The Honorable Frank Pallone, Jr.
Chair, Energy & Commerce Committee
House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member, Energy & Commerce Committee
House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member McMorris Rodgers,

On behalf of Giskit Pharma and ExEm Foam, Inc., a manufacturer and marketer of a novel contrast imaging agent drug, I write to thank you for the inclusion of Section 803 in H.R. 7667, the Food and Drug Amendments of 2022, and to offer our full support for these provisions. The language codifies the well-established regulatory regime for contrast agents – which for decades have been uniformly regulated as drugs – while also preserving the holding of Genus Medical Technologies, LLC v. FDA, No. 20-5026 (D.C. Cir. 2021) that a product can be a drug or a device, but not both.

Giskit developed, and received FDA approval, for its contrast agent – ExEm Foam – in November 2019. ExEm Foam provides a safer, less painful, and more convenient way of assessing the patency (openness) of fallopian tubes, which is a crucial step in diagnosing infertility and making treatment decisions. The approval of ExEm Foam in the United States, through the 505(b)(2) pathway, is a success story, and testament to the fact that even very small companies can bring innovative, safe and effective, products to market in the United States through the drug approval pathway if they have a good product and an interest in patient care.

Existing statutes give FDA the authority to regulate ExEm Foam and all other contrast agents as drugs; however, without the legislative clarification offered by Section 803 there could be serious repercussions for industry, FDA, and patients. We expect that without this provision, there will be additional litigation which will be a huge waste of resources by companies and FDA. Also, there will be a potentially lengthy and complicated product reclassification process, which will also use precious FDA resources, as will the ensuing challenges thereto. On the whole, the language in Section 803 provides the regulatory certainty to innovative companies like Giskit, which, above all, need to make investments that help patients.

There are a lot of things that could be said about the threat of reclassifying contrast agents. Reclassification is a taking – robbing companies of investment-backed expectations in products that were lawfully brought to market as drugs under a uniform and fair regulatory regime. Reclassification is an insidious tax – asking companies that have complied with the law to invest extensively in rebuilding their business to change from drug to device companies. Reclassification is a waste – asking FDA and companies to spend resources on regulatory 'inside baseball' that offers no benefit to patients. Above all though, reclassification and the threat thereof, harms the public health because instead of being able to dedicate resources to

developing new products or improving patient access to innovative technologies, law-abiding companies like Giskit and one of our premier public health agencies will be spending time in disputes on reclassification.

The issue of consistency in contrast agent regulation was the subject of a prior court decision 25 years ago[1] which resulted in the uniform classification of all contrast agents as drugs,[2] and approval of innovative products like ExEm Foam. However, the *Genus* decision has created a lot of uncertainty around the regulatory framework going forward. As we understand, this all started when a manufacturer launched its barium sulfate products based on an argument that they were grandfathered drug products that did not require (or receive) FDA approval. That manufacturer received an FDA warning letter[3] for marking an unapproved new drug, and then submitted a 'request for designation' to FDA asking that its barium sulfate products be classified as devices even as it continued (and continues) to market its products as unapproved drugs.[4]

Unfortunately, FDA did not do the kind of thorough analysis it needed to in order to classify the barium sulfate products in question. As a result, the Court in *Genus* remanded the case to FDA for further consideration. The Court acknowledged that it was not at all clear that FDA could regulate barium sulfate as a device based on the statute (i.e., the court thought it may well be a drug),[5] but ultimately left the question to FDA.

The remand then, unexpectedly, led to a far reaching and costly administrative process at FDA[6] that has created a lot of confusion and uncertainty for Giskit and many other companies. This has been a large drain on limited resources that Giskit had hoped to dedicate to bringing ExEm Foam to more patients and to further research for other products. It is sadly ironic that Giskit – which followed the law, went through the request for designation process, underwent FDA review, subsequently received FDA new drug approval, and only marketed its product after

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[1] Bracco Diagnostics, Inc. v. Shalala, 963 F.Supp. 20 (D.D.C. 1997).

[2] Before this time, FDA was regulating many contrast agents as drugs already – going back to at least the 1950s – but there were a couple of outliers.

[3] See: Warning Letter, Genus Medical Technologies, FDA (2017) at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/genus-medical-technologies-506486-05022017.

[4] Products are listed with FDA under National Drug Code ("NDC") numbers as 69307-1024-2, 69307-4496-2, and 69307-4096-2 (all designated in the "Unapproved Drug Other" category by the manufacturer.

[5] *Genus, at* 634, n. 3 ("[I]t is not immediately obvious to us how a contrast agent satisfies the device definition's requirement that the regulated product be "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)(1). [The "instrument clause"] Nor is it altogether settled that [the manufacturer's product] satisfies the device definition's mode-of-action clauses. . . Because neither question is part of the administrative decision now under review—the FDA found only that Genus's products "appear to meet" the device definition . . . and both parties continue to agree that they do—we reserve the question whether [the product] satisfies the device definition's instrument and mode-of-action clauses.)

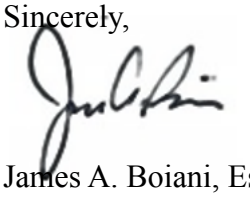
[6] Genus Medical Technologies LLC Versus Food and Drug Administration; Request for Information and Comments, 86 Fed. Reg. 43553.

approval – has had to carry a burden created by others who took a different path and a poorly written FDA decision on an unrelated product.

But Section 803 will right this wrong by appropriately clarifying that contrast agents are drugs – as they have been for decades – while maintaining the broader holding of Genus – that a product can be a drug or device, but not both.

We respectfully thank you and your staff for your work on this issue, and the help it will provide to innovators like Giskit and the patients we serve. If you have any questions, please contact our government affairs liaison, Cara Tenenbaum, at cara@strathmorehealth.com.

Sincerely,



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