Submitted electronically February 6, 2024 to the Federal eRulemaking Portal Docket No.: 230831-0207
T1International Comments on Interagency Guidance Framework for Considering the Exercise of March-In Rights

To: Mojdeh Bahar
Associate Director for Innovation and Industry Services, National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, MD 20899

Re: Federal Register 88 FR 85593, Docket 2320-26930

T1International is grateful for the opportunity to provide comments to support and finalize the Interagency Guidance Framework for Considering the Exercise of March-In Rights.

T1International is a global type 1 diabetes advocacy organization led by and for people with diabetes. T1International believes in a world where everyone with diabetes – no matter where they live – has everything they need to survive and achieve their dreams. We do not accept funding from pharmaceutical companies and we provide advocacy training and support to advocates across the US and around the world. In 2014 T1International launched the #insulin4all campaign, which has grown into a global movement. In the US, T1International supports advocates via 41 #insulin4all Chapters as well as through our Global Advocacy Network around the world.

In January of 1923, the discoverers of insulin sold the patent for $1, saying “insulin does not belong to me, it belongs to the world”. Rather than the gift it was intended to be, their discovery has become the poster child for pharmaceutical price gouging. Over the last 100 years, while insulin has improved, even many of the newest insulins are decades old. This has allowed for the price of insulin to skyrocket to hundreds of dollars a vial and has led to patients’ serious health consequences including death.

Taxpayers pay over $50bil annually to support research and development of prescription drugs, including many new FDA approved drugs in recent years. While insulin is over 100 years old, new drug developments are critical for many aspects of diabetes care. Despite the integral role in prescription drug R&D that the US government and institutions support, drug companies routinely charge US patients many times the prices charged in other comparable large and wealthy countries. These exorbitant prices strain family and health program budgets alike and lead to patients rationing treatment due to unaffordable costs.

One in four patients living with diabetes has rationed insulin due to cost, with life-and death consequences as well as with long term complications as a result. Additionally, nearly 18 million people living in this country cannot afford the medications they need. This is due to Big Pharma’s price gouging as a result of monopoly power on prescription drug patents. Big Pharma abuses our federal patent system, putting their profits above patients' lives.

It doesn't have to be this way. We can allow robust generic competition to bring drug prices down. This competition can include using March-In Rights to expand affordable access to medicines by authorizing generic manufacturers and providing reasonable;e compensation to the patent holder. We appreciate the framework's commitment to assisting agencies in assessing health or safety need, but we are concerned it imposes new conditions beyond statutory requirements that will deter agencies from exercising March-In. Language should support agency use rather than impose complicated conditions.

Taxpayers invest heavily in research and development and yet can often not afford the resulting inventions because of too high pricing. Fair prices should include the cost to develop, produce, and deliver or distribute the product, and should be relevant to the price offered in peer countries. We encourage the final framework to direct agencies to review all federal funded inventions in their purview to determine March-In eligibility and priority, along with Section 1498 and/or royalty-free rights.

To ensure transparent and timely proceedings, March-In proceedings should include a right to appeal by petitioners and all appeals should receive independent and fair review by a new, impartial party, and have timeliness requirements to ensure that bureaucratic proceedings do not halt March-In's intention.

Drugs invented with federal funds should not price gouge the public. Patients with diabetes and the public have an interest in ensuring drugs are made more affordable and accessible because of the effect on insulin and other drugs, drug-device combinations, glucose testing supplies, insulin pumps, and other medical innovations that improve the lives of our community of patients.

Thank you for your attention to this matter and we look forward to collaborating on implementing a strengthened final framework to provide financial relief to taxpayers and drug users.

Sincerely,

Shaina Kasper
Policy & Advocacy Director
T1International
skasper@t1international.com