April 14, 2023

Chiquita Brooks-LaSure
CMS Administrator
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Meena Seshamani, M.D., Ph.D.
CMS Deputy Administrator and
Director of the Center for Medicare
7500 Security Boulevard
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Dear Ms. Brooks-LaSure and Dr. Seshamani,

The Council for Innovation Promotion (C4IP) appreciates the opportunity to respond to your March 15, 2023, Solicitation of Comments concerning initial guidance on the Inflation Reduction Act's (IRA) Medicare Drug Negotiation Program.

C4IP is a bipartisan coalition chaired by two former U.S. Patent and Trademark Office directors. We are dedicated to supporting a strong and effective patent system that bolsters U.S. innovation, strengthens our nation's economic competitiveness, and fuels investment in technology that improves lives everywhere.

Unfortunately, several aspects of the Centers for Medicare & Medicaid Services (CMS) guidance would needlessly undermine these goals and devalue the IP protections underpinning life-saving and life-improving innovation.

Section 60.3.4 of the memorandum is particularly concerning in this regard. According to that section, the agency "intends to consider the length of the available patents and exclusivities" when determining the price of medicines under the negotiation program. The agency also notes that "if the selected drug has patents and exclusivities that will last for a number of years, CMS may consider adjusting the preliminary price downward."

In effect, under this guidance, the agency would subjectively lower the initial prices for medicines with longer patents and exclusivities. In so doing, CMS would create a significant disincentive for life sciences firms to perform additional research on medicines already approved by the Food and Drug Administration (FDA), thus impeding continued discoveries that benefit patients.

A great deal of valuable research occurs after a drug's initial FDA approval. During this time, innovators can improve its formula, dosage, and delivery mechanism to reduce side effects and boost treatment adherence. They can also investigate whether a particular medicine has additional applications. In the field of oncology, for instance, it is particularly common to discover that a drug approved for one cancer can treat other forms of the disease. And often, these new indications are only found years after the initial FDA approval.

Under CMS' guidance, however, firms would be penalized for making such progress. If a post-approval discovery yields a new patent or exclusivity, the agency will treat those protections as a reason to devalue a medicine's price further. Once follow-on research becomes a financial liability in this way, companies will lose the asset required to justify the investment of time and resources into these vital ventures. The result will be a significant reduction in the number of medical advances generated by post-approval research.

The precedent established by this guidance would also carry broad consequences for IP-driven innovation in all sectors of the U.S. economy. Virtually every step taken to improve science, manufacturing, or technology is incremental -- and follow-on -- as inventors build on their own progress and the progress of others. For instance, U.S. companies in the high-tech and automotive sectors routinely improve existing products and obtain new patents for these improvements.

The very purpose of patents and other IP protections is to incentivize the disclosure of pathbreaking discoveries so that others can build upon them. The IP system grants researchers and inventors exclusive rights to their creations for a limited period of time. But for IP rights to perform this function, innovators' inventions must be appropriately valued. Otherwise, even the most beneficial innovations would fail to recoup their initial investment costs.

The initial guidance -- and the Medicare Drug Negotiation Program more generally -- would compromise patent-based innovation by empowering the government to devalue the IP rights secured by innovators on a massive scale. A pall of uncertainty would be cast over the entire patent system, weakening the incentives for innovation in a wide range of industries.

We at the Council for Innovation Promotion urge CMS to thoroughly examine the consequences this guidance will have on America's innovative ecosystem, especially on research into the next generation of medicines and technologies.

Thank you again for the opportunity to comment.

Sincerely,

Frank Cullen
Executive Director
The Council for Innovation Promotion (C4IP)