FDA and Dispute Resolution: It's Not Personal and Be Realistic

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Recently, we were asked to speak to a group of C-Suite officials within the pharmaceutical industry in a particular therapeutic space. Our topic was the Food and Drug Administration and its Dispute Resolution process. Here, we will not describe FDA's guidance document on the subject or the pros and cons of proceeding with such an approach; these are far too complex and numerous for this type of Bulletin.[1] However, based on the Q&A that followed, which included a panel discussion with a former Division Director, as we have counseled clients with dispute resolution issues, we thought a few general observations are worthy of consideration. While our talk and subsequent panel was to a pharmaceutical audience, we believe the issues can apply equally to the medical device industry.

One, we know from clients that there is a fear of reprisal or retribution by FDA if a company appeals or disputes a review division decision. In my house, my kids know not to go to Dad if Mom said no. We do not want to discount this concern but, in our experience, the agency does not punish a company for exercising its right, as described in the agency guidance, to take a scientific dispute up the FDA chain of command. Humans are, well, human, and it is possible that a particular individual may hold a grudge. However, the agency employs professionals who take their jobs seriously. For the most part, we do not see personal vendettas. Strong opinions, yes, but vendettas, no. Furthermore, the appeals process is established to minimize personal bias or retribution and, in fact, specifically discourages such pettiness.

During the panel discussion, the former Division Director noted that the agency focuses on data, not personalities. Certainly, a hostile or belligerent discussion by a company is counterproductive. That said, in our experience, senior and seasoned agency officials experience such exchanges on more than one occasion and can typically separate human emotion, typically frustration with bureaucracy, from the scientific data at issue. In other words, while an irate CEO might believe "it's personal," it most likely isn't.

Two, dispute resolution should be a matter of last resort. FDA strongly encourages the company and review division to work it out, if possible. To quote the former Division Director, "it's less when two ships are passing in the night, but more when the ships crash and collide." Again, back to the point of retribution, the collision occurs when, despite numerous efforts to resolve the issues, it's not going to get resolved to the company's satisfaction. Only then, after all efforts have been made, perhaps involving the Ombudsman, should a company consider dispute resolution after evaluating a variety of factors. But, the company should ask itself whether it makes more sense (i.e., financial, staffing, time) to swallow hard and attempt to meet FDA's request or challenge.

Three, not surprisingly, one should not expect a complete victory. First, dispute resolution is not often chosen – whether due to money, fear of retaliation, or resignation (or all). It can take months, if not years, to complete the process. Second, the individual who reviews the dispute or appeal is a fellow FDA official, as is the Ombudsman. This statement is not to disparage the reputation or

1 See, Draft Guidance for Industry – Formal Dispute Resolution: Appeals Above the Division Letter (March 2013); see also Center for Devices and Radiological Health Appeals Process – Guidance for Industry and Food and Drug Administration Staff (issued on May 17, 2013), at www.fda.gov/regulatoryinformation/guidances/ucm284651.htm www.fda.gov/downloads/drugs/guidancecompliance/regulatoryinformation/guidances/ucm343101.pdf.

integrity of the reviewing individual but, assuming the review division's decision was reasonably based on sound science and no one acted improperly, it is difficult to overrule the division merely because a company is upset.

Finally, and perhaps most important, "success" is a relative term. A company's goal or objective must be rationally defined within the company. While it is possible that FDA might completely reverse a review division's decision, although not likely, there can be other "successes." For example, a company may gain clarity of an agency expectation, achieve a compromise of a contentious point, or reach an agreement to revisit an issue, all which can help a company move forward with its clinical and regulatory development program. So, expectations must be reasonable and realistic.

John Mellencamp sang, "I fight authority, authority always win." Yes, it is difficult to fight FDA and win. In fact, fighting might not be the most effective approach, although specific facts might dictate otherwise. With a nod to Warren Zevon, Lawyers, Guns and Money may be required. However, if a company keeps the aforementioned points in mind, authority might not always win. To quote another song lyric, "one can fight the good fight" and live to tell about it and "ride the storm out."

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