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WLF Tells Court FDA Illegally Used Guidances To Expand Drug Definition

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Free speech advocates are using a district court case as an opportunity to challenge FDA guidance released last year outlining the difference between drugs and devices, with the advocates saying the agency's policy conflicts with the statutory definition of medical devices. The draft guidance documents -- including one saying any product that brings about a chemical action is a drug -- could cause some medical products previously classified as devices to be reclassified as drugs, attorneys said, adding that these documents show the agency is changing its interpretation of the difference between the two products.

In an amicus brief filed Thursday (Jan. 19) in U.S. District Court for the District of Columbia in *Prevor v. FDA*, the Washington Legal Foundation argued that new classification policies outlined in a draft guidance issued by FDA in June conflict with the federal statute that defines what constitutes a device. The case challenges FDA's decision to regulate Prevor's skin wash as a drug although similar products have previously been regulated as medical devices.

Washington Legal Foundation argues that FDA in the past classified a product as a device -- even if one of its clinical effects involved a chemical action -- if the predominant intended purposes of the product did not involve a chemical action. However, the new draft guidance said a product should be classified as a drug if any of its clinical effects involves a chemical action.

Richard Samp, chief counsel at the Washington Legal Foundation, said there are going to be "quite a few products" caught up in this new policy, adding that, in general, manufacturers would prefer to have their products classified as devices, which often makes it easier to obtain marketing clearance from FDA.

Samp said there has been a "fair amount of concern" about FDA's apparent move to treat as drugs certain products that have always been considered devices. The shift began to appear in guidance last June, he said, when FDA released two documents, one on product classification and another outlining how FDA defines 'chemical action.'

In addition, the group argues that FDA violated the Administrative Procedures Act by changing its long-standing policy without formal notice-and-comment rulemaking. Samp said FDA has been moving toward regulating through guidance for many years, a process that is easier than formal rulemaking.

The agency, however, says the change is not a new policy, and the guidance is only interpreting and clarifying what the agency has been doing.

Bob Klepinski, an attorney at Fredrikson & Byron, said the "chemical action" definition under the new guidance is broad and subjective, which could lead reviewers to classify products as drugs rather than devices. He said the product classification guidance, along with the chemical action guidance and other agency actions, is "one more step in tilting the table toward the drug side."

Klepinski added that the guidance is "changing the whole analysis to push more and more things into that position" and could make device clearances and approvals more difficult, adding that some products long-classified as devices, like devices that are coated, could be regulated differently without regard for how they have been judged in the past.

Klepinski said that he has already seen questions raised over commonplace products and anticipates getting more inquiries, adding that the trend is likely to get worse.

"It is unnecessarily complicating something that worked well," he said. "This is just another example of FDA deciding to make things more difficult and complex and doing it through guidance rather than regulation." -- *Nanci Bompey*

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