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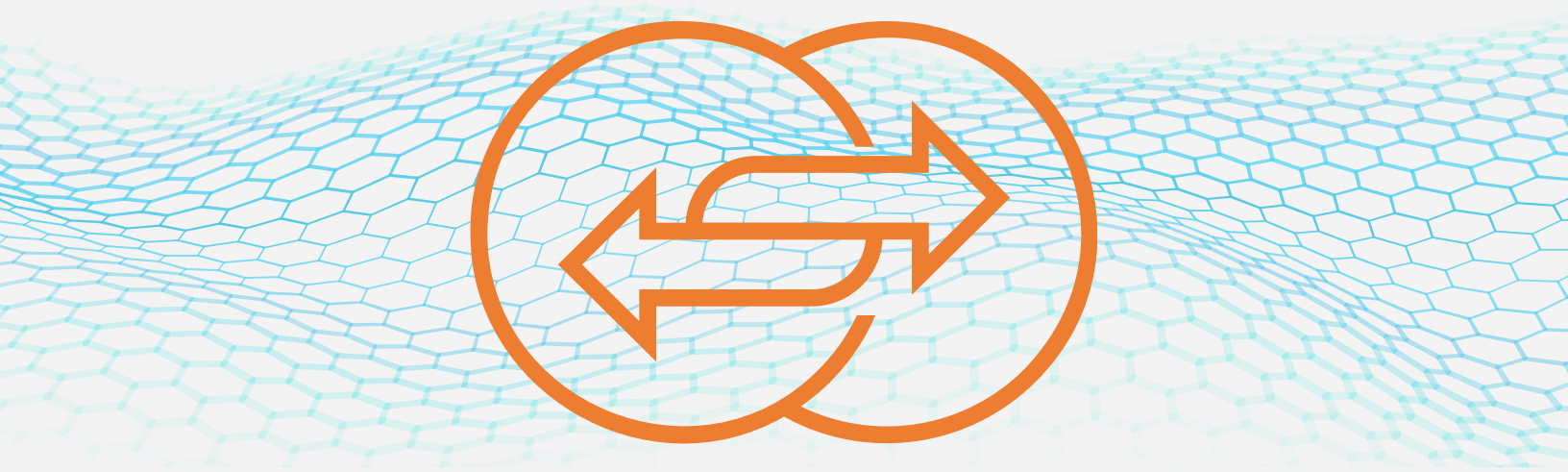

Navigating Organizational Change, Judicial Constraints, and Emerging Opportunities for Medical Device Manufacturers

FDA and CDRH in Transition:

Navigating Organizational Change, Judicial Constraints, and Emerging Opportunities for Medical Device Manufacturers

By Bryan Feldhaus, President of Legal-Regulatory & Compliance

Over the past year, medical device companies have found themselves in a regulatory environment that is being reshaped on multiple fronts at once. Restructuring at FDA, landmark judicial decisions that curb agency deference, a lengthy government shutdown, and continued pressure on MDUFA V performance goals are all converging at once. Together, these forces are changing how CDRH operates, how it interprets its statutory authority, and how companies should plan, submit, and promote their devices in the United States. This DuVal Client Alert comprehensively analyzes these developments, their tangible consequences, and emerging avenues for mutually beneficial industry-FDA collaboration.

CDRH Experiences Significant Transformation in 2025

Over the past year, FDA and, specifically, the Center for Devices and Radiological Health (CDRH) have experienced unprecedented turnover and administrative restructuring, including: (i) leadership transitions across HHS and FDA; (ii) workforce reductions affecting approximately 3,500 FDA employees, including support personnel within CDRH; and (iii) judicial developments eliminating *Chevron* deference and constraining agency authority under *Loper Bright*.

The transformation began with unprecedented personnel turnover in senior leadership and key roles. Within roughly a year, two HHS Secretaries, two FDA Commissioners, and two CDRH Directors departed, along with two heads of OPEQ and several high-profile scientific leaders, including the FDA Chief Medical Officer and senior directors in CDRH's science and drug offices. These departures were followed by a February 2025 reduction in force ordered by the Presidential Administration that terminated more than 200 probationary staff and more than 100 MDUFA-funded hires, with roughly half of the affected positions funded at least in part by user fees. Some individuals later returned, but the effect was a loss of institutional knowledge and instability for medical device companies with pending or planned submissions.

Subsequent to those changes, administrative restructuring accelerated in April 2025 again at the behest of the Presidential Administration when HHS implemented a department-wide "efficiency" initiative that eliminated approximately a quarter of its workforce. FDA lost roughly 3,500 employees, with cuts concentrated in administrative, policy, financial management, and communications functions. For CDRH, that meant that while core review divisions were not directly targeted, personnel and structures that support device review—such as submission processing, communications, and performance tracking—were eliminated.

Despite these challenges, CDRH has responded by implementing strategic initiatives to improve communication and review, while continuing to meet MDUFA V commitments. The current environment creates both risks and opportunities: medical device companies face greater uncertainty but also have stronger footing to advocate for statutory fidelity, least burdensome approaches, and collaborative regulatory engagement.

In this context, MDUFA V has served as a stabilizing framework. CDRH's 2025 annual report acknowledges resource challenges but emphasizes the Center remains on track to meet MDUFA V metrics. Looking forward, the MDUFA goals allow for tightening of review timelines in 2026 and 2027 if earlier-year performance is achieved and fee revenues support further improvements.

Overlaying these developments was also an unexpected policy shock in early 2025: a moratorium on new guidance documents. On January 20, 2025, President Trump issued an executive order instructing agencies not to propose or issue new rules until they had been reviewed and approved by a newly appointed department or agency head. A follow-on order directed agencies to identify regulations that may be inconsistent with recent Supreme Court decisions, especially *Loper Bright Enterprises v. Raimondo* and *West Virginia v. EPA*. The guidance freeze arrived on the heels of a period of extraordinary regulatory activity: in 2024 alone, FDA issued 145 guidance documents, including 41 from CDRH, with several additional CDRH guidances appearing in early 2025 before the moratorium took effect.

For device companies, the moratorium was a mixed blessing. On one hand, the moratorium created uncertainty about FDA's "current thinking" on relevant topics, left important draft guidances unfinalized, and delayed clarity for novel technologies such as software, SIUU devices, and cutting-edge AI applications. On the other hand, the pause temporarily slowed the constant "firehose" of new expectations and gave

companies space to absorb and implement FDA's guidance finalized in the run-up to 2025.

Now that the moratorium has now been lifted, CDRH's recent introduction of new guidance documents has reshaped what FDA expects to see in device submissions. For example, through FDA's Guidance, cybersecurity has been elevated from a collection of recommendations into a de facto core quality and safety obligation. Device companies are now expected to present robust threat modeling and risk assessments, maintain and disclose software bills of materials, and demonstrate plans for updates, patching, and coordinated vulnerability disclosure. These elements are now standard in premarket review rather than optional add-ons.

Likewise, FDA's approach to AI/ML and software has matured into a total product lifecycle framework that demands transparent documentation of model development and training data, performance metrics tied directly to claimed indications and clinical claims, systematic evaluations of bias and generalizability, and, where appropriate, use of predetermined change control plans for adaptive models.

In addition to these internal changes, external judicial developments are narrowing the room FDA has to maneuver when interpreting its statutes. In *Loper Bright Enterprises v. Raimondo*, the Supreme Court rejected the Chevron doctrine and made clear that courts may not defer to agency interpretations merely because a statute is ambiguous. For FDA, this means that guidance documents and informal policy positions carry less automatic weight, and industry has a firmer basis to challenge interpretations that appear to go beyond the text, structure, and history of the FDCA and related laws. That trend is reinforced by decisions such as *American Clinical Laboratories Association v. FDA*, which vacated FDA's final rule extending device jurisdiction to laboratory-developed tests on the ground that the rule conflicted with the FDCA and CLIA. *See American Clinical Laboratories Association, "The final rule contemplates expanding FDA's jurisdiction to cover laboratory-developed test services as medical 'devices' under the FDCA. That expansion is foreclosed by the text, structure, and history of the FDCA and CLIA*." Collectively, these cases signal that future attempts by FDA to broaden its jurisdiction will face new scrutiny.

For medical device companies, the effects of these changes are already visible. Reductions in management, communications, regulatory program support, and support staff influence everything from MDUFA performance to registration and listing, recall coordination, MDR review, and allegation investigations. And companies may encounter delays in areas that do not directly implicate immediate patient safety. At

the same time, the departure of seasoned leaders and subject-matter experts, particularly in CDRH and related offices, has reduced institutional knowledge, which has seemingly resulted in inconsistent feedback, shifting regulatory expectations, and the lack of historical context for device reviews.

Interestingly, the same resource constraints that create pressure may also provide opportunity. With fewer personnel and, consequently, less time per file (and FDA's greater reliance on ELSA, its AI-review tool), there may be potential for review teams to focus more on essential data rather than academic, or "nice-to-have" requests. For sponsors willing to engage constructively, this presents an opportunity to reinforce statutory principles such as "least burdensome" statutory requirements and to push for clarity and discipline in the pre-submission process.

For example, the FD&C Act explicitly instructs FDA to request only the minimum information necessary to make a substantial equivalence determination when technological differences are at issue and defines "necessary" as the minimum required information that supports such a determination. Against the backdrop of *Loper Bright*, sponsors are better positioned to respectfully contest when requested data appears to exceed that standard, offer alternative approaches, and insist that evidentiary escalations be grounded in statute and binding guidance rather than evolving regulatory preference.

Ultimately, we believe this creates an opportunity for both FDA and industry, and we're reminded of the importance of that relationship and the regular recalibration by Nancy Buc, former FDA Chief Counsel:

> *"I have been to many a meeting at which the working assumption seemed to be that sponsors should simply do what FDA told them to do.* ***That isn't good science, it isn't good law, it isn't good policy, FDA shouldn't do it, and sponsors shouldn't acquiesce in it.***
>
> *More and more, FDA seems to assume that industry people are not entitled to be fully part of that process because their views are tainted by their membership in industry.* ***I have sometimes said to FDA people that an industry person is not wrong just because he or she is in industry any more than an FDA person is right just because he or she is in FDA.****"*

Nancy Buc, Fourth Annual Regulatory and Compliance Symposium, FDLI (Sept. 30, 2009)

In today's environment, that framing feels appropriate. Industry is an equal stakeholder in the user fee system, which funds a significant portion of FDA's device review structure, and both sides share responsibility for enabling innovation while protecting patients. With FDA undergoing internal change and facing external judicial constraints, there is real space for medical device companies to engage as constructive partners appreciative of FDA's public health mission and the pressures on its staff, while simultaneously defending statutory limits and least burdensome rights to speed device innovation.

Looking Ahead

In our opinion, the disruptions of 2025 have already provided significant opportunities for the industry in 2026. For example, several of our clients have successfully leveraged FDA's recent changes as an opportunity to participate in meaningful engagement with the Agency and ensure a focus on the shared regulatory goals: faster patient access to safe and effective technology and efficient use of public and user fee resources.

Other clients have chosen to pursue a balanced advocacy posture while engaging with FDA during this time of change. For example, when it comes to challenging FDA decisions, asserting least burdensome rights, and appealing adverse decisions, we strive to be "affably contentious" by advocating for our client positions while acknowledging FDA's public mission. Adopting a similar mentality has proven successful for several of our clients in their regulatory interactions with CDRH, CDER and CBER.

Finally, for the remainder of 2026, medical device companies should continue to invest in regulatory intelligence and scenario planning. That means dedicating resources to monitor ongoing regulatory and judicial developments, build and maintain relationships with FDA and industry peers, and leverage consultants and outside counsel with deep FDA experience to plan for and navigate regulatory interactions. Doing so will continue to position a company to achieve its regulatory objectives. For companies willing to engage strategically, 2026 may be not only interesting, but transformative just as it has been for FDA.

DuVal & Associates
Drug, Device and Food Law

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