ClearView Convos: Navigating an Evolving Vaccine Landscape

Executive Summary

Amid ongoing uncertainty in the U.S. vaccine landscape, ClearView convened leaders from our Vaccines Center of Excellence for a panel discussion on the evolving vaccine regulatory ecosystem and impact on vaccine commercialization as part of our new ClearView Convos digital series.

The discussion (Part 1 / Part 2), moderated by Sam Ulin (Partner) and featuring insights from Andrew Kang (Managing Director), Kai-Ming Pu (Partner), and Seth Berman (Partner), explored the implications of shifting CDC and ACIP policies, the challenges facing vaccine manufacturers, and the increasing need for proactive engagement with a range of stakeholders to ensure continued vaccine access and innovation.

Shifting Regulatory and Advisory Dynamics

The U.S. vaccines landscape is experiencing pronounced change. Among recent developments was the complete overhaul of ACIP membership[1] and the cancellation of a substantial amount of vaccine funding (i.e., nearly $500 M in funding for mRNA vaccine research and development, as well as $300 M for GAVI[2]).

The shifts continued with adjustments to several vaccine recommendations:

- ACIP and CDC now recommend that COVID-19 vaccination should be informed by shared clinical decision-making between individuals and their healthcare providers for people six months and older, departing from universal booster recommendations[3,4]
- CDC now recommends that toddlers receive varicella as a standalone immunization and not in combination with the measles, mumps, and rubella (MMRV) vaccine[4]
- ACIP committee members voted 8-3 in September 2025 to no longer recommend the MMRV vaccine in children under four years of age[5]

Key members of the administration and new ACIP members have signaled potential for additional changes to vaccine regulatory policy. For example, statements[6] have suggested the possibility of requiring placebo-controlled trials for regulatory approval and/or recommendations for new vaccines. A more recent public statement[7] hinted at the possibility of requiring aluminum to be removed from vaccines.

These dynamics have contributed to growing uncertainty and risk across the vaccines market, creating complications for the future development, access, and commercialization of both established and novel vaccines.

Challenges for Vaccine Manufacturers and Investors

The majority of changes instituted or proposed by ACIP and others in the administration are suggested to be in relation to safety concerns. While no explicit regulatory guidance has been defined for the development of future vaccines based on these concerns, the safety bar is unquestionably being raised.

First, and most notable, is the proposal for placebo-controlled vaccine trials. While this is expected to have limited impact for the development of vaccines targeting diseases without a currently available vaccine – trials for such vaccines often include a placebo control arm already – significant uncertainty persists regarding development of next-generation vaccines (e.g., pneumococcal, flu, RSV). Historical precedent for next-generation vaccines has entailed non-inferiority against an active vaccine comparator. Forgoing this approach in favor of a placebo control arm would likely lead to ethical concerns for needlessly exposing individuals to disease when a preventative measure is available. From a logistical perspective, this could create substantial recruitment challenges, as participants may be reluctant to enroll in studies where they risk assignment to the placebo group. Additionally, it would become more difficult to compare newer vaccines to previously marketed vaccines without a head-to-head studies.

Another implication, most relevant to novel vaccines, is the potential requirement for a substantially larger safety database pre-approval and more comprehensive ongoing real-world evidence collection post-approval. Such changes could meaningfully increase late-stage development costs as well as post-launch monitoring expenditures. Moreover, development timelines could be extended, increasing the time to launch. Overall, the economics of vaccine development could be meaningfully negatively impacted.

These uncertainties and hurdles may ultimately deter investment in vaccine research and development. Large pharma companies may decide to invest their resources in other, non-vaccine opportunities. Additionally, if external access to capital contracts for vaccines, it may not be possible for biotech companies to fund the large-scale clinical trials and commercialization activities necessary to develop and launch a new vaccine. Ultimately, the combination of increased costs, extended timelines, unpredictable regulatory outcomes, and increasing difficulty accessing capital has the potential to dramatically curtail innovation in the vaccine space.

Future U.S. Vaccine Access and Commercialization Considerations

Due to the increasing difficulty in predicting future ACIP and CDC decisions, manufacturers must consider scenarios in which an approved vaccine may not receive a recommendation from vaccine regulatory bodies and the associated favorable access. For example, if CDC determines more vaccines should be considered via shared clinical decision-making, manufacturers will increasingly need to engage directly with key stakeholders to ensure inclusion in immunization programs and insurance coverage.

Specifically, manufacturers may seek to engage medical societies, key opinion leaders (and other clinical champions), payer organizations, and governmental stakeholders earlier and more frequently over the course of vaccine development. In so doing, a vaccine may be incorporated into medical society guidelines (e.g., IDSA) that can fill gaps left by vaccine agencies such as CDC. This can increase the probability of securing favorable access and reimbursement with payers, and it can enhance clinician and consumer willingness to use the vaccine. Historical precedents, such as HIV PrEP products, illustrate that payer coverage for preventative infectious disease products can be achieved outside the traditional ACIP/CDC recommendation pathway.

Many states are also now issuing independent vaccine recommendations or creating pathways to enable continued access to vaccines. One such example is the unified recommendations for COVID-19, influenza, and RSV issued by California, Oregon, Washington, and Hawaii as part of the West Coast Health Alliance, which anchor to independent medical organization guidelines (e.g., AAP, AAFP, ACOG) amid narrowing federal vaccine recommendations[8]. The shift toward focusing on independent assessment of medical organization guidelines as opposed to federal guidance (i.e., CDC, ACIP) to inform state vaccine recommendations is broad and has been reported in 22 states to date[9]. Consequently, manufacturers may need to contend with a more fragmented stakeholder set that requires evolving and/or bespoke commercial activities.

Conclusion and Outlook

The U.S. vaccines ecosystem stands at a pivotal juncture. Shifts in regulatory and health policy have created uncertainty, requiring manufacturers to rethink traditional approaches for clinical development and commercialization of vaccines. Manufacturers and innovators are encouraged to strengthen their engagement with medical societies, key opinion leaders, payer organizations, and government stakeholders to ensure vaccine data and benefits are effectively communicated beyond the CDC in order to sustain broad vaccine access and adoption in an increasingly challenging and unpredictable regulatory environment.

Success in this environment will require:

- Rigorous scenario planning
- Broader engagement with medical societies, clinician champions, payer organizations, and government stakeholders Rigorous scenario planning
- Bespoke medical, commercial, and payer strategies tailored to fragmented ecosystem

ClearView Healthcare Partners continues to monitor these developments and is committed to providing actionable insights to support vaccine innovation and access in a rapidly evolving landscape. To learn more about ClearView Healthcare Partners and explore other emerging trends and hot topics in the life sciences discussed in the ClearView Convos digital series, please visit our website and our ClearView Convos podcast page.

Sources

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About ClearView Healthcare Partners

Founded in 2007, ClearView Healthcare Partners is a global strategy consulting firm serving the life sciences sector, with offices in Boston, New York, San Francisco, London, and Zurich ready to support clients in complex engagements with local expertise.

ClearView combines international industry knowledge and deep scientific expertise in every major therapeutic area and across modalities with an extensive network of external stakeholders to deliver practical and actionable recommendations. ClearView's projects include cross-functional support at the corporate, franchise, and product levels for pharmaceutical, biotech, medtech and digital, and diagnostics companies, along with investment support across all phases of the transaction cycle for private equity and institutional investors.

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