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Client Alert

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Genus Medical Technologies LLC v. FDA: D.C. Circuit Holds FDA Cannot Regulate Devices as Drugs

FDA regulation of biomedical products can be like a very complex game theory decision tree. Choices made at each intersection impact the ultimate regulatory framework under which any given product is developed, seeks approval, and enters the market. The D.C. Circuit Court's decision in *Genus Medical Technologies LLC* v. *United States Food and Drug Administration*[1] affects the first branch of that tree.

The threshold question in any regulatory pathway analysis is whether the biomedical product at issue meets the definition of "drug" or "device." The *Genus* court took on the unique question of whether, if a particular product (in this case a contrast imaging agent) meets the statutory definitions of both "drug"[2] and "device,"[3] FDA has unfettered discretion to regulate that product as a drug. The answer was a resounding "no."

BACKGROUND

The definitions of "drug" and "device" in the Federal Food, Drug, and Cosmetic Act ("FD&C Act") clearly overlap. Both encompass products ("articles" for drugs[4] and "instrument[s], apparatus[es], implement[s], machine[s], contrivance[s], implant[s], in vitro reagent[s], or other similar or related article[s]" for devices[5]) that are "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease."[6] Contrast imaging agents are products that are "used in medical imaging to enhance the visualization of tissues, organs, and physiological processes," typically in conjunction with a diagnostic imaging device such as a magnetic resonance imaging ("MRI") device.

Perhaps not surprisingly given this statutory overlap, the *Genus* case is not the first time the question of how FDA should regulate contrast imaging agents has ended up before the courts. In *Bracco Diagnostics, Inc.* v. *Shalala*,[7] the D.C. district court determined that, while the contrast

imaging agents at issue in that case also "likely me[t] both the definition of a drug and the definition of a device,"[8] FDA needed to make a rational choice about how to treat the class of products as a whole and "to treat all" ultrasound contrast agents "as medical devices *or* as drugs."[9] In response to the *Bracco* decision, FDA announced that it would regulate all such contrast agents as drugs from that point forward. FDA pointed to reasons of administrative efficiency, noting that that all "ultrasound contrast agents" would qualify as drugs, but not all would qualify as devices.[10] Thus, as FDA pointed out in its *Genus* briefing documents, FDA has treated all contrast agents as drugs since 1997.[11]

Fast forward almost 25 years, the product in question in the *Genus* case is another contrast imaging agent, Vanilla SilQ.[12] In early correspondence with *Genus*, FDA acknowledged that Vanilla SilQ "appear[ed] to meet the definition of 'device'" in addition to meeting the definition of "drug."[13] Perhaps relying on its established policy of treating all contrast agents as drugs, the Agency did not undertake a scientific analysis to confirm whether Vanilla SilQ met the "device" definition. In fact, the *Genus* court seemed exasperated by FDA's reliance on legal arguments rather than fact-based ones, noting that "[b]ecause the FDA's legal theory did not require it to do so, it made no factual findings about whether the Vanilla SilQ products satisfied the particular requirements of the FDCA's device definition."[14]

In the absence of a factual dispute about whether Vanilla SilQ properly could be classified as a "device," the case turned on the legal question of FDA's discretion to choose between the drug and device pathways for a product that could fit squarely within either. Basing its determination largely on established canons of statutory interpretation, the D.C. Circuit explained that the FD&C Act is "clear" that "a product may be regulated as a drug *or* a device, but not both."[15] Reading the legislative history as providing "additional evidence that Congress established separate regulatory tracks for drugs and devices," and that the "bifurcated scheme" requires the articulated result,[16] the court rejected FDA's textual arguments, noting that the FD&C Act's "structure, purpose and legislative history confirm our reading of the text."[17] Congress, said the *Genus* court, did not grant FDA blanket discretion "to classify a device as a drug."[18] Thus, "to the extent the drug and device definitions conflict, it is the narrower definition—the device definition" that must prevail."[19]

In an interesting concurring opinion, Judge Pillard joined in the court's holding that "FDA misread the statute in concluding that the drug definition fully subsumes devices."[20] But, she argued, the majority "overshoots in the other direction."[21] She would have had the court juxtapose the "drug" definition's inclusion of "articles" intended for "medical uses" against the "device" definition's inclusion of "any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory" intended for the same medical uses.[22] That these two sets of characteristics do not overlap is, according to Judge Pillard, evidence that "FDA is wrong to view the device definition as describing a fully nested subset of the drug definition."[23]

IMPLICATIONS

The *Genus* decision arguably left FDA with significant discretion to operate going forward. FDA retains the discretion to determine regulatory classification "in close cases,"[24] and FDA certainly can justify the regulation of any product as a "drug" by undertaking a fact-based, scientific analysis to determine whether that product fits into the definition of "device." If FDA reaches the conclusion that a product achieves its primary intended purpose through "chemical action," then the Agency clearly can still regulate such a product as a "drug." Similarly, an Agency finding that a product is an "article" but not an "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, *or other similar or related article*, including any component, part, or accessory" would correctly result in regulation as a drug.

More broadly, however, *Genus* calls into question the categorical framework under which FDA has been regulating contrast imaging agents since *Bracco*. Moving forward, FDA arguably will need to undertake an early,[25] case-by-case analysis of contrast imaging agents. Assuming that different applicants will have different regulatory goals—some may prefer to be regulated as "drugs," for example, given the possible eligibility for exclusivity; others may prefer regulation

as a “device” given the significantly lower user fees—we may see an uptick in the number of challenges to FDA’s determinations in this arena.

There also may be larger ripple effects into other FDA-regulated waters. Will the rationale in *Genus* bleed over into the way that FDA regulates combination products more broadly?[26] Will it impact perceptions about the drug approval standard compared to the device approval standard or cast a shadow over the “substantially similar” review FDA described in draft guidance on combination products?[27] If an imaging agent is regulated as a “device,” does that mean that it will not be a combination product when cross-labeled with another imaging device?[28] And how will this thinking affect FDA’s regulation of other product categories, like sunscreens and ophthalmology products, where FDA has similarly defined classes of products categorically as “drugs”?[29] We wonder, too, whether there may be an impact of the *Genus* decision on the type of fact-specific, case-by-case analysis FDA already conducts on products for which regulatory status may be less clear. Does the decision alter FDA’s flexibility with regard to hyaluronic acid, and products like it, which arguably could be classified as a device for some intended uses and as a drug for others?[30]

Given the importance of these issues, and many others, FDA may seek rehearing and potentially petition the U.S. Supreme Court for a writ of certiorari. FDA has 45 days to seek panel rehearing and/or rehearing *en banc*, so we should know more on that front soon. In the meantime, manufacturers who hold approved NDAs for affected products, and those considering submission of applications, may want to think carefully about which pathway might be in their best interest and how best to frame their submissions to the Agency.

King & Spalding LLP regularly counsels pharmaceutical and device manufacturers on development and submission of drug and device marketing applications to FDA. Please let us know if you have any questions regarding the *Genus* decision.

[1] ___ F.3d ____ , 20221 WL 1437211 (D.C. Cir. 2021).
[2] Federal Food, Drug, and Cosmetic Act (“FD&C Act” or “FDCA”) § 201(g)(1), 21 U.S.C. § 321(g)(1) (defining “drug” in relevant part as including “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals”).

[3] FD&C Act § 201(h), 21 U.S.C. § 321(h) (defining "device" in relevant part as including "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ... 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,... 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").
[4] FD&C Act § 201(g)(1), 21 U.S.C. § 321(g)(1).
[5] FD&C Act § 201(h), 21 U.S.C. § 321(h).
[6] FD&C Act §§ 201(h), (g)(1), 21 U.S.C. §§ 321(h), (g)(1).
[7] 963 F. Supp. 20 (D.D.C. 1997)
[8] *Id*. at 28.
[9] *Id*. at 31 (emphasis added).
[10] FDA's Genus Brief (citing CP response)
[11] *Id*.; *see Bracco Diagnostics, Inc. v. Shalala, 1997 WL 614485, at *1 (D. D.C. 1997)*
[12] 21 WL 1437211, at *1.
[13] *Id*. at *3.
[14] *Id*. at *5
[15] *Id*. at *6.
[16] *Id*. at *8.
[17] *Id*. at *9.
[18] *Id*.
[19] *Id*. at *5 (citing the "traditional canon" that "the specific governs the general").
[20] *Id*. at *10.
[21] *Id*.
[22] *Id*.
[23] *Id*.
[24] *Id*. (expressly reserving that question in this case).
[25] For combination products, for example, FDA recommends that requests for designation be submitted prior to the filing of any investigational application for the product. See FDA, guidance for industry, How to Write a Request for Designation (RFD) (Apr. 2011), https://www.fda.gov/media/80495/download.
[26] *See* FDA, draft guidance for industry, *Principles of Premarket Pathways for Combination Products* (Feb. 2019), https://www.fda.gov/files/guidance%20documents/published/Principles-Premarket-Pathways-Combination-Products-guidance.pdf.
[27] *Id*.at 5 ("To appropriately assess the safety and effectiveness of a combination product in a single application, such application should enable a substantially similar evaluation to that which would be applied to each constituent part if they were reviewed under separate applications, including consideration of data and information that would be reviewed under separate applications.")
[28] 21 C.F.R. § 3.
[29] See,.e.g., 21 C.F.R. § 200.50.
[30] *E.g.*, FDA, *Intent To Consider the Appropriate Classification of Hyaluronic Acid Intra-articular Products Intended for the Treatment of Pain in Osteoarthritis of the Knee Based on Scientific Evidence*, *available at* https://www.federalregister.gov/documents/2018/12/18/2018-27351/intent-to-consider-the-appropriate-classification-of-hyaluronic-acid-intra-articular-products (explaining that for certain uses, the primary purpose may be achieved through chemical action within the body).