CAPITOL STREET

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Federal Vaccine and Prevention Policy Remain at Risk

USPSTF, VICP Next Targets; Legal Challenge to RFK Moves this Fall

Relevant Companies

Our Take & Next Up

The Preventive Services Task Force (USPSTF) and the Vaccine Injury Compensation Program (VICP) are likely to reform coverage of tests and vaccines, with our expert's take on specific risks below. Our KOL noted that recent moves by RFK has led to "destruction" rather than "disruption" of public health institutions and norms. Recent actions include the wholesale removal of members of the vaccine advisory committee ACIP and the removal of a COVID vaccine recommendation for pregnant women and children. Under RFK, ACIP could also open childhood vaccination schedules, with scrutiny of MMR (MRK), Hep B (MRK, GSK), Polio (SNY, GSK, MRK), and HPV (MRK) vaccines. Hours after our webinar, HHS eliminated mRNA contracts under BARDA. Our take on what may be next is below.

Key Points

The *Public Readiness and Emergency Preparedness (PREP) Act* could be dismantled and multiple COVID vaccine makers could be open to liability claims (MRNA, BNTX, NVAX, and PFE). The HHS Secretary holds the authority to redefine the current measures of the *PREP Act* including its elimination, which has implications for manufacturers of COVID vaccines.

Vaccines using messenger RNA (mRNA) are being targeted under BARDA (MRNA, BNTX, PFE, ARCT, CSL, SNY, AMPL, AZN) with an announcement Aug 5 from HHS (here). The Department is scaling back vaccine work under BARDA, which includes canceling or shrinking 22 contracts and project proposals. The move comes after a full review of all the mRNA funding that ramped up during the COVID emergency.

- mRNA vaccines will be further pressured as RFK Jr. enacts a phased approach targeting mRNA to assuage his MAHA base while attempting to avoid litigation.
- RFK Jr. has systematically targeted mNRA vaccines with over $1 B in mRNA contracts cancelled, including the Moderna contract cancellation.

COVID vaccines are less likely to be included in the National Vaccine Injury Compensation Program (VICP). The ACIP and USPSTF have been demonstrating a "two steps forward, one step back approach" with the cancellation of committee meetings and then rescheduling, and COVID vaccines remain exposed to losing their preventive status. As a reminder, for a vaccine to be covered by VICP, the CDC must recommend the

category of vaccine for routine administration to children or pregnant women, and it must be subject to an excise tax by federal law.

What is the National Vaccine Injury Compensation Program (VICP)? VICP was created (here) in 1986 to provide financial compensation to individuals who were injured by a covered vaccine. The program was created to swap legal liability for manufacturers with a no-fault compensation system for those injured by vaccines. The program is funded through a $.75 excise tax on vaccines recommended by the CDC for routine administration.

Autism could be added to VICP as a vaccine injury, our KOL warns. In line with the HHS Secretary's views on autism and vaccination skepticism, there is still the push to link autism to vaccine injuries. Our KOL points to the over 5,000 autism claims in court and warns how the Secretary wants to identify environmental causation of autism. The report could serve as a basis to add it as an injury that qualifies for VICP reimbursement.

ACIP could open up childhood vaccination schedules (MRK, GSK, SNY), along with others. In addition to COVID vaccines, other vaccines under scrutiny include (1) MMR (MRK, GSK), (2) Hep B (MRK, GSK,DVAX), (3) Polio (SNY, GSK, MRK), and (4) HPV (MRK). Discussions have already begun around reevaluating the Childhood Vaccine Schedule, but it remains unclear which vaccines will be targeted first. MMR is a potential early target if the administration wants to suggest a link to autism.

Vaccine-related legislation is unlikely this year. Our KOL points to three bills:

- *Let Injured Americans Be Legally Empowered (LIABLE) Act* (here) introduced by Rep. Chip Roy (R-TX) empowers Americans to hold COVID-19 vaccine manufacturers liable for any harm their vaccines caused.
- *Vaccine Access Improvement Act of 2023* (here) introduced by Rep. Lloyd Doggett (D-TX) allows a faster process of adding new vaccines to the VIPC and automatically applies the 75 cent excise tax on covered vaccine doses.
- *Vaccine Injury Compensation Modernization Act of 2023* (here) introduced by Rep. Lloyd Doggett (D-TX) aims to improve the VICP by increasing the number of special masters, extending the limitations for filing claims, and moving COVID-related injury claims from the CICP to the VICP.

The outlook for the USPSTF is shaky, as we have noted, with the following as potential recommendation changes (after new members are appointed). In terms of its recommendations, our KOL sees that it is unlikely they will get rid of colorectal cancer screenings, but we may see a removal of the PrEP recommendation as RFK Jr. has a record of being an HIV denier (potentially impacting **GILD, GSK**). As a reminder, we stated previously that RFK is likely to reconfigure the task force to reflect & push MAHA priorities, but that cancer screenings are likely to remain in place **(EXAS, GH, HOLX, MYGN)**. See our previous analysis here.

Major shifts in USPSTF recommendations could begin taking shape by early fall. Our KOL predicted that within a couple of months RFK will reschedule USPSTF meetings, remove current members, and appoint new members aligned with his views.

- Once reconstituted, the task force will likely begin a trickle of recommendation changes, with key screenings and preventive services being reevaluated or rolled back.
- The USPSTF could embrace alternative medicine approaches such as vitamins/supplements and wellness interventions in lieu of screenings, such as hyperbaric oxygen therapy.

Products that are not vaccines but are vaccine-like (e.g., monoclonal antibodies from MRK, PFE, JNJ, GSK, BMY, LLY) have the potential to be revisited as preventive products. Other products that could be

impacted include prophylactic products **(PFE, MRNA, NVS, MRK, GILD)**. This may open the way to the USPSTF rewriting what preventive measures mean across the board.

A possible split of the FDA's Center for Biologics Evaluation and Research (CBER) could provide more dedicated resources or be detrimental to vaccines. It's too early to tell. There's talk of splitting CBER into two divisions - one for vaccines and one for therapeutics. According to our KOL, this could further isolate vaccines and increase regulatory scrutiny in a politically motivated way.

Although the CDC hasn't been fully eliminated, its influence is shrinking. Our KOL noted that while the new CDC Director Susan Monarez is more moderate on vaccines and prevention, the risk is that her role will be diminished with policymaking happening at the HHS level.

A lawsuit will challenge RFK's moves on vaccines and prevention (Oct. 14 catalyst). A lawsuit joined by many physician groups is challenging recent HHS actions, arguing that while the Secretary has authority over ACIP and USPSTF, that power can't be used in an arbitrary or capricious way. A government motion is expected in early September, with a preliminary injunction and merits trial scheduled for Oct. 14 in Boston. A decision is likely by late October or early November. Plaintiffs in the case include the American Academy of Pediatrics, the American College of Physicians, the American Public Health Association, and the Infectious Diseases Society of America (here).
