Legal Backgrounder

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D.C. Circuit Corrects FDA's Abuse of Discretion in Drug vs. Device Determination

by Sara W. Koblitz

Citing agency experience and expertise, courts have long afforded federal agencies discretion in administering their respective statutes. But, in *Genus Med. Techs., LLC v. United States FDA*, 2021 U.S. App. LEXIS 10928, 994 F.3d 631 (D.C. Cir. 2021), the U.S. Court of Appeals for the District of Columbia Circuit decided that the Food and Drug Administration had taken that leeway too far.

For years—since approximately 1997—FDA has claimed unfettered discretion to subject medical devices to the much more onerous regulatory scheme for drugs based on an overlap in the statutory definitions of the intended uses of "drug" and "device." *See* FDA, Consolidated Response to Pending Citizen Petitions on the Regulation of Ultrasound Contrast Agents, Docket No. 96P-0511, 53 (July 25, 1997); FDC Act § 201. Essentially, FDA's position was that it is only by the grace of the agency that any particular medical device is *not* regulated as a drug. FDA claimed that this interpretation permitted the agency to regulate any device as a drug for "convenience" and "administrative ease," regardless of the limitations set forth in the statute, counter to the certainty sought by medical device manufacturers.

In *Genus Med. Techs., LLC v. United States FDA*, a small device manufacturer challenged this position. *Genus Med. Techs., LLC v. United States FDA*, 2021 U.S. App. LEXIS 10928, *27-28, 994 F.3d 631 (2021). On April 16, 2021, the D.C. Circuit expressly cabined FDA's discretion, agreeing with the U.S. District Court for the District of Columbia that "[t]he FDCA's structure, purpose and legislative history . . . make plain that the Congress did not grant the FDA near-limitless discretion to classify any device as a drug." Provided that the decision of the three-judge panel is not further appealed within the D.C. Circuit or reversed by the U.S. Supreme Court, manufacturers can rest easier knowing that their devices will be regulated as devices. *Id.*

Central to the *Genus* decision is the distinction between drugs and devices under the FDC Act. Under the Act, a drug is defined as

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C) . . . .

21 U.S.C. § 321(g). The definition of "device" is notably narrower than the drug definition:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

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> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> **which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes**.

Id. § 321(h) (emphasis added). The key statutory distinction between a drug and a device, therefore, is that a device does not achieve "its primary intended purposes through chemical action within or on the body of man" and "is not dependent upon being metabolized for the achievement of its primary intended purpose." *Id*. As a result, FDA typically classifies a product as a device where the product sponsor provides "mode of action" data demonstrating that a proposed product does not achieve its primary intended purposes through chemical action. FDA, Guidance for Industry, Classification of Products as Drugs and Devices & Additional Product Classification Issues (Sept. 2017) ("Classification Guidance").

FDA, however, took a different approach with respect to regulating contrast agents. In response to a Citizen Petition in 1997, FDA decided that it would regulate all contrast agents as drugs due to "administrative efficiency" and "regulatory consistency." *See* FDA, Consolidated Response to Pending Citizen Petitions on the Regulation of Ultrasound Contrast Agents, Docket No. 96P-0511, 53 (July 25, 1997). Though some of these contrast agents—like barium sulfate—may meet the definition of device because they do not achieve their primary purposes through chemical action or by being metabolized, others did not. FDA argued that "[t]he definitions of drug and device are overlapping, rather than mutually exclusive," so FDA may and will "regulate certain types of products that meet both definitions as drugs," Genus Motion for Summary Judgement, Docket No. 1:19-cv-0544 (June 3, 2019) at 18. Under that theory, FDA decided that all contrast agents, regardless of their mode of action, should be regulated as drugs. *Id.*

The decision to regulate all contrast agents as drugs has considerable consequences for a sponsor. New drugs are held to more demanding premarket approval requirements that mandate extensive and expensive clinical trials, as well as requiring payment of millions of dollars in user fees. Approval requirements for generic drugs require less investment of company resources, but still significantly more than device approval or clearance. *Id.* at *6. Further, "[t]hroughout the lifecycle of a medical product, its treatment by the FDA depends upon its classification as either a drug or a device." *Id.* For that reason, FDA's regulation of a drug imposes substantial regulatory hurdles on a sponsor—often rendering market entry impossible for small businesses, particularly if the sponsor anticipated that its product would be regulated as a device.

A small barium sulfate manufacturer, Genus Medical Technologies, was unable to convince FDA to reconsider its blanket regulation of contrast agents as drugs. Genus's barium sulfate products, marketed as affordable imaging agents since 2015, physically coat, and thereby opacify, the gastrointestinal tract to absorb X-rays for better visualization. FDA never disputed the physical (rather than chemical) operation of the barium sulfate, stating that it "appears" to meet the definition of device, but nevertheless refused to regulate it as a device and threatened enforcement action unless Genus obtained approval as a drug.

Genus therefore sued FDA in 2019 alleging that FDA's regulation of Genus's barium sulfate device as a drug was arbitrary and capricious and contrary to the plain language of the statute in violation of the Administrative Procedure Act. The District Court granted Genus's Motion for Summary Judgement, rejecting FDA's attempt to regulate barium sulfate as a drug, because Congress did not afford FDA such discretion. Instead, the court explained that FDA's theory of unfettered discretion to regulate devices would render the device definition in the statute superfluous and meaningless. Judge Boasberg explained:

> If a product that meets both definitions is nonetheless treated as a drug, then the device-drug distinction would be rendered meaningless. Put otherwise, the FDA could classify any

> diagnostic device as a drug because no limiting principle would trammel its authority. That would turn the statutory scheme on its head.

Genus Med. Techs., LLC v. United States FDA, 427 F. Supp. 3d 74, 83 (D.D.C. 2019). Employing Step 1 of the framework established by *Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837 (1984), Judge Boasberg rested his decision on the statutory language: "In the end, the plain text dictates the result here. Congress readily could have afforded the agency discretion to determine which of these pathways a product must take. . . But it did not do so here." *Id.* at 84. Finally, the court held that such discretion neither is implicit in the statutory language nor is the statute ambiguous enough to support such an interpretation.

FDA appealed, and in April 2021, a three-judge panel of the D.C. Circuit upheld the District Court's decision. Like Judge Boasberg in the District Court, the D.C. Circuit rejected FDA's broad discretion: the majority opinion (signed by two of the three judges) again explained that the statutory scheme directed FDA to treat products meeting the definition of devices as such. A concurring opinion by the third judge argued that while FDA may have discretion to classify as drugs some products meeting the device definition, depending on the characteristics of the product in question, FDA had not adequately justified its decision as to barium sulfate. Though the majority disagreed with the District Court that FDA's interpretation renders the drug-device definition superfluous, the court nevertheless agreed that "this a case where the specific must govern the general." *Genus Med. Techs., LLC v. United States FDA*, 2021 U.S. App. LEXIS 10928, *16-17 (D.C. Cir. 2021). Because the device definition is narrower than the drug definition, and because the provisions are "interrelated and closely positioned as parts of the same statutory scheme," the court held that the more specific language in the device definition is controlling. *Id.*

Because the general-specific canon applies where statutes are in conflict, the court then assessed whether the definitions of drug and device actually are in conflict. The court looked to the distinct *mandatory* statutory schemes for drugs and devices, which apply the drug framework to "any new drug" and the device framework to "all" new devices. "In short, it is not textually possible to say that an item *is* a drug (or device) but need not be regulated as such." *Id.* at 18. As a result, the court explained:

> The statute, then, is clear: a product may be regulated as a drug *or* a device, but not both, and while a single product may simultaneously satisfy the linguistic elements of two definitions, it is not possible for the FDA to give simultaneous *effect* to both.

Id. at *18-19. The court further rejected FDA's reliance on a 1990 amendment to the drug and device definitions which removed language that made the definitions mutually exclusive, as it was clear that such provision was removed so that FDA could regulate combination products as drugs, if appropriate. *Id.* at *20.

The majority also looked at the "structure, purpose, and legislative history" of the FDC Act and its two distinct regulatory tracks for drugs and devices. Based on the very different premarket review requirements, the court explained "[i]t would make little sense then, for the Congress to have constructed such elaborate regulatory regimes—carefully calibrated to products' relative risk levels—only for the FDA to possess the authority to upend the statutory scheme by reclassifying any device as a drug, no matter its relative risk level." *Id.* at *23-24. The legislative history of the Medical Device Amendments of 1976—initially setting forth the drug and device distinction—the majority explained, supported this interpretation.

The majority opinion expressed concern about the breadth of FDA's claimed authority. FDA, in oral argument, was unable "to articulate a limiting principle with which to cabin its asserted discretion," and instead deferred to the APA arbitrary and capricious standard. The narrow arbitrary and capricious limitation was not enough for the majority:

> Thus, what the FDA attempts to claim for itself is the near-limitless authority to classify *any* device as a drug, subject only to a highly deferential standard of judicial review. We cannot reasonably infer such broad discretion without a clearer statement.

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Id. at *28-29. As the majority stated, "the text, statutory structure and legislative history of the Act make plain that the Congress did not grant the FDA such sweeping discretion." *Id.* at *2.

Judge Pillard, in the concurring opinion, agreed that FDA's decision on Genus's barium sulfate product should be reversed and remanded to FDA, but argued that the overlap in the drug and device definitions are only partial and the definitions not mutually exclusive. *Id.* at *37. According to Judge Pillard, therefore, it is not the definitional overlap—and the subsequent "specific governs the general" adage on which the majority relies—that precludes FDA from classifying a device as a drug; instead, Judge Pillard pointed to the "instrument" clause, which specifically defines a device as an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory." 21 U.S.C. § 321(h). Judge Pillard thought that both parties "incorrectly treated the instrument clause as a nullity," and FDA "fell short in neither acknowledging the detailed instrument clause nor providing a lawful and nonarbitrary explanation of whether and how regulating Vanilla SilQ as a drug accords with both that clause and the mode-of-action exclusions in the device definition." *Id*. at *44-45. Instead, Judge Pillard implied, FDA's decision here would fail at *Chevron* Step 2 because FDA "failed to explain its decision to regulate Vanilla SilQ as stringently as a drug in any way that accounts for the factors Congress deemed relevant to its design of distinct drug and device regimes. The explanation it did provide, turning on little more than administrative convenience, falls short, so requires remand to the FDA."

Both the majority and the concurring opinions made clear that FDA still has discretion to decide to regulate a product as a drug or device but only within the confines of the statutory definitions. When the application of the definitions is ambiguous, both acknowledge that courts should defer to FDA, but that deference does not extend where the product clearly satisfies the device definition or where the agency "did not invoke its expertise." *Id.* at *30. In turn, the D.C. Circuit remanded this case to FDA for further evaluation of whether barium sulfate meets the statutory definition of device. FDA has not indicated whether it will lodge further appeals, or what it will do on remand.

Genus significantly limits FDA discretion: where FDA asserted breathtakingly broad—potentially unchecked—authority, the court disregarded the traditional deference afforded to the agency to correct that overreach. In theory, FDA's claimed discretion would allow the agency to classify *any* medical device as a drug in spite of the entirely distinct, statutorily-enacted regulatory scheme for drugs and medical devices. In practice, FDA's claimed discretion made it impossible for a small business to even enter the contrast agent market—shielding the one (large) sponsor of approved barium sulfate drug applications from competition—due to the prohibitive differences in regulatory approval and costs. To address these serious concerns, the majority opinion effectively mandates that FDA regulate as a device any product that "does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes."

While the departure from routine agency deference is notable, it is important to add that the majority based its opinion on a plain language *Chevron* Step 1 argument rather than an arbitrary-and-capricious *Chevron* Step 2. This means that the case itself has virtually no impact on the oft-questioned arbitrary-and-capricious standard—and the deference courts typically afford federal agencies under this standard—and, in turn, has little impact of the potential abrogation of *Chevron* deference from this perspective. Nevertheless, any limitation on discretion afforded to FDA under the FDC Act is important, as FDA, in the name of science and healthcare, typically grabs as much discretion as it thinks it can justify. But industry should not forget that the plain meaning of the FDC Act places limitations on FDA's administrative decisions.

This decision further demonstrates that, even as a small business, taking the risk to litigate against FDA can pay big dividends, both for business and for industry. Now, small companies like Genus who manufacture products that meet the definition of device are no longer at FDA's mercy.

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