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Product Liability Legislation & Regulation To Watch In 2016

By **Sindhu Sundar**

Law360, New York (December 24, 2015, 8:38 PM ET) -- The U.S. Food and Drug Administration is poised to finalize the last two major rules under the Food Safety Modernization Act, while Congress mulls requiring some form of labeling on genetically modified foods amid controversy kicked up by Vermont's own GMO labeling rule.

In 2016, the FDA is also expected to finalize rules pertaining to its proposed historic overhaul of nutrition labels from 2014, while Congress and auto regulators contemplate how to handle the increasing threat of cybersecurity breaches in vehicle systems.

Here are some key developments attorneys will be following:

Final Food Safety Modernization Act Rules

The FDA will be continuing its rollout of final major rules under the 2011 FSMA overhaul, including the sanitary transportation rule, which is expected to be finalized in March, and its intentional adulteration rule expected to be finalized in May.

The sanitary transportation **rule —** the seventh and final one, proposed by the agency in January 2014 — requires companies transporting food distributed or consumed in the U.S. to ensure that it does not get contaminated while being shipped.

The intentional adulteration rule, also billed an "anti-terrorism" rule, was proposed in December 2013 to require large food companies to take steps to prevent the intentional contamination of their products by terrorists.

The rule would target the processes in food facilities most vulnerable to an attack, with facilities required to develop a written plan to address weaknesses in the supply. Companies would have to monitor vulnerabilities in the food supply, ensure personnel receive appropriate training and keep records related to their prevention efforts.

"There have been some changes in the FDA leadership, specifically some of the food and nutrition advisers, that slowed down some momentum in the last six months," said Brad McKinney of Faegre Baker Daniels. "But it is clear that this administration is hell-bent on making its mark on the food and

regulatory world."

Final Nutritional Labeling Rules

The FDA is expected to finalize certain rules related to its nutrition labeling overhaul proposed in the spring of 2014. The planned overhaul would require food companies to reveal more precise information on issues important to consumers, including serving sizes and ingredients tied to serious illnesses, such as calorie counts and sugar content.

Under the overhaul, the agency has proposed, for instance, that companies include how much sugar they have added to the product, instead of listing only its overall sugar content per serving size. The agency has also proposed to reduce the maximum daily sodium intake from 2,400 mg to 2,300 mg.

The rules also require companies to label nutritional information based on more realistic serving sizes, taking into account the practical ways consumers eat or drink their product.

"These final rules on nutrition facts panels were proposed in 2014 and have since gone through several extentions and comment periods," McKinney said. "These are real overhauls of the panels — it's not only changing what is included in the label, but also changes the formatting to make it more readable, and to make certain things really stand out more to consumers."

Generic-Drug Cos.' Control Over Labels

The FDA has continued to postpone finalizing its proposal to allow generic-drug makers to have more control over changing their labels to reflect new safety information. The agency had planned to finalize the rules in 2015, but it has pushed the date tentatively to July 2016 in light of comments it has received over the highly controversial issue.

The agency is considering whether to grant the expanded powers to both companies that make generic drugs and those that make biosimilar products, a form of biologics, or drugs made by living cells. The FDA is specifically considering whether to allow such manufacturers to use the "changes being effected" process that branded-drug makers use to change labels to reflect the latest available safety information for the drug.

Generics makers, which are currently required to match the drug composition and labeling language of their branded-drug counterparts, have been able to deflect failure-to-warn suits by patients alleging injuries caused by their products by arguing that such claims are preempted by FDA rules that require their product labels to be rigidly aligned with those on their branded versions.

The FDA rule to give generics more control over their labels could expose them to more liability in patient injury lawsuits, experts say.

Courts have generally agreed, particularly since the landmark U.S. Supreme Court decision in Pliva v. Mensing in 2011 that such failure-to-warn claims against generic-drug makers are preempted by FDA rules. But some courts have in the meantime allowed plaintiffs to proceed with claims that generic-drug makers failed to update their labels to match the latest warning information on some corresponding branded-drug labels.

"This is an issue that's been hanging around for a long time, weaving its way through various appellate

courts," said Geoff Coan of Hinshaw & Culbertson LLP. "It will be interesting to see how that will be resolved."

GMO Labeling Measures From Congress

Vermont's Act 120, the first to require genetically modified ingredients to be labeled, goes into effect in July 2016, although the food industry group Grocery Manufacturers Association is challenging it to the Second Circuit. In the meantime, experts say there is some traction in Congress for measures that could encourage the labeling of GMOs in food products, particularly since the FDA's recent decision to make it voluntary for food manufacturers to disclose such ingredients.

The House in July passed H.R. 1599, the Safe and Accurate Food Labeling Act, sponsored by Rep. Mike Pompeo, R-Kansas. The measure calls for the FDA to oversee the labeling of such foods and to prevent the agency from making it compulsory to label foods containing GMOs as such. The Senate is working on its own version of the measure.

"A lot of companies are thinking that Congress may pass legislation that preempts all state law in this area," McKinney said. "Talks have been ongoing in Congress, where Democrats are pushing, saying something has to be mandatory on the label. But whether that's a big fat skull and crossbones, or just codes on a product that can show consumers what its ingredients are, there's been no decision yet."

Cybersecurity Legislation for Cars

In July, Sens. Edward Markey, D-Mass., and Richard Blumenthal, D-Conn., introduced the Security and Privacy in Your Car Act, which seeks to prevent hackers from gaining access to vehicle software. The measure involves creating a rating system that shows drivers how secure vehicles are from cyberattacks, according to the bill.

The act also calls for greater involvement by the National Highway Traffic Safety Administration and the Federal Trade Commission to push for technology to prevent or limit the potential impact of hacking attacks and to keep drivers aware of their personal data that is being tracked by their vehicles, according to the measure.

"As it stands today, there are no specific federal motor vehicle safety standards that apply to cybersecurity," said Tom Branigan, the managing partner for the Detroit office of Bowman and Brooke LLP. "The average new vehicle today has a number of electronically controlled systems that rely on a network within the vehicle. The auto industry and NHTSA have been working on ways to secure that network, and now it has attention from Congress."

--Editing by Jeremy Barker and Rebecca Flanagan.