DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

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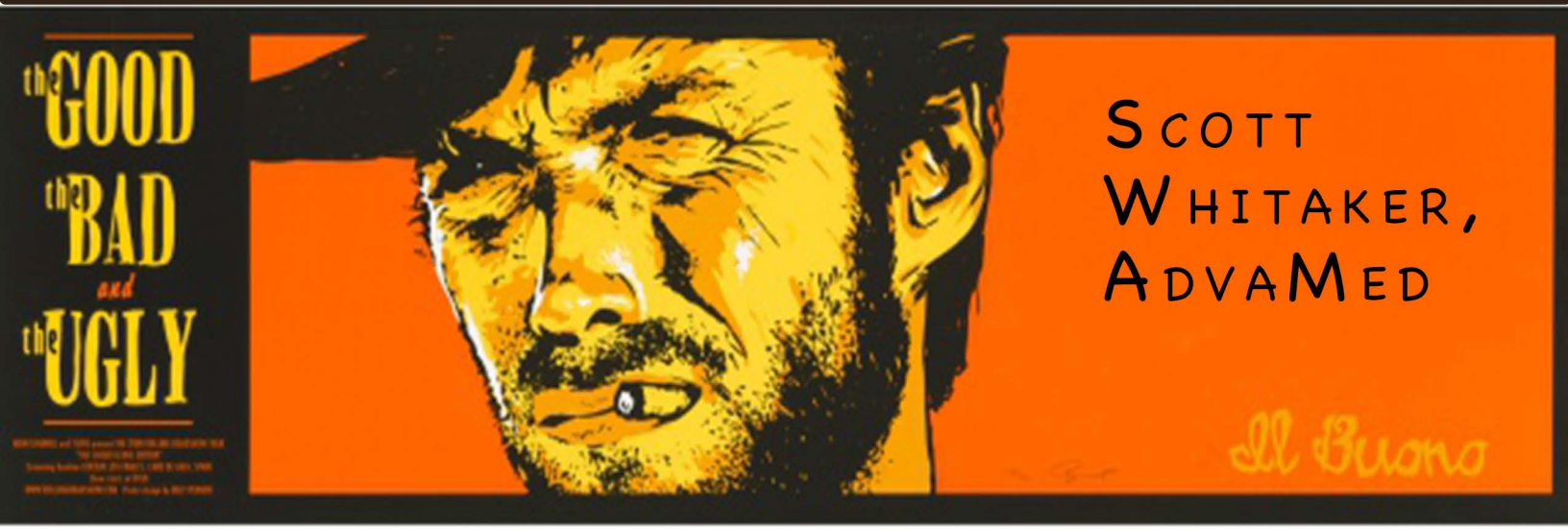

The Good, the Bad and Avoiding the Ugly--FDA in the eyes of AdvaMed vs Small & Mid-Sized Companies

Our firm wanted to report on an interesting phenomenon we experienced at the Medtech MVP Conference in Minneapolis on Tuesday, September 28, 2021. We witnessed two panels with divergent views of the performance of CDRH and wanted to report briefly on the juxtaposition of two views of CDRH and ask "How can that be?" Our firm was a sponsor of the Medtech MVP Conference and did a breakout session entitled "FDA: A Pandemic Unto Itself?: Addressing the problem of submission delays" which used the analogy of the COVID-19 pandemic to describe what is going on at FDA today. On that panel were three senior representatives of DuVal & Associates--Mark DuVal, J.D., FRAPS, President & CEO, Lisa Pritchard, BSEEE, Vice President of Regulatory, Quality, Clinical and Engineering and Bryan Feldhaus, J.D., LL.M., Vice President of Legal-Regulatory & Compliance.

Later in the conference Scott Whitaker, President & CEO of AdvaMed, chaired a panel entitled "Panel Discussion: View from the Beltway: What Should We Expect from the New Administration, FDA, and CMS?" On that panel were Anand Shah, M.D., Former Deputy Commissioner for Medical and Scientific Affairs, FDA, and Nadim Yared, President & CEO, CVRx, and a former board chairman of AdvaMed. Before going any further, let us state Scott Whitaker is a very effective, likeable and strong leader. He has done the medical device industry a world of good, but AdvaMed does not fully appreciate the plight of the innovative smaller companies and we hope to expand their awareness with this DuVal Client Alert. *With User Fee negotiations underway, we need to give FDA realistic feedback on its performance. FDA must appreciate how critical its role is to the entirety of the medical device ecosystem because it is often difficult for the average small to mid-size company to efficiently and effectively navigate through the FDA review process.*

"View from the Beltway."

It is appropriate that the AdvaMed panel started with a perspective a "View from the Beltway." Therein lies the problem. AdvaMed's perspective on CDRH's performance is insulated from and disassociated with the experience of small to mid-sized medical device companies. "Innovation" by large is often via late-stage investments in small companies. It is the little, small and mid-sized companies that have to navigate the FDA's processes to obtain IDE approval or negotiate the basis for and process of product clearances and approvals. They do not have the financial wherewithal to acquiesce to FDA's insistence upon expanded bench, animal, biocompatibility, and clinical testing beyond that required to establish substantial equivalence or essential safety and effectiveness. To make matters worse, FDA's regulatory behavior can border on imperialistic. Their positions are often based upon FDA's positional strength (i.e., "because we say so") and not out of the correctness, persuasiveness or reasonableness of its position, and FDA frequently revisits its positions which is a topic unto itself (see the slides from our presentation).

In our MedTech MVP presentation and panel, we acknowledged the challenges FDA has faced over the past year and a half due to the COVID-19 pandemic, but also critiqued FDA's recent review performance because of its direct effects on device innovation. And our critique included a pre-COVID timeframe. Conversely, the AdvaMed-led panel applauded FDA for the progress and predictability of its review process over the last decade.[1] How can these views be so divergent?

The divergent views between FDA's review performance were punctuated by the following remarks made by Mr. Whitaker regarding FDA's management of device submissions at the MedTech MVP conference:

[1] Mr. Whitaker acknowledged that FDA's timelines to decisions have slipped, but attributed such delay to the COVID-19 pandemic and the volume of work resulting from the pandemic, and not a change on FDA's bureaucratic approach.

> *"It feels to me that the progress we've seen over the past ten years with FDA has been quite remarkable, right? It's not that it's perfect every time, but it's quite predicable. You know when you start what the process is going to be in order to get the outcome that you hope for."*

It is this perspective by Mr. Whitaker and AdvaMed that illustrates the reality of larger medical device companies but contradicts the experiences of smaller and mid-sized medical device companies. Indeed, it is the lack of process and predictability in FDA's review processes that has troubled a large segment of the medical device industry. And while we often admit that we may be too close to our work and the FDA is a large and varied organization and is in many cases doing better than we give them credit for. We also know, for our many clients, we have experienced innumerable occasions in which FDA has acted with inconsistency, failed to adhere to established processes, divorced itself from the plain meaning of the regulations and statute, avoided precedent, introduced new standards in the middle of a submission, overlooked the Least Burdensome requirements and, frankly, made things up as they went along, and so on.

We have had many conversations with insiders at FDA, some present, some recent past, and they also acknowledge that improvement is needed. Thus, while Mr. Whitaker is correct that the past ten years has illustrated progress at FDA, more uniform progress is needed, especially as it relates to smaller and mid-sized medical device companies that are disproportionately burdened by inconsistencies within FDA's processes. Training also remains a critical need for FDA and the Agency needs to bring in industry perspectives to counteract the natural group think that can go on with any large organization. This can include demonizing industry too. We admit that can happen on industry's side as well. We suspect no one disagrees—FDA or industry—that the Agency can do better in its training to ensure greater consistency in the establishment and implementation of submission requirements and review standards.

The answer to the different perspectives lies in the title of this DuVal Client Alert: "*The Good, the Bad and Avoiding the Ugly--FDA in the eyes of AdvaMed vs Small & Mid-Sized Companies.*"

The Good

AdvaMed's comments represented the "Good" of FDA. The AdvaMed panel chronicled the very best of FDA's performance and what FDA should aspire to consistently achieve across their organization. Scott Whitaker, President and CEO of AdvaMed, operates in the stratosphere working with the Commissioner, Dr. Jeffrey Shuren, Bill Maisel and the upper echelon of CDRH. DuVal & Associates, and others like us, represent those of us operating in the trenches at the FDA, where the rubber meets the road. We work with the frontline reviewers, through middle management up to the Office Directors and Dr. Bill Maisel, Director of the Office of Product Evaluation and Quality (OPEQ). In addition, AdvaMed's membership and focus has never been particularly friendly to pre-revenue start-ups, small and even mid-sized companies because it caters to the larger medical device companies. They represent "the Club."

The Bad

We represented the "Bad" part of CDRH, the current state reflecting the recent significant management and review staff turnover, which is correctable.[2] Our view may come off as tough, but we like to think it is realistic. We love working with CDRH, but we have a vantage point AdvaMed does not seem to have. We have had many great experiences working with review staff, but they are becoming less frequent. We challenge FDA advocating for individual client positions in many hundreds of Pre-Subs, 510(k)s, de novos and Breakthrough Designation negotiations, LB Flag meetings, 21-day Submission Issues Requests, and appeals (under 21 CFR § 10.75 and § 517A and advisory panel meetings), and in that process see the underbelly of CDRH. We have filed Citizen Petitions, docket submissions and spoken at innumerable conferences, and written DuVal Client Alerts challenging the FDA's administration of the 510(k) program and other policy positions.

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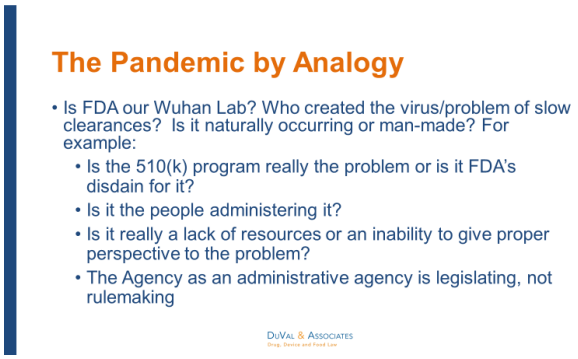
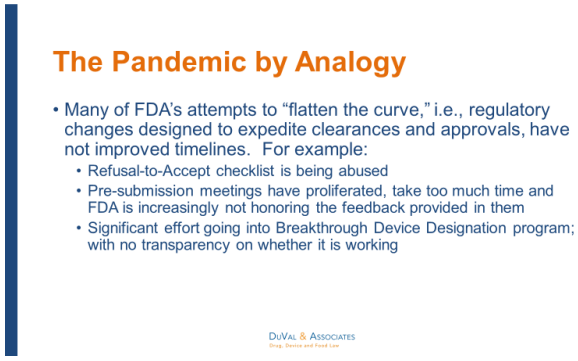
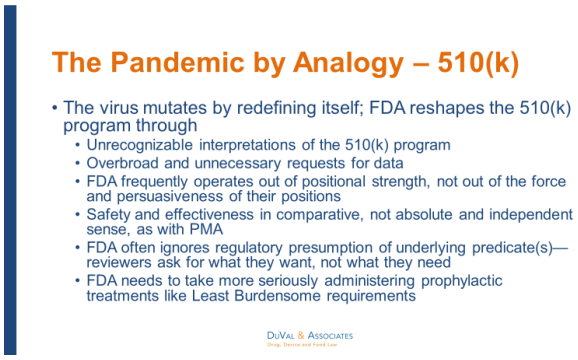
[2] The views we present are also not related to COVID-19, because these are behaviors that were not influenced by the pandemic. It had to do with the quality of decisions and the basis for them. And some of our comments on the Agency's responsiveness are related to pre-pandemic activity. The Agency's lack of responsiveness varies greatly by division pre-and post-pandemic. We realize, however that FDA's responsiveness **during** the pandemic **was** affected. We greatly appreciate FDA's heroic efforts during those time frames.

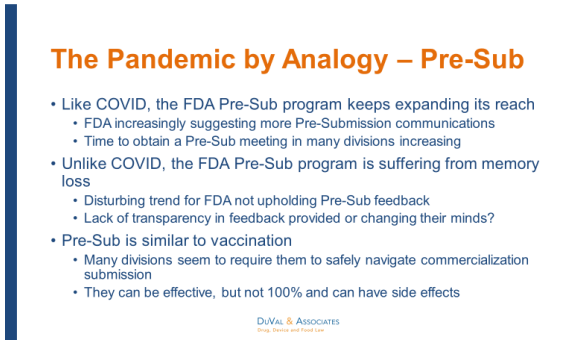
We also see FDA review staff find ways to avoid negative User Fee metrics (i.e., the negative association of failing to meet timelines) by inventing creative ways to buy themselves more time on the review clock. The tactics include such things as providing an AINE letter at the 11th hour stating the sponsor's device is unlikely to be cleared because it does not meet one of the definitional elements of the 510(k) program. This is accompanied by a seemingly benign and helpful offer to have the sponsor withdraw their 510(k) to avoid receiving an NSE decision. They suggest having a Pre-Sub meeting to iron out issues and then refiling the 510(k). This allows the review staff to obtain more time or else they would be forced into an NSE decision, which they try to avoid if possible (for the negative impact on User Fee metrics). Or a review staff will use the tactic in which reviewers ask sponsors to make a Submission Issues Request (SIR) instead of the sponsor responding to their AINN letter; this is done presumably so the 90 day statutory review clock does not run out on the reviewers. Another tactic many clients complain about is what we call being in "Pre-Sub purgatory" where the Agency requests multiple Pre-Subs for discrete issues in which little is definitively resolved.

Our perspective is born out of the exhaustive, creative and important work of helping explain our client's position to FDA and persuading them to our client's position, to avoid unnecessary or duplicative work, or putting clients on an inappropriate regulatory path, ensuring timely reviews that are not waylaid by delays, and advocating for the appropriate application of Least Burdensome requirements. It is important work because the inevitable evolution of a bureaucracy is to become more academic, scientifically siloed and deliberative. This translates into never being satisfied with a sponsor's submission–even if near perfect—and find it is not adequate or sufficient. It is a regulatory psychology. FDA reviewers always ask for more whether the regulatory framework, as created, requires it or not. Data requests often satisfy scientific curiosity and a desire to use each sponsor to expand the available science, which, in the case of the 510(k) program, is antithetical to its foundations. Here are some representative slides from our presentation. The full presentation can be found by clicking here.









We might have had a more balanced view between theMedtech MVP panels if we would have added Mark Leahey, President & CEO of the Medical Device Manufacturers Association (MDMA), an association that understands the plight of the smaller to medium-sized companies much better. MDMA "gets it" when it comes to the problems encountered by small companies. And it also understands the difficulty of FDA's job. MDMA has a solid and balanced approach fashioned out of the experiences of its members.

Avoid The Ugly

At the end of the day, we want to help people "Avoid the Ugly" at FDA. Let's put Mark Leahey, MDMA, in the role of helping us to come to some middle ground. FDA does a lot of good things, but honest self-examination is not one of its strong points. FDA is sheltered from that kind of exercise when it has an adoring trade association like AdvaMed. AdvaMed is too close to FDA. It does not mean to be, it just is. It is ironic,

with our vast experience with FDA, and the consistent challenges we have made in filing Citizen Petitions and public docket submissions, AdvaMed, unlike MDMA, has never sought our firm's insights on FDA's performance. ***It would be vitally important to understand how FDA is doing in its real-world performance, especially with User Fees negotiations in full swing.*** We reward FDA for Dr. Shuren's grandiose initiatives that are promoted to help the industry, but oftentimes those ideas are merely a façade and provide little benefit in actual practice to smaller companies (i.e., Breakthrough Device Designations and Real World Evidence). Moreover, those initiatives do little to improve accountability within FDA for more pedestrian performance metrics like time to clearance. From the International Medical Device Regulators Forum (IMDRF), to NEST, MDIC the newly proposed "collaboration communities," and an endless flood of guidance documents (which CDRH either follows ***before*** they are finalized or selectively departs from them when it is in their interest), the Agency has gotten increasingly complex, academic, and unaccountable.

User Fee negotiations are underway. Our fear is that all FDA will be told is that they are doing a fantastic job from those who do not seem to appreciate how difficult it is for the average small to mid-size company to get through FDA or benefit from the predictability that should be inherent in FDA's processes. We have legions of stories to tell if FDA, Congress and AdvaMed, want to hear them. MDMA already knows…

It benefits everyone to work efficiently and effectively with the Agency and help them improve to better realize their twofold mission of speeding innovations beneficial to patients to the market while protecting them from unnecessary risks. It is natural that relatively inexperienced and overburdened staff at FDA tend to focus on finding and dwelling on risk, not so much at the finding and embracing benefit. And it is through this focus on risk that the predictability of FDA's review processes has suffered. By requesting more data, delaying submission reviews, and engaging in other tactics, FDA has erected more and more obstacles to device approvals and clearances, and the victims of FDA's tactics are the small and mid-sized medical device companies that are disproportionately burdened by such obstacles and the United States citizens that should be able to benefit from innovative medical technologies.

Finally, does the additional increment of information FDA invariably squeezes out of industry really change the trajectory/success of the device in the marketplace or does it unnecessarily delay valuable technologies? We have never studied that question. It is a valuable question to evaluate. We blindly accept that FDA's additional deliberations and required data change the end game, i.e., that this information really does save or improve lives. Do we know that? FDA is behind other parts of the world in approving devices. We need Congress and the trade associations to critically ask and honestly examine whether FDA's increasing demands for data and the extra time taken to make decisions are merely satisfying their need to be architects of regulatory perfection or is it a unnecessary escalation of data requirements which is increasing cost and killing innovation.

DuVal & Associates
Drug, Device and Food Law

DuVal & Associates is a boutique law firm located in Minneapolis, Minnesota that specializes in FDA regulations for products at all stages of the product life cycle. Our clientele includes companies that market and manufacture medical devices, pharmaceuticals, biologics, nutritional supplements and foods. Our clients range in size from Global Fortune 500 companies to small start-ups. As one of the only dedicated FDA regulatory law firms in the United States, our mission and absolute focus is providing our clients appropriately aggressive, yet compliant, guidance on any FDA related matter. We pride ourselves not only on our collective legal and business acumen, but also on being responsive to our client's needs and efficient with their resources. DuVal & Associates understands the corporate interaction between departments like regulatory affairs, marketing, sales, legal, quality, and clinical, etc. As former industry managers in the drug and device spaces, we have been in your shoes. Our firm has extensive experience with government bodies. We understand what it takes to develop and commercialize a product and bring it successfully to the market and manage its life cycle. Impractical or bad advice can result in delays or not allow for optimal results; while practical, timely advice can help companies succeed.

CALL ON US FOR ASSISTANCE WITH YOUR REGULATORY NEEDS

For more information, visit our website at www.duvalfdalaw.com or call Mark DuVal today for a consult at 612.338.7170 x102.