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Drug-Device Applecart Upset Again

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On Sept. 9, 2014, in Prevor v. Food and Drug Administration, the D.C. District Court held against the FDA's interpretation of the definition of a medical device included in the Federal Food, Drug and Cosmetic Act (the act). This case, going on now for five years, highlights the difficulties inherent in the statutory definitions of drug and device in the act, and raises the question — is it time for Congress to act?

Background on Prevor v. FDA

Prevor developed Diphoterine Skin Wash (DSW) — a liquid substance contained in a canister, intended to be sprayed on the skin in the event of accidental exposure to chemicals in the industrial workplace, to help prevent and minimize accidental chemical burn injuries. In August 2009, Prevor submitted a Request for Designation to the FDA's Office of Combination Products (OCP), recommending that DSW be classified as a device. In October 2009, OCP classified the liquid substance inside the canister as a drug, and assigned DSW to the Center for Drug Evaluation and Research for review and regulation under the new drug provisions of the act. Prevor and the FDA have been arguing ever since:

- Prevor sought supervisory review within the FDA. In April 2011, the FDA's Associate Commissioner for Special Medical Programs confirmed OCP's conclusion that the liquid is a drug.
- Prevor filed suit against the FDA. In September 2012, the D.C. District Court disagreed with the FDA's interpretation of the statutory definition of a device, and remanded the issue back to the FDA (Prevor I).
- In May 2013, the FDA's Associate Commissioner for Special Medical Programs again concluded that the liquid inside the canister is a drug.
- In August 2013, Prevor sued again (Prevor II). The opinion in Prevor II has just been issued, and the court again rejected the FDA's interpretation of the statutory definition of a device.

The specific issue is the meaning of the phrase "achieve its primary intended purposes through chemical

action …" contained in the statutory definition of a device — a product is not a device if it achieves its primary intended purposes through chemical action. In this case, FDA and Prevor agree that DSW works by physical action (by washing the noxious chemicals off the user's skin) and by chemical action (by interacting with the noxious chemicals on the user's skin and neutralizing them). The parties sharply disagree about the relative contribution of the physical and chemical actions to the overall effectiveness of DSW. In its October 2009 designation letter, OCP stated:

Since this liquid achieves its primary intended purposes, *at least in part*, through chemical action, it does not meet the definition of a device.[1] (emphasis added)

In Prevor I, the court found that it was beyond the statutory definition of a device to preclude products from being regulated as medical devices if they achieve their primary intended purposes "at least in part" through chemical action, and remanded the issue back to FDA for a further action consistent with the opinion.

Upon remand, FDA stated:

The device exclusionary clause, "does not achieve its primary intended purposes through chemical action within or on the body of man," does not expressly state how much chemical action suffices for a product to be excluded from the device definition ... Congress chose to use the unmodified phrase, "through chemical action," instead of "primarily through chemical action" or "solely through chemical action" or any other phrase establishing a threshold amount or proportion of chemical action. … Certainly, some chemical action is necessary for a product to be so excluded; but the statute identifies no minimum threshold if a product works through both chemical and non-chemical action …

…FDA has interpreted the device exclusionary clause to mean that a product "… does not achieve its primary intended purposes through chemical action" if the evidence indicates that chemical action *does not meaningfully contribute* to its primary intended purposes. Under this interpretation, the clause would not exclude a product from being a device if the chemical action at issue is de minimis or insignificant. (emphasis added)

The Prevor II court didn't buy it, stating:

Chemical action that helps or plays a significant part in bringing about a specific result is more than de minimis involvement, but it does not fulfill the congressional directive that chemical action must achieve, i.e. accomplish or attain, the primary purpose. Simply put, in plain English, "achieves" and "meaningfully contributes" are not synonymous. Congress used the former and not the latter and critically, FDA provides no analytical basis for equating the two.

The court remanded the issue back to the FDA, and did not order the FDA to classify DSW as a device. So five years later, the FDA is still trying to figure out how to implement the most fundamental provision of the entire act, and Prevor is still trying to get the FDA to review and regulate its product as a device.

Confusion Over Product Classification

It's not clear how the FDA will finally decide how to classify products that achieve their primary intended purpose through both chemical and physical action. Will the FDA ask for data demonstrating the relative contribution of the chemical and physical action, and classify products as devices if their effect is due to

chemical action 50 percent or less, and as drugs if their effect is due to chemical action 51 percent or more? Requiring companies to develop, and the FDA to review, that sort of data simply to determine what kind of marketing application to submit, is certainly a mind boggling prospect.

The problem is that there is not necessarily a connection between the classification standard (achieves its primary intended purposes through chemical action) and the public health need for the type of marketing application that must be submitted based on that standard. To put it another way, the public health may not require that all products that achieve, at least in part, their primary intended purposes through chemical action, be supported by two adequate and well controlled clinical trials comprising substantial evidence of effectiveness. There may be a disconnect between the classification of the product as a drug or device, and the type and amount of data required to protect the public health even when the chemical action makes a meaningful contribution to the effect of the product. Throw in the astonishing differences in user fees [in FY 2015, a nearly $2.34 million new drug application fee versus a $5,018 fee for a 510(k)], and it is very clear why companies like Prevor are concerned about whether their product is regulated as a drug or a device.

Clarification Needed From Congress?

Is it time for Congress to rethink the statutory definitions of drug and device? Is there a better way to identify products that should be supported by NDA/BLA-level data in order to assure their safety and effectiveness? Could it be possible to determine the type and amount of data required to support the product in a risk-based way, based on the characteristics and risks of the product? Determining what kind of marketing application to submit shouldn't be this difficult. Given the current statutory language, we may see more cases like this unless Congress steps in and clarifies its intent.

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Suzanne O'Shea is counsel in Faegre Baker Daniels' Indianapolis office. She previously worked in the FDA's Office of Combination Products, where she served as the product classification officer and helped classify many products as drugs or devices. She had already left the agency when Prevor submitted its Request for Designation in 2009.

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[1] See also Draft Guidance: Classification of Products as Drugs and Devices & Additional Product Classification Issues, 2011, which states on page five: "…a product that depends, even in part, on chemical action within or on the body of man to achieve any one of its primary intended purposes, would not be a device."

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