May 6, 2022

The Honorable Frank Pallone, Jr.
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Anna Eshoo
Chairwoman
Health Subcommittee, House Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris-Rodgers
Ranking Member
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Brett Guthrie
Ranking Member
Health Subcommittee, House Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Pallone, Ranking Member McMorris-Rodgers, Chairwoman Eshoo, and Ranking Member Guthrie:

We write to you to express our major concerns about a legislative proposal that would stifle innovation, harm competition, and impede patient access to imaging agents (contrast media and radiopharmaceuticals) used for medical procedures. We understand this proposal, which would deem all imaging agents to be drugs, is being considered as part of the reauthorization of the Food and Drug Administration (FDA) User Fee Program.

Deeming all imaging agents as drugs is contrary to established law, to recent decisions by a U.S. District Court and the D.C. Circuit Court of Appeals, and to FDA's own historical and established definition of what constitutes a drug versus a device. Importantly, this proposal would not provide any discernible benefit to patients as there is no identifiable clinical or safety concern that would be addressed by this proposed statutory change. Instead, it favors administrative convenience over access to affordable medicines.

Imaging agents come in many different forms and routes of administration, including intravenous, oral, pulmonary, and rectal routes of administration, all of which have different clinical and safety profiles depending on specific products' physical properties and mechanism of action. Because of their distinct characteristics, under current longstanding statutory provisions, some are regulated as drugs and others as devices. This proposal treats all imaging agents as drugs, regardless of their distinct characteristics.

Changing the regulatory threshold for all imaging agents, by requiring all to be classified by FDA and regulated as drugs, would unnecessarily stifle innovation, harm competition, and impede patient access to affordable medicines. Of equal importance, the additional clinical costs and regulatory requirements that follow from this legislative reversal of the longstanding statutory distinction between drugs and medical devices would discourage companies from developing new and innovative products and entering the market – and force existing small businesses to exit the market completely. This could result in monopolies and even drug shortages as we have previously seen with some contrast media.

We are also concerned about the process surrounding this proposal. Though this legislation would have an enormous impact on our companies and the imaging agent market, none of the relevant committees in either the House or Senate has held any hearings on the policy, and it has not been publicly shared or open to industry and patient feedback. Finally, we are not aware of any information detailing how many products this change would impact, as it could result in FDA requiring companies to pull existing products from the market and lead to significant disruptions for patients and providers.

Respectfully, we ask that Congress omit language that would regulate all imaging agents as drugs as part of the FDA User Fee reauthorization.

Sincerely,

Genus Medical Technologies
Cosmo Pharmaceuticals
G3 Medical
ImaginAb Inc
Interpharma Praha, a.s.
Serac Life Sciences Ltd
Voyageur Pharma

Cc: House Energy & Commerce Committee Members