**III. TECHNICAL CONTEXT: STERILIZING IMMUNITY AND REGULATORY DEFINITIONAL SLIPPAGE**

The concept of *sterilizing immunity*—the complete elimination of a pathogen before it can replicate in the host1—has long served as the gold standard for vaccine evaluation. Yet no vaccine has ever been 100% effective in achieving it2. This is not a new insight. In fact, when the CDC revised its public definition of "vaccine" in **September 2021**, its stated reason—quoted in an AP fact check—was precisely that2:

“The previous definition could be interpreted to mean that vaccines were 100% effective, which they never have been”.

That statement is *technically correct*. Even among traditional vaccines, real-world performance varies. Consider the **mumps component** of MMR: outbreaks today occur *primarily among vaccinated populations*3, and immunity is known to wane substantially after 20–30 years4,5. A 2022 review noted that even two doses conferred only **88% median effectiveness**5, with lower efficacy against circulating genotype G strains6. Similarly, studies comparing natural infection with measles versus vaccination show longer-lasting immunity from wild-type exposure than from the vaccine7.

What’s important is that these limitations were *known*—and yet, under the pre-2021 definition8–10, these products were still considered vaccines, because they very often **prevented transmission** and **reliably induced long-term protection**, even if not perfectly.

That’s what changed in 202111.

**The Direction of Definition: From Immunity to Protection**

Until 2021, the CDC defined a vaccine as:

“a product that stimulates a person’s immune system to produce immunity to a specific disease” (2015-August 2021 definition)8–10

After the September revision:

“a preparation that is used to stimulate the body’s immune response against diseases”11

This change is subtle but profound. "Immunity" implies a system state—resistance to infection. "Response" merely implies a reaction. As regulatory language, that shift **relaxes the evidentiary burden**. It enabled the introduction—and mass authorization—of COVID-19 biologics that reduce symptom severity but **do not block infection or transmission**.12

**A Break from Historical Baseline**

Traditional vaccines weren’t 100% sterilizing, but many came close:

* **Smallpox vaccine**: >97% retained protective titers decades after inoculation13
* **OPV (oral polio vaccine)**: Provided mucosal immunity14, drastically reducing community transmission. Referred to as “close to the ideal of sterilizing immunity” in intestinal challenge studies15
* **Measles vaccine**: 99.6% vaccine effacay (VC) after two doses16 in a 10 yr longitudinat study with 2-5 year olds; long-term observational data show protection approaching natural immunity in scale if not duration. Notably the VE declined significantly in the older cohort 26-31 years old with a 91.4% VE16

By contrast, a 2023 meta-analysis published in *JAMA Network Open* pooled 40 high-quality studies and found that **vaccine effectiveness against Omicron symptomatic disease was <20% at 6 months**, and <30% even after boosters17. This is not "protection" as the public understands it. Under the pre-2021 regulatory framing, a biologic with this performance profile would not plausibly be labeled a vaccine.

Yet by replacing “immunity” with “response,” it now qualifies.

**What the Change Enabled**

New vaccine concepts have emerged that wouldn’t have met earlier standards. One example is a 2024 white paper by Arunachalam proposing **“homeostatic immunity”**, where vaccines are designed to *modulate* the immune system—not eliminate pathogens. The author explicitly frames this in terms of CDC’s new “protection” model, not sterilization18.

“Vaccines generate Goldilocks immunity, balancing pro- and anti-inflammatory signals…” — *Arunachalam (2024)*

This is a fascinating and potentially powerful approach. But it would not have satisfied the historical understanding of a vaccine. Don’t harangue him for what sounds like a cool idea.

**From Technical Precision to Legal Drift**

This definitional slippage has consequences beyond terminology:

* **Statutory requirements** for vaccines under Section 351 of the Public Health Service Act (“safe, pure, and potent”) remain unchanged19—but the interpretation of “potent” has drifted from immune prevention to clinical modulation
* **Mandates and liability shields** historically depended on public understanding that vaccines prevent transmission
* **Public trust**, built on products that stopped outbreaks cold, is now extended to products that do not

**Conclusion**

No vaccine was ever perfectly sterilizing. But most were good enough that the **colloquial understanding** of a vaccine—something that keeps you from getting or spreading a disease—remained broadly true.

That is no longer the case.

The CDC’s 2021 definition change opened the gate for a different kind of product—one that would never have met the evidentiary bar of “immunity,” but can now pass under the softened standard of “response.”

It wasn’t the pathogen that changed. It was the word.

**Footnotes / References (Nature Format)**

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