CIFE
CENTER FOR INNOVATION & FREE ENTERPRISE

U.S. Patent and Trademark Office
600 Dulany Street
P.O. Box 1450
Alexandria, VA 22313

RE: Request for Comments Regarding Joint USPTO–FDA Collaboration Initiatives (Docket No. PTO-P-2022-0037)

The Center for Innovation and Free Enterprise would like to respond to the Request for Comments Regarding Joint USPTO–FDA Collaboration Initiatives (Docket No. PTO-P-2022-0037).

CIFE agrees and recognizes the United States as a global leader in the development of drugs and biologics, mainly due to our historically strong patent system and robust and reliable patents it produced. These patents incentivize and protect the immense research and development investments that are essential to bring life-saving and life-altering products to market. CIFE believes policymakers should be incentivizing these innovations rather than trying to eliminate and erode protections for-them.

Intellectual property protections are crucial to incentivizing innovation that results in the original medicine and provides for the important post-approval benefits that physicians and patients alike have come to enjoy. CIFE is concerned about any effort by the PTO to encourage new collaborations with other agencies. New regulatory initiatives, such as the proposed increased collaborations with the Food and Drug Administration (FDA), would prove both confusing and burdensome for all innovators who rely on the patent system to bring their inventions to market. If adopted, the rules currently being considered would increase uncertainties for inventors and investors, thus threatening a key driver of innovation and economic growth for the nation.

Furthermore, increased information-sharing across agencies creates confidentiality concerns. Currently, the FDA and PTO have different missions and practices for handling confidential information, including what type of information should be disclosed to the public. This could threaten the nation's confidential trade secrets, and risk hundreds of millions of dollars' worth of investments in critical products and technologies. Additional collaborations between the FDA and PTO would not only distract the agencies from their important core functions but could result in delays and greater costs in bringing new products to patients. Current estimates show that it already takes nearly 14 years at a cost of over $2 billion.

The private sector response to the COVID-19 pandemic exemplifies how important it is for the government to encourage innovations. The U.S. patent system made possible the rapid clinical development and production of the COVID-19 vaccines that helped save millions of lives around the world. Any policy changes to the current patent system that is helping to facilitate such innovations should be supported by sound and verifiable evidence. Unfortunately, the effort to increase collaborations between the PTO and the FDA is based on unverified and unreliable evidence that does not support the need for systemic changes to the patent system. The nation's inventors deserve better. If adopted, this effort will be a disaster both for the fragile U.S. economy and for millions of vulnerable communities around the country.

We urge the USPTO and FDA to consider the importance of America's innovation ecosystem before implementing potentially devastating changes to our systems that will undermine the country's leadership position in the world.