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‘Get Ahead Of The Curve’ By Preparing for EUA End, Attorneys Say

by Elizabeth Orr

Two regulatory attorneys spoke to Medtech Insight about the most important steps to take before the public health emergency ends, as well as what enforcement tactics they expect to see from the FDA.

With the official end of the COVID-19 public health emergency in the US just a few short weeks away, device manufacturers are gearing up for the next step: Transitioning devices that reached market under emergency use authorizations (EUAs) or other forms of enforcement discretion to a conventional US Food and Drug Administration regulatory pathway. *Medtech Insight* interviewed two veteran attorneys about what steps manufacturers should prioritize.

The agency issued final guidance documents explaining its three-step approach to EUA transition last month. However, the agency’s plans go into effect when pandemic-era policies are revoked – meaning that what to do now is up to manufacturers. [(A#MT147770)]

Barbara Binzak Blumenfeld, co-chair of the FDA and biotechnology section at law firm Buchanan Ingersoll and Rooney, said that the most important thing right now is to stay on top of what the FDA is doing. The network of Federal Register notices, updated guidance documents, and other statements from the FDA make up “a pretty complex web of things out there,” all of which could impact the EUA transition process, she says.

Additionally, Binzak Blumenfeld urged manufacturers of life-supporting or life-sustaining devices such as ventilators to alert the FDA as to whether they plan to keep marketing the products or pull them after their EUAs expire. The information could help the FDA avoid device shortages, she says.

“The devil’s in the details, and it’s just a matter of keeping track of the moving parts,” Binzak Blumenfeld said. “To be quite honest, that will be the biggest challenge.”

Her recommendations were echoed by those of Foley Hoag partner Nancy Stade, though Stade also noted that companies that plan to continue to market their devices will also need to determine which regulatory pathway to pursue – PMA, de novo, or 510(k). That may mean working with a regulatory attorney or even the FDA, she said.

Another challenge may be the 180-day timeframe the FDA plans to give device makers to apply for regular clearance or remove their products from the market after EUAs are no longer in effect. This may be enough time for manufacturers of simpler products like masks, but developers of more complex items could find the deadline tight, Binzak Blumenfeld said.

However, she also pointed out that while the public health emergency is set to end on 11 May, it's still unknown when EUAs will be revoked. Because the FDA hasn't announced that deadline yet, she said, "it's giving companies a chance to get ahead of the curve" by preparing ahead of time.

Similarly, Stade said that companies that started their preparations in a timely manner shouldn't run into any trouble meeting the deadline. "Folks really should have been planning for this for … close to a year now, or at least six months," she said. "The emergency conditions have been winding down."

That may be especially vital for companies that jumped into the device market during the pandemic, and may be less aware of regulatory requirements. Firms in that position should come up with a specific transition plan as soon as possible, Binzak Blumenfeld said.

Expect Enforcement Prioritization

In terms of enforcement, Binzak Blumenfeld expects the FDA to "pick its battles" and prioritize enforcement actions against riskier products.

Stade, meanwhile, draws on her experience as a former deputy director for policy at the agency's device center in predicting that the agency may take a slightly softer approach to companies new to the device sector, who may not be used to how closely the FDA monitors marketing claims even after regulatory clearance.

"I expect what they'll see from the FDA is more like, instead of going straight to a warning letter, it'll be a phone call – 'We saw that you are marketing test XYZ in a way that's not appropriate. What are you going to do?'," she said. "And manufacturers who aren't used to that are going to have to figure out what it means to be FDA-regulated."

But regardless of the FDA's enforcement approach, some regulatory bottlenecks may be unavoidable, Stade said. "There's no way around that, because many of the EUA-authorized products are going to want to come in for 510(k)s, and it's not going to be just a matter of rubber-

stamping: They're going to have to evaluate it in conditions that aren't emergency conditions," she said. "So I do imagine that folks with these products and also with products that aren't under EUA, but that are in the same divisions, may well see some some bottlenecks."

These bottlenecks, she said, may be especially acute for diagnostics – both because they're less standardized than other device types, and because the FDA had authorized a wide range of tests for home use.

"There's always been pressure on [the FDA] to authorize more diagnostic products for home use, and they've always resisted that," Stade said. "Then of course, there was a lot of pressure during the pandemic to have tests authorized for home use. When they're going from EUA to a 510(k) clearance, there might be stumbling blocks and there might be some hesitation on the part of CDRH and interest in upping the standards."