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at the

U.S Food and Drug Administration Public Hearing

on the

Commissioner's National Priority Voucher (CNPV) Pilot Program

June 4, 2026

Thank you for the opportunity to speak today[1]. The Commissioner's National Priority Voucher (CNPV) program has the potential to advance public health goals by directing the FDA's limited resources toward therapies most likely to deliver meaningful benefits to patients. However, to realize the program's intended benefits, the agency should establish clear criteria — through rulemaking or guidance — outlining how products are selected for the program, how they are evaluated, and what procedural guardrails govern these reviews.

It's important to begin by recognizing that FDA has substantial inherent authority to prioritize its resources, including in the context of product reviews. That authority is vital to FDA's public health mission, in part because it gives the agency latitude to respond in a timely way to new challenges — for example, by prioritizing treatments for emergent novel pathogens. One of the potential benefits of the CNPV program is that it could provide a more structured way to make some of these prioritization decisions. With transparency around how these decisions are made, the program could further incentivize development activities that benefit public health or national security interests.

But robust programmatic guidance is critical to achieving these goals. Other programs that have established priority vouchers or designations for expedited review — including fast track,

[1] The opinions offered today are my own and do not represent the views of the University of Southern California or the USC Schaeffer Institute for Public Policy & Government Service.

breakthrough therapy, and priority review — are built on top of statutory provisions and guidance documents that explain how the programs operate, provide clear criteria to qualify, and set predictable expectations for product developers, patients, and providers.

These guardrails are important. For one thing, they help ensure programmatic integrity. When the selection process is informal, or the criteria are not clearly and prospectively defined, it creates the potential for public confusion around how and why decisions are being made and could invite challenges to the agency's actions.

A transparent and regularized process, led by the career officials who are closest to the issues, helps to dispel notions that any decisions are being made on the basis of improper considerations. It helps to promote long-term viability by providing a durable framework that can guide future leadership and keep the program focused on advancing its public health objectives. It also reduces the risk that the program might be used to influence activities outside of FDA's jurisdiction, such as pricing decisions.

Formalizing these practices would also improve transparency and predictability for participants. This would help them understand what to expect when seeking a voucher and what will happen once one is issued. This clarity matters not just as a matter of due process or good regulatory procedures, but because it makes product sponsors more likely to participate.

Finally, more formalized operations would strengthen the program by reducing the risk of collateral challenge. By that, I mean the risk that an interested third party might try to challenge an approval decision for a product that participated in the CNPV program, on the basis of alleged procedural defects. For example, one could imagine a competitor, or some other interested third party, trying to attack a decision under the Administrative Procedure Act on the ground that the benefits of the program — such as a faster review, and a tumor board-style process not otherwise available — were conferred arbitrarily and capriciously, or on the basis of factors that the agency was not authorized to consider.

That is not to say that a challenge would succeed. But adhering to clear procedures and criteria would make it less likely for a such an action to be brought in the first place. And by reducing the risk of a challenge, it makes participating in the program more attractive to product sponsors, and makes it more likely that they will choose to do so.

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For these reasons, I strongly encourage FDA to prioritize the development of notice-and-comment rules or guidance that would put the program on strong footing and help deliver benefits to American patients. Thank you.