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# FDA Slaps 'Unique' Limit On Bayer's Essure Sales

By **Jeff Overley**

Law360 (April 9, 2018, 5:53 PM EDT) -- The U.S. Food and Drug Administration on Monday slapped an unusual limitation on Bayer AG's sales of the birth control device Essure, saying the product can only be used if individual patients are directly informed of potentially serious side effects.

The limitation, which the FDA described as a "unique type of restriction," will only allow Essure to be sold and distributed to health care providers who give patients a checklist that outlines the product's risks. The most serious risks, including perforation of the uterus or fallopian tubes, are covered by a black box warning that has appeared on Essure's label since 2016.

The checklist has also been part of Essure's label since 2016. In a statement on Monday, FDA Commissioner Scott Gottlieb said some patients nonetheless haven't been getting the information.

"That is simply unacceptable," Gottlieb said. "Every single woman receiving this device should fully understand the associated risks."

After the checklist is provided, doctors must sign an acknowledgement, and patients must be given an opportunity to sign. Bayer must implement the restrictions right away. The FDA on Monday pointedly stated that it intends to monitor the implementation and "take appropriate action for a failure to comply, including applicable criminal and civil penalties."

More than 16,000 women have sued Bayer over side effects allegedly caused by Essure, with major blocs of cases playing out in California and Pennsylvania. Monday's announcement adds a new wrinkle to **the ongoing litigation**, said Justin Parafinczuk, a Koch Parafinczuk Wolf Susen PA shareholder who represents many of the women.

"We're happy with this action by the FDA, and we think it's a big step in the right direction regarding this product," Parafinczuk told Law360. "There are definitely going to be arguments raised in the litigation regarding this announcement."

Bayer recently reported more than $300 million in expenses last year related to "significant legal risks," and it said the expenses mostly involved three products, one of which was Essure. Sales of Essure in the U.S. have plunged 70 percent since the FDA in 2016 required more research on Essure and applied the black box warning and checklist, according to Monday's announcement.

Essure won approval in 2002 and was originally marketed by Conceptus Inc., which Bayer **acquired in 2013**. The product, which consists of flexible coils, is the only form of permanent birth control for women that doesn't require a surgical incision. It is implanted and gradually encased by body tissue that prevents sperm from reaching eggs.

In a statement on Monday, Bayer said it will "continue to reinforce the use of the checklist with health care providers and will inform them about this important label update."

The company added that Essure "is a safe and effective medical device that benefits women by providing them with a valuable contraception option."

--Editing by Kelly Duncan.