

U. S. House of Representatives
Washington, D. C. 20515

August 4, 2015

Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Acting Administrator Slavitt,

We write to express our serious concerns with provisions relating to biosimilar reimbursement in the Centers for Medicare and Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule proposed rule.

Specifically, we are concerned with the agency's proposal to assign all biosimilars of a single reference product one Healthcare Common Procedure Coding System (HCPCS) code and to reimburse biosimilars with the same HCPCS code based on the weighted average of their average sales price under Medicare Part B.

In this proposal, CMS treats biosimilars as if they are generic drugs. As a primary matter, it is important to recognize that traditional small-molecule pharmaceuticals and biologics are fundamentally different in their development, manufacture and chemical makeup. A biologic is a large, complex molecule, which is grown in living systems such as a microorganism, a plant or animal cell.

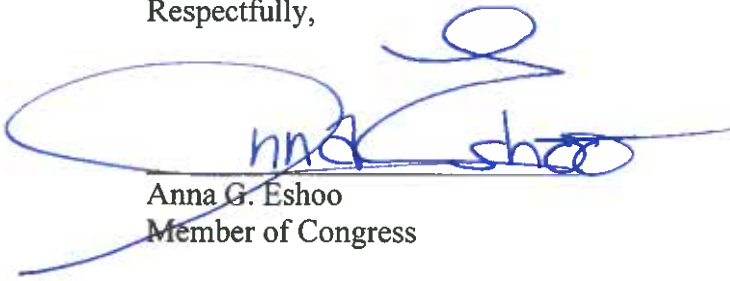
These differences are acknowledged by the statutory provisions establishing the biosimilars pathway and by the Food and Drug Administration (FDA).

Section 1847A of the Social Security Act ("SSA"), 42 U.S.C. § 1395w-3a states that the calculation for reimbursing biosimilars shall be made separately, such that each biosimilar will have its own unique payment rate and unique HCPCS code. This language reflects congressional intent to encourage a vibrant biosimilars market and we urge you to enact a final payment rule that provides each biosimilar with a unique code.

Thank you for your attention to this highly important issue and we look forward to your timely response. If you need further assistance, please contact Hannah Murphy in

Congresswoman Anna Eshoo's office at Hannah.Murphy@mail.house.gov or Krista Rosenthal in Congressman Joe Barton's office at Krista.Rosenthal@mail.house.gov.

Respectfully,



Anna G. Eshoo
Member of Congress



Joe Barton
Member of Congress



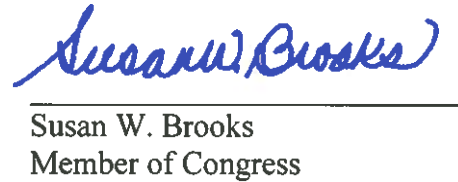
Diana DeGette
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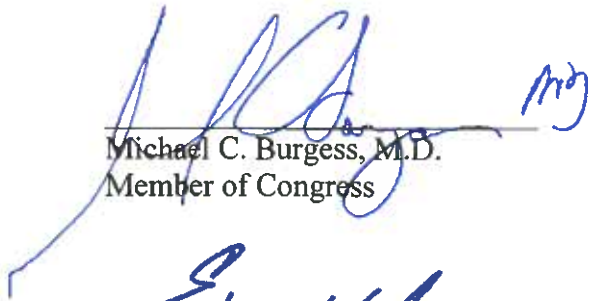
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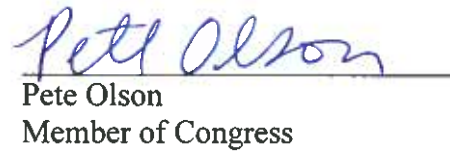
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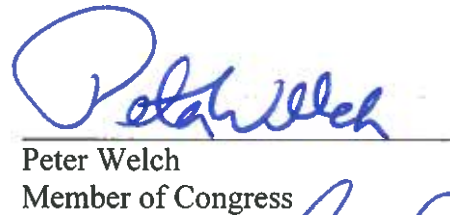
Michael C. Burgess, M.D.
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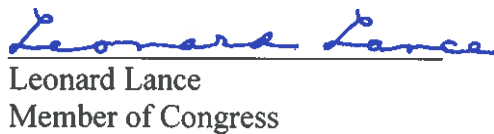
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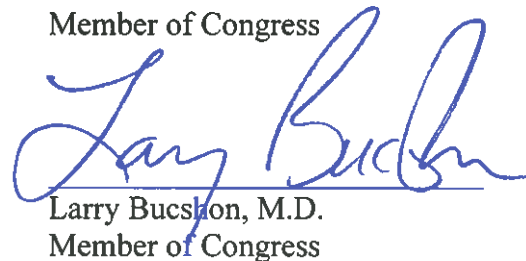
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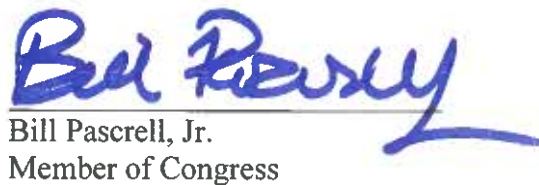
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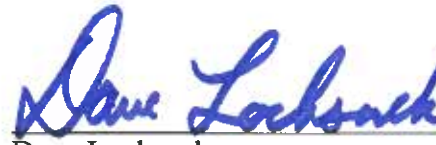

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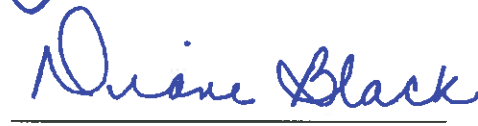

Doris Matsui
Member of Congress

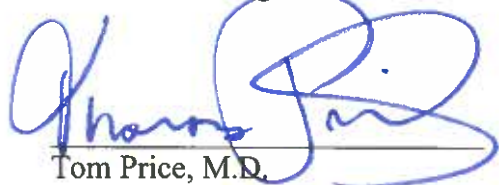

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