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Electronic Cigarettes

E-Cig Battery Fixes Delayed by FDA Rule, Industry Says

Electronic-cigarette companies are effectively blocked from making improvements to battery safety under current regulations, an industry representative says.

E-cigarette fires and explosions have injured dozens of people. Relatively simple circuitry changes might fix at least some problems leading to such incidents, one attorney has said.

But the Food and Drug Administration's April 2016 regulation deeming e-cigarettes, hookahs and other items ''tobacco products,'' and bringing them under the Tobacco Control Act, gets in the way, Tony Abboud, national legislative director at the Vapor Technology Association, told Bloomberg BNA in a recent interview. The VTA is a trade association for the e-cigarette industry.

The deeming rule prevents manufacturers from making changes to the physical devices without submitting a full application for premarket review, he said.

Before and After Effective Date. The deeming rule allows staggered deadlines for premarket tobacco applications (PMTAs) for products on the market before Aug. 8, 2016, the date the deeming rule became effective.

But for products introduced or changed after that date, the provisions of the TCA apply immediately, according to Mark Gottlieb, executive director of Northeastern University School of Law's Public Health Advocacy Institute in Boston. Those provisions include the requirement that the products first have FDA approval before going on the market.

''A change in a component would likely mean that the product would be considered new and a separate application would need to be submitted,'' Gottlieb told Bloomberg BNA in an e-mail.

Abboud also said this would be the case. ''Any type of new formulation that's manufactured after Aug. 8 requires this premarket approval application process,'' he said.

''In other words, you cannot decide, 'Hey, I've got a new formulation for the liquid,' or for the flavoring or frankly—this is how absurd the regulation is—you can't have a new formulation for any piece of the device.''

''You've seen these articles about what happens with batteries that catch on fire,'' Abboud said. ''Let's say Company X figures out, 'We now have a foolproof way to keep that problem from ever occurring again.' They can't make that innovation.''

Vapers Hurt. FDA scientists have identified a total of 134 reports of overheating incidents, fires and explosions in e-cigarettes from 2009 into early 2016.

One plaintiffs' attorney handling e-cigarette cases, Gregory L. Bentley, says he's spoken to more than 130 people over a period of six or seven months who say they've been injured this way. Bentley is with Bentley & More LLP in Irvine, Calif.

Short circuits due to overcharging or overdischarging, among other issues, have been blamed for the incidents involving lithium-ion batteries in e-cigarettes and other products.

Producing high-quality, safe lithium-ion batteries may be complex and difficult. But to some, like Bentley, the overcharging and deep-discharging can be controlled through circuitry. ''It's an easy fix,'' he said.

Applications: How Difficult? The reason companies can't improve their batteries or circuitry is the burdensome up-front process, Abboud said.

''A purely technological modification is forbidden by the FDA unless you first go to the FDA, and you take the time to conduct all the studies,'' he said. Manufacturers would have to ''demonstrate that that particular change or that new device is going to be beneficial to public health, which is going to take years to prove,'' he said.

''And then of course you need to go through all the paperwork submissions, and those submissions that, once filed, go to the back of the line of all the other submissions that have been filed,'' he said.

The effect of the rule is that ''the products that exist on the market have to stay on the market, but without the benefit of any innovation,'' he said.

FDA spokesman Michael Felberbaum confirmed in an e-mail that the premarket review process would apply. ''All newly-regulated tobacco products are required to undergo premarket review and obtain market authorization from the FDA, unless they are eligible for grandfather status (were on the market as of Feb. 15, 2007),'' he said in response to a question about changes to improve battery safety.

The agency, in not-yet-final recommendations for submitting applications, urges companies to describe their products' various electrical and battery specifications to ''enable the FDA to assess the risks of a battery that would be used in a product,'' he said.

But Gottlieb says a new, separate application ''would mean essentially resubmitting the original application with only a few changes to the battery specs.'' Still, that's ''not an ideal solution for manufacturers or for

the agency which would need to evaluate the new application,'' he said.

Gottlieb doesn't see as grave an impact on industry. ''In the case where there is a better battery now available, applications for the product currently on the market and the one with an improved battery design could be submitted simultaneously,'' he said.

''Because the differences between the applications would be minimal, this would not represent a significant increase in time or money required for the additional application,'' he said.

But he agreed with Abboud about the practical effect until the FDA begins approving PMTAs. The ''products and technology for sale in the next couple of years will be stuck in August of 2016,'' he said.

Solutions. ''What this would logically call for is something like the Substantial Equivalence application process where no new health issues arise for a substantially similar product,'' Gottlieb said. ''Important innovations in circuitry or batteries won't change the public health profile of the products.''

Abboud, meanwhile, is hoping Congress will approve a bipartisan amendment to an agriculture funding bill that requires the FDA to act within 12 months on battery safety.

The amendment, sponsored by Reps. Tom Cole (R-Okla.) and Sanford Bishop (D-Ga.), would allow some FDA regulation of e-cigarettes under the deeming rule, but would limit the agency's premarket review of the products by pushing the date for grandfathered products up from 2007 to 2016.

''The FDA has done nothing over the last two-plus years, as they've been considering how to regulate this product, to deal with the issue of battery safety,'' Abboud said.

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