FDA Today: Some Observations

Nancy L. Buc
Buc & Beardsley, LLP

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Over the last several months, FDA has intensely emphasized science, and getting tough. Implicit in its emphasis on science, and on getting tough, has been another theme – one that I'm not sure FDA understands or recognizes it is conveying but surely is. That theme is that FDA is not just the primary arbiter but really is and should be the sole arbiter of what good science is, and of what constitutes compliance. Omitted from this emphasis on FDA as the only one with the answers, the only one with the science, the only one who knows what's right, are two key points. First, everyone at FDA and everyone who deals with it needs in some cases, possibly many cases, to think through, talk about, consider, and wrestle with what standards, including what law, apply to the science. Second, those at FDA need to recognize that cutting themselves off from real interchange with others, including industry people, impairs the quality of decisionmaking.

One preliminary aspect of the science.

We have seen numerous cases recently – including ReGen and Plan B – where the argument seems to be that if senior management overrules middle or junior management that is somehow unscientific. One aspect of this that baffles me is how it can be unscientific for one set of scientists to make a scientific decision, even if it differs from the decision other scientists would make. Is it unjudicial for the court of appeals to overrule the district court? Another aspect of this that baffles me is why FDA senior management – up to and including the Commissioner – is supposed to stay out of FDA decision-making. After all, the law reposes in the Secretary of HHS, and through her the Commissioner of Food and Drugs, the responsibility to run the agency and make decisions. The idea that the Commissioner and other members of senior management should refrain from making decisions or having input into decisions turns them into figureheads or potted plants, not at all what the law intended.

I certainly understand why those who are overruled might disagree with a decision, and I can understand that there are sometimes process questions which mar the decision-making process and may even cause a bad result. But if a Commissioner or Center or Office or Division Director who is himself or herself a scientist – M.D., Ph.D., or both – reaches a different decision from others with M.D.s, Ph.D.s, or both – is that an unscientific decision or just a different decision? We really cannot be in a position where senior management cannot do or is loathe to do what senior management is supposed to do – make the final decisions – if every time they do so they are accused of invading the scientific prerogatives of their juniors.

If only the juniors can decide things, then it becomes problematic for sponsors to ask for supervisory or senior management review of a decision, because it will offend the first level decision makers, who will have it in their power to declare by whistle blowing or otherwise that what is happening is unscientific. Mind you, I am not arguing that first or second level decision makers should be excluded from further proceedings, nor that appeals should always be taken or always succeed. I am arguing only that some appeals should be taken and some of them should succeed, because the original decisions are not always the best decisions. (And senior management must take great care to insure that exercising the right of appeal does not result in retaliation by those whose decisions are being appealed.)

The second aspect of science that I want to talk about is the need for the rule of law and the role of law in agency decisionmaking about science. Again, I can take ReGen as my text. In that case, as far as I can tell from the recent report, the transcendent issue was not what the science told us about the performance (or lack thereof) of the device itself, but rather the standard to be applied by the decisionmakers. As the report outlines, some of the decisions about some 510(k)s are complex and complicated by uncertainties and inconsistencies in the standards – the legal standards – by which decisions are to be made about substantial equivalence. As I read the report, most of the problem stemmed from the fact that few if any of the decisionmakers at any level were willing to think through and articulate the standards by which decisions needed to be made. The absence of standards – and especially the absence of an articulated thought process – had everybody, within and without FDA, talking past each other.

Oddly, although the ReGen report discusses this issue at length, its recommendations do not explicitly include better law and better thinking about the law. Instead, they make "science" their first recommendation, as the current culture would want them to do. But if that wasn't really the problem – if the problem was failure at many levels to think through the legal and regulatory questions and integrating them with the science – and if senior management was also doing science, just as the Branches were, then focusing only on science won't help with the problem, because that wasn't the problem in the first place.

This issue also plays into the first issue – the question of who gets to decide. If first level decisionmakers are willing to and do take into account the standards, including the law, by which decisions should be made, then what gets reviewed at higher levels can address both law and science, if need be. But if they do not, if they just make decisions and call them science and are heedless of the principles the law imposes on them, then more senior decisionmakers will have to include the principles of law in their decisionmaking, and should not be criticized for doing so.

By the same token, it would help greatly if first line and higher levels of decisionmakers were all equally willing to engage seriously with sponsors who have views about the science, the applicable law, or both. I have been to many a meeting at which the working assumption seemed to be that sponsors should simply do what FDA told them to do. That isn't good science, it isn't good law, it isn't good policy, FDA shouldn't do it, and sponsors shouldn't acquiesce in it.

One of the oddest things about FDA's current practices with respect to science is the one-sidedness of it in a way that seems to me to be profoundly unscientific. I would think that science is best conducted where a proposal, a hypothesis, can be tested and vetted and debated and argued about by everyone with an interest. More and more, FDA seems to assume that industry people are not entitled to be fully part of that process because their views are tainted by their membership in industry. I have sometimes said to FDA people that an industry person is not wrong just because he or she is in industry, any more than an FDA person is right just because he or she is at FDA. If the FDA person smiles when I say that, I am usually right in predicting a successful discussion (successful meaning good discussion, not any particular result). Many FDA people do not laugh, however, showing that they lack a sense of humor or that the line isn't funny or that they really don't understand the problem.

The current meetings procedure is actually at odds with the concept of engagement on issues. All too often, sponsors are required to send in a briefing package, FDA holds its pre-meeting, and then decides everything at the pre-meeting. In effect, FDA holds the meeting without the sponsor. I know that courts sometimes do without oral argument, and I guess FDA should be allowed to do the same thing, but I think FDA should give greater consideration to the possibility that exchanges of written documents (which may not be written too well by either sponsors or FDA) may not be as productive as an actual discussion at which both sides try to make sure they have not just listened to but heard each other.

In that regard, I also want to note that the meetings SOP for one FDA center says meetings with sponsors will be held for only two purposes. One is in the enforcement context, the other so that FDA can tell the sponsor what the sponsor should do. Every time I read it, I wonder why the SOP doesn't cover the situation in which the sponsor wants to convey something to FDA. Surely no center should fail to mention that possibility?

In the enforcement context, FDA's "I will tell you what to do approach" is all too evident in the recent announcements about new enforcement procedures. These procedures incorporate a set of processes in which FDA tells you what it (actually, its inspectors) thinks in a 483, you deal with that promptly and fully, or else you get a warning letter in which FDA (actually someone a little higher up than the inspector) tells you what it thinks, and if you don't respond promptly and fully, presumably the next step is court. There is no specified point – not even one – at which any company can say, hold on, wait a minute, the observations in the 483 are wrong as a matter of fact, law, or both, or can say hold on, wait a minute, the observations in the warning letter are wrong as a matter of fact, law, or both. The tone of warning letters is particularly odious – peremptory verging on nasty, demanding – utterly without humility, not a hint that they are merely allegations, not final agency decisions, and not even allegations from the agency as such but merely from one official authorized to sign warning letters. The media accords them far too much weight and finality, compounding the problem FDA has created.

I think that an agency that is enforcing law – not just running wild – should be more than willing to give companies a real opportunity to say wait a minute, hold on. Despite the 483s and warning letters, some companies are not violating the law, and their GMPs and QSRs are OK and their ads are not misleading, and their foods are not adulterated. Throwing the book at innocent companies produces no gain in public health. Arguably it produces a loss, because resources that ought to be devoted to real problems are being wasted on non-problems. Moreover, bullying companies into expensive but unnecessary changes is wasteful – it increases the prices of foods, drugs, medical devices, and government.

Instead of discouraging debate about compliance, FDA should be encouraging it.

I recognize that thinking – hard thinking – about difficult issues, be they scientific, legal, or enforcement issues, is hard, time-consuming, and vexing. I recognize that entertaining many views, including sponsors' views, is time-consuming and vexing. It is nevertheless necessary if we are not all to have to just fall in and do what FDA wants done, as if there is no law, no science, and no debate. What is the line from the old movies – there's no law west of the Pecos?

Or was it no law west of the Rockies? It's important that there be law in Silver Spring, Rockville, and other places where FDA does business.

Yes, I'm a lawyer. But that doesn't make me wrong.