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RFK to HHS: Biopharma / Lifesciences Smoke or Fire?

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Key Takeaways: We are initially skeptical that Trump's selection of Robert F. Kennedy Jr. (RFK) to lead HHS can survive Senate confirmation but, if we are wrong, would note that any HHS secretary is constrained by congressionally delegated authorities. From that standpoint, the immediate weakness in **vaccine manufacturers [PFE, MRNA, BNTX, NVAX]** and fears for biopharma more generally may be overdone. For **diagnostics firms [HOLX, EXAS, GH, MYGN]**, the risk is that HHS would abandon coverage mandates for other preventive services enshrined in law, though we suspect most insurers would maintain long-standing benefits shown to reduce longer-term costs through earlier detection / prevention.

Regarding **providers** and **insurers**, RFK has not espoused the same Medicare, Medicaid or Obamacare reforms that others in the Trump administration would be pushing. That said, he is a strong advocate of **health savings accounts (HSAs) [HQY, WBS]** and broader price transparency, both intended to empower consumer choice, but material expansion of these initiatives would require legislation.

Product Approvals

While RFK has long been critical of the role the biopharma industry plays in the drug approval process, we note that the current FDA User Fee Agreements with manufacturers are codified to remain in place until September 30, 2027. Since that expiration represents the most realistic opportunity for broad agency reforms, near-term structural changes to the FDA appear unlikely.

In the interim, we think immediate and material disruption will be difficult. In short, the HHS Secretary is somewhat constrained in what they can accomplish, in that they: (A) typically defer to the *FDA* commissioner, who must also be confirmed by the Senate (as does the NIH Director), for traditional product oversight; and (B) does ***not*** have authority to unilaterally revoke prior product approvals.

As outlined in statute, product withdrawals must follow a clearly-defined process that is predicated "on a finding that there is an imminent hazard to the public health," with manufacturers then being afforded the opportunity for a public hearing before FDA can *propose* to rescind an approval through a filing in the Federal Register. This triggers a 60-day public comment period before the agency can finalize its decision, wherein it is also required to address all "substantive" comments that are received.

At the heart of any such effort, however, is the requirement that FDA actions be based on "clinical or other experience, tests, or other scientific data showing that the drug is unsafe for use under the conditions of use upon the basis of which the application or abbreviated application was approved." Actions taken in the absence of such evidence are likely to find themselves the subject of litigation.

Pfizer Inc (PFE)

Price:	$26.02
52-Week High:	$31.54
52-Week Low:	$25.20

Moderna Inc (MRNA)

Price:	$39.77
52-Week High:	$170.47
52-Week Low:	$38.76

EXACT Sciences Corporation (EXAS)

Price:	$50.93
52-Week High:	$79.62
52-Week Low:	$40.62

Myriad Genetics Inc (MYGN)

Price:	$15.68
52-Week High:	$29.30
52-Week Low:	$15.53

Gilead Sciences Inc (GILD)

Price:	$92.11
52-Week High:	$98.90
52-Week Low:	$62.07

Agilent Technologies Inc (A)

Price:	$130.22
52-Week High:	$155.35
52-Week Low:	$111.33

Waters Corporation (WAT)

Price:	$376.72
52-Week High:	$393.38
52-Week Low:	$258.90

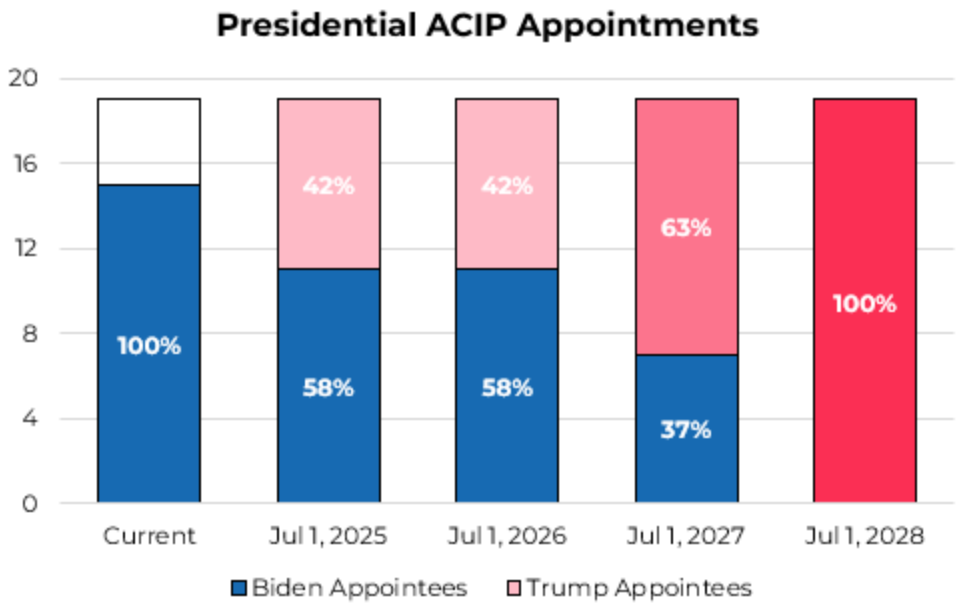
HealthEquity Inc (HQY)

Price:	$95.70
52-Week High:	$101.17
52-Week Low:	$62.10

Vaccine Utilization

As it specifically relates to vaccines, recall that insurer coverage mandates are also codified in statute, whereby the Affordable Care Act (ACA) requires most private health plans and Medicaid programs that expanded following the ACA to cover vaccines recommended by the Advisory Committee on Immunization Practices (ACIP), without any patient cost sharing. While an HHS apparatus that undermines public trust in the *efficacy* of current vaccination schedules may therefore erode patient demand, those products are nevertheless likely to remain available without out-of-pocket expenses.

The risk would, therefore, seem to skew more towards *future* recommendations. Since ACIP determinations are based on a majority vote, the term duration of current members suggests that Trump / RFK appointments would be unlikely to achieve that status prior to mid-2027 or mid-2028, depending on whether current HHS Secretary Xavier Becerra is able to fill four current vacancies of the "up to 19 voting members."



Source: ACIP, Capitol Policy Partners

In the pediatric market, childhood / student vaccine schedules are at the discretion of each individual state, many of which are similarly aligned with ACIP recommendations. However, 30 states allow exemptions for religious reasons, with 13 allowing exemptions based on either religious *or* personal objections, and another two additional states leaving the rationale unspecified. The five remaining states do not allow for any manner of objection. Tangentially, RFK's presence at HHS may embolden more states to grant individual exemptions.

Preventive Health

An additional signal coming from RFK's selection is that the incoming administration may abandon the Biden team's defense in ongoing litigation challenging the ACA's requirement that insurers cover *other* preventive health measures – e.g., prophylactic medications, disease screening – recommended by the U.S. Preventive Services Task Force (USPSTF), which is under consideration for Supreme Court review this term.

Investors will recall that, following a legal challenge in 2023 against mandatory coverage of preexposure prophylaxis for **HIV [GILD]**, a federal district court in Texas struck down in its entirety the USPSTF coverage requirement and imposed a nationwide injunction on government enforcement. Notably, similar provisions regarding vaccines recommended by the CDC's ACIP were upheld. Following the Biden administration's appeal to the 5th Circuit Court of Appeals, the appellate justices overturned the national injunction. With litigants now appealing to the Supreme Court, the fate of this provision remains uncertain, particularly if the Trump administration were to abandon the government's defense.

In that scenario, we would nevertheless expect Democratic state attorneys general or patient advocacy groups to assume the defense role, but it seems likely that the Trump administration may also exercise greater enforcement discretion over insurance plan benefits. Even then, however, we find it notable that the health insurer industry organization AHIP has previously signaled the intent of its members to continue providing USPSTF services while the case is adjudicated, suggesting they are motivated by *both* government dictates *and* long-standing customer reliance on such benefits.

NIH Research Agenda

Kennedy's recent calls for the immediate elimination of 600 NIH employees would seem likely to have more immediate consequences for the pace of grant reviews and the **contract research organizations (CROs) [CRL, MEDP, CTLT, IQV]** and **lab tool companies [A, ILMN, WAT, BRKR]** that are reliant on them, rather than biomedical manufacturers.

That said, it is unclear to us exactly where this figure came from or what percentage would be eligible for termination without cause, could be reclassified as "at will" employees under a revised Schedule F, or subject to replacement. An immediate gutting of NIH staff capacity strikes us as unlikely, however, while also being more within the purview of whomever is selected as director of the NIH itself.

Republicans have nevertheless been open in their desires to restructure the NIH more generally, including through a June 2024 white paper calling for the consolidation of the current 27 research centers into 15. Such a massive overhaul would require congressional enactment, and is not something we believe RFK could impose unilaterally.

More narrow initiatives, such as greater transparency in grant reviews and auditing, could conceivably be pursued administratively, but a wholesale pivot towards chronic disease research at the expense of current priorities strikes us as unlikely. Recall that each NIH research center's budget is appropriated by Congress, which is provided along with authorizing legislation to define the *intent* of that funding. It is unclear to us whether an HHS secretary can merely direct the NIH director or any of the research centers to disregard such directives.

Health Insurers, Providers, & HSAs

Kennedy has not expressed many views specific to these sectors or how he would reform Medicare, Medicaid, Obamacare, or private insurance, outside of wanting to lower healthcare costs, reduce the prevalence of chronic disease, and focus more on preventive / homeopathic / alternative care and behaviors rather than treatment.

This suggests RFK's HHS would encourage insurers to broaden coverage of alternative care that facilitates greater patient choice, though this could also lead to higher associated costs / plan premiums. Mostly, however, this suggests RFK is unlikely to spearhead the fight for federal entitlement changes.

Additionally, we think his HHS would support expanding and enforcing hospital, insurer and provider price transparency efforts. While this too is intended to empower consumers and reduce spending over time, it is unlikely to materially change practice patterns in the near term.

Purveyors of **health savings accounts (HSA) [HQY, WBS]** nevertheless stand out as potential beneficiaries under RFK in light of past statements that they should be provided to every American that could be used to pay for medical and preventive services. While this is consistent with GOP orthodoxy, legislation is required to loosen restrictions on the types of health plans that can be associated with these tax-free accounts, HSA contribution limits, and the types of benefits that they can fund. Even when Republicans controlled both the White House and Congress in 2017, HSAs were never a legislative priority.

As HHS Secretary, RFK could encourage his CMS to approve state Medicaid waivers, state innovation waivers, or a Medicare demonstration project expanding use of these accounts, but this would likely be on a limited basis, rather than nationwide.

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