DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

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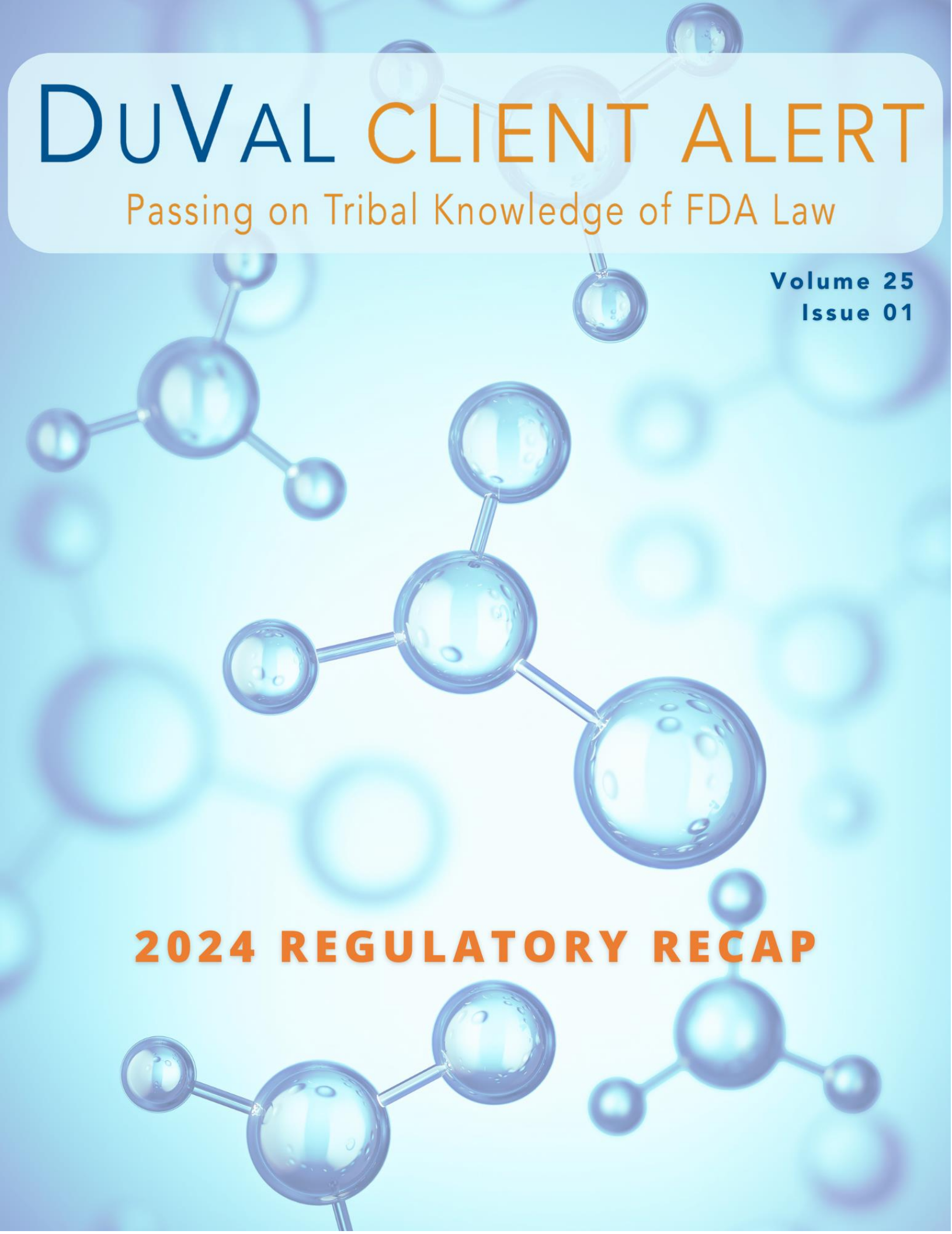

2024 REGULATORY RECAP

TOPIC QUICK LINKS

2024 Regulatory Recap

Introduction

Welcome to a belated 2024 year-end review with this DuVal Client Alert. We are pleased to have waited until now to observe the initiatives rapidly introduced by President Trump's new administration over the last six weeks. Those initiatives have ushered in significant changes, questions, and concerns pertaining to the medical device industry. This DuVal Client Alert is intended to address last year's developments, and those issues raised by the new administration, and provide a comprehensive overview of the developments as we move into 2025 and beyond.

This DuVal Client Alert is limited to our interactions and expectations relating to the Center for Devices and Radiological Health (CDRH) at FDA. **From a macro perspective, we lead with the new Trump Administration.** Everyone wants to know what impact the new Administration will have on administrative agencies like the FDA, and we have seen encouraging opportunities as it relates to administrative performance, transparency and accountability. Before we comment further, we provide a short, insider's perspective on the recent reduction in force at FDA.

We were recently surprised to learn of the decision over the President's Day holiday weekend to eliminate probationary status personnel at the Food & Drug Administration (FDA). That appears to have been temporarily rectified when the Department of Government Efficiency (DOGE) reversed those decisions for probationary FDA employees, but it remains to be seen what the fallout will be. On February 28, 2025, our firm held a Zoom call with displaced employees and service providers and human resources professionals to help FDA employees consider how to obtain new employment. Our thanks to our own Lisa Pritchard who is chair of the Twin Cities RAPS Chapter for spearheading this event with the San Francisco/Bay Area RAPS Chapter and the DC/Baltimore RAPS Chapter. Suffice it to say, these firings and rehires have sent unease throughout the FDA and we are unsure how it will impact workload and morale.

While we acknowledge the importance of government efficiency and right-sizing, we are concerned that the Office of Product Evaluation and Quality (OPEQ) will be indiscriminately and disproportionately affected by any reduction in force. We are especially saddened by the loss of Dr. Ross (Rusty) Segan, Director of OPEQ, with whom we've had great experiences. As external regulatory lawyers and consultants, we collaborate with FDA daily on behalf of medical device companies and understand the Agency's inner workings. **OPEQ's role is fundamental to FDA's mission** and should not be the target of an

indiscriminate reduction in force. Ultimately, the elimination of employees from OPEQ will hinder the timely and safe introduction of new innovations to patients and their physicians. OPEQ is crucial for the well-being of patients, and its operations are primarily funded by industry through user fees. As a result, it should not be a target of government budgetary reductions. To this end, we are concerned that any reduction in force within OPEQ will detract from the FDA's mission and are hopeful that the Department of Health and Human Services (HHS), Congress, and @DOGE_FDA reconsider the broad and seemingly haphazard reduction within OPEQ, and contact us to obtain an insider's perspective before further changes are instituted.

FDA is an excellent Agency with a genuine commitment to ensuring patient safety, but our input to Congressional representatives is that during Dr. Shuren's tenure there was substantial administrative creep that undermined the Agency's ability to speed device innovation. In our experience, the Agency has grown increasingly academic and lacking in pragmatism. This is the inevitable evolution of any administrative agency—to proliferate ever-increasing complexity and unnecessary granularity of its operations and decision making. That evolution creates substantial burdens on industry, which is increasingly challenged to keep up with an Agency's constant and unrelenting changes in decisions, new guidance documents and regulations, and mission creep. Ultimately, the Agency's ongoing evolution translates into risk averseness and delayed decision making, all under the auspices of patient safety. Examples of this include FDA-sponsored studies, grants (like NIH) for third party studies, programs like MEDIC, NESTcc, Collaborative Communities, the Division of Partnerships and Innovation (DPI), The Idea Lab, increasing reliance and participation with the International Medical Device Regulators Forum (IMDRF), along with an avalanche of guidance documents drowning industry, etc. CDRH is dedicated to creating and defining the new field of "regulatory science" instead of faithfully applying the law and regulations that would expedite the approval of devices into physicians' hands for the benefit of patients.

These efforts by the Agency represent serious administrative creep, are increasingly academic and burdensome to industry, and redirect the Agency's effort to focus on matters other than their core mission. Taken together, it undermines the expeditious and affordable delivery of new, safe and innovative products to patients in the United States.

Due to this administrative creep, the Agency has developed new ways to manage their performance metrics and hide from Congress the actual length of time it takes to complete the review process. For example, endless pre-submissions alone account for much time that is never accounted for on the User Fee clock. It has become known as "pre-sub purgatory" in which the Agency, rather than getting on the User Fee clock, plays the game

of requesting endless pre-submission cycles. This, practically speaking, gives FDA much more review time before starting the User Fee clock against which FDA performance is measured. It also gives the Agency the chance to pontificate and ask for their "wish list" of data demands that frequently exceed what is actually needed to clear or approve a product. Other problems include the lack of specific feedback from FDA in those pre-submission meetings so that companies have definitive direction and agreed-upon plans to study their device to bring it to market.

Couple this with the Agency's practice of changing its mind, between pre-subs or mid-sponsor submission, on data requirements and requiring more or different data after a study is midway or, worse yet, completed. FDA becomes an architect of regulatory perfection, front-end loading submissions with data expectations that exceed the regulatory standard for clearance/approval. FDA continues to escalate the quality and quantity of the data it needs, especially in the 510(k) program, far beyond what has been requested of other devices in the predicate family. FDA has little to no regard for the safe precedent established in a longstanding predicate family or for ensuring that only the "minimum necessary" amount of information is demanded under statutory Least Burdensome requirements. The Agency recites Least Burdensome requirements in an obligatory way with no real intention of paying any attention to them.

Another maneuver the Agency utilizes is requesting a company withdraw its file, provide additional information, and refile the submission. All of these tricks and maneuvers result in time spent not attributed negatively to FDA in a Congressional User Fee review. It is time wasted, costly and inefficient, for both FDA and industry, and sometimes fatal, for the small companies that bring most innovation to the Agency. ***As a result, the timelines have grown in ways hidden from the Congress in a User Fee review.*** Moreover, the practical effect is significant as it produces investor fatigue and often the abandonment of good technologies sold elsewhere in the world.

We are still fond of saying that American entrepreneurs still invent most of the world's medical device innovations, but U.S. patients are the last to enjoy the benefits of them.

Industry also wonders what percentage of User Fees are really being utilized for the review and clearance/approval of medical devices? It seems clear to anyone close to the Agency's operations that a high percentage of User Fees are siphoned off to address the myriad of programs Dr. Shuren implemented during his tenure.

The expedited access programs rarely expedite anything. We will not get into the Breakthrough Designation Devices (BDD) program, in which FDA often designates devices, but does not shepherd them through to clearance or approval and into the medical marketplace. Frequently, FDA's input stops at the BDD designation. FDA, as their BDD guidance instructs, is supposed to partner with companies, to ensure BDD devices get through the clinical trial development process to clearance/approval. That is not happening. ***Our strong opinion is that the BDD program often fails of its essential purpose.*** Another good example of this is the Safer Technologies Program (STeP) for Medical Devices, which was introduced by FDA in January 2021. Shortly after its introduction, we wrote the following in a DuVal Client Alert regarding concerns with the STeP Program and similar Agency initiatives:

> *"The STeP Program is not the result of legislative activity and will require buy-in from the FDA and industry . . . As a result, the resources and support for the STeP Program must be committed by the FDA and industry. It is unknown whether this will limit the STeP Program's effectiveness or whether there will adequate buy-in to ensure its success. The legacy of the programs that came before the Breakthrough Devices Program (2011 Innovation Pathway Pilot and Priority Review Program, and the 2015 Expedited Access Pathway) gives pause for the success of a program that is not backed by legislative support. However, given its relationship to its successful, powerful older sister (the Breakthrough Devices Program), and the opportunities afforded to the industry, we are optimistic the STeP program will benefit from the Breakthrough Devices Program's recent success . . .* ***Frankly, the Agency's track record with expedited programs has not been good. The Agency does not have the capacity to deal with its current workload. How will it do this with yet another promise to expedite things?"***

https://duvalfdalaw.com/clientAlerts/DuVal_Client_Alert_V21_I01_FDA_STeP_Program.pdf

Perhaps our feedback was prescient given that the benefits of the STeP program touted by FDA have not been realized four years later. Instead, that program, like other initiatives by the Agency, have become Agency baggage that has seemingly distracted the Agency from one of its fundamental obligations: to speed innovation beneficial to patients to the market. ***FDA excels at risk aversion and blocks many good devices from the market.*** And so, the Agency's self-created distractions, combined with its increasingly academic and risk averse perspective, has resulted in a significant escalation of data, with little to show for it.

Ultimately, we do not know what the Trump Administration will bring to FDA, but we have aspirations. We have initially seen a major review of government spending and operations spearheaded by Elon Musk under the umbrella of a non-governmental agency that has been named the Department of Government Efficiency (DOGE). We also know the swift action taken against USAID and rumors about the Department of Education and the IRS. Robert Kennedy, Jr. has been nominated and confirmed as Secretary of HHS and Dr. Martin Makary is close to confirmation as FDA Commissioner. Dr. Michelle Tarver, Director of CDRH, is a bright, fair-minded, and excellent leader with whom we enjoy working. People want to make the government more responsive and transparent to the public and reverse the presumption the public must defer to governmental agencies rather than have government agencies serve the public.

We greatly appreciate the Trump Administration's moratorium on new regulations and guidance documents as they proliferate at an unmanageable and unnecessary rate. When we appeal negative decisions on 510(k)s, De Novos and PMAs, we are often in the position of training the review staff on guidance documents they have not even read because they, like industry, cannot keep up with them. And guidance documents are not always written with fidelity to the statute or implementing regulations and we are often forced to challenge them.

We also applaud the Trump Administration's call back to the workplace. A significant frustration for industry is to engage with FDA in interactive meetings only to have FDA representatives distracted, while offline, from the topic at hand. Another frustration is the lack of attendance at face-to-face meetings with FDA. As a regulatory law firm (of lawyers, biomedical engineers, chemists, and biostatisticians), we have likely handled more administrative appeals to FDA than any other firm in the country and, in doing so, we always suggest our clients request an in-person meeting at FDA. Through this experience, however, we have increasingly attended meetings and appeals where there are only a few FDA attendees, and the rest are virtual without their faces on-screen. This is frustrating when six to ten company employees travel to FDA to make a bet-the-company case for their product clearance or approval and their FDA counterparts are not in attendance. Face-to-face meetings are critical to having vital conversations where expressions can be read, people are better understood, and after-meeting-conversations can be held, that advance the ball on submissions. Today, FDA employees are allowed to be online and turn off their cameras and sound. It is unknown if they are listening, or are they distracted by activities at home or other work matters while online? This is an enormous disservice to industry.

We appreciate FDA and its management team and there are many, many great employees there. We also cherish the opportunity to work with the Agency to introduce new device innovations, but those interactions need to improve, especially with review staff. Through our daily interactions with FDA, we have many great interactions and we applaud those employees. We have, however, increasingly observed cynicism, skepticism, negativism, and sometimes arrogance (and in some OHT groups a sort of imperialism) in the way FDA review staff interacts with the medical device industry. Those who tell you otherwise are simply fearful of how the Agency might treat them in individual submissions, enforcement matters, or inspections.

But this is why there is concern that the Trump Administration's review of agency operations will receive feedback such as ours. FDA saw the shifting sands before the election in the United States Supreme Court's decision ***in Loper Bright v. Raimondo, 603 U.S. 369, 2024.*** In that decision, the United States Supreme Court overturned Chevron deference concluding that administrative agencies for decades have been granted too much deference in their administrative decision making. Courts are now relatively free to make their own interpretation of statutes and regulations and, importantly, FDA guidance. The Loper Bright decision should concern FDA because FDA's history in federal court is not good. *See, e.g.*, the Washington Legal Foundation, IMS, Caronia, Amarin, Pacira, Howard Root/Vascular Solutions, Prevor, Genus, etc. FDA has also suffered legislative losses when trying to unilaterally change the regulatory scheme without Congressional authority, e.g., the VALID Act and the guidance document regulating LDTs, the proposed wound dressing regulation, that were attempted without legislative buy-in or authority.

When you combine the Loper Bright decision with the mandate given to President Trump to reform our government, there is a movement underfoot to make government more responsive to industry, less wasteful and costly, less risk averse, and exhibit greater fidelity to the statutes and regulations they are to implement. <u>The next four years will be interesting</u>.

The rest of our 2024 Client Alert specifically addresses other issues and initiatives at FDA. Read on!

Current Status of the Breakthrough Devices, Safer Technologies, and Total Product Life Cycle Advisory Programs

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The FDA has several programs intended to shorten the time required for new or improved medical devices to get to market. Strategic consideration must be given to how and when these can be applied effectively to achieve successful outcomes for companies, payors, healthcare providers and patients.

1. Breakthrough Devices Program

The FDA's Breakthrough Devices Program was created by Congress through the 21st Century Cures Act in 2017 with the intent of providing patients timely access to designated medical devices (including device-led combination products) by expediting their development, assessment, and review. The program is available for devices subject to 510(k), PMA, and De Novo commercialization paths and that meet the following eligibility criteria:

> ***(1)*** that provide for ***more effective treatment or diagnosis*** of life-threatening or irreversibly debilitating human disease or conditions; and
>
> ***(2)(A)*** that represent breakthrough technologies; ***(B)*** for which no approved or cleared alternatives exist; ***(C)*** that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or ***(D)*** the availability of which is in the best interest of patients

FDA issued an update to their guidance on the Breakthrough Devices Program in September of 2023 to clarify:

- How the Program may apply to certain medical devices that promote health equity.
- Considerations in designating devices, including eligible devices that may support innovation of new and existing technologies that address inequities.

- That the Breakthrough Devices Program may be available for certain non-addictive medical products to treat pain or addiction.
- How the FDA discloses the Breakthrough status of designated devices once they receive marketing authorization.

Intended industry benefits of the program include:

- Dedicated and faster interactive communications with the agency
- Priority Reviews
- Opportunity to have specific requirements (i.e. inspection) waived or reduced
- Balance of pre and post market data obligations
- Flexible clinical trial design
- Reimbursement opportunities

As of December 31, 2023, FDA has accepted 933 devices into the Program granting these the status of Breakthrough Device Designation (BDD). Note, this includes devices that were under the precursor program – Expedited Access Pathway (EAP). Yet, the Breakthrough Device Program has only produced 95 marketing authorizations from the 933 brought into the Program, raising questions of its effectiveness in bringing new technology to market.

2. Safer Technologies Program (STeP)

Similar to the Breakthrough Devices Program, FDA offers another voluntary program for device and device-led combination products that will be commercialized through the 510(k), PMA, or De Novo pathway. Like the Breakthrough Program, STeP intends to provide patients access to devices expected to significantly improve the safety of currently available treatments by expediting the development, assessment, and review of these products. Where this program diverges from Breakthrough is the focus on safety rather than effectiveness, and with the treatment or diagnosis of a disease less serious than required for BDD. Specifically, the disease being treated or diagnosed does not need to be life-threatening or irreversible.

FDA released guidance on the Safer Technologies Program in January of 2021 with the following eligibility criteria for inclusion in the Program:

(1) should not be eligible for the Breakthrough Devices Program due to the less serious nature of the disease or condition treated, diagnosed, or prevented by the device; and

(2) should be reasonably expected to significantly improve the benefit-risk profile of a treatment or diagnostic through substantial safety innovations that provide for one or more of the following: ***(A)*** a reduction in the occurrence of a known serious adverse event, ***(B)*** a reduction in the occurrence of a known device failure mode, ***(C)*** a reduction in the occurrence of a known use-related hazard or use error, or ***(D)*** an improvement in the safety of another device or intervention.

Much of the same benefits established in the Breakthrough Program apply to the Safer Technologies Program, however, the reimbursement opportunity does not exist in STeP. Transparency is also lost with STeP, in that FDA does not publish devices that have received marketing authorization through the Safer Technologies Program. Nor does FDA inform the number of devices accepted into the Program, and which FDA Panels are involved. Improved access to information on devices accepted into the Program is needed to better understand the value the Safer Technologies Program is bringing to industry and patients.

3. Total Product Life Cycle Advisory Program (TAP)

The goal of the Total Product Life Cycle Advisory Program, or TAP, is to expedite patient access to innovative medical devices through FDA and industry facilitation within the earlier phases of the product development process. Specific criteria must be met for enrollment into the Program:

(1) Devices have been granted Breakthrough Device Designation status; and
(2) No pre-submissions (including Breakthrough Sprint discussions) related to the device were submitted after BDD was granted, and
(3) The device is early in the development process (for example, the potential participant has not yet initiated a pivotal study of the device)

Enrollment in the TAP is exclusive to medical devices (combination products are not available for inclusion) with a phased-in approached by reviewing FDA office. A maximum of one device may be enrolled for each TAP participant per FDA's fiscal year. A historic look and forthcoming expansion of offices and number of devices to be accepted into the Program, by FDA's fiscal year follows:

FY 2023: Enroll up to 15 devices reviewed by the Office of Cardiovascular Devices (OHT2).

FY 2024: Enroll up to 60 total devices reviewed by OHT2 and the Office of Neurological and Physical Medicine Devices (OHT5).

FY 2025: Enroll up to 125 total devices reviewed by OHT2, OHT5, and devices reviewed by the Division of Ophthalmic Devices (DHT1A) and Office of Radiologic Health (OHT8). And, as of January 1, 2025, devices reviewed by the Office of Orthopedic Devices (OHT6).

FY 2026-27: Enroll up to 225 total devices in FY 2026 and 325 total devices in FY 2027 within existing OHTs or expand to additional OHTs, depending on lessons learned in prior years.

Intended benefits of Program inclusion are:

Speed and collaboration of FDA interactions

- Regular informal touch-base meetings with TAP advisor and review teams
- Teleconferences on requested topics within 14 days
- Written feedback on requested topics within 40 days (accelerated to 21 for biocompatibility or sterility topics)

Access to Non-FDA parties that have expertise in areas such as

- Patient Engagement
    - Identifying unmet patient needs
    - How new technology fits into daily health management
- Clinical Evidence Development
    - Defining intended use/indications
    - Clinical study design
- Clinical Practice and New Technology Adoption
    - New technology impact on clinical workflow
    - Feedback on early-stage device designs

- Reimbursement
    - Insight on coding strategies
    - Evidence and payor coverage strategies

Additionally, in October of 2025, devices included in the Safer Technologies Program may also be eligible.

As of October 30, 2024, there are currently 55 devices enrolled in the TAP.

Conclusion

The **BDD**, **STeP** and **TAP** programs have the potential to reduce the time and cost in bringing important new and improved medical devices to market. While on the surface more and more frequent engagements with FDA during the product development process via these programs would appear to be helpful, these also engender the risk of project delays if not managed carefully. The FDA's inherent conservative approach and limited depth of knowledge regarding the application of innovative technology or unique applications of existing technology can lead to development delays rather than acceleration. Companies must carefully balance educating the FDA review staff while focusing formal feedback requests to specific least burdensome process and evidence requirements that establish equivalence or safety and effectiveness.

The TAP program has significant potential to improve the overall success and timeliness of the product development and market access process. Having an FDA TAP advisor as essentially an extended project team member engenders significant potential for risk and reward. The development and deployment of this program should be expanded to all medical device types and employed effectively by FDA and companies in engaging and addressing the needs of the patients, healthcare providers and payors.

Cybersecurity and Medical Devices: New Expectations for Safe and Effective Devices

Bryan Feldhaus, J.D., LL.M., President

Imagine a scenario where a hospital's critical medical devices—such as pacemakers, insulin pumps, or diagnostic imaging equipment—are compromised by a cyberattack. What would that mean for patient safety, operational continuity, and even the providers' reputation?

As medical devices become increasingly interconnected, the risks posed by cybersecurity threats are growing exponentially. In response, the U.S. Food and Drug Administration (FDA) has ramped up its focus on cybersecurity, issuing new guidelines that demand manufacturers take a more proactive, rigorous approach to safeguarding their devices. These updated requirements are not just about protecting sensitive data—they are about protecting lives.

In December 2023, I wrote a DuVal Client Alert regarding cybersecurity expectations for medical device manufactures and identified ***three primary expectations that govern the design, manufacture, and sales of medical devices:*** (1) ***appropriate device design*** - a device must be designed with appropriate risk mitigation, validation and cyber protections to establish a safe and effective use; (2) ***appropriate risk mitigation*** - a device must be subject to updates to mitigate new risks and vulnerabilities; and (3) ***appropriate user disclosure and communication*** - the use, risks and vulnerabilities of a device must be adequately communicated to patients and clinicians.

In this 2025 DuVal Client Alert, we reaffirm our expectations for medical device manufacturers and emphasize the FDA's most recent cybersecurity developments and their implications for manufacturers, healthcare providers, and other industry stakeholders.

Cybersecurity Updates from FDA

FDA has remained very active with respect to cybersecurity concerns for medical devices. Much of FDA's activities are detailed on the "Cybersecurity" page hosted by the FDA Digital Health Center of Excellence, including FDA's cybersecurity video entitled "Tips for Health Care Facilities: Cybersecurity Incident Preparedness and Response," May 2023, FDA's final Guidance, "Cybersecurity in Medical Devices: Quality Systems Considerations and Content of Premarket Submissions," Sept. 26, 2023, and FDA's Draft Guidance, "Select Updates for the Premarket Cybersecurity Guidance; Section 524B of the FD&C Act," March 2024.

In addition to these resources, FDA also provides both an Incident Response Playbook and Threat Modeling Playbook for industry, recommendations for mitigating cybersecurity risks, as well as Cybersecurity White Papers and Safety Communications. For example, on January 30, 2025, FDA issued a Safety Communication entitled "Cybersecurity Vulnerabilities with Certain Patient Monitors," Jan. 30, 2025. This Safety Communication addresses the cybersecurity risk associated with certain patient monitors utilized in healthcare facilities and home settings. Specifically, it highlights vulnerabilities in these devices that could enable unauthorized access and manipulation by third parties. Notably, this is the first Safety Communication issued by the Agency since September 2022, and it may serve as a precursor to future safety alerts and communications pertaining to the use of connected medical devices.

Cybersecurity Best Practices

As I indicated in the 2023 DuVal Client Alert, there are several developments that medical device manufacturers should be mindful of relating to their design, development, regulatory review, and commercialization of medical devices.

First, Section 524B became effective in March 2023, which introduced new cybersecurity requirements into the Food, Drug & Cosmetic Act. On December 29, 2022, Section 3305 of the Consolidated Appropriations Act was enacted, which added Section 524B to the Food, Drug & Cosmetic Act. Section 524B, which is entitled "Ensuring Cybersecurity of Medical Devices," and authorized FDA to establish cybersecurity requirements for manufacturers of digital health devices. Therefore, under Section 524B(a), any person who submits a 510(k), PMA, PDP, De Novo, or HDE for a cyber device (as defined in Section 524B(c)), is required to submit information to FDA to ensure the cyber device meets the requirements of Section 524B including, without limitation, risk mitigation and validation requirements, design considerations, etc.

Second, FDA issued its final guidance relating to cybersecurity requirements for premarket submissions for medical devices. On September 26, 2023, FDA issued its final guidance entitled "Cybersecurity in Medical Devices: Quality Systems Considerations and Content of Premarket Submissions." This Guidance provides recommendations on medical device cybersecurity requirements and the information that must be included in premarket submissions, including (1) the implementation of a secure product development framework (SPDF) to identify and mitigate cybersecurity risk; (2) the evaluation of cybersecurity risks associated with device interoperability; and (3) the use of a software bill of materials (SBOM). Importantly, this Final Guidance also superseded FDA's prior premarket cybersecurity guidance from 2014, and supplements FDA's postmarket cybersecurity guidance, guidance

for medical devices containing off-the-shelf software, and premarket submissions guidance for device software functions.

Finally, several other resources and best practices have been recently issued for medical device manufacturers. These resources, such as the Medical Device Cybersecurity Response Playbook and the Playbook for Threat Modeling for Medical Devices, were published through the joint collaboration between FDA and MITRE, a not-for-profit firm that serves as an independent advisor to government agencies and is responsible for advancing national security interests. Additionally, other, relevant resources have been provided by FDA to educate the medical device industry regarding expectations and requirements for cyber devices. However, despite these resources we believe there is also a burgeoning conflict between FDA's expectations and requirements for cyber devices and its obligations under the Least Burdensome statutory requirements and the statutory framework of the 510(k) and De Novo programs.

Resources for the Development of Cyber Devices

The ongoing evolution of cybersecurity measures for medical devices, coupled with the implementation of stringent regulatory requirements outlined in FDA's Guidance, will inevitably lead to a progressive increase in complexity. Fortunately, the Agency has provided several additional resources for ***medical device manufacturers to navigate such complexity.***

For example, FDA's development of its Digital Health Center of Excellence within CDRH, its FDA Fact Sheet "FDA's Role in Medical Device Cybersecurity," and its Cybersecurity FAQs provide information regarding the implementation and requirements under Section 524B, the definition of cyber devices, the application of Section 524B requirements and post-market obligations under FDA's 2014 and 2016 Guidance Documents.

The Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook, which is a collaborative effort between FDA and MITRE, is also a helpful resource. The Playbook recommends best practices for cybersecurity protection and outlines a framework for responding to cybersecurity incidents involving medical devices. In fact, the Playbook is a particularly helpful document because it is addressed to clinicians, device manufacturers and healthcare delivery obligations and represents the most recent recommendations on cybersecurity incident responsiveness.

Finally, FDA's playbook entitled, "Playbook for Threat Modeling for Medical Devices," which was also a collaboration between FDA, MITRE and the Medical Device Innovation Consortium

(MDIC), identifies best practices for understanding cyber device threat modeling, and how organizations can develop an effective approach to threat modeling for medical devices.

Leveraging these resources, along with our regulatory and professional experience, will help you more effectively address key cybersecurity requirements for medical devices:

- ***Cybersecurity Design and Risk Mitigation*** – Medical device manufacturers must integrate cybersecurity risk mitigation practices into the design and development stages of medical devices. This includes a thorough risk assessment to identify potential cyber vulnerabilities and incorporate appropriate safeguards. Additionally, FDA stresses that cybersecurity must be considered an integral part of the device's architecture, not an afterthought.

- ***Cybersecurity Monitoring and Vulnerability Management*** – FDA stresses that cybersecurity is not a one-time effort. Manufacturers are required to actively monitor devices after they are in the field and address any emerging vulnerabilities. This includes providing timely updates for vulnerabilities that could affect the device's functionality or patient safety.

- ***Cybersecurity Documentation and Communication*** – Finally, medical device manufactures are required to document all cybersecurity risk management activities in detail and make this information available to the FDA upon request. This includes providing clear communication channels for reporting vulnerabilities and addressing them promptly to the Agency, customers and patients.

Conclusion

Medical device users expect their devices are safe and effective. This is also an expectation of FDA when evaluating premarket submissions for medical devices. Recent legislative action and FDA guidance has formalized FDA's cybersecurity expectations to ensure the safe and effective use of cyber devices. Manufacturers must continue to monitor and implement these changes to avoid potential compliance issues and mitigate cybersecurity risks.

Drug Referencing Drugs (DRD)

Aaron Hage, J.D., Vice President of Legal-Regulatory & Compliance

The FDA's abandoned policy on Devices Referencing Drugs (DRD) continued to create issues in 2024 and further demonstrates that the Center for Drug Evaluation and Research (CDER) has an inordinate level of influence over the Center for Devices and Radiological Health (CDRH) decision-making. Under FDA's current unwritten, unpublished, unadopted policy, CDER does not allow CDRH to approve or clear a medical device if the use of the device, as indicated, would allow for a drug to be used for an unapproved use, regardless of whether the drug is approved for other uses or whether that unapproved use is a standard of care in the practice of medicine. In CDER's mind, whether the device meets the standards for approval or substantial equivalence does not matter. If there is an outstanding drug question that CDER has not evaluated, it is a complete barrier to marketing authorization. Any company with such a device is stuck. It cannot gain approval unless there is an expensive drug study conducted demonstrating safe use of a particular drug with that device. This is despite the fact FDA has cleared many universal drug delivery system devices such as drug delivery catheters, iontophoretic patches, nebulizers, and many other examples. And it is despite the fact many of these drugs have been safely on the market for years for these uses.

We have argued, as others have before, that such a policy on the part of CDER exceeds their statutory authority as nothing in the Food, Drug, and Cosmetic Act gives CDER any ultimate decision-making authority over a medical device being used in such a fashion. It is arbitrary and capricious for the Agency to not clear or approve devices that would otherwise meet the statutory and regulatory requirements for market authorization under the 510(k) program. Additionally, this unpublished policy violates due process requirements because the policy did not undergo the required notice, comment, and rule-making requirements. It has been kept in the shadows of the FDA, which allows CDER to have ultimate oversight over how medical devices may use drugs that CDER has not evaluated for the indicated use, even when a specific drug is not referenced by the device.

We recently had the opportunity to appeal an FDA decision denying a labeling change to a client of ours on grounds that took us truly by surprise. In short, our client manufactures a 510(k)-cleared tool that is utilized routinely in surgical procedures to deliver therapeutic solutions to patients, which may include a drug approved for a separate use. The efficacy, safety, and utility of this technique has been extensively published over multiple decades. It has become standard of care. Its use can be found in published medical society

guidelines. Nevertheless, the agency will not allow our client to have a label that reflects the potential use of agents from the drug class of interest.

Casting aside precedence from their extensive history clearing universal drug delivery systems as mentioned above, CDRH instead denied the expanded label based upon an internal, non-visible (unwritten and unadopted) CDER policy stating that a device cannot reference a drug in its label if that drug has not been tested for that use.

The issues here are manifold. Most importantly, FDA should not be allowed to deny any clearance/approval based upon internal unwritten, unpublished agency policy. The core of our appeal argument was that our client is being denied due process as they are being held to a standard that is not published in any statute, regulation, or guidance. Should FDA wish to have such a policy in place, it should be made public. This would allow for a comment period while the policy is in draft form and, if finalized, would ultimately allow for legal challenge if the policy is found to be overly broad or inconsistent with other statues or regulations.

Further, we argued that the label could be appropriately expanded under the 510(k) standard of substantial equivalence. As laid out in CDRH's 510(k) Decision-Making Flowchart in FDA's guidance document: "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] Guidance for Industry and Food and Drug Administration Staff," issued July 28, 2014), if a subject device has the same intended use and the same technological characteristics as the predicate device, the regulatory evaluation is over and the device is deemed substantially equivalent, assuming the submitted descriptive or performance data supports the conclusion that the technological characteristics are the same.

Given our client is using their own cleared device as the predicate, the only remaining question is whether the expanded label would represent a new intended use – which it does not. The use of our client's tool to facilitate this surgical technique is well known, widely published, and has been the focus of myriad discussions with the agency going back to the early 2000s. In fact, it is the only use to which this device is put in the United States. It is labeled for the use being denied by the FDA in the rest of the world. Is this not classic FDA arrogance, that they know more than the rest of the world.

To CDRH's credit, they proposed a DRD policy in 2017 that would allow devices to come to market even when a drug company was not seeking the specific indication for their drug. The Federal Register Notice (82 Fed. Reg. 44803) stated (emphasis added):

> *FDA seeks to ensure that safe and effective medical products can be brought onto the market in a timely manner. The Agency encourages the development of products that advance public health, particularly those that significantly improve the safety or effectiveness of an existing treatment or that address an unmet medical need.* ***DRDs have the potential to advance public health by offering new uses with approved, marketed drugs that might not otherwise be developed because the drug sponsor does not wish to pursue the new use.*** *At the same time, DRDs raise unique public health, scientific, regulatory, and legal issues.*

Unfortunately, after several years of resistance from drug manufacturers and CDER, this DRD Policy was abandoned in 2020. Going forward, device manufacturers that reference drugs must battle CDRH, drug companies, and CDER to get their devices cleared or approved. CDER's stance is find a drug company to do the studies necessary to get the product to market with approved labeling the problem is that these are generic drugs and there is not economic incentive for a pharmaceutical company to divert precious resources to create a new, small market for a generic drug. ***So that creates the CDER-created impractical impasse.*** The device is used throughout the world with this generic drug and CDER will not let it come to market in the U.S. without an expensive drug trial for which there is no market incentive to conduct.

Now in 2025 maybe the tide will start to turn. Last year's ***Loper Bright Enterprises v. Raimondo*** Supreme Court decision cast out the decades-old Chevron Deference doctrine that gave administrative agencies, such as the FDA, ultimate deference to interpret their authority under the statute. Now, under ***Loper Bright,*** FDA's automatic deference has been removed and has opened the door for the courts to interpret FDA's broad interpretation of statutes and their authority. This will allow the courts to thoroughly scrutinize agency actions if a party is brave enough to raise the issue in the courts.

Additionally, we have a new Presidential Administration under Donald Trump. The Trump Administration 2.0 has promised to hold administrative agencies accountable and within the bounds of their authority. Maybe in 2025 we will see a DRD Policy gain new life and encourage the innovation, development, and market authorization of devices that reference drugs to meet unmet needs and propel public health.

From Commercial Authorization to Coverage - the Increasing Demands on Clinical Evidence

Chris Lyle, M.S., Vice President – Evidence Strategy

Early in my career I attended a management training program where the instructors often returned to a central idea: ***"just because you can doesn't mean you should."*** While this mantra is useful on many levels, I believe it also serves as conceptual guide to navigating the journey from FDA authorization to widespread payer coverage. We often hear of the ***"valley of death"*** whereby payers demand more evidence to support coverage decisions, but it can be difficult to discern what is they require. Manufacturers can benefit by planning early to facilitate the difference in arguments needed to support that a technology ***can*** be used and demonstrating where it ***should*** be used.

FDA provides authorization that a medical technology ***can*** be considered for a particular patient. That is what their statutory authority to assess ***safety and effectiveness*** covers. On the other hand, payers are charged with determining what treatments are ***reasonable and necessary*** – or said another way – what ***should*** be considered for that patient. It is now widely recognized that this second threshold often requires more comprehensive support.

Therefore, it is always appropriate to ask the question: ***if we are going to need additional evidence to obtain coverage anyway, are there steps we can take to de-risk our regulatory strategy from the start?*** Every situation is unique, however, there are times when it is relatively straightforward to discern the breadth of evidence that payors will need to see. To the extent that additional requirements are built into the clinical evidence plan from Day 1, the FDA pathway may be smoothed out and lead to a more predictable market authorization journey.

Learnings Through the Lens of FDA Appeals

Having supported hundreds of FDA appeals, we have in-depth knowledge of how submissions find themselves in rocky water. Many appeals are focused on arguments over whether the clinical evidence provided can be deemed sufficient. Regardless of the regulatory pathway, FDA "not approvable" decisions often point to questions of:

- **Benchmarks** (adequacy of control groups, performance thresholds, historical controls, etc.)
- **Clinical significance** (is there a recognized minimum level of improvement?)

- **Primary endpoint(s)** (appropriateness of selections, utility of surrogates, is FDA more interested some other result that would require a larger sample size or longer follow-up?)
- **Safety signals** (small trials often run a risk of seeing elevated AE rates due to chance alone)
- **Data robustness** (blinding, adjudication of AEs or radiographs, missing data, impact of protocol deviations, choice of analysis populations)

These hurdles are often foreshadowed in pre-IDE and/or Q-Submission feedback as ***additional factors for consideration*** (i.e., concerns that do not preclude completion of the planned trial but that are noted as potentially affecting interpretability of the results if not resolved). We routinely advise clients to get these matters resolved quickly so that agreement can be reached with the FDA on ***how the data will be assessed and what is required to have a successful result.*** Waiting until the end and hoping the results are strong enough to overcome stated concerns can backfire. All too often, pre-IDE additional considerations come back around from the review team as "we told you we were concerned about…please conduct a new study implementing our recommendations". When handled promptly, tactics for addressing these lingering concerns often do not require marked clinical study modifications. The statutory framework of FDA reviews often allows for precedential and least burdensome arguments or additional bench testing to temper review team concerns. ***No matter how these issues are confronted, reaching agreement with the FDA that good results in the trial as designed will support marketing authorization is often preferable to going "at risk".***

Increased Evidence Demands from Payors

Notwithstanding the availability of regulatory arguments supporting the provision of the minimum clinical data necessary to FDA, it can also be true that increasing the rigor and breadth of a trial can temper review team concerns - and may also align better with future payor needs. For emerging technologies in particular, payers tend to focus on published evidence showing durability of effect, improved clinical outcomes, and the long-term comprehensive safety profile. They also often cite third-party recommendations (e.g., society treatment guidelines, technology assessments, meta-analyses) providing independent assessments of what is considered reasonable and necessary.

The National Association of Managed Care Physicians (NAMCP) provides a template for medical technology dossiers than can be used to guide evidence development initiatives.[1] Dossiers are often provided to payers upon marketing authorization to introduce a new

technology. In stark contrast to regulatory filings, dossiers are typically on the order of 20-30 written pages. Particularly important arguments to develop include:

- Epidemiology of the condition
- Health consequences of the condition
- Description of the unmet need and how the technology addresses it
- Indicated patients and technology fit in the clinical pathway.
- Summary of published evidence showing (often long term) effectiveness, safety, and core value drivers

It is noteworthy that there is relatively little overlap between this list and the elements where FDA often pushes back on evidence plans. As opposed to focusing on the minutiae of success definitions, primary endpoints and sample size, ***payers want a more comprehensive demonstration of:***

- ***What*** patients are ***best indicated*** for the technology
- ***Why*** the technology should be considered ***amongst the range of available therapies*** at a particular juncture of clinical care
- ***What consequences can reasonably be expected*** over the coming years

For many payors, this is the standard for when a technology matriculates from something ***that can be considered to one that should be considered.***

Beginning with the End in Mind

It is widely understood that regulatory and reimbursement planning should happen early and in concert with each other. Evidence plans follow from the joint needs identified from these early assessments. While DuVal does not provide coding and payment analysis, we do assess likely differences between FDA and payor evidence requirements. Having knowledge of these gaps early on can inform a range of strategies, ***including how to respond to FDA pre-trial feedback.*** In certain circumstances, it may be entirely appropriate to consider "over designing" an IDE trial if those data are going to be required to support payor arguments anyway. At the very least, consider extending subject follow-up beyond the point of submission to allow durability data to accumulate. Narrowing the gap from ***"can"*** to ***"should"*** increases the rate of commercial uptake. It may also mitigate the likelihood of receiving the dreaded Not Approvable/NSE letter.

[1] **https://www.namcp.org/journals/Medical%20Technologies%20Dossier.pdf**

Laboratory-Developed Test (LDT)

Aaron Hage, J.D., Vice-President of Legal-Regulatory & Compliance

As anticipated, last year brought increased uncertainty to the Laboratory-Developed Test (LDT) space, and more uncertainty is expected in 2025.

As we have discussed before, the FDA has spent the past fourteen years asserting its regulatory authority over LDTs by claiming that they are in vitro diagnostic devices regulated under the Food, Drug, and Cosmetic (FD&C) Act. However, understanding that they were on shaky legal ground, the Agency exercised a risk-based approach to regulating LDTs and placed the burden on Congress to provide the FDA with the proper authority to regulate LDTs. But as expected, following the failure of the Verifying Accurate Leading-edge IVCT Development (VALID) Act to pass through Congress and provide a new regulatory scheme for IVDs, the FDA issued its final rule on LDTs on May 6, 2024. Under this final rule, the Agency plans to phase out its enforcement discretion approach to LDTs so that LDTs align with the current regulatory scheme for IVDs.

However, the issue remains that LDTs are inherently different than IVDs. LDTs are generally considered an assembly of procedures and devices used within a single laboratory, tailored to that lab's needs and capabilities. They are not introduced into interstate commerce as they remain within the laboratory.

Yet, the Agency, has taken the position that an element of interstate commerce is not required for FDA to regulate LDTs. FDA's Final Rule FDA states:

> ***We disagree that introduction or delivery for introduction into interstate commerce is required for FDA jurisdiction of devices, including LDTs, under the FD&C Act.*** The FD&C Act's definition of a "device" subject to FDA's jurisdiction does not include an interstate commerce element. Whether a particular provision of the FD&C Act requires a connection to interstate commerce goes to the reach of that specific provision, not of the device definition or of the Act as a whole. ***If an FD&C Act provision does not contain an interstate commerce element, "interstate commerce" imposes no limit on FDA's powers beyond the constitutional minimum.***

This continues to be an absurd position. Although the Supreme Court has interpreted that Congress's authority under the Commerce Clause is broad and may extend to intrastate

activities that substantially affect interstate commerce, an administrative Agency, such as the FDA, does not have the same constitutional authority as Congress. ***The FDA's authority to regulate interstate commerce is only to the extent provided by Congress through the legislative process.*** As far as the FDA's authority to regulate devices, it is clear that the FDA's authority is restricted to those devices introduced into interstate commerce. Although not every provision of the FD&C Act makes reference to interstate commerce provision, these provisions tie back to the main purpose of the FD&C Act and its prohibitions, as outlined in the preamble to the statute and later specified in Section 301 of the Act: ***"To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes."*** Therefore, if the devices, such as LDTs, are not being introduced, delivered, received, or otherwise moving within interstate commerce because they remain within a single laboratory, they are not within the scope of the statute's adulteration and misbranding provisions, and FDA would not have authority to regulate these LDTs without an act of Congress, like through the passage of the VALID Act.

From a more practical perspective, this Final Rule will have a detrimental effect on laboratories. As in all cases of over-regulation, laboratories will have to determine which tests are sufficiently profitable to justify the increased financial burden that must be incurred for continued FDA compliance. This will undoubtedly result in reduced access to testing, delaying responses to testing needs, such as during a public health crisis. Additionally, it will result in stifled innovation that will fail to meet unmet patient needs. All these downsides while still having likely little impact on patient safety, given that many of these tests are low risk and have been safely available to doctors and patients for decades.

However, much uncertainty awaits the implementation final of this Final Rule, given the ongoing litigation and the new Trump administration. In 2024, multiple lawsuits were filed against the FDA to stop this Final Rule, including those filed by the American Clinical Laboratory Association and its member company, HealthTrackRx, and the Association for Molecular Pathology. These lawsuits allege, in part, that FDA exceeded the scope of its authority in issuing this Final Rule and that the Agency acted arbitrarily and capriciously in creating this rule given there was no need for additional legislation because LDTs are already regulated under the Clinical Laboratory Improvement Act (CLIA).

Additionally, the Trump administration is heading to Washington with promises of cutting regulations and red tape to help promote growth and innovation. Presumably, this would include not throwing a wrench into a medical space that is generally used for lower-risk applications, can quickly meet unmet needs without burdensome FDA oversight, and is appropriately regulated under CLIA and the Centers for Medicare & Medicaid Services.

Industry groups and professional associations, such as the American Society for Clinical Pathology, have contacted the Trump transition team regarding rescinding the Final Rule. However, given other priorities in Washington, it would seem unlikely that President Trump or Congress would take any direct action, including reviving and passing the VALID Act. However, it is far more likely that Trump's appointments to the Department of Health and Human Services and FDA take more direct action in the non-implementation of the Final Rule. As it goes with FDA, the most likely outcome may be continued "enforcement discretion" in the LDT space, an often-used term when FDA has questionable jurisdiction to regulate a particular space.

In any event, it is safe to say that 2025 will again bring much uncertainty to the LDT space and much to look forward to in 2025 and beyond.

Proposed Wound Dressing Rule

Mark DuVal, J.D., FRAPS, CEO

Introduction

Last year we saw no movement on the proposed Wound Dressing Rule. We published a Client Alert titled "Halting the Runaway Train: United Opposition to FDA's Wound Dressing Classification." We complained that FDA's proposed rule was a solution in search of a problem. We believe that with the Trump Administration's DOGE initiative, and the Presidential Executive Order halting the promulgation of new rules, this is likely permanently on hold.

By way of background, on November 29th, 2023, FDA posted a Proposed Rule to Regulations.gov titled "Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes" (the "Proposed Rule"). The open comment period for the Rule was designated to close on February 28, 2024, with 74 total unique comments uploaded to date. In its own summary, FDA stated:

> *"[We] are proposing to classify certain types of wound dressings and liquid wound washes containing antimicrobials and/or other chemicals (unclassified, preamendments devices) as solid wound dressings; wound dressings formulated as a gel, cream, or ointment; and liquid wound washes."*

We filed our objecting comments (found here) **that addresses significant concerns propagated by this Proposed Rule.** We have assembled and categorized below the comments to the proposed rule found on FDA's website. We encourage you to see the strong opposition to this rule. It remains to be seen if FDA is truly interested in these comments or is this a runaway train and the comments are small obstacles to be removed from the tracks or run over.

In Summary

As more intricately detailed by our full comment, the Proposed Rule attempts to reclassify a class of products that has been de facto classified for decades. It is a well-established family of products. There is no need for classification. We have survived for decades without it. The Proposed Rule imposes new stringent requirements on wound product clearances and approvals under the pretext of addressing antimicrobial resistance ("AMR"). However, these regulations appear to be based on unsubstantiated and exaggerated scientific and medical concerns regarding the impact of antimicrobial wound products on the microbiota and AMR. While FDA emphasizes its efforts to address AMR, the underlying motive seems to be to take advantage of a perceived AMR crisis to permit a rapid implementation of substantial regulatory changes within the Wound Products sector. This includes proposed changes to the labeling of new and existing products and an attempt to impose as yet undefined special controls that are unnecessary. The attempt to regulate Wound Products is hindered and undermined by:

- past administrative proceedings in which FDA's own advisory panels did not agree with FDA to change the regulatory framework,
- a thin (to non-existent) administrative record that does not scientifically or medically support FDA's conclusions (i.e., scientific literature not supportive of the Proposed Rule), and
- decades of existing clearances and marketing with an unremarkable safety record.

Somehow, this has led FDA to leverage the perceived issue of AMR and its effect on the microbiota as a justification to impose new burdensome regulations and retroactive adjustments to the 510(k) program, despite lacking substantiated evidence for such actions. **Why is it that FDA often feels the need to over-regulate quiet, well-known, well-settled, product categories? Is it fiefdom building, a scientific expedition without a destination, a mindless escalation of data requirements, regulatory boredom, or all the above?** Some surmise it is an attempt to collaborate with research-based academia to generate more clinical trials and government grants for a new vista of scientific information to satisfy scientific

curiosity and fill the coffers of university research departments. Others believed it was a rush is to get this done in the event there is a potential change in Presidential Administrations that might not allow this Proposed Rule to proceed, at least not as currently drafted. Whatever the motivation, necessary or unnecessary, or a little of both, this seems to be a solution in search of a problem.

We recognize and appreciate that FDA has a bona fide concern for AMR and its collateral effect on the microbiota, but there is no objective or circumstantial evidence to support such a belief as it relates to Wound Products. We certainly can agree there is a category of Wound Products, impregnated with more serious AMRs, that need to be regulated with Class III PMAs. There is also a category of products containing well-known drugs that can safely remain in the Class II category without adding to the regulatory regime governing them. The purported concern appears to be an artificially manufactured crisis, enabling the imposition of unnecessary regulations and controls on wound products. Antimicrobial Wound Products actually serve as a solution to AMR by reducing the need for systemic drug use. Yet, FDA persists in proposing additional testing requirements that are unnecessary to the supposed threat posed by these products, which may further complicate the regulatory landscape without addressing the core issues of AMR.

An attempt to implement sweeping regulations for Wound Products based on a speculative hypothesis regarding AMR reflects a broader trend of administrative overreach. Despite industry objections, laid bare in the public comments provided by many organizations and individuals, and the lack of convincing evidence, FDA persists in its endeavor to change the regulatory framework for clearing a Wound Product. The Proposed Rule takes a serious shot at changing the 510(k) program and its reliance on predicates. FDA is an administrative agency, not a legislative body. If such significant changes are to be made, Congress needs to be involved, and a sturdier scientific justification must be provided, neither of which is currently evident in FDA's proposed rulemaking on this matter.

The approach to addressing the issue at hand is infirm, and unlawful, from a number of perspectives.

- **First**, ***FDA creates a regulatory fiction by treating wound products as unclassified entities,*** despite their long-standing de facto classification.
- **Second**, ***FDA's administrative record, largely based on public scientific literature, fails to adequately support the drastic regulatory changes proposed***, particularly concerning larger antimicrobial resistance (AMR) and microbiota issues. It would behoove the government to initiate long-term studies

to understand the AMR issue better by considering the everyday use of antimicrobial products in various settings.

- **Third**, ***the Rule indirectly attempts to alter the 510(k) program by de facto negating the existing process, invalidating labeling for currently cleared devices, and possibly requiring new studies*** to lawfully promote existing intended use statements. This maneuver undermines the statutory framework and due process associated with 510(k) clearances, as FDA lacks the authority to rescind or alter clearances without substantial cause presenting a clear and present danger to the public. A 510(k) is a legal order and cannot be changed without due process.

- **Fourth**, ***the Proposed Rule imposes unclear requirements on both new and existing 510(k) Wound Products, mandating new clinical data submissions without clear evidence or justification for such drastic changes.*** This not only places undue burdens on manufacturers but also fails to acknowledge existing products' lawful clearances and safety records. Furthermore, the Rule appears to suggest current labeling for cleared devices must change and subsequent devices will not be able to inherit the labeling of their chosen predicate. FDA seems intent on taking away currently cleared claims such as "may aid healing" and "may help in wound management."

- **Fifth**, ***FDA's acceptance of the World Health Organization's classification of AMR constitutes an unlawful delegation of authority***, given that the WHO lacks jurisdiction and authority within the US governmental framework.

- **Sixth**, ***the Proposed Rule is antithetical to the statutory Least Burdensome requirements*** imposing unnecessary regulatory burdens without proportional risk assessment, violating both "substantial equivalence" and "minimum necessary" principles.

- **Finally**, ***the potential ramifications of implementing the Proposed Rule include*** stifling innovation, reducing product availability, and exacerbating the of AMR by limiting the use of antimicrobial Wound Products, ultimately undermining patient care and public health efforts

To conclude, our concern is the Proposed Rule is a solution in search of a problem. It attempts to address the issue of antimicrobial resistance in a precipitous, unsubstantiated, overbroad, and unnecessary manner. Wound Products today are well-known and well-characterized by nearly fifty years of tried-and-true testing and everyday use. Ultimately, this Proposed Rule will hamper innovation, reduce product availability, limit options for physicians, and harm patients. This is analogous to what has occurred in Europe under the

Medical Device Regulations, where unnecessary increased regulatory requirements have caused significant regulatory burden and acute product shortages—a self-inflicted wound created by the government. Let us not replicate that here with Wound Products.

To Ask or Not to Ask? That is the Pre-Sub Question

Lisa Pritchard, BSEEE, VP of Regulatory, Quality, Clinical and Engineering

Clearly, the FDA Pre-submission has not been around as long as Shakespeare. However, as part of the overall Q-Submission program, the Pre-Submission has been around a long time (as the pre-IDE program since 1995 and the Pre-Submission program since 2013). This provides a significant data set upon which to ask the (improvised) age-old Shakespearean question ***"To ask or not to ask?..."*** or translated to current language: ***when does is make sense to engage FDA in a Pre-Submission communication and when is it better not to?***

Briefly, a Pre-Submission (or "Pre-Sub") is one of the most common early communication methods available to companies to receive formal feedback directly from FDA. Specific details of the program are included in the current FDA Q-Submission guidance. Topics frequently covered in a Pre-Sub include test plans, animal study designs, clinical study designs, proposals for addressing biocompatibility, and adequacy of proposed predicate device selection, to name a few. The process begins with submission of a Pre-Sub request that provides background information about the product and the specific topic(s) to be addressed and outlining the questions that you want FDA to answer. Feedback for a Pre-Sub can be provided either in written form only or in written form followed by a meeting. After receiving the Pre-Sub request, expect it to take about 70-75 days to obtain feedback. If a meeting is held, minutes will be required, adding another 30-45 days to the schedule. We recommend that feedback not be considered final until FDA has either accepted the minutes as final or provided their edits to the minutes (typically 30 days after the sponsor provides the proposed minutes).

FDA appears to love the Pre-Sub process. In the most recent FY2023 MUDFA Performance Report, FDA reports that there were 3904 Pre-Subs filed in FY2023, an increase of 24% from the five year average of 3154. Each Pre-Sub provides an opportunity to jump on a company's development team and obtain early information about new products. It is an opportunity to provide their "wish list" of testing (which may or may not be aligned with Least Burdensome

principles). Through the DuVal & Associates experience with Pre-Subs over the years, and spirited discussions that have taken place in the Q-Sub interactions segment of our popular RAPS Workshop "Survivor: the FDA 510(k) Edition," we recognize that it is imperative to take a strategic approach to utilizing the Pre-Sub process. This contrasts with the often-popular opinion that the program should be used early and often, giving FDA the opportunity to weigh in on about every product decision to be made.

When does it make sense "To Ask" or engage FDA in a Pre-Sub? If your commercialization submission will be a De Novo or PMA, it will be appropriate to engage FDA to ensure that the planned scope of testing is aligned with FDA expectations. Due to the "stand alone" demonstration of reasonable assurance of safety and effectiveness for the product and the significant user fees associated with these submissions. If the commercialization submission will be a 510(k), this a tougher and closer call, which you should think through carefully. Increasingly, we are telling clients to consider being presumptive about their position and consider using the submission itself, and the ensuing 180 period given after an AINN, to operate as a de facto Pre-Sub. A Pre-sub can be helpful in a 510(k) when the predicate device selected is not ideal, or animal or clinical testing are needed. It can also be helpful in cases where there is a particularly complicated device design that may benefit from using the Pre-Sub partially as an educational opportunity for the review team prior to the commercialization submission. Often, Pre-Subs are utilized to build confidence for investors regarding the regulatory strategy. Finally, Pre-Subs can be helpful in determining product modifications that could be considered part of a Predetermined Change Control Plan (PCCP).

Conversely, when does it make sense "Not to Ask" or bypass the Pre-Sub and go straight to your submission (e.g., IDE or 510(k))? There are several cases where it likely makes sense to skip the Pre-Sub, be presumptive about your position, and go straight to your submission. Examples include a regulatory pathway with a straight-forward predicate device for a 510(k) pathway. This is especially true if the predicate is your own device, the knowledge gained from a Pre-Sub is likely to be limited and may result in a need for more testing than would have been required if the 510(k) had simply been filed. If the predicate is not your own device, but you have detailed information about the testing conducted (e.g., there are recognized standards that need to be followed, or performance standards for the device available), you should be in good shape to move forward with the 510(k) submission. If you are conducting a significant risk clinical study that will require an IDE submission, it may be more beneficial to design your study and submit the IDE to obtain formal FDA feedback. The IDE review clock is only 30 days (compared to the 70-115 days for feedback through a Pre-Sub), and the feedback is binding. Even though you may need to plan for a first-round rejection of the IDE, this can be an effective strategy for reducing the overall timeline.

If you decide to engage in a Pre-Sub, below are a few recommendations to make this as successful as possible:

1. ***Strategic Scheduling:*** Wherever possible, schedule your Pre-Sub(s) at a time in the development schedule when the required timeline (plan 70 – 115 days) will not slow down other required activities (e.g., you don't want to have to wait for the Pre-Sub feedback after you have product available to begin testing).

2. ***Pre-Sub Content:*** In addition to the required content described in the FDA Q-Submission guidance, include an executive summary to summarize your position and initiate advocacy for the positions included, and think about what you will want to say in the Pre-Sub meeting and make sure that supporting information is included in the Pre-Sub request. Most FDA review teams are rigidly opposed to providing insight on information they consider to be "new" in a meeting, which can cause you to enter a never-ending cycle of Pre-Subs.

3. ***Strategic Questioning:*** Limit the number of questions asked in a Pre-Sub to position FDA to provide helpful feedback. Also, do not ask open ended questions (e.g., what testing should we conduct); instead, provide a proposal in the Pre-Sub and request FDA feedback on that proposal. Providing an "open checkbook" to FDA will inevitably result in a need to conduct more testing than is necessary to meet the applicable regulatory threshold.

4. ***Be Well Prepared for the Pre-Sub Meeting:*** It is critical that you have the appropriate expertise participating in a meeting (e.g., talking about clinical study? Include your medical advisor and clinical expert. Talking about bench testing? Include your project manager or engineer). Then, it is critical that everyone is prepared and trained for the meeting to prevent hazardous tangential discussions or commitments that cannot (or should not) be upheld. Request the list of planned FDA attendees from your lead reviewer, and as much as possible, determine who they are and what their background is. Prepare a clear and concise slide deck, then make sure all attendees understand their roles.

5. ***Prepare Detailed Minutes:*** Within 15 days of a Pre-Sub meeting, the sponsor will be expected to provide proposed minutes for the meeting. We recommend submitting these as quickly as possible so that meeting discussions are as fresh as possible when minutes are prepared and reviewed by FDA. Minutes should be detailed enough to allow reconstruction of what was discussed up to several years later, as this often is when the minutes are needed to support development of the

commercialization submission. Although FDA generally will not allow minutes to include the specific names or roles of FDA personnel who said something in a meeting, we recommend maintaining a version of the minutes that provides this clarity. It makes a difference who said what in the meeting.

6. ***Review DuVal & Associates' Client Alert:*** Finally, we recommend checking out our 3-part Client Alert Series "**Navigating the Interesting and Sometimes Strange Pre-Sub Experience"** (using the Addams Family as a playful analogy) in which the Pre-Submission meeting is compared to a visit to the Addams Family home for additional details to help you understand the Pre-Sub program, decide when to use it, and provide tips for success when you do!

PCCP – The FastPass to Medical Device Modifications

Kathy Herzog, BSME, Senior Regulatory, Quality & Compliance Consultant
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Introduction

If you are planning a trip to a popular theme park, you may consider the value of obtaining a FastPass to skip the long lines for your favorite rides. Since the advent of medical device regulations, many modified products have had to stand in the same FDA review line as new products. Thanks to Congress and implementation of Section 515(C) of the Federal Food Drug and Cosmetic Act in December of 2022, there is now a FastPass option for many modifications, called the ***Predetermined Change Control Plan (PCCP)***. This option broadens the scope of product modifications that can be implemented by the manufacturer, bypassing the long line of the FDA review process.

However, as with any FastPass system, there are limitations for its use and requirements that must be met to enjoy its benefits (e.g., faster release of modified product for commercial use). And decisions to be made to determine if the cost of obtaining the pass is worth it (e.g., how many times are you likely to use it).

What is a PCCP?

A PCCP is a controlled document that is reviewed and approved, granted, or cleared by FDA as part of a PMA, De Novo or 510(k) submission or supplement, respectively. The

plan provides clear definition of future changes that may be made by the manufacturer without prior FDA review to the product including description of the modification, the protocol for developing, validating and implementing those modifications, and assessment of the benefits and risks of implementing modifications through the PCCP. An authorized PCCP specifies planned modifications that if not included in the PCCP, would otherwise require a new marketing submission or supplement. Changes implemented in accordance with a PCCP are documented internally with no submission to FDA prior to distribution.

What types of changes can be managed via a PCCP?

The PCCP process can be considered for changes what would otherwise require submission of a 510(k), De Novo, or PMA (e.g., changes to dimensions, materials, chemical composition, energy source, or manufacturing) ***and*** which do not significantly modify an existing risk (e.g., no change to risk score, risk acceptability category, or duration of risk). Thus, a risk assessment is an essential part of assessing whether a change can be made under an authorized PCCP.

Changes that impact the Intended Use, introduce a new risk and the pre-mitigation risk level/ is not considered acceptable, or are intended to address a recall or safety issue, cannot be made through a PCCP. These changes need to stand in line and wait for the FDA review process. Most modifications that will require clinical validation will also be excluded and need to go through the standard review process.

As of early December 2024, a total of 63 submissions reference a PCCP, including 55 510(k)s (across 54 product codes) 3 De Novos, and 5 PMAs, with a clearly increasing trend (see Figure 1). The Radiology group has taken the lead with 15 of these, followed by the Cardiovascular group who has 9, and the Microbiology and Orthopedic groups who both have 7. Example modifications that were represented in recent authorized PCCPs include:

- A microbiology product that will utilize a PCCP for modifications to device labeling in response to breakpoint changes (K241324);
- A neurology product that will utilize a PCCP for modifications to improve algorithm performance through expanded training data or optimizations (K240408); and
- An orthopedic device that will utilize a PCCP for modifications to thread length and pitch (K241504).

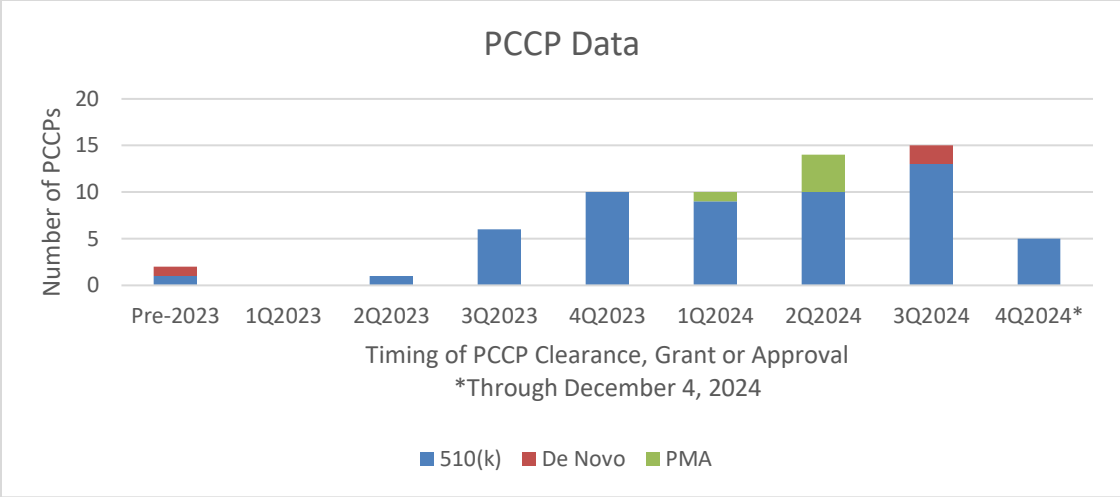

Figure 1: PCCP Data

How do I submit a PCCP?

To obtain clearance, grant, or approval of a PCCP, the PCCP will need to be submitted for review by FDA. This can be in an original submission for the product or in a follow-up submission (e.g., new 510(k) or PMA supplement) once details of potential changes are defined.

A PPCP includes three major content sections:

A. **Description of Modification**: a detailed description of each planned modification;

B. **Modification Protocol**: description of the methods for developing, validating, and implementing specific modifications with predefined acceptance criteria and traceability of how the verification and validation (V&V) methods support each planned modification; and

C. **Impact Assessment**: of the benefits and risks of implementing a PCCP, risk mitigations, and how the V&V activities assure ongoing device safety and effectiveness.

The PCCP must have a title and version number and is provided as a standalone document within the marketing submission. The eSTAR template includes a place to attach the PCCP document. Other submission content may also reflect the PCCP, such as labeling.

Note that for 510(k) devices, FDA considers the PCCP to be part of the technological characteristics of the device. Thus, when making a determination of substantial equivalence

where the predicate device was authorized with a PCCP, the subject device must be compared to the version of the predicate device cleared prior to changes made under the PCCP.

Manufacturers should have processes in place to manage the implementation of PCCP authorized modifications and address any non-compliance with the requirements of the PCCP. A PCCP can be modified after initial authorization via a 510(k) or PMA supplement.

There are several resources available to learn more about PCCPs, including:

- FDA final guidance: Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions;
- FDA draft guidance: Predetermined Change Control Plans for Medical Devices;
- FDA webinar slides on PCCPs; and
- Guiding Principles for PCCP for Machine Learning-Enabled Medical devices.

Summary

The PCCP is an exciting development in the regulation of medical devices and in vitro diagnostic devices and provides a Least Burdensome approach to manage some device modifications. Utilization is device specific, and the scope of modifications is contingent on risk assessment and changes for which the verification and validation strategy and acceptance criteria can be predefined. As a result, utilization of a PCCP will require strategic planning to understand what types of changes will occur, to determine if implementation of a PCCP would be advantageous. The potential for and scope of modifications in a PCCP should be considered in your regulatory strategy for new or existing devices.

Although a FastPass is not free, it does offer freedom, but freedom always comes with increased responsibility. Preparation of a PCCP for review by FDA requires a significant amount of work, incurs a user fee if submitted on its own, and must be maintained. The reward is the ability to "skip the line" (of FDA review) and market device modifications immediately after successful completion of verification and validation activities. PCCP use is increasing, and we see many opportunities for utilizing a PCCP as a strategic tool in your regulatory strategy and competitive advantage for your business. Let's talk about how this option may benefit you!

FDA Guidance in Transition: A Snapshot of 2024's Published Documents

Bryan Feldhaus & Austin Wetmore

In 2024, the U.S. Food and Drug Administration (FDA) continued its efforts to provide clear regulatory frameworks, issuing numerous guidance documents that continue to shape device development. It was on a fast pace, but not torrid. From January 1, 2024, to October 10, 2024, FDA published 145 guidance documents, with 41 issued by or in collaboration with the Center for Devices and Radiological Health (CDRH). This pace in 2024 fell short of 2023's total of 220 published guidance documents, with 63 issued by or in collaboration with CDRH.

In the "Proposed Guidances for Fiscal Year 2024 (FY2024)" CDRH outlined its priority target guidance documents for publication. Amongst the "A-list," some goals included addressing "Remanufacturing of Medical Devices" and "Marketing Submission Recommendations for A Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)" as well as draft guidances regarding "Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices," "Predetermined Change Control Plans for Medical Devices," and "Requests for Feedback and Meetings for Medical Device Submissions." The archived 2024 list can be found here.

Key themes from these 2024 guidance documents include FDA's ongoing efforts to address decentralized clinical trials, integration of real-world data, streamlining of electronic submissions, and improvement of participant comprehension in clinical trials. While these initiatives aim to modernize regulatory processes, there remain significant questions about the practicality and execution of some changes. The push toward digitalization and data integration, while promising, raises concerns about regulatory burden and compliance challenges, especially for smaller entities. The list below is an overview (in no particular order) of FDA guidance documents published in 2024 that are likely to be prevalent in impacting the road ahead for Industry. Select headings to view each source guidance page.

1. Remanufacturing of Medical Devices: Guidance for Industry, Entities That Perform Servicing or Remanufacturing, and Food and Drug Administration Staff (Final Guidance - May 2024)
    - This guidance provides updated insights into distinguishing between "servicing" and "remanufacturing" activities for medical devices. The document emphasizes

that remanufacturing involves activities that significantly change the performance or safety specifications of a device, potentially requiring additional regulatory oversight. It offers clarification, through determination Q/As, on when an activity crosses the line into remanufacturing, detailing specific factors such as the impact on the device's intended use, performance, or labeling. It also addresses changes involving software with an emphasis that "software changes are likely remanufacturing because of their impact on a product's software architecture, software requirements specifications, unresolved anomalies, [etc.]." The guidance also includes examples regarding both component/part/material activities and software activities to help entities correctly classify. Smaller service providers may face operational challenges in upgrading their processes or documentation to meet remanufacturing standards, which could require more stringent quality controls and oversight than routine servicing. Entities performing servicing or remanufacturing might consider implementing more thorough evaluations of their activities to ensure proper classification. Establishing internal review mechanisms to regularly assess whether specific activities alter device performance or safety could help prevent misclassification.

2. **Conducting Clinical Trials with Decentralized Elements** (Final Guidance **-** September 2024)

    - This final update includes recommendations for sponsors and investigators using decentralized elements in clinical trials. Decentralized trials involve activities such as remote monitoring, telemedicine visits, and the use of local healthcare providers or technologies to collect data outside traditional clinical sites. Specific considerations for using telehealth, ensuring data integrity when collecting information remotely, and maintaining proper oversight throughout the decentralized process are addressed. FDA underscores the importance of maintaining data consistency and reliability across varied collection methods, which can be challenging given variability in data collection techniques, technologies, or local standards of care which could lead to inconsistencies. To mitigate potential data integrity issues, the guidance signals benefits from the development of robust remote data collection protocols and, where necessary, training local healthcare providers.

3. **Real-World Data: Assessing Electronic Health Records and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products** (Final Guidance **-** July 2024)

- Although primarily focused on drugs and biological products, this guidance also offers insights for medical device manufacturers looking to leverage real-world data (RWD) to support regulatory submissions. It discusses FDA's expectations for the quality and reliability of electronic health records (EHRs) and medical claims data used in regulatory submissions for devices. It outlines the criteria for determining the reliability and relevance of RWD, emphasizing data quality, completeness, and the need for rigorous data collection methods. The guidance also provides recommendations for assessing the suitability of RWD sources and ensuring that the data used is accurate, verifiable, and fit for regulatory purposes. One potential concern is the variability in data quality across different RWD sources, such as EHR systems or claims databases, which may not consistently capture all necessary information. This inconsistency can impact the reliability of the data, leading to potential regulatory hurdles.

4. **Purpose and Content of Use-Related Risk Analyses for Drugs, Biological Products, and Combination Products** (Draft Guidance - July 2024)

    - FDA's draft provides recommendations for manufacturers on conducting use-related risk analyses to identify and mitigate risks associated with the use of medical products. The guidance emphasizes the importance of evaluating potential use-related errors that could occur during product handling, administration, or storage, and how these errors could affect patient safety. It outlines the process for systematically identifying, assessing, and addressing use-related risks throughout a product's development lifecycle. The document also includes recommendations on what should be included in a use-related risk analysis and how manufacturers can use this analysis to improve product design and labeling to minimize risk. Manufacturers may encounter concerns when implementing use-related risk analyses, particularly around ensuring that all potential user errors are identified and adequately addressed. Given the wide variety of users, from healthcare professionals to patients, evaluating how each group might interact with a product can be complex. There may also be challenges in determining the appropriate mitigation strategies for identified risks, particularly when balancing ease of use with safety. To align with this guidance, manufacturers may need to refine their risk management processes, ensuring that use-related risk analyses are conducted early and iteratively throughout product development. Manufacturers might also consider incorporating feedback from healthcare providers and patients to better understand potential use errors and how to mitigate them.

5. **Laboratory Developed Tests: Small Entity Compliance Guide** (Draft Guidance – June 2024)

    - This compliance guide is tailored to assist smaller entities in meeting regulatory requirements for Laboratory Developed Tests (LDTs). It provides step-by-step guidance on the processes, documentation, and quality control practices necessary to align with FDA regulations on LDTs. It addresses common questions about when and how FDA regulatory requirements apply to these tests, particularly regarding quality control, labeling, and reporting. Specific topics include compliance responsibilities for clinical laboratories performing LDTs, the importance of maintaining accurate and consistent testing methods, and ensuring that LDTs meet established clinical and analytical validation standards. Smaller entities may face challenges in resource allocation for comprehensive compliance processes; this guidance aims to help streamline the implementation of required protocols by clarifying which FDA regulations apply specifically to LDTs and which aspects of testing and documentation are considered the highest priority for regulatory scrutiny.

6. **Key Information and Facilitating Understanding in Informed Consent Guidance for Sponsors, Investigators, and Institutional Review Boards** (Draft Guidance - March 2024)

    - This guidance provides recommendations for improving the informed consent process in clinical trials. It emphasizes the importance of presenting key information in a clear and concise manner at the beginning of the consent form and outlines the types of information that should be highlighted as "key," including the purpose of the trial, potential risks and benefits, and the voluntary nature of participation. Ensuring that key information is both concise and comprehensive enough to convey the necessary context often requires an iterative process of revisions to balance both sides of the same coin.

7. **Use of Data Monitoring Committees in Clinical Trials** (Draft Guidance - February 2024)

    - This draft provides detailed recommendations for sponsors on the role and responsibilities of Data Monitoring Committees (DMCs), also known as Data Safety Monitoring Boards (DSMBs). The guidance emphasizes the importance of DMCs in independently monitoring patient safety and the effectiveness of interventions during clinical trials, particularly for studies that are blinded, involve high-risk populations, or are intended to support regulatory approvals. Key functions of DMCs, such as reviewing interim data, making recommendations on trial

continuation or modification, and ensuring participant safety are outlined. It also provides advice on the formation, operation, and reporting practices of DMCs. Several concerns arise for sponsors when implementing DMCs, such as maintaining the independence of the committee while ensuring that the DMC is equipped with sufficient information to make informed decisions. Sponsors may also encounter challenges in balancing the confidentiality of interim data with the need for timely DMC recommendations, especially in large or complex trials where early data trends could influence study outcomes.

8. **Electronic Systems, Electronic Records, and Electronic Signatures in Clinical Investigations: Questions and Answers** (Final Guidance – October 2024)

    - In this series of Q&As, FDA offers clarity on the use of electronic systems for managing records and signatures during clinical trials. It addresses common questions from sponsors, investigators, and institutional review boards (IRBs) about compliance with regulatory requirements when using electronic methods for data collection, storage, and signing. Emphasis is placed on ensuring data integrity, security, and accuracy in electronic records, with specific recommendations for system validation, audit trails, and proper authentication of electronic signatures. The signaled aim is to help stakeholders in clinical investigations maintain compliance with FDA regulations while leveraging the efficiencies of digital tools. That said, several concerns may arise for sponsors and clinical trial teams when implementing electronic systems. A key issue is ensuring that these systems are properly validated and capable of preserving the integrity of data across the trial's lifecycle. This includes making sure that electronic records are accurate, complete, and unalterable, which can be challenging when using third-party software or cloud-based platforms.

9. **Predetermined Change Control Plans for Medical Devices: Draft Guidance for Industry and FDA Staff** (Draft Guidance – August 2024)

    - This draft guidance introduces recommendations for creating Predetermined Change Control Plans (PCCPs) to manage anticipated modifications to medical devices post-approval. The document provides a framework for manufacturers to proactively address device changes by developing a PCCP, which outlines expected device updates and justifies their safety and effectiveness without requiring a new FDA review. Key considerations include the types of changes suitable for PCCP inclusion, such as updates to software, materials, or minor design adjustments, and criteria for maintaining device functionality and safety. This guidance highlights the importance of clear documentation within the PCCP to

demonstrate how future changes will remain within the bounds of regulatory compliance. For manufacturers, implementing PCCPs may present challenges, particularly in anticipating all necessary updates and ensuring sufficient pre-approval data to support the safety of future modifications. Establishing a robust PCCP can streamline regulatory processes, potentially allowing faster implementation of safe and effective device changes.

10. Addressing Misinformation About Medical Devices and Prescription Drugs: Questions and Answers (Draft Guidance – July 2024)

    - This draft guidance offers recommendations to help manufacturers and other stakeholders address and correct misinformation about medical products circulating online and in public forums. The guidance emphasizes the importance of providing accurate, science-based information to counteract false or misleading claims about medical devices and prescription drugs. It explains how manufacturers can respond to misinformation without triggering regulatory scrutiny, highlighting that responses should be factual, non-promotional, and aligned with FDA-approved labeling. The guidance also provides examples of appropriate corrections and outlines the best practices for engaging with public misinformation.

Looking forward, CDRH has published its priority "CDRH Proposed Guidances for Fiscal Year 2025 (FY2025)" page found here. The coming year's priority development "A-list" will likely have wide-reaching impacts and include: "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management Considerations and Pre-market Submission Recommendations," "Enforcement Discretion Policy for Certain Laboratory Developed Tests for Unmet Needs: Frequently Asked Question" and "In Vitro Diagnostics: Labeling" amongst a bevy of other topics. Although these are the expressed priorities, the current moratorium on new guidances may compel the Agency to reorient its guidance priorities for 2025.

FDA's 2024 guidance documents highlight a drive to modernize regulatory processes, particularly through support for emerging technologies such as artificial intelligence and decentralized trials. While these initiatives aim to clarify regulatory pathways, they also introduce complexities that may require significant adaptation from device developers, especially smaller entities with limited resources. Meanwhile, the incoming 2025 government administration has the potential to markedly reorient FDA's moorings as a whole, leaving Industry in the interim to cautiously manage its practical implementation capabilities and watch for shifting currents ahead.

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