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Incoming Admin May Shake Up Life Sciences Regulation

By **Jacqueline Berman, Michele Buenafe and Kathleen Sanzo** (November 14, 2024, 6:41 PM EST)

The reelection of former President Donald Trump, coupled with Republicans gaining the Senate majority and poised to gain the House majority, has prompted many in the life sciences industry to question how this political shift may affect the regulation of drugs, devices and other life sciences products by the U.S. Food and Drug Administraiton and related regulators.


Jacqueline Berman

While Trump has not yet articulated specific policy priorities with respect to the life sciences industry, what is clear is that the sector is positioned to see significant changes. We describe below key areas to watch as the new Trump-Vance administration takes shape.


Michele Buenafe

New Agency Heads and Priorities

As is generally the case, the president-elect is expected to make changes at the top levels for those agencies that oversee drug and device companies, including the U.S. Food and Drug Administration and U.S. Department of Health and Human Services.

In addition, there have been public reports since the election that the new administration may consider revamping entire FDA departments, but no details have yet been provided.


Kathleen Sanzo

On Nov. 14, Trump nominated Robert F. Kennedy Jr. to lead HHS. New FDA and HHS leadership could result in significant changes in public health policies and priorities, affecting everything from the FDA's approach to drug exclusivity and generic drug approvals, to the availability of over-the-counter drugs, to laboratory-developed tests and digital health.

These changes, combined with anticipated increased judicial review and scrutiny of FDA actions in the wake of the U.S. Supreme Court's decision in Loper Bright v. Raimondo, may speed up the evolution of FDA policies and priorities over the next few years.

Potential Decrease in Federal Oversight and an Associated Increase in State and Private Actions

Republican administrations have historically taken a more restrained approach to regulation and enforcement, often resulting in fewer enforcement actions and a loosening of regulatory restrictions.

For example, at the conclusion of the previous Trump administration, the FDA attempted to reclassify 91 devices — including gloves, surgical gowns, respirators and ventilators — from requiring premarket clearance as well as attempted to expand the number of unapproved prescription drugs that could be marketed without FDA approval, i.e., grandfathered drugs.

A regulatory vacuum at the federal level may create incentives for others to step in. For example, states with well-established regulatory infrastructures — e.g., California's Food and Drug Branch and the New York Department of Health — may be incentivized to step up their oversight or create regional enforcement groups should they view the FDA's to be lacking.

This could potentially create tension and legal battles between federal and state regulators. Similarly, private actions initiated through litigation or through self-regulatory organizations, such as BBB National Programs' National Advertising Division, may also increase in response to a decrease in federal oversight.

Reproductive Rights and FDA Oversight of Related Drugs and Devices

In the wake of the U.S. Supreme Court's Dobbs v. Jackson Women's Health Organization decision in 2022 striking down Roe v. Wade, and the variation in state legal protections, the battle over reproductive rights and access to related products and services has heated up.

While Trump's current position on these issues is not fully clear, with the overall conservative shift in government, we are likely to see increased scrutiny for access to related drug and device products, such as mifepristone, contraceptive drugs and devices, and drug and device products used for in vitro fertilization procedures.

There may also be added attention given to other products including products used for gender-affirming care.

Rescheduling of Marijuana

The new president-elect is likely to prioritize his decision on who will be the new attorney general for the U.S. Department of Justice, a decision that will have significant implications for the U.S. Drug Enforcement Agency, which sits within the DOJ.

This will potentially affect the future of DEA's proposed rulemaking to reschedule marijuana from Schedule I to Schedule III and the use and FDA approval of other controlled substances for therapeutic purposes, e.g., psilocybin.

Should the DEA withdraw the proposed rescheduling under new leadership, this could set up potential legal battles due to conflicts between the federal position and various state laws that have loosened restrictions around medical and personal use of these products.

Supply Chain Policies

One of Trump's major policy positions focuses on increasing both U.S. manufacturing capacity — an effort that President Joe Biden also advanced — and tariffs on imports.

This could have potential implications for life sciences companies by increasing the cost of importing medical product components, e.g., active pharmaceutical ingredients, excipients, device components and parts, especially from China.

It could also bolster current efforts to decrease reliance on non-U.S. suppliers through legislative initiatives such as the BIOSECURE Act. In contrast, however, we could also see a renewed interest in the importation of drugs from Canada, a policy that was enacted during the prior Trump administration.

Changing Approaches to Vaccines and Novel Treatments

Due to continuing questions about vaccines developed during the COVID-19 pandemic, incoming FDA officials are likely to review agency policies on vaccine development, including requiring additional evidence of safety and effectiveness for vaccine and related product approvals.

The Centers for Disease Control and Prevention could also revise its standards for adoption of certain vaccines as public health mandates, and a Republican Congress could consider narrowing the CDC authority to make such determinations.

There may also be more of an appetite at the FDA to advocate for less traditional treatments, including homeopathic medicines, psychedelics, nutraceuticals and stem cell therapies. This could result in renewed emphasis on moving regenerative and personalized medicine therapies, among others, forward.

Additional Momentum for Over-the-Counter Drugs

Another change that could come about from a piqued interest by incoming FDA leadership in exploring alternative treatments is making consumer products that are available in other parts of the world more accessible to U.S. consumers, including over-the-counter drugs. Such receptivity to enlarging access will potentially prompt additional innovation in the over-the-counter drug industry and access to exclusivity for those products under the CARES Act.

FDA Policies for Digital Health Technologies

Given the general Republican historical trend to be more industry-friendly, we may see a shift in the FDA's policies related to digital health and other advanced technologies.

More recently, the FDA has signaled more scrutiny for cutting-edge technologies as evidenced by its 2022 guidance document on clinical decision support software, which was generally viewed to reflect a highly conservative interpretation of the clinical decision support software exemption, and the FDA's final rule to regulate laboratory-developed tests.

While there is still much uncertainty on exactly how the new administration's policies for healthcare and life sciences will take shape, it is clear that change is in the air.

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