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Opinion: The Only Thing That's Permanent in Life Is Change

by Steve Silverman

The US Food and Drug Administration is undergoing seismic leadership changes, from the expected post-election departure of two-term Commissioner Robert Califf to the retirement of longtime Center for Devices and Radiological Health Director Jeff Shuren. What might the new management mean for the medtech industry? Silverman Group President and former FDAer Steve Silverman has some insight.

It's good that the ancient Greeks employed philosophers because Heraclitus was a smart guy and he deserved a job. Heraclitus observed that the world is in constant motion and 2,500 years later that's still true, even at the FDA.

Big changes are afoot at the agency, including the FDA's Center for Devices and Radiological Health (CDRH). Robert Califf, the FDA Commissioner, almost certainly will leave the FDA after the November election, regardless of who wins. And on his way out first is Jeff Shuren, who reshaped the CDRH during the nearly 15 years that he directed it.

These changes are tectonic, but what do they mean?

A New FDA Commissioner

Califf's departure will have a ripple effect in the Commissioner's office as senior staffers find new positions in and outside the agency. And the next FDA Commissioner will bring in his or her own top team, so expect new faces in the Commissioner's Office in 2025.

The next Commissioner may also have priorities other than industry engagement, which CDRH adopted and Commissioner Califf endorsed. Also, it will take time for the new Commissioner to get up to speed on key regulatory, legal, and administrative duties. So, it's unlikely that FDA will

launch bold new initiatives in the coming year. Look instead for the FDA to focus on its core mission: premarket review and assurance that regulated products are safe and effective.

Here's a caveat: If we face another health crisis like COVID-19, all bets are off. In that case, the crisis will become the FDA's 600-pound gorilla.

A New CDRH Director

In late July, Shuren announced that he was retiring as the CDRH director. A search for his successor is underway and Commissioner Califf will influence the result. But the next FDA Commissioner likely will make the final call, meaning that the new CDRH director may not share Shuren's openness to industry or passion for innovation. If the new director comes from academia or public health, for example, there may be less enthusiasm for business-focused initiatives, even if they help assure that CDRH gets devices to market "first in the world."

Like the next FDA Commissioner, the new CDRH director will need time to get up to speed – expect a year for that transition. During this time, CDRH will look inward, focusing on premarket device review and postmarket regulatory compliance. A key exception is initiatives already underway. CDRH will satisfy its 2023 device user-fee commitments, and it will launch the Quality Management System Regulation, which harmonizes US regulations with international device-quality standards. Plus, CDRH's authority to regulate lab-developed tests will remain a central public concern. Industry groups have challenged this authority in court and calls for Congress to resolve this matter persist.

A New CDRH Office of Product Evaluation and Quality (OPEQ) Director

OPEQ is CDRH's "super office" responsible for deciding which devices come to market and if device makers meet regulatory mandates for quality manufacturing, adverse event reporting, and device recalls, among others. OPEQ's long-standing director, Bill Maisel, left earlier this year to be replaced by Ross "Rusty" Segan. Segan brings broad experience to the job, including time teaching and senior roles with Johnson & Johnson, Olympus, and other large device firms.

Given OPEQ's huge device portfolio and myriad demands, this experience is an asset. Still, Segan faces a steep climb as he joins CDRH. And he will have little idea what his new boss, or his new boss's new boss, will want from him. So, expect Segan to keep his head down while he learns his job. This means a steady focus on OPEQ core functions like pre- and postmarket product review. Don't bank on new, innovative initiatives, especially ones that stretch CDRH's regulatory authority.

Effect on FDA Stakeholders

Readers will ask, "What do these changes mean for me?" Yes, the future is hazy – the presidential election may massively affect the FDA (and the country) and we've seen disruptions

from natural disasters and health crises. Still, there's a likely trajectory for CDRH heading into 2025.

CDRH will maintain and, where possible, strengthen core duties like product review and stakeholder engagement. CDRH's Acting Director, Michelle Tarver, will advance this work. She's a talented FDA veteran who's more than able to run the center while a permanent director is selected.

This means continued product review and postmarket oversight. CDRH will assess submissions, oversee recalls, send warning and untitled letters, and take enforcement action where needed. After the recent furor over the safety of Philips Respironics sleep apnea/ventilator devices, look for CDRH to oversee marketed devices aggressively, even while new leaders come on board.

Strong stakeholder support and FDA investment guarantee that initiatives like the Breakthrough Devices Program and the Digital Health Center of Excellence will continue. But the pace at which these programs operate, and their ability to innovate, is uncertain. This is especially true for initiatives going beyond core regulatory functions or needing expanded authority. These initiatives may get traction eventually, but incoming leaders will focus first on core regulatory duties.

The Lessons for Stakeholders

Faced with these changes, how can stakeholders positively influence FDA policy and regulatory choices? There are several steps:

- Respect the Selection Process. I'm sorry if this is obvious. Certainly, stakeholders should give input on prospective FDA leaders, even when that input is negative or raises concerns. But input must be public, and it must recognize that Congress and federal officials make the final call. No stakeholder wants to be accused of putting their thumb on the scale. Past examples show that these efforts (mostly) don't work, they become public, and they damage stakeholder reputations.
- Get Ready Now. Stakeholders must be ready, today, to help incoming leaders learn how FDA best operates. This includes formal regulatory and policy practice and, as critical, the informal practice and strategies that drive success. We in the "FDA world" have stories about effective initiatives and ones that die on the vine. Stakeholders that help FDA leaders apply these lessons will be seen as valuable resources, sometimes meaning a seat at the table when FDA leaders makes regulatory and policy choices.
- Engage Strategically. Next, stakeholders must decide whether to engage individually or as groups with aligned interests. Groups speak with a louder voice, as trade associations show. These associations represent broad constituencies, meaning that FDA often pays attention when they raise concerns and flag issues. Even better is when groups propose solutions

aligned with FDA policy and practice. This is when FDA leaders are most likely to listen, especially when proposed solutions broadly serve stakeholders.

There's also room for individual engagement. A stakeholder can reinforce group messages or explain why its circumstances need separate attention. Success here requires groundwork. As I've explained before, *FDA isn't a monolith* and effective stakeholders understand which parts of the agency they're talking to, whether those parts can do what the stakeholder wants, and if other FDA groups should be at the table.

Just as important is proactive FDA engagement, before specific concerns arise. Smart firms, for example, engage FDA when it seeks input on new regulatory and policy topics (like digital devices and real world evidence). This engagement lets FDA chiefs know who the thought leaders are on key regulatory and policy topics, and those thought leaders are more likely to get a listen when they engage the agency.

Steve Silverman is the president of The Silverman Group, a consultancy that serves medical product companies on regulatory, strategy, and policy issues. Steve's professional experience includes extensive time in senior FDA roles. At the FDA, Steve directed the CDRH Office of Compliance, where he led device-quality initiatives, engaged Congress and the press, and guided the office's reorganization.