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The FDA's proposed changes to device regulation are thin on detail

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The FDA has made a lot of noise about its plans to make medical devices safer. But these plans are somewhat amorphous; any meaningful steps would likely require congressional approval, and could thus take years.

Over the past month the US FDA has made 10 statements detailing its past achievements and future plans when it comes to changing the way medical devices are regulated. These have ranged from increasing inspections of device companies to making the *de novo* pathway more efficient and transparent. But the actual steps the agency intends to take remain ill-defined.

"It is somewhat unclear," says Allyson Mullen, an associate at the FDA-focused law firm Hyman, Phelps & McNamara. "They haven't proposed any specific changes. They are more espousing preferences, mostly for newer predicates. We don't consider that a major change because that's the FDA's preference now."

Last month the agency said it wanted medtech companies to use more recently approved predicates when applying for 510(k) clearance of new products (*The US FDA plays it safe, November 28, 2018*). It also said it wanted to "sunset" certain older predicates, but did not explain exactly what this would involve.

Might the FDA refuse to allow 510(k) applications that rely on predicates approved more than 10 year previously, for instance? Or even revoke prior clearances based on decade-old predicates? As far as the next steps go, "It was such an odd announcement that it's hard to tell," says Ms Mullen.

Legislation

In any case, if the FDA does intend to force device makers to use newer predicates, this would probably take a change in the law, and as such is a very long-term proposition.

"If the FDA is going to take some real concrete steps we expect that they would need to work with Congress, and Congress would have to change the [Food, Drug and Cosmetic] Act in order for FDA to begin sunsetting 510(k)s," Ms Mullen says. This is not impossible – the 21st Century Cures legislation passed last year was a major statutory change to the Food, Drug and Cosmetic Act.

But it is more likely that if the FDA wants to change legislation these changes would be rolled into the reauthorisation of the Medical Device User Fee Amendments (MDUFA) Act. This act is reauthorised every four years, the most recent changes having come into force in October 2017. The changes the FDA is planning now,

such as they are, are therefore unlikely to be made manifest until late in 2021.

The FDA has made it very plain that its announcements over the past two weeks have nothing to do with the Implant Files investigation into unsafe devices and, to be fair, the 510(k) clearance pathway has been morphing into something more rigorous over the past few years anyway.

The FDA has been asking for, and receiving, a lot more information in these submissions, with the average number of pages in a 510(k) submission being 1,185, compared with 475 pages in 2009. And the agency expects that if medtech companies are compelled to use only newer predicates more devices will have to go through the *de novo* process, which does not use predicates at all.

This could lead to more onerous requirements being expected of medtech groups. They would have to establish that the product is a low to moderate-risk device – in FDA parlance, Class 1 or Class 2 – and submit a thorough risk-benefit analysis.

Clinical data tend to be required more frequently in a *de novo* than a standard 510(k), Ms Mullen says. “Many *de novos* include clinical data. Not the randomised controlled trials you would expect in a PMA, but smaller observational studies.” Nevertheless, any clinical study can be costly and time-consuming to perform.

Liability

It is intriguing that the FDA is putting so much effort into tweaking the rules governing 510(k) and *de novo* clearances when the most complex, high-risk devices are regulated via the PMA (premarket approval) pathway.

In fact, tightening the clearance route, even though it might mean a longer and more expensive path to market, should in one sense benefit device makers. This is because the PMA pathway confers legal protections on a company, where clearance does not.

“If they take the PMA route then effectively the FDA is affirming the safety of the device, through the rigorous process,” says David Kaplan, director of the healthcare group at the credit ratings agency Standard & Poor’s. “So if, years later, it becomes known that the device was actually unsafe the company cannot be sued for product liability.”

This is why – to pick one example – companies producing pelvic meshes, most of which were cleared under 510(k), have ended up paying billions of dollars in compensation to patients harmed by the products, whereas Bayer, which owns the Essure contraceptive device that was found to be so dangerous it was eventually withdrawn from sale, has not. Essure was granted PMA in 2002.

This legal immunity only exists, of course, if the company went through the PMA process properly, and unknown to them the product caused more damage than was realised. If the company had submitted fraudulent information it would be a different story.

Mr Kaplan points out that from the company’s perspective this is a trade-off: a high-risk device might take more time and money to get approved, but at least it is covered from a liability angle. Liability payouts over a faulty product usually dwarf the revenue the company had made from its sale, and this has pushed some groups to prioritise high-risk devices that take the PMA route.

“There are some companies that indicated that maybe they’ll stay out of 510(k) products, and just work within the PMA, because they didn’t like the fact that they have to pay a billion dollars in settlements on something that only made $50m or $100m in revenue,” Mr Kaplan says.

That said, some medtechs rely on the 510(k) clearance route to get their products on the market as soon as possible – and still others regard the risk of product liability lawsuits as little more than the cost of doing business. If the FDA does take action to make devices cleared via 510(k) safer theoretically this would decrease the likelihood of medtechs getting hit with lawsuits.

Medtech v pharma

“From a liability perspective usually a medical device company would have more exposure than a pharmaceutical company,” says Mr Kaplan. But in terms of a group’s stock price movement or creditworthiness the recall or withdrawal of faulty medical devices seem to affect medical technology companies to a lesser extent than the recall of a dangerous drug would a pharma company.

Mr Kaplan posits a couple of possible reasons for this. “Pharmaceutical companies, at least some of them, have a more concentrated portfolio – they’re selling fewer drugs then the medical device companies [sell devices].”

If a company sees its biggest selling drug pulled from market, it might lose 30% of its revenues, he says, hugely damaging its prospects. “But what we found from a creditworthiness perspective is that even the big example of Vioxx, which was withdrawn, the product liability part of the equation was not enough to move the rating.” Merck voluntarily withdrew its painkiller in 2004, at which point its sales were around $2.5bn.

“It could also be that pharmaceutical products often are distributed more widely and they’re viewed as being less invasive, so the public interest and media attention to recalls is higher,” Mr Kaplan says.

Even so, if tighter regulation limits medtech companies’ loss of revenue and exposure to litigation, it ought not to be entirely unwelcome by industry. Over to the FDA.