DuVal Client Alert

Passing on Tribal Knowledge of FDA Law

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2021 Retrospection Highlight

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The 510(k) Program

2021 was a mixed bag for the 510(k) program. The vast majority of products that come to the market are through the 510(k) path. As such, it remains critical that we evaluate how the FDA is doing with clearances. There have been both fans and critics of the 510(k) program. Critics say the program is cumbersome and driven by a three-part definition of (1) same intended use, (2) same technological characteristics, and (3) if there are different technological characteristics, do they raise different questions of safety and effectiveness. We understand that critique and we spend a lot of time ensuring FDA review staff interpret those terms with great fidelity so our clients can remain on the 510(k) path.

To understand FDA's view of the 510(k) path, one has to understand the history of Dr. Shuren's tenure with CDRH. Dr. Shuren has done many good things, but every improvement has a corresponding downside. For example, Dr. Shuren has greatly improved communications with industry but when expressed in terms of guidance documents, his leadership has resulted in too much communication. The proliferation of guidance documents has overwhelmed industry and FDA staff alike. He has also improved the expertise and professionalism of the staff, especially review staff, to address the myriad of new technologies coming to market. But that increased expertise often results in a silo-effect within FDA, which, in turn, invites ultra-granular examination of products that do not merit that much attention. Everything becomes a scientific expedition for FDA reviewers who justify their behavior by waving the banner of patient safety in everything they do, as if this should justify bad decision making. This banner-waving has been at the expense of generalists and scientific pragmatists who understand Least Burdensome requirements and the role of administrative agencies.

Dr. Shuren has also improved the meeting system within FDA, i.e., Pre-Submission meetings, 10-day meetings, LB Flag meetings, 21-day Submission Issues Requests (SIRs), and appeals (under 21 CFR § 10.75 and

§ 517A and advisory panel meetings). As a result, industry is guaranteed an FDA meeting, which has been a positive development. But the flip side is FDA can use those meetings to protract the review time and distract from meaningful or unequivocal direction. For example, one 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, but much time and money is expended. Each meeting simply kicks other issues (the can) down the road.

To return to Dr. Shuren's tenure, he has worked hard for over a decade to either rid CDRH of the 510(k) path, which he attempted to do early in his Administration using the Institute of Medicine (IOM) to examine the program and make serious recommendations and attempt to alter it through administrative fiat. Dr. Shuren forgot, or ignored the fact at that time, that he and CDRH are administrators, not legislators. CDRH has no place thinking it has the power and the authority to change something Congress has created. There have been many other attempts to dismantle the 510(k) program and they have been renewed more recently. There is not enough time to chronicle all those efforts in this year-end piece. Suffice it to say, the tack CDRH has taken over the last decade is to erode the edges of the 510(k) program for years by using guidance documents and undocumented decision-making within review groups to change or restrict the definition of the 510(k) program and a device's eligibility to stay on the 510(k) path. They have also unilaterally made increasingly burdensome data requests. The totality of that erosion has been substantial and the 510(k) program has been effectively reshaped by FDA over the years. As a result, FDA has been permitted to legislate, instead of merely regulate.

Our longstanding position is that the statutory framework of the 510(k) program is the last line of defense for an Agency that naturally gravitates to "more" whether it is needed or not. Without the 510(k) definitional framework and the Least Burdensome requirements, there would be nothing to prevent FDA from transforming the 510(k) program into a mini-PMA. This is, in fact, occurring as reviewers at the Agency often define many

devices off the 510(k) path. Those reviewers believe the 510(k) program is archaic and restricts their ability to ask for the quantum and quality of data they want even if it exceeds Least Burdensome requirements. The Agency's reviewers have also gotten savvy by playing with the definitional elements of the 510(k) program. Reviewers are more frequently identifying minor technological differences with a device to suggest there are different questions of safety and effectiveness thus moving the device off the 510(k) path and onto the de novo or PMA path.

Once on the de novo or PMA path, FDA is not restricted in its data requests to 510(k) precedent or the standard of substantial equivalence, a comparative standard of safety and effectiveness. Instead, FDA has a clean slate in terms of the data they feel they can request because the standard for a de novo and PMA is reasonable assurance of safety and effectiveness in an absolute and independent sense, allowing the review staff immense freedom to ask for the type and amount of data they want. Industry needs the framework of the 510(k) program to keep FDA tethered to the comparative standard and must be aware of the FDA dynamics at work. FDA is constantly requesting endless amounts of information for well-established device categories. Where predicate families came to the market years ago without clinical data, the Agency—almost in an unwritten initiative to "update" predicate families— asks for clinical data, where none was historically considered necessary. It often becomes data, for data's-sake.

Despite our concerns, there are bright spots at the Agency. We have seen glimmers of hope at the Division Director and Office Director levels. Rather than allow review staff to misinterpret the definitional determinations of the 510(k) program to push devices off of the path or requesting data that is not commensurate with or proportionate to the risk represented by these devices, Division Directors and Office Directors are giving meaning to Least Burdensome requirements by reigning in review staff and re-focusing their attention. Nonetheless, our appeal to the Agency is to do a better job training review staff to understand the definitional elements of the 510(k)

program and to help review staff understand that the continual escalation of data requirements is concerning.

In the end, 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 patient risk rather than finding and embracing patient benefit. And it is through this misaligned focus on risk that the predictability of FDA's review processes has suffered. By redefining the 510(k) program, requesting more data, delaying submission reviews, and engaging in other tactics, FDA has imposed more and more obstacles to device approvals and clearances. And, unfortunately, the victims of FDA's tactics are the small and mid-sized medical device companies that are disproportionately burdened by FDA's obstacles as well as the United States citizens that should be able to benefit from innovative medical technologies.

DuVal & Associates
Drug, Device and Food Law

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