DuVal & Associates

Passing on Tribal Knowledge of FDA Law

CLIENT ALERT

WHAT WILL WE SEE MORE OF IN 2019?

The medical device industry is ever evolving.

Our experts weigh in on what 2019 will bring.

Increased Product Complexity and Risk Aversion

New 510(k) Program

Mark DuVal, President & CEO

Commissioner Gottlieb and CDRH Center Director ended 2018 with a bang announcing their intention to "modernize" the 510(k) program with sweeping new changes. Drs. Gottlieb and Shuren stated that "We believe firmly in the merits of the 510(k) process.

But we also believe that framework needs to be modernized to reflect advances in technology, safety and the capability of a new generation of devices." Among other proposed changes, CDRH's fundamental attack is on the use of predicates older than 10 years.

CDRH wants to eliminate from use predicates older than ten years. The Agency also wants to sunset predicates older than ten years by publishing a list of newly cleared devices which use older predicates for clearance, essentially "shaming" them publicly.

Finally, the Agency wants to create a new, as yet undefined, alternative pathway for the clearance of devices. The Agency does not seem to realize that there is nothing wrong with older predicates and that the predicate family updates itself through innovation.

FDA seems to want to involve itself in influencing the medical marketplace to make decisions about which devices to use or not. The question is, should this really be the role of FDA and where does it get the statutory authority to make these changes?

This seems to be a solution in search of a problem. Industry is fatigued keeping up with Dr. Shuren's endless proposals to "update" the 510(k) program over his tenure. It has caused endless and unnecessary turmoil.

For those who remember, this is reminiscent of Dr. Shuren's first attempt to get rid of (or at least substantially alter) the 510(k) program in 2009 when he requested that the Institute of Medicine (IOM) evaluate and improve the consistency of decision making in the 510(k) process.

Many saw that as a thinly-veiled attempt to obtain the imprimatur of the IOM to propose the abolishment of the 510(k) program. There was a tremendous industry backlash over the ensuing years, and then Commissioner Hamburg

and Dr. Shuren engaged in a roadshow to calm fears. Dr. Shuren then used many "transparency initiatives" (read: guidance) over the last nine years to nip around the edges of 510(k) program until it could shape it as CDRH wanted it shaped.

We need to remind FDA they are an administrative organization, not a legislative body, and if they want to make some of these changes, like the 510(k), they will have to propose them to the Congress. Next year will be interesting. We'll see if AdvaMed and MDMA protect the industry from debilitating change.

Increased Risk Aversion by FDA

Mark DuVal, President & CEO

As a corollary to what is going on with the 510(k) program, FDA continues to become more risk averse as new young biomedical reviewers continue to see boogeymen in every closet. What happens with FDA is that when a rare event occurs within a discrete product or predicate family, FDA responds by attempting to over-regulate the 98% of products that have never had (and probably never will have) a problem. The problem with that approach is that rare events will always occur. In an attempt to be architects of regulatory perfection, FDA begins to require so much information upfront that innovation is stifled. And the risk aversion is not limited to device submissions, it impacts post-marketing requirements as well.

Medical devices do not make the margins of pharmaceuticals and if we continue to impose so many burdensome and expensive testing and post-marketing requirements on Class II moderate risk devices, and in some cases Class III high risk devices, we will stifle the introduction of new innovative products. FDA has paid lip service to statutory Least Burdensome requirements for a decade.

When you add to FDA's natural propensity to be risk averse, the "documentaries" being done by Netflix ("The Bleeding Edge") and the International Consortium of Investigative Journalists (ICIJ) covering medical device stories on implantable devices you get a perfect storm for the request for new, over-reactive laws and regulations. These perceived "crises" give FDA (and the plaintiffs' lawyers) political cover to ask for more regulation.

CDRH, for example has had a disdain in the last decade for the 510(k) program. It does not like being tethered to the standard of establishing

safety and effectiveness in a comparative sense to another predicate. FDA would rather have an open mini-PMA standard of (re-)establishing safety and effectiveness in an absolute and independent sense, i.e. the PMA standard of reasonable assurance of safety and effectiveness.

With that standard FDA can ask for any amount of data it wants. FDA should take into account what it already knows about a given device, predicate family, technological platform, and/or material, etc. The idea behind a predicate is precedence, i.e. not unnecessarily re-inventing the wheel, or asking for data on what is known and can be scientifically extrapolated.

But that is just one example, think of the myriad of post-marketing requirements that have been put into place or are coming (see below), not by law or regulations, but by FDA guidance. It is an avalanche of (over-)regulation. We had hoped with a new presidential administration seeking regulatory reform that FDA would have been more carefully examined.

But when your agency waves the banner of patient safety, politicians are reluctant to get involved.

PMA

Lisa Pritchard, Regulatory, Quality & Compliance Consultant

As medical devices become increasingly complex, it is expected that the number of products with a potential for high risk but high benefit will be increasing. These high risk products require approval and maintenance of a Premarket Approval (PMA) to be commercially distributed in the United States.

PMAs currently make up a vast minority of premarket submissions for medical devices (compare 2 original PMA approvals in November 2018 to 291 510(k) clearances). Similar to the devices that are described within them, PMAs can be described as "high risk but high benefit."

The PMA is the one commercialization process that has not been the subject of the very vocal and targeted media attacks of the oversight of medical devices. Clearly, a PMA requires much work, both prior to approval, and after approval, to achieve and maintain. However, it also provides the ability to use the coveted claim "FDA

Approved," and for small companies, the ability to have the significant user fee waived for the first PMA submission.

There are mechanisms available to help make the pre-approval process more manageable (e.g., pre-submissions, ensure that your submission advocates for your product and doesn't merely check the required boxes, modular reviews, 100-day meetings).

Done right, a PMA can be a considerable asset to a company that either wants to have success in the commercial space, or to provide the "curb appeal" necessary to attract a strategic partnership or acquisition.

Quality Compliance

FDA Re-organization

Jeff Zumhofe, Quality Systems Consultant

The Center for Devices and Radiological Health (CDRH) launched pilots of its Total Product Life Cycle (TPLC) approach across the organization in 2018 and will continue to progress the substantial changes in 2019. Full implementation of the restructure plan will occur upon approval by FDA, HHS and Congress, anticipated in early-mid 2019.

The overall intent of the restructure is to improve information sharing across CDRH resulting in better process and policy consistency and improved efficiency. One of the more significant planned changes will be the merging of the Office of Compliance, Office of Device Evaluation and Office of Surveillance and Biometrics into one "Super Office," the Office of Product Evaluation and Quality (OPEQ). OPEQ will consist of three offices: Office of Health Technology (OHT), Office of Clinical Evaluation and Analysis (OCEA), and the Office of Regulatory Programs (ORP).

CDRH will organize along product category groupings intended to better facilitate access to product lifecycle data and thereby improve efficiency and collaboration. The ORP will have responsibility for submission support, establishment support (registration and listing, audits, and FDA inspections), and market intelligence (complaints, MDRs, recalls, product shortages).

With regard to FDA inspections and post inspection communication, be aware the Office of Medical Device and Radiological Health Operations (OMDRHO) within ORP has established three geographically defined Divisions, and the previous line of follow-up with the local District to discuss concerns has now been shifted to the appropriate Division contact.

Healthcare Compliance

Volume to value discounts

Beth Luoma, Associate Attorney

The shifting landscape from fee-for-service to value-based health care will continue to build momentum. In the fee-for-service health care model, there may be an incentive to promote value propositions but there is a primary focus on volume. With value-based health care, manufacturers have to demonstrate that the value propositions actually play out.

The ongoing challenge will be answering this change and creating value-based arrangements with customers that appropriately share risk but fall within the current legal and regulatory framework for discounts and warranties under the Anti-kickback Statute.

Changes in Technology

Digital Health

Lisa Pritchard, Regulatory, Quality & Compliance Consultant

Digital Health is likely to see a radical innovation explosion in the coming months, particularly in the areas of mobile applications, artificial intelligence, augmented reality, and cloud-based processing.

These products bring exciting innovation options to improve the delivery of healthcare, often at reduced costs. FDA, through its Digital Health Innovation Action Plan, is working to redefine how Digital Health technologies are regulated.

The challenge will be in effectively partnering with FDA to manage the data expectations to allow these new types of products to efficiently make it to commercialization.

Mobile Medical Apps

Lisa Pritchard, Regulatory, Quality & Compliance Consultant

It seems everyone has a smartphone. Accordingly, an increase in the design and use of Mobile Medical Apps (MMA) is underway and only expected to grow. Significant associated challenges will include interactions with FDA by companies that are not typically used to interpreting medical device regulations.

Having a healthy marriage of an innovative idea, a solid Quality Management System to ensure appropriate controls through the life cycle of MMA, and a 510(k), De Novo, or PMA submission that not only meets the requirements of the regulation, but also allow for product claims, will be a winning combination for our society.

General Wellness

Aaron Hage, Associate Attorney

The 21st Century Cures Act and FDA's Final Guidance, "*General Wellness: Policy for Low Risk Devices*" have provided a safe haven for certain low risk products intended to only be used for general wellness purposes, and not for the cure, mitigation, treatment, or prevention of disease.

Many manufacturers have taken advantage of this statutory exemption and FDA's regulatory enforcement discretion to create devices capable of allowing people to take a more active role in their own wellness decisions. However, many of these technologies have advanced to include diagnostic capabilities and claims, and thus have moved back into FDA's realm of regulation and oversight.

As the line between a wellness product and a medical device starts to blur, FDA may decide to step up its enforcement powers on those "wellness products" that may meet the definition of a medical device but do not fit the defined boundaries of its enforcement discretion.

Similarly, manufacturers will have to decide whether to stay on the wellness product side of the line and be safe from prosecution.

Alternatively, manufacturers may decide to compete with more sophisticated technology and claims and comply with the medical device regulations to have the marketing advantage of claiming FDA clearance or approval.

Human Factors

Lisa Pritchard, Regulatory, Quality & Compliance Consultant

Rapid changes in technology often result in modifications of the human interface. This is expected to continue to increase the importance FDA places on verification that user interfaces have been appropriately designed to support the intended product use. FDA will likely continue the push to require human factors evaluations for increasing numbers of products, citing this as appropriate under 21CFR820.30(g). While human factors evaluations can help make products work better, we must work hard to prevent "creep" in the requirements which would unnecessarily stifle innovation.

Cybersecurity

Greg Spar
Software & Design Consultant

Interest in Cybersecurity, and demand for increased threat awareness has steadily increased over the last 10 years. In 2014 the FDA published "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices – Final Guidance*" as their definitive opinion of how the medical device industry should address cyber risk.

Then in 2016 they published "*Postmarket Management of Cybersecurity in Medical Devices,*" to provide additional guidance on how to continue to manage cyber risk through the product lifecycle. In October of 2018, FDA increased their role in directing industry to address cybersecurity with the release of a draft update to the original guidance, "*Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.*"

This draft adds to the original 2014 guidance by including a recommendation that organizations design "trustworthy devices" which employ the National Institute of Science and Technology (NIST) Cybersecurity Framework in the specification and validation of their designs.

When this guidance is finalized it will supersede the original 2014 version, bringing product design requirements in line with recommendations from the NIST, and into the product life cycle.

What this means for industry is that 2019 will likely show that medical device companies will need to "toe the line" with respect to their cybersecurity policies to gain regulatory approval.

The "cowboy" days of keeping your device unplugged to be compliant are over. And this trend is not only being felt in the U.S. The European Union brought the General Data Protection Regulation (GDPR) into effect in May of 2018, and by 2019 the protections demanded by this standard will likely become even more burdensome.

The global economy will need to adapt GDPR in order to be allowed to continue to do business in the EU, or else risk heavy fines.

Ad/Promo

Digital Marketing

Mimi Passalacqua, Regulatory Consultant

With the increase of media scrutiny over the life sciences industry, it is very likely that FDA will not only continue their research on promotional communications and how these are understood by patients as well as health care practitioners, but play closer attention to how product information is being communicated to audiences.

This, along with technological advancements such as mobile apps and different social media platforms with space limitations, will present challenges on how to effectively communicate product information in a competitive way without losing the marketing pitch.

Commercial Speech

Mark DuVal, President & CEO

FDA will likely continue to struggle with the line of demarcation between its right and desire to review commercial speech and the constitutional limitations placed on FDA's jurisdictional authority by the 1st Amendment.

We expect that line to be tested and challenged by both FDA, industry, and

various advocacy groups. FDA will continue to struggle to find a proper balance between protecting patients and physicians from information that it has not reviewed and approved with the paternalistic temptation to suppress the free exchange of medical and scientific information, in whatever format or venue it is created and communicated.