The Food and Drug Administration in the Trump Administration

By Wayne Pines

Elections have consequences, and this year's presidential and congressional elections certainly will have consequences for health and regulatory policy. Washington and the political media are abuzz speculating on what the Trump election and the new Republican majorities in the Senate and almost certainly the House will bring us, and what the changes mean for us as individuals, for the foods we eat and the medical products we use, and for the industries that make products regulated by the Food and Drug Administration (FDA)—which represent at least 20% of consumer spending.

We're still very early in the process, but to try to put the evolving picture into perspective, here are 10 observations on the impact of the presidential election on FDA and health/regulatory policy more generally:

1. While the leadership of Department of Health and Human Services, FDA and the Centers for Disease Control and Prevention (CDC) will be replaced, the day-to-day decision makers will all remain. At FDA, the leaders of the product centers (food, drugs/biologics, devices, veterinary drugs, tobacco) will stay in place. The scientists and investigators and compliance officials will also remain in their jobs. This includes the staff that reviews product applications for new drugs and devices. So, on January 21, 2025, the agency will function the same as before.

Traditionally it has taken until April of the first year of a new presidency for an FDA commissioner to be nominated. So, if history holds, for the first few months of the new term, an acting commissioner is likely to be in place. If President Trump follows the pattern of his first administration, the acting commissioner will be brought in from outside the agency to serve on a temporary basis.

A temporary commissioner could initiate changes but is more likely to wait for permanent leaders to arrive. Until then, FDA is likely to conduct business as usual.

2. The role of Robert F. Kennedy Jr has yet to be defined. President Trump's rhetoric during the campaign suggested that Kennedy would play a major role in health care policy. News stories speculate about his role.

One truism in Washington: political rhetoric and governing are two different concepts. We'll have to await further announcements by the Trump team before we know what Kennedy's real role will be.

Kennedy is best known as an anti-vaxxer, but he has also said he will fire FDA employees, especially in the nutrition division, and seek to set the agency in a new direction on some issues. The media report that Kennedy views the food and drug industries as greedy and corrupt for making unhealthy products.

It is not likely that Kennedy will have a Cabinet appointment as secretary of health and human services. If anything, he could serve as an adviser to the president. Kennedy could seek to influence how CDC makes its vaccination recommendations and how FDA treats any new vaccines being developed. If and when that occurs, he will get pushback from the agencies' staffs.

However, Kennedy is likely to have a platform to express his views and given the volatile and partisan state that the country is in, his views on vaccines, fluoride, processed food and drug development are likely to have an impact on public behavior. For many years there have been substantial elements in the United States who oppose having their children vaccinated based on the current CDC advice. Kennedy could strengthen those who oppose vaccinations. The companies that make and develop vaccines must play attention as his role unfolds.

3. We will have a president and White House staffers who are familiar with FDA. For the first three years of the first Trump Administration, FDA went about its business of overseeing the nation's food, medical products and cosmetics products in its traditional way—approving many new drugs and devices, inspecting facilities and taking enforcement action when needed. The White House paid scant attention to the agency.

Then, in the last year of the Trump term, came COVID-19. FDA was on the front pages of the media every day as it dealt with the most severe pandemic in a century. The agency was at the forefront of approving effective masks and COVID-19 laboratory tests and working with Operation Warp Speed and drug/vaccine manufacturers to develop vaccines and drugs to prevent and treat COVID-19.

Consequently, the Trump team, including the president himself, came to know the FDA very directly. Commissioner Steve Hahn shared a podium with Trump on many occasions. Trump learned about vaccine and drug development.

It remains to be seen how the president's knowledge of FDA will play out, and whether the new Trump White House will seek to play an unprecedented active role in some of the decisions that FDA makes. If so, this could change the dynamics of regulation.

Special attention should be paid to who serves in the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA). OIRA reviews all new FDA regulations. At a recent meeting, current FDA Commissioner Robert Califf cited OIRA's as a large factor in any effort to adopt new regulations or change overall agency policies. In the next administration, OIRA is likely to play a similar role and could have a strong, behind the scenes influence over FDA policy. We must pay attention to Trump's appointee to OMB and who will be on OIRA's FDA/CDC desk.

4. One issue that is likely to be front and center in the next administration is abortion. FDA is marginally involved with abortion because it approves the drugs used for abortion.

The issue is most likely to arise in a legal context. A recent Supreme Court decision, *Loper Bright Enterprises v. Raimondo*, gave the courts new authority to overrule FDA and other federal agencies on scientific/technical judgments. The decision overturned the principle of *Chevron* deference, which was created in a 1984 Court decision.

The *Chevron* standard established that courts must defer to the authority of an agency's interpretation of a law when the law was ambiguous, and the agency's interpretation was reasonable or permissible. This gave agencies like FDA a great deal of authority in the rule making process. The *Loper Bright* decision overturned the *Chevron* doctrine, and has been and will continue to be cited by anti-abortion litigants who seek to challenge the FDA's decades-old approval of the abortion pill mifepristone. Anti-abortion advocates contended that the approval was inappropriate, not scientifically justified and that the approval of abortion pills should be revoked.

To date, FDA has resisted such efforts, largely on legal procedural grounds, but more litigation is almost certain. This has obvious implications and ramifications for all drug and device companies: any judicial decision that overturns a single decades-old drug approval would threaten to undermine the entire FDA drug/device approval process.

On a broader scale, since judges no longer must defer to the expertise of the FDA, the *Loper Bright* decision can be cited by any judge who wants to overrule an FDA decision. There already have been several cases citing the decision. Depending on who the new Commissioner and staff are, they will need to develop a strategy on how to handle such cases. FDA already has started to put into place internal strategies to assure that current and future scientific decisions can be supported in court in front of judges who seldom have the expertise to evaluate scientific decisions.

5. One of the issues that President Trump clearly has knowledge of is the "right to try" issue—the right of seriously-ill patients to take drugs not approved by the FDA. During his debate with President Biden, Trump mentioned "right to try" in passing.

FDA has procedures in place to facilitate patients' use of unapproved drugs on an individual basis, and the agency approves virtually all such requests. It's not clear what more the agency can do to satisfy the "right to try"

advocates, but some advocates want still more flexibility in patient use of drugs and devices under investigation may raise the issue and have a willing ear at the White House.

6. Perhaps the most challenging issue that the new leadership at FDA must face is artificial intelligence (AI). How to manage AI is generally not a partisan issue but there is a split between those who want more and those who want less regulation. But AI promises to change dramatically how FDA—and we all—do business.

There are two aspects of AI at FDA. One, FDA itself must increasingly use AI in evaluating new products, in helping to design clinical trials for new drugs, in tracking the supply chain for products and their ingredients. The adoption of AI by FDA itself will require significant internal education plus investment in the AI tools.

Second, FDA must, and already has, seek to regulate AI's use in medical and other products. If AI is used in the software for a medical device, for example, or in collating the data from a clinical trial, FDA must have a way to validate its proper use. FDA already has published a paper on AI and machine learning and the agency's website explained:

"Artificial intelligence (AI) and machine learning (ML) technologies have the potential to transform health care by deriving new and important insights from the vast amount of data generated during the delivery of health care every day. Medical device manufacturers are using these technologies to innovate their products to better assist health care providers and improve patient care. The complex and dynamic processes involved in the development, deployment, use, and maintenance of AI technologies benefit from careful management throughout the medical product life cycle."

For many at FDA, AI is priority number one.

7. Drug costs, which FDA does not directly influence or control, is another issue that is generally non-partisan. FDA does not set drug costs; its role is to expedite the approval of lower-cost generic drugs and to work with innovative companies in how to lower the cost of development and manufacture of products such as cell and genetic therapy. Lowering drug costs is a goal of both political parties. A new team at FDA is going to have to help support the administration's commitment to lower drug costs.

8. Food safety will be toward the top of the agenda for a new Trump administration. Under the Biden administration, the entire food oversight apparatus at FDA was reorganized. During the coming year, under new leadership at the top of FDA, that reorganization will be implemented.

Robert Kennedy Jr. has stated his concern about processed foods and nutrition. However, whatever role Kennedy plays, the ingredients in processed food and the need for Americans to eat healthy diets will merit attention from FDA's new leaders. These issues have long been on the agenda and with the reorganization of the food center, they are likely to have priority attention.

9. Whatever changes are proposed at FDA, the regulated industries cannot lose sight of what they really want in a regulatory agency: fair oversight based on good science and above all, consistency in regulation. No one deeply involved in drug approvals and food regulation wants FDA to respond to outside pressures with changes in how they approach regulatory oversight—regulated companies plan around having a consistent standard.

For example, a company that is developing a new drug must conduct clinical trials that take a long time. They want to be able to rely on consistent FDA standards. A food company building a new facility needs to plan to comply with FDA good manufacturing practice standards and does not want those standards to be subject to change. So even while the political rhetoric make it appear that there is a

clamor for basic changes at FDA, the reality is that as a practical matter whatever changes occur will be incremental. At least we hope so.

10. All regulated companies must, of course, plan for any new administration. A few tips on what companies should do now:

    - In the next two months the departing leaders at FDA may want to finalize the issuance of certain regulations or guidance. So, companies may see a surge in issuances. For example, one guidance that many FDA staffers want to see issued is a final guidance on how best to achieve diversity in clinical trials.
    - Toward the end of any calendar year, employees who are eligible for retirement leave their jobs. Companies that have products or issues pending before FDA should be alert to any retirements among the staff they deal with.
    - Companies should monitor closely the overall environment to see how changes will affect them. For example, vaccine manufacturers must stay attuned to any statements made by Kennedy or others who may influence public perception. Drug manufacturers must keep tabs on what FDA is doing to expedite generic drug or biosimilars approvals.

One final anecdote to help put this all in perspective: in October 2020, at the height of the COVID-19 pandemic, FDA scientists were evaluating studies to see whether the newly developed vaccines met FDA standards for safety and effectiveness. The November 2020 presidential election was just around the corner.

Officials at the White House communicated their desire for the vaccines to be approved before the election. The reason was not stated but obvious—having COVID-19 vaccines approved could be a boost for the election.

The scientists at FDA had not yet completed their review process and the vaccines were not approved before the election. They were approved just a few weeks after the election.

The moral of the story is that the president and White House do not have unlimited control in Washington and, in this case, over FDA. Health and regulatory decisions must be based on good science and the laws enacted by Congress. Because of the products that FDA regulates are so widely used and so fundamental to our health and safety, real changes in policy generally occur incrementally.

FDA has been around since 1906 and has provided scientifically based, stable regulation since. That's what we should expect in the future. But remain vigilant.