

Product Liability Regulation and Legislation To Watch In 2017

By **Emily Field**

Law360, New York (January 2, 2017, 1:03 PM EST) -- With the New Year and a new Trump administration, product liability attorneys will be watching to see whether mass tort reform efforts gain favor with a business-friendly White House bolstered by a Republican-majority Congress, as well as keeping an eye on increased activity at the National Highway Traffic Safety Administration regarding autonomous vehicles and who will be tapped to head the U.S. Food and Drug Administration.

Here, Law360 takes a look at the legislative and regulatory movements likely to shape product liability in 2017.

Mass Tort Reform?

In 2016, legislative efforts directed at mass tort reform passed the U.S. House of Representatives, but stalled at the Senate level.

Last January, the U.S. House of Representatives passed a bill aimed at raising standards for class certification in lawsuits, and would also require asbestos bankruptcy trusts to make claimants' details public.

By a 211-188 vote, lawmakers passed H.R. 1927, the Fairness in Class Action Litigation and Furthering Asbestos Claim Transparency Act, over the objections of Democratic lawmakers who contended it would harm access to justice and invade asbestos victims' privacy.

If signed into law, the bill would require that class action plaintiffs show potential class members have both the same type and "scope" of injury to win class certification and that asbestos trusts make public the details of trust claimants. The Obama administration had threatened a veto a day before the vote.

Although tort reform didn't play a role in the presidential campaign, some attorneys expect that the the Trump administration would be receptive to such legislative efforts.

The House Judiciary Committee has held several hearings on class action and mass tort abuses, as well as on some jurisdictional issues — that is, whether cases should be heard in federal or state court — raising the possibility of legislation on those issues, noted John Beisner of Skadden Arps Slate Meagher & Flom LLP.

"In the business community, there would be a lot of interest in the legislation that would address those

sorts of [class action] abuses, particularly with a White House coming in that may be more receptive to those sorts of reforms,” Beisner said.

However, lawmakers poised to draft business-friendly legislation would also do well to keep in mind the populist surge that helped propel Donald Trump to his unexpected win, cautioned Max Kennerly, of counsel at TorHoerman.

“I do think Trump himself would describe himself as a populist — he ran on trying to benefit the people — so I think legislators who want to cheerfully deny justice should have a moment of pause there to understand the forces that brought Trump to the White House,” Kennerly said.

Trump himself has been more than willing to turn to litigation in various disputes and his wife Melania is also currently a plaintiff in a defamation case, Kennerly noted.

“The hope would be that he would understand from a plaintiff’s perspective the need for access to justice,” Kennerly said.

Self-Driving Cars & NHTSA

NHTSA this past fall released guidance on the safe development and deployment of self-driving cars on American streets, which included a safety assessment for the design, development and testing of driverless vehicles and recommended policy areas for states to consider while regulating those types of vehicles.

“Given the guidance, I’m expecting heavy activity from NHTSA on those issues in 2017,” Thomas Branigan of Bowman and Brooke said, noting that he expects the agency to engage in rulemaking on the technology in the next year.

The DOT’s announcement hit at a time when driverless or semi-driverless vehicle systems have already taken to U.S. roads. Tesla Motors Inc.’s Model S has a feature called “Autopilot,” which has come under investigation after the May 7 death of a man whose vehicle equipped with partially autonomous braking and steering features was involved in a crash.

Despite Tesla’s assertion that the Model S brakes were to blame for the crash, not the autopilot feature, the incident has still drawn scrutiny from concerned regulators and consumers.

Newly passed legislation in Michigan seeking to open the state to wider use of the technology has generated feedback from companies like Google Inc., which has an autonomous vehicle program, and Ford Motor Co., which wants to use Michigan as a testing ground for such vehicles.

“There’s no question that the new laws in Michigan support the operation of auto vehicles in a way that’s not just limited to testing ... but used in vehicle hailing-type system or a taxi-like system,” Branigan said.

Leadership Changes at the FDA

Although Trump has not yet named a new head for the agency, two possible picks — one, Jim O’Neill, is a Silicon Valley investor without a medical degree — are reportedly under consideration, and attorneys will be watching closely to see who gets the nod, given the unlikelihood of a Democratic administration-

backed commissioner staying on.

O'Neill has called for the FDA to do away with its efficacy standards and let the market sort out which drugs and medical devices are effective, a position that would find little favor with companies, medical care providers and patients, says Michael Gaba of Holland & Knight.

"Patients want to know that products are effective for what they're intended to do and companies want to be able to make claims about what their products do," Gaba said.

The other potential FDA chief, Scott Gottlieb, has a medical degree and served as a deputy commissioner at the FDA under the Bush administration, a much more direct and relevant experience for the position than O'Neill's, Gaba noted.

Although the areas regulated by the FDA didn't play much of a role in the campaign, Trump has called for getting drugs to the marketplace faster, attorneys say.

One way for the FDA to accomplish that goal without undertaking statutory changes would be loosen restrictions on the off-label promotion of drugs and medical devices, Gaba said.

The FDA in November held a two-day forum on the topic, as it's revisiting its restrictions after losing a number of losing multiple First Amendment challenges in recent years.

"I think that this in next administration, no matter who running the agency, I would anticipate a leaning toward being less prescriptive around off-label promotion to facilitate access to products sooner," Gaba said.

--Additional reporting by Jeff Overley, Daniel Wilson and Suevon Lee. Editing by Rebecca Flanagan.

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