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FDA Nominee Makary Likely to Uphold Safe & Effective Standard

CDC Director Nominee Weldon is a Vaccine Skeptic

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FDA Commissioner nominee Marty Makary, MD, is unlikely to drastically alter the trajectory on new medicine and device approvals, upholding the gold standard, providing stability. Dr. Makary is less disruptive to the system than others considered for the post, as a transplant surgeon who has written on drug pricing, misaligned orphan incentives and surprise medical billing. He is unlikely to change the FDA's course on rare diseases, oncology, and cell/gene & innovative therapies. He wants to better understand vaccine adverse events, not pull vaccines from the market.

Dr. David Weldon, a former FL House member and physician, 71, is a vaccine skeptic, and aligns with some of RFK Jr's views (autism). However, Dr. Weldon's vaccine views are likely to be intensely scrutinized as CDC nomination hearings commence. If confirmed, Weldon could approve or deny ACIP recommendations on vaccine use going forward; there is precedent to go against the advisory committee.

We think Dr. Makary would likely be Senate-confirmed. Both FDA and CDC require 51 votes for Senate confirmation which would take place in 1H25, after HHS confirmation plays out. See our analysis [here](#) of HHS nominee RFK, Jr and prospects going forward.

»» Key Points

Dr. Marty Makary (FDA nominee) is a transplant surgeon and a more traditional pick than the others in the running. The good news for industry is that he is a more conventional pick that will likely keep the FDA on its current trajectory of promoting novel medicines and MedTech/Diagnostics. FDA is unlikely to change clinical trial standards or the review process significantly, as the agency has a data-driven approach.

FDA novel therapeutic designations -- like platform technology or advanced manufacturing -- are likely not going away, which is good news for biopharma. Both programs are legislatively established (our FDA platform tech analysis [here](#)). Designation updates are expected in 2025. Vaccines are unlikely to be pulled from the market altogether, but new approvals may require more stringent requirements, along with a focus on gathering data on additives. Dr. Makary supports modern vaccination efforts, but not vaccine mandates. He has also voiced his support for RFK Jr. as HHS Secretary, and we expect them to align on some agency reforms.

Regulatory policy at FDA and CDC will likely include vaccines, food safety, and family planning/abortion.

- The new administration is concerned about corruption within the agencies. DOGE will play a role, particularly at CDC. We would see funding diverted towards food over medicines, during the appropriations process, at FDA. We do not foresee user fees going away but could see some around-the-edges movement via Congress.
- Both nominees are likely to focus on ways to enhance public transparency and improve agency efficiency (“cut down on waste”). CDC decides which projects are funded and may increase barriers to vaccine research. Recall CDC accepts/denies ACIP recommendations around immunization guidelines.

What does the Centers for Disease Control & Prevention (CDC) do? CDC (est. after WWII) tracks and responds to infectious disease outbreaks, including recommending licensed vaccines such as routine vaccines used in childhood and those given during the COVID-19 pandemic. Roughly 2/3 of its budget funds state and local health agencies' public health and prevention activities. Recall that ACIP, an outside panel of vaccine experts, provides recommendations to the director, which can be overruled.

Weldon may reject the tradition of adopting Advisory Committee on Immunization Practices (ACIP)'s vaccination recommendations. The Advisory Committee on Immunization Practices (ACIP) develops recommendations on vaccines, including guidance on age, number of doses and timing of doses. The CDC director is responsible for adopting recommendations as official CDC policy which are published in the Morbidity and Mortality Weekly Report (MMWR).

- **It is highly unusual for a CDC Director to reject ACIP's recommendations, but Weldon has the discretion to not adopt (or restrict) what he may consider as too broad or potentially harmful.** There is precedent for the CDC director overriding advisory committee recommendations. In 2021, the CDC director (Rochelle Walensky, M.D.) overrode ACIP to recommend the PFE COVID booster to healthcare workers with a higher risk of COVID-19 exposure. We could see CDC policy adopt the opposing mindset and restrict ACIP recommendations.
- **We also could see the ACIP committee re-worked (or possibly terminated) under Weldon to limit the committee's function.** ACIP charter requires that committees be terminated after two years, unless they are renewed (next renewal: 2026), and CDC has the discretion to do so. Charters can also be rewritten to change the rules under which the committee's function, impacting the committee's guidance for evaluating the data and their evidence-based approach.

Dr. Dave Weldon, CDC Director nominee, is a practicing physician and former House member from FL (71 years old). As a reminder, the CDC director will require Senate confirmation in 2025 due to the 2023 Consolidated Appropriations Act. Dr. Weldon's views on vaccines are likely to be questioned by Senators as he previously promoted the idea that vaccines can cause autism (since debunked). However, he is a supporter of conventional research on other healthcare issues including obesity, cancer, and rare diseases.

ABOUT MAKARY

Dr. Marty Makary is a surgeon and professor at Johns Hopkins University. He is also a public policy researcher and author who has written on reducing healthcare costs for patients, increasing transparency in the

medical industry, and promoting value-based care. He has written on global capitated value-based arrangements and how to determine appropriateness of care. He was an advisor on healthcare issues to the Trump administration, particularly during discussions surrounding the Affordable Care Act (ACA), of which he is a vocal critic.

He is a more conventional pick (compared to other potential candidates). Dr. Makary was particularly critical of the federal response to COVID and of mask and vaccine mandates. However, his skepticism is more muted compared to RFK Jr.'s vaccine skepticism (Makary has publicly voiced his support for RFK Jr. as HHS Secretary). He is also critical of the current conventional medical system, but he is in support of reforming the medical establishment rather than dismantling it entirely. He has called for increasing healthcare transparency and promoting patient choice.

During confirmation hearings, senators will likely question Dr. Makary about his views on regulating drugs, medical devices, and public health initiatives, as well as his stance on the FDA's role in overseeing healthcare products. His expertise in both surgery and health policy would make him a strong candidate, but his work which is critical of "medical dogma" and of COVID-19 response will likely be under scrutiny.

Makary believes in value-based care and supports lowering overall healthcare costs or improving patient experience & outcomes. He himself was critical of the FDA during the pandemic for their delay in drug approvals and the inflexibility at the agency. However, he has been vocal about the gaming of the orphan designation by manufacturers and called for a re-evaluation of the pathway. His previous work on patient choice and transparency means that he is likely to push for increased transparency measures at the FDA to increase public awareness of risks.

ABOUT WELDON

Dr. Dave Weldon is a practicing physician and former lawmaker. He represented Florida in the House of Representatives from 1994 to 2008. He returned to practicing medicine and working as the Chief Medical Officer at Luke & Associates (a healthcare staffing company based in Florida). He is also a clinical university professor of biomedical engineering at Florida Institute of Technology.

He has extensive policy experience and supports biomedical research on rare diseases and cancers. He cosponsored several healthcare bills that support healthy behaviors awareness (for obesity), rare disease and breast cancer research. Funding for traditional research in these spaces is likely to continue. However, the CDC had come under increased scrutiny due to their vaccine and masking recommendations and we expect Weldon to enact significant change in infectious disease research, oversight, and recommendations.

A major concern for the CDC (and for Senate confirmation) is Dr. Weldon's vaccine skepticism and safety concerns, which aligns with RFK's Jr. Senators are likely to question his views on vaccine safety, and his anti-abortion stance. He previously promoted the idea that thimerosal, a mercury-containing vaccine preservative, caused children to become autistic. In 2007, he introduced a bill that would remove vaccine safety research from CDC's oversight into an independent HHS agency. We could see Weldon seek to restructure the organization and aim to raise the vaccine evidence bar or focus funding efforts on vaccine safety.

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