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United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

September 28, 2015

Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Acting Administrator Slavitt,

I am writing in support of the Center for Medicare & Medicaid Services' (CMS) proposal regarding biosimilar biological products (referred to below as biosimilars) that was published in the 2016 Medicare physician fee schedule proposed rule (80 Fed. Reg. 41686 (July 15, 2015)). I urge CMS to finalize this proposal, because it creates a competitive marketplace that will ensure beneficiaries have access to life-saving drugs at affordable prices.

The Affordable Care Act (ACA) created a regulatory pathway for the Food and Drug Administration (FDA) to approve biological drugs that are determined to be "biosimilar" to, or "interchangeable" with, an FDA-licensed biological product. The ACA also specified a payment methodology for these products.

Biosimilars hold the potential to offer lifesaving treatments for a vast number of diseases. While only one biosimilar has been approved by the FDA to date, these products are already available in Europe, and there are a number in the pipeline for domestic use today. These products will offer American patients, private payers, and the federal government more affordable treatment options while expanding therapy choices.

The Medicare statute specifies that Medicare payment to physicians for biosimilars be equal to the average sales price (ASP) for products assigned to the same billing and payment code, plus an administrative fee equal to six percent of the reference biologic's ASP. (SSA 1847A(b)(8)). To implement this provision, CMS proposes to maintain a separate code for the reference biologic product and group the biosimilar products associated with that biologic into a single code. Each biosimilar associated with a single reference biologic drug will be paid based on the average sales price for all of the biosimilars in the code plus the six percent reference biologic add-on.

CMS's proposal seeks to create a competitive environment amongst therapeutically equivalent products, which will have a real-time effect of driving down costs for patients and payers alike. With this proposal, biosimilar manufactures that produce lower-cost products will be more

successful in securing greater market share than manufactures that produce higher-priced drugs, as they directly compete against one another.

In contrast, a payment structure that grants individual biosimilar products their own codes also establishes individual ASP payment rates for those codes. In this scenario, the incentive to gain market share and drive down costs disappears. Instead, this alternate payment structure increases the likelihood of higher costs products entering the market. As stated by the non-partisan Medicare Payment Advisory Commissions (MedPAC), "[p]utting all biosimilar products in the same billing code would be expected to spur more price competition among biosimilars than if each biosimilar received its own billing and payment code." (MedPAC September 8, 2015, Letter to Andrew Slavitt, CMS Acting Administrator, at page 8).

Some observers have raised concerns that putting biosimilar products into a single code will make it difficult to track individual products for purposes of identifying safety and/or quality problems. I agree with these concerns but believe proper monitoring can be accomplished without assigning each individual product its own payment code. I urge CMS in the final rule to lay out how successful monitoring will be achieved.

Biosimilars hold great promise in treating the most difficult diseases, and I applaud the development of these products. The CMS proposal is a foundation that will ensure a robust market for biosimlars. As with any new policy, CMS should monitor over time the impact to development of, and access to, new products and make subsequent policy changes as necessary.

Sincerely,

Ron Wyden

Senator Ron Wyden
Ranking Member
U.S. Senate Committee on Finance