“MODERNIZING” THE 510(k)

Summary of Comments Posted to Regulations.gov

The Regulatory Watchcat

In reviewing the comments on FDA’s propose to “modernize” the 510(k), I was struck by: 1) the diversity of the perspectives represented, 2) the strong consensus among the commenters, especially given the diversity of perspectives, and 3) the time, considered thought, and effort that many commenters had clearly invested in their responses.

Personally, I was also surprised at how many of my own comments about the proposal were echoed by others. I’ve never considered myself to be any kind of bellwether for the industry; maybe more like the opposite. But perhaps I’ve just been swimming in the wrong tidepools.

“MODERNIZING” THE 510(k) – The Commenters

A total of 55 comments represented a diverse range of stakeholders, including 6 device companies (large and small), 1 software company, 6 trade associations, 1 third-party payor, 19 individual industry professionals, 14 individual patients, 5 patient groups, and 1 "think tank." Not all commenters addressed all of FDA's questions; some didn't address any.

Only 6 of the commenters who chose to comment anonymously. Of these, 4 included information in their comments that allowed me to classify them with reasonable confidence into one of the groups listed above. I classified 2 anonymous posters as unknown, but it seemed clear that they were either industry professionals or reasonably knowledgeable and undramatic patients.

The software company took the opportunity to pitch their benchmarking product. I included their input as a single suggestion to use benchmarking. The other companies provided comments that were often extensive, and mostly on point.

The majority of individuals who commented on the proposal were medical device professionals commenting on their own, instead of on behalf of their company. The majority of these commenters were RA professionals. Individual commenters also represented the personal perspectives of healthcare industry professionals and an attorney.

Many of the patients did not address FDA's proposal or its questions about the proposal, but instead told their stories of being injured by devices, provided detailed information about adverse events reported for certain types of devices, and/or complained about the 510(k), FDA, device companies etc. If a patient made a statement that was responsive to a question, whether they intended to answer that question or not, I included that response. No comments were included for 10 patients, because they were not responsive to FDA's proposal.

“MODERNIZING” THE 510(k) – The List

FDA's first question confounded several different questions: 1) whether to publish a list of devices for the purpose of encouraging "modernization," 2) whether the age of the predicate was an appropriate criteria for inclusion in the list, and 3) whether 10 years was an appropriate cut-off for the age of the predicate. As a result, answers were often also garbled, making it difficult to determine with certainty which question(s) the commenter intended to address.

To summarize comments on the usefulness of publishing a list of devices for the purpose of encouraging the use of more modern predicates, I identified 20 responses that I thought had addressed this narrow question, regardless of which criteria might be used to determine inclusion on the list. Of these 20, 16 said **NO**.

Three patient groups and one inventor supported publication of a list, but it was not clear they were aware that information on the "history of predicates" was already publicly available in FDA's 510(k) database. The comments

of all three patient groups clearly had a common authorship; two groups submitted identical comments; the third group submitted comments that might be called, ironically, "substantially equivalent" to those submitted by the other two groups.

The rest of the commenters were trade associations, device companies, or individual industry professionals. All were opposed the publication of this type of list.

Multiple commenters expressed doubt that such a list would serve any purpose, including to encourage "modernization." There was a strong consensus that publication of this type of list was likely to have a number of undesirable consequences, including:

- Perception by "the public" that the listed devices as less safe and effective than other 510(k) devices.
- Confusion among patients and physicians regarding the meaning of the list.
- Refusal of reimbursement for the listed devices.
- Refusal of insurance for liability related to use of the listed devices.
- Removal of the listed devices from the market.
- Damage to the device manufacturer's reputation, earnings, and future potential.
- Damage to innovation of the listed devices and their predicates, because they would be perceived as "bad" predicates.
- Perception that FDA is allowing devices that are not adequately safe or effective to remain on the market.
- Damage to public perception of the substantial equivalence framework as adequate to assure device safety and effectiveness.
- For prescription devices, a perception that FDA is attempting to regulate the practice of medicine.

"MODERNIZING" THE 510(k) – Age of the Predicate

A total of 26 commenters answered FDA's question as to whether the age of a device's predicate was an appropriate exclusion criterion. All 26 said **NO**.

A few commenters seemed open to the idea that age was a factor worth considering, but none thought it should be the only factor, nor even the primary consideration. Most argued that a predicate's age was not an appropriate criterion at all. The lack of evidence to support FDA's proposal was noted by numerous commenters.

Almost all of the commenters also expressed their opinions (often at great length) as to whether devices with newer predicates should inherently be preferred over devices with older predicates and whether discouraging the use of older predicates was likely to promote the incorporation of more modern technologies into 510(k) devices.

A lot of commenters argued in favor of older devices as predicates over newer ones, eg:

"Older devices are still in use because they meet current standards of care, represent a more affordable option than the latest technology and are well understood by the user."

"Devices on the market longer than ten years are those that are most often described in medical and scientific literature."

"Widespread usage, which comes with the passage of time and the exposure to thousands, if not millions, of patients, can lead to rich real world evidence for the device and its materials."

"The use of an older predicate may be a strong indication that the product is very well characterized from both a technology perspective and also from a clinical use perspective. Products with a long use history demonstrate a deeper knowledge of product performance, safety and efficacy. In general, predicates that have longstanding field experience, more developed technology, and higher levels of user knowledge may actually be beneficial to showing safety and efficacy."

One comment noted that FDA actually advises the use of older technologies in some guidance documents, because these technologies are the "gold standards" to which the performance of new technologies must be compared.

Many commenters felt that discouraging use of devices with older predicates would have a negative impact on innovation in a number of ways:

- By substantially reducing the number of predicates to choose from.
- By incentive to innovate devices for which only an older predicate is available.
- By incentive to innovate devices for which an older device is otherwise the best choice for a predicate, as is often the case when manufacturers want to use their own devices as predicates.
- By dramatically curtailing the time period during which devices may be used as predicates once patents have expired.

Few commenters addressed FDA's question about other criteria it might consider in its efforts to "modernize" the 510(k), probably because there was so little enthusiasm for the whole idea in the first place. The few that were suggested mostly mirrored the criteria for a 510(k) – changes in technology and intended use.

Only one person answered FDA's question about a more appropriate time period. He suggested 20 years, which, based on some of the other comments, seems likely to raise significant issues related to patents.

"MODERNIZING" THE 510(k) – Other Criteria

I identified 10 commenters as having responded to FDA's question about whether it should consider criteria other than the age of the predicate "to inform our point of reference." I interpreted this phrase to mean "to identify devices for inclusion on a public list." One commenter said no, because they thought that "the current substantial equivalence process is robust." Since the current process doesn't include a list, I gathered this commenter interpreted FDA's somewhat murkily worded question to mean other criteria it should use "to inform a determination of substantial equivalence."

The other 9 commenters suggested a variety of criteria, including:

- Commercial availability and viability
- Type of and changes to technology
- Nature of and changes to intended use
- Scope and rapidity of innovation for that device type
- Conformance to standards, guidelines, specifications
- Demonstrated safety and effectiveness
- Clinical track record
- History of adverse events, recalls, market removals
- Risk class, risk profile, risk analysis, risk to benefit
- Specific concerns about a particular device or device type

Most of those who offered suggestions had shown little to no enthusiasm for a list, and appeared to be offering these suggestions just in case FDA decided to publish one despite everyone's best efforts to persuade it not to.

One patient group suggested a clinical record of at least a 95% survival rate at 10 years from entry to market.

"MODERNIZING" THE 510(k) – Uncertain Actions

By my count, FDA's last two questions elicited responses from 27 different commenters. Both questions asked about actions FDA might take. Most of the commenters offered one or more suggestions, but there didn't seem to be much meaningful difference between the suggestions offered in response to one question or the other:

- The first of FDA's last two questions was limited to actions it might take "to promote the development and marketing of safer, more effective 510(k) devices." Not all commenters appeared to understand the development and marketing of 510(k) devices well enough to know if the actions they suggested fell within this scope. Others seemed not to feel the need to limit their suggestions to the scope of FDA's question.
- FDA's last question was limited to actions that would require "new authority." It seemed unlikely that many of the commenters were in a position to know whether their suggestions would require "new authority."

Some of the suggestions were actions that FDA could take to make it easier to develop 510(k) devices and/or get clearance, rather than safer, more effective 510(k) devices. A few suggestions were actions that would serve some other purpose. Suggestions that I thought were responsive to FDA's question included:

- Add the age of the predicate device to the RTA checklist and require justification of the use of an older predicate.
- Advise manufacturers to use the latest relevant predicate available
- Consider sunsetting certain older predicates.
- Allow manufacturers, particularly in low-risk, well-defined industries to justify the use of older predicates.
- Provide more transparency on safety and performance information for predicates, as well as a fast, easily accessible way to check predicates.
- Address the limited availability of predicate device information.
- Develop a way to "reward" devices that clearly make an effort to advance safety and/or effectiveness.
- Issue special guidances to address specific concerns about a device or device type.
- Require sufficient testing before approval.
- Update the current classification system to keep pace with the risk/benefits of today's technologies and materials.
- Make each intended use statement condition specific, rather than clearing devices for broad use throughout the body.

A few suggestions seemed intended to "modernize" 510(k) devices. Since the proposal was based on the assumption that "more modern" meant "safer and more effective," I decided these suggestions were also responsive, if somewhat indirectly.

- Update the performance testing criteria for the latest technology.
- Encourage design development processes during the early phase of development that evaluate if a technology is within the state of the art, and which provide ongoing assessment throughout the product lifecycle.
- For products that could benefit from improved technology or performance standards, reclassify the procode, set performance standards, and let manufacturers respond with new submissions.

In contrast to those who suggested actions, those who said no further actions were needed had different perspectives, depending on which of the two questions they were answering:

- Five commenters said no to alternative actions to promote the development and marketing of safer, more effective 510(k) devices. One thought action should only be taken when concerns existed for a particular device or device type. The other four said that the 510(k) should simply be scrapped. Several referred to the Institute of Medicine's 2011 report.
- Eleven commenters said no to "certain actions" that might require new authority, because they thought FDA already sufficient, if not more than sufficient authority already. One patient added that the problem with device safety was FDA's failure to enforce the authorities it already has.

“MODERNIZING” THE 510(k) – Postscripts

It was very difficult to “count” anything in these responses. I’m not only certain that others would get different counts than I did, but that I would get different counts myself, if I started over and repeated the process.

In this case, I don’t think it matters much. There was such a strong consensus in the responses to FDA’s main questions, one or two overlooked or miscounted responses wouldn’t make a dent. The diversity was in the details. And there were plenty of them, lol. Regardless, I hope my summary will give those who don’t have time to read all 55 responses a good idea of the overall response to FDA’s proposal. This is the first time I’ve been that ambitious; usually I just click on a selected sample, to get a general idea of how the different constituents are responding.

I found many of the responses very educational, a rare opportunity to get the prospective of numerous players on a topic of interest. Some raised points I hadn't considered; others provided different perspectives on the same points I had raised.

I will say yet again how impressed I was with the time and effort that many organizations and individuals put into their comments. Some, almost too much, lol. The companies and trade associations sometimes seemed to confuse regulations.gov with a lecturn, writing fairly lengthy treatises on the 510(k) process. They also often responded at some length and then finished with their answers to FDA's questions, which by then were often redundant.

If you would like to do some directed reading, you might want to peruse some of these comments:

AdvaMed and MDMA - Both did a very capable job, IMO, and their comments are presumably based on a consensus among multiple device companies.

I thought the Consumer Healthcare Products Association (CHPA) did a great job at describing the value of older predicates.

BCBSA – This is the first time I've read a payor's comments on a regulatory matter. I thought it did a capable job as well.

If you like evidence, read Jeff Shapiro. If you like standards, read MITA. If you like the "real world," try the BRIDGE Coalition.

Several individual companies did a capable job of responding as well, but, without going back to do a point-by-point comparison, I don't think they raised any significant issues that you won't find covered in comments above. An issue addressed by several trade associations and companies was the bad rap that the 510(k) has taken lately, and suggested ways to improve public perception. Not that FDA asked.

Jean Bigoney's comments are well worth a read. In particular, you can tell Jean has personally worked through the predicate selection process many times, in contrast to a number of other "expert" commenters. Not to name any names.☺

Easily my favorite comments were those made by Samuel Lynch, not only for their content (i.e., he agrees with me, including on some points I didn't include in my own comments), but also because of the diversity of experience they reflected.

Don't bother to read any patient comments. Some are not bad, but in the end you won't learn anything, except maybe why patient activists are so seldom taken seriously. Unless you are looking for prime suspects behind the KHN article on "hidden" reports and similar garbage that's been in the news lately, avoid the comments by the National Center for Health Research. Ugh.

"MODERNIZING" THE 510(k) – My Take

1) From the perspectives of the various constituencies were represented by the commenters, it seems to me that this proposal was unarguably a fail. This brings me back to Jeff Shuren's statement that CDRH needed permission to fail at its efforts to modernize the 510(k), which he made over two weeks after the comment period had closed. If he had been referring to this proposal, at that point, clearly it was too late to seek permission and the only option left would have been to seek forgiveness. I wonder if that means the actual fail is yet to come. This seems likely to be the result if the FDA decides to publish the list in spite of all the comments, which I found to be more than persuasive on that point. Time will tell.

2) I was again struck by the extent to which FDA doesn't seem to be walking its talk these days. Like numerous other commenters, I picked up the lack of evidence to support its proposal, although I think I was the only one to point out the disparity with its talk. I completely missed the most glaring example of "all talk/no walk." Fortunately, numerous other commenters did not. FDA talks endlessly about "real world" evidence. Then it proposes to publish a list that is intended to encourage the use of predicates with "modern" technology over the

very predicates that are most likely to be solidly supported by decades of clinical experience and “real world” evidence. Ouch.

3) This exercise got me to re-thinking policy. In another life, I worked with a number of different policy experts, education and healthcare, at the state and federal level. They struck me as knowledgeable in their areas and thoughtful in their policy considerations. I thought policy was pretty cool, and I could have easily gone down that path professionally. Now I’m wondering if I just got lucky in the policy experts I worked with, or if, over time, policy has deteriorated into yet another area that operates largely in ignorance of its subject matter. This proposal seemed be founded in near total ignorance of how the 510(k) process is used, including how predicates are selected, and what characteristics are important in a good predicate.

4) I come back to the time, thought, and effort that many commenters had so clearly put into their comments, whether they commented on behalf of an organization, a company, or just themselves. For some, it was part of their jobs, but for others, it wasn’t. Regardless, people invest time and effort into things that matter to them, for whatever reason. I found the contrast between many of the comments and FDA’s proposal, which was based on no evidence, little thought (at least, I hope not), and, IMO, was generally a mediocre document, to be both striking and discouraging. My most enduring take away from this exercise will probably be that the only player in the game to whom FDA’s regulation of 510(k) devices doesn’t seem to matter much is FDA.

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