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Comments on Center for Medicare & Medicaid (CMS) Services Maximum Fair Prices (MFPs) and Qualifying Single Source Drug (QSSD) Interpretation

Meena Seshamani, M.D., Ph.D.,
Deputy Administrator and Director
Centers for Medicare and Medicaid Services
200 Independence Avenue, SW., 20201

Dear Director Seshamani:

National Taxpayers Union (NTU), the nation's oldest taxpayer advocacy organization, appreciates the opportunity to provide comments on the recent interpretation of "qualifying single source drugs" (QSSDs) under the Inflation Reduction Act's (IRA) Medicare Drug Price Negotiation Program.

During the course of the Inflation Reduction Act's passage through Congress, NTU repeatedly warned of the dangers of government price controls. Price controls reduce the supply of the good in question by reducing the incentives for suppliers to come to market. This distortion is already having negative impacts even before the price controls come into effect. Estimates for the reduction in research and development spending range from a 12.3 percent to 18.5 percent cut and up to a loss of $663 billion. Depending on how the QSSD definition is finalized, the loss of R&D could be even more substantial, since the expansive draft definition would essentially combine all indications, delivery systems, and drug dosages into one QSSD. Concerning too, is the possibility that companies will not continue to develop clinical testing of drugs after initial approval. New indications could be discovered from continued research post-approval, but this proposed incentive system substantially reduces this likelihood if companies know they could be subjected to price controls.

On a more expansive view, the overall drug price control scheme introduced by the Inflation Reduction Act is likely to be harmful. Beyond reducing availability and development of drugs through an overly broad QSSD definition, as an NTU-led letter signed by dozens of economists indicates, the punitive nature of another IRA provision, a drug excise tax, is unworkable and damaging to outcomes for patients and taxpayers. As the economists noted:

> "Nonetheless, it is axiomatic that taxing a product or service at exorbitant rates tends to reduce its availability. The very existence of a 95 percent excise tax could therefore lead to shortages in the prescription drugs that patients need, as well as less innovation toward future cures as manufacturers are deterred from engaging in R&D that could carry a new 95 percent premium. Taxpayers could no longer count on as many future drug breakthroughs to bend the cost curve of more expensive treatments such as surgeries and hospital stays in government healthcare programs. The policy goal should be to encourage life-saving treatments that benefit seniors in Medicare, and ultimately, all taxpayers. This tax scheme will do the opposite."

By discouraging innovation through statute and guidance, the stated goals of the Inflation Reduction Act will not be realized. The "excise tax" (in reality a coercive mechanism) is fundamentally unserious and unworkable, while an overly broad definition of QSSDs will most likely result in even worse outcomes than projected with the IRA's passage.These and other proposed policies raise the prospects that taxpayers will not receive the value they stand to gain from prescription drug development.

NTU appreciates your consideration of the foregoing comments. Should you have any questions, I am at your service.

Sincerely,

Nicholas Johns
Senior Policy and Government Affairs Manager