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Former FDA Drug Regulatory Adviser Joins Covington In DC

By **Kevin Stawicki**


Julie Dohm

Law360 (April 5, 2019, 9:52 PM EDT) -- Covington & Burling LLP has added to its office in Washington, D.C., a former top Food and Drug Administration attorney who oversaw efforts to expand compounding pharmacy oversight and represented the agency in a long-running dispute with Amarin Pharma over off-label free speech.

Julie Dohm, who left the FDA in March, joined Covington's food, drug and device practice as of counsel on April 1, the firm said. It's her first foray into private practice after leading the agency through the implementation of the 2013 Drug Quality and Security Act to regulate the manufacturing of compounded drugs.

"I was excited about trying to get into private practice," Dohm told Law360 on Friday. "I really want to work with people that are the pillars of food and drug law, and a number of those folks are at Covington."

Dohm's focus at the firm will center on regulatory matters for pharmaceutical and biotechnology clients, she said.

During her time at the FDA, Dohm took the reins of the compounding initiative created following the nationwide meningitis outbreak in 2012, which was caused by contaminated steroids from the New England Compounding Center. Under her watch, the program has expanded with dozens of guidances, new regulations and hundreds of inspections of outsourcing facilities, she said.

"There are still a lot of risks associated with compounded drugs that have to be addressed," Dohm said. "We've got a really good starting place, but there needs to be a continued effort to reduce risks to patients."

Before her compounding role, Dohm was an FDA associate chief counsel, and she handled cases involving preemption, drug exclusivity and generic drug approval standards. Dohm represented the agency in Amarin Pharma's suit over the extent to which the drugmaker could make statements about off-label uses of its omega-3 drug.

The parties reached a settlement in 2016 in which FDA officials agreed to be bound by the court's ruling that Amarin can engage in truthful and nonmisleading speech promoting the off-label use of its drugs.

Denise Esposito, co-chair of Covington's food, drug and device group, said in a statement that the firm is happy to welcome Dohm aboard.

"Julie is a rising star in the drug regulatory field and adds important strength to the firm's next generation of senior drug regulatory lawyers," Esposito said. "She brings strong FDA experience, grounding in a range of important drug regulatory issue areas, and a valuable scientific background that is of critical importance to our pharmaceutical industry practice."

--Editing by Nicole Bleier.