genetic. The decision about whether to accept that risk should belong to Idaho families and their physicians, not the state legislature.

Equally consequential, the bill's prohibition on mRNA products for pregnant women would sever a critical pathway for protecting newborns: maternal immunization. Vaccines administered during pregnancy generate antibodies that cross the placenta and protect infants during their most vulnerable first months of life [6]. The FDA approved Abrysvo, a protein-based RSV vaccine, for administration during pregnancy for exactly this purpose [7]. mRNA-based



maternal RSV vaccine candidates are in clinical development. A 2022 study in *Nature Communications* found no evidence of mRNA vaccine products in maternal blood, placenta tissue, or cord blood at delivery, and no infants had a fetal immune response to Spike protein, confirming that mRNA itself does not reach the fetus [8]. A 2023 placental explant study confirmed minimal mRNA uptake and no inflammatory response in human placental tissue exposed to mRNA vaccines [9]. The bill's provisions do not protect children in the womb — they eliminate a mechanism designed to protect children after the womb, when they are most at risk, and they strip expectant mothers of the right to make that choice for their families.

While this legislation seeks to narrowly define the scope of prohibited mRNA medical products, it fails to recognize that mRNA technology is highly versatile. The same research methods and platforms used to develop mRNA-based therapies for infectious diseases are also essential for creating vaccines and treatments for cancer and rare diseases. Any legislation that restricts the use of mRNA medicines—even those targeted at specific products—will ultimately undermine patient care and the future development of new medicines for a range of deadly diseases.

2. SB 1346 incorrectly classifies mRNA vaccines as “human gene therapy products”

SB 1346 incorrectly classifies mRNA vaccines as “human gene therapy products.” Messenger RNA vaccines deliver a temporary set of molecular instructions to cells; they do not integrate into the recipient’s genome.

In 1960, an American scientist discovered that the body naturally produces billions of mRNAs. mRNA medicines use our bodies’ natural ability to make proteins to fight disease. For decades, America’s researchers have tested mRNA-based therapies in placebo-controlled, double-blind studies to prove they are safe and effective—the same gold standard used for all new medicines. mRNA medicines do not change or interact with your DNA. In fact, mRNA medicines utilize your body's natural ability to produce proteins to combat disease. The mRNA stays on the outer part of your cells and never enters the nucleus, where your DNA lives. Once the mRNA has delivered its message and your body creates the corresponding protein, the mRNA breaks down and naturally exits the body.

3. SB 1346 would adversely impact individuals seeking innovative treatments and harm the broad community of companies and academic researchers driving mRNA research and development in Idaho and across the nation

This bill would stifle research on mRNA medical products that is already happening in the state. Idaho is home to clinical trials for mRNA products in the following locations:

- **Beacon Cancer Care (Post Falls) – Non-Small Cell Lung Cancer**
- **Bingham Memorial Hospital (Blackfoot) – Flu, RSV**
- **Clinical Research Prime (Idaho Falls) – Norovirus, RSV**



- **Clinical Research Prime (Rexburg) – RSV**
- **Snake River Research (Idaho Falls) – RSV**
- **Velocity Clinical Research (Meridian) – COVID, Flu, Norovirus, RSV, Epstein-Barr Virus**

This has an impact not just on patients, but on the economy. A comprehensive market analysis conducted by our organization in partnership with User Cue [10] found that companies working in mRNA currently employ an average of 328 employees, (ranging from 2 to 6,000) with budgets of less than a million to greater than \$250 million. Roughly two-thirds (66%) of mRNA jobs are based in the United States. The report concluded that “mRNA technology is at an important developmental stage. The research demonstrates unequivocally that mRNA technology represents a transformative platform with substantial healthcare and economic implications. With appropriate policy support, mRNA can strengthen American biotechnology leadership, generate high-value employment and manufacturing, enhance national security preparedness, and deliver innovative therapeutic approaches for patients with limited treatment alternatives. Without strategic support, innovation activities will likely migrate internationally, potentially redefining the United States' position from innovation leader to technology recipient.”

4) SB 1346 would require Idaho to create a “shadow FDA”, at great cost to taxpayers, to evaluate whether products should be exempted from the moratorium

SB 1346 includes a provision allowing the legislature to approve mRNA vaccines through exemptions. With respect to the members of this Committee, no legislator in Idaho — or any other state — possesses the scientific and regulatory expertise required to evaluate the safety and efficacy of a vaccine. That is not a criticism; it is simply a reflection of how extraordinarily complex and specialized this work is. The FDA employs thousands of scientists, physicians, biostatisticians, and regulatory experts and conducts a thorough independent review before approving any vaccine for use. Replicating even a fraction of that capability at the state level would require Idaho to establish, in effect, its own drug regulatory agency — a “shadow FDA” — at a cost of tens of millions of dollars annually, with no guarantee of scientific credibility or legal defensibility.

The science of vaccine approval is not a matter of political judgment — it is a matter of evidence, methodology, and years of specialized training. Subjecting that process to legislative vote would be the equivalent of asking the Idaho Senate to rule on the findings of a Phase 3 clinical trial. The exemption provision in SB 1346 does not solve this problem; it simply creates an unworkable and potentially dangerous workaround that invites political considerations into decisions that must remain grounded in science. Idaho taxpayers deserve neither the cost nor the risk of that approach.

5. SB 1346 would harm national security by limiting access to lifesaving mRNA medicines



Restricting mRNA medicines in Idaho is not only a public health concern — it is a national security concern. The same mRNA platform that produced COVID-19 vaccines represents America’s most powerful defense against biological threats, including engineered bioweapons. Modern advances in synthetic biology and artificial intelligence have dramatically lowered the barrier to designing dangerous pathogens. Adversaries can now develop and deploy engineered biological agents in weeks, while traditional countermeasures can take years to develop. mRNA technology is the only medical platform that can match that pace: once a pathogen’s genetic sequence is identified, an mRNA countermeasure can be designed in a matter of hours.

American leadership in mRNA research is therefore not just an economic advantage — it is a strategic one. State-level restrictions on mRNA medicines directly undermine this national security posture. They discourage the private-sector investment and clinical research activity that sustains America’s mRNA innovation base.

Senior officials from President Trump’s own first administration have been unequivocal on this point. Dr. Brett Giroir, who served as Assistant Secretary for Health, explained “mRNA platforms enable medical researchers to design targeted interventions in days and manufacture them within weeks. This speed and precision in delivering instructions that train immune systems to recognize and eliminate threats – from COVID to cancer – provides America a critical weapon against pandemics, bioweapons and other deadly diseases that could affect American families.” [11] Dr. Jerome Adams, Trump’s Surgeon General and a key participant in Operation Warp Speed, was equally direct, writing in a Washington Post op-ed that “abandoning mRNA for antiquated technology is a national security disaster”. [12] SB 1346 would compound that damage within Idaho’s borders, sending a signal to researchers, manufacturers, and investors that the state is hostile to the very technology that keeps America safer.

6. SB 1346 would undermine the legacy of President Trump’s leadership in Operation Warp Speed

Finally, restricting access to certain mRNA medicines would also undermine the legacy of President Trump’s leadership in Operation Warp Speed, which saved lives and catalyzed American leadership in mRNA research. The research foundation built by Operation Warp Speed has played a central role in advancing the next generation of life-changing medicines and creating new jobs. Turning our backs on that legacy now would be a disservice to American patients and workers.

Conclusion

AMM thanks the members of the Committee for holding this hearing to discuss this legislation. This hearing is an important part of a larger, ongoing discussion taking place across the country about the value of vaccines and our government’s response to the recent pandemic. There is no question that mistakes were made then, including mistakes that overpromised the benefits of



vaccination, downplayed the risks, and imposed coercive mandates on the American people. We share those concerns and believe we need to learn from these mistakes to be better prepared in the future.

At the same time, we should not abandon what President Trump once called an “American medical miracle.” Continued support for mRNA technology can help more patients fight serious diseases, create good-paying jobs, and preserve America’s global leadership in medical innovation. We hope you will consider the harmful impacts this legislation would have on this state and its citizens.



Appendix 1: Background Information

What are mRNA medicines?

Messenger RNA, or mRNA, is a natural molecule found in every cell in the human body that carries instructions for making proteins essential to health and disease prevention. mRNA medicines work by delivering instructions that prompt cells to produce specific proteins that create an immune response to fight or prevent illness. After a protein is made, the mRNA naturally breaks down and leaves the body, while the therapeutic effect remains. Researchers have spent more than 60 years preparing the science and infrastructure for mRNA technology which is unlocking new treatment options across a wide range of life-threatening illnesses, including cancer, infectious diseases, rare diseases, and genetic conditions.

Why mRNA medicines matter to patients

mRNA therapies help keep Americans healthier and living longer. Many mRNA therapies offer a highly targeted approach to treatment. Because they are based on natural processes in the body, these treatments may cause fewer side effects than other treatments like chemotherapy. For some patients, an mRNA medicine could be the only treatment option.

mRNA is highly versatile. The same mRNA platform used to develop cancer treatments is utilized for vaccines and rare disease therapies. Limiting access to certain mRNA therapies will not only leave people exposed to infectious diseases, it also will harm the pipeline and manufacturing capacity for future mRNA therapies targeting other diseases.

People should be free to choose the best available treatments for themselves and their families. By encouraging further mRNA research, we provide Americans more options to stay healthy and live longer, more productive lives. The government should not be in the business of picking winners and losers, deciding which patients can receive a potentially life-saving treatment and which patients cannot. Everyone deserves the freedom to consult with their doctor and make the best health decision possible.

Decades of research have shown that mRNA therapies are safe and effective. In 1960, an American scientist discovered that the body naturally produces billions of mRNAs. mRNA medicines use our bodies' natural ability to make proteins to fight disease. For decades, America's researchers have tested mRNA-based therapies in placebo-controlled, double-blind studies to prove they are safe and effective—the same gold standard used for all new medicines.

mRNA medicines undergo robust and comprehensive clinical testing, rigorous independent and FDA review processes, and ongoing safety monitoring. Like any treatment or developed drug, health authorities closely monitor mRNA medicines to ensure continued safety and efficacy.



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mRNA medicines do not change or interact with your DNA. In fact, mRNA medicines utilize your body's natural ability to produce proteins to combat disease. The mRNA stays on the outer part of your cells and never enters the nucleus, where your DNA lives. Once the mRNA has delivered its message and your body creates the corresponding protein, the mRNA breaks down and naturally exits the body.

Investing in mRNA medicine maintains America's global leadership in medical innovation. The U.S. is the world leader in drug development, and we should not cede our competitive advantage to other nations. Investing in mRNA protects our economic and national security interests and the ability to provide breakthrough care for patients, so Americans are not overly dependent on medicine from other countries.



Appendix 2: References

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