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May 10, 2022

The Honorable Frank Pallone
U.S. House of Representatives
2107 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
1035 Longworth House Office Building
Washington, D.C. 20515

The Honorable Anna Eshoo
U.S. House of Representatives
272 Cannon House Office Building
Washington, D.C. 20515

The Honorable Brett Guthrie
U.S. House of Representatives
2434 Rayburn House Office Building
Washington, D.C. 20515

Re: Section 803 of The Food and Drug Amendments of 2022 (H.R. 7667)

Dear Honorable Pallone, Eshoo, McMorris Rodgers, and Guthrie:

I am writing to offer our support and endorsement of Section 803 of The Food and Drug Amendments of 2022 (H.R. 7667).

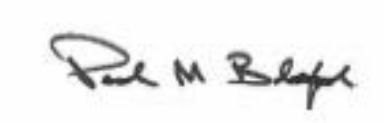
Lantheus is an established leader and fully integrated provider committed to innovative imaging diagnostics, targeted therapeutics and artificial intelligence solutions to Find, Fight and Follow serious medical conditions. Our pioneering products assist physicians in the diagnosis and treatment of conditions affecting the heart, prostate, brain, lungs and other organs using echocardiography, nuclear imaging, radiotherapeutics, and targeted PET imaging agents. We are headquartered in North Billerica, Massachusetts with offices in New Jersey, Canada and Sweden. The company has more than 600 employees worldwide. We manufacture, market and distribute DEFINITY®, (Perflutren Lipid Microsphere) the most used echocardiography contrast agent. We launched PYLARIFY® (Piflufolastat F 18) injection in May 2021, a diagnostic agent for positron emission tomography of prostate-specific membrane antigen positive lesions in men with prostate cancer, which has already changed the standard of care for prostate cancer care.

As a developer, manufacturer, marketer and distributor of contrast imaging agents and diagnostic radiopharmaceuticals, we are writing to thank you for the inclusion of Section 803 in the Food and Drug Amendments of 2022 (H.R. 7667). This provision clarifies that contrast agents and diagnostic radiopharmaceuticals constitute “drugs” under the Federal Food, Drug, and Cosmetic Act.

As you are aware, the outcome of recent litigation has created uncertainty regarding the future regulation of a range of FDA-approved drugs, especially imaging contrast agents and diagnostic radiopharmaceuticals. The statutory and accompanying regulatory certainty which Section 803 will provide is of significant importance to both developers, manufacturers and patients. It will allow our Company to continue to safely and effectively manufacture, market and distribute current FDA-approved products under the existing Good Manufacturing Practices requirements, without a costly and unnecessary transition to a different regulatory regime that would provide no clear benefit to patient safety and that would burden the FDA with significant costs to undertake. It will also allow us to bring new drugs to market through established regulatory pathways to better serve patients. It will also ensure that the regulatory requirements for these products will not fall out of sync with regulatory requirements in other jurisdictions, such as Canada and the European Union.

Lantheus is pleased to support Section 803 of H.R. 7667, The Food and Drug Amendments of 2022, and we look forward to seeing this legislation enacted into law.

Sincerely,



Paul Blanchfield
Chief Commercial Officer, Lantheus Holdings, Inc.