

Congress of the United States
Washington, DC 20515

May 5, 2017

The Honorable Tom Price, M.D., Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Secretary Price and Administrator Verma,

We write to encourage you to reverse the current biosimilar reimbursement policy established by the Centers for Medicare and Medicaid Services' (CMS) 2016 Medicare Physician Fee Schedule final rule.

Under the final rule issued by CMS on October 30, 2015, each follow-on biologic, or biosimilar, that is tied to a common reference product under the same Healthcare Common Procedure Coding System (HCPCS) code will be reimbursed at a single payment rate calculated based on the weighted average of their average sales price under Medicare Part B.

We urge you to reverse the current reimbursement policy and employ a separate billing code and reimbursement rate in order to give each biosimilar its own unique HCPCS code. Biologics and biosimilars are large, complex molecules grown in living systems such as a microorganism, a plant or animal cell. A reimbursement structure must appropriately reflect the complexity of these products and the differences between individual biosimilar products.

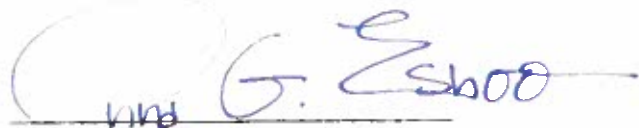
These differences are acknowledged by the statutory provisions establishing the biosimilars pathway and by the Food and Drug Administration (FDA). Section 1847A of the Social Security Act ("SSA"), 42 U.S.C. § 1395w-3a states that the calculation for reimbursing biosimilars shall be made separately, such 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 reconcile the final payment rule to provide each biosimilar with a unique code as it is instructed to do in current statute.

Since championing the Biologics Price Competition and Innovation Act of 2009 (BPCIA), it has been our goal that biosimilars can compete with innovative biologics to increase competition and lead to more options and lower prices for patients. A fair Medicare reimbursement policy helps ensure this happens.


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 Rachel Fybel in Congresswoman Anna Eshoo's office at (202) 225-8104 or Gable Brady in Congressman Joe Barton's office at (202) 225-2002.


Respectfully,


Anna G. Eshoo
Member of Congress


Joe Barton
Member of Congress


Gus Bilirakis
Member of Congress


Diana DeGette
Member of Congress


Doris Matsui
Member of Congress


Leonard Lance
Member of Congress

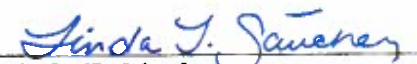

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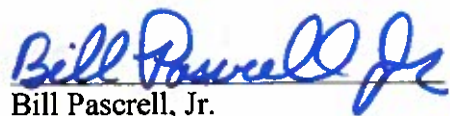
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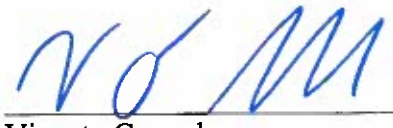
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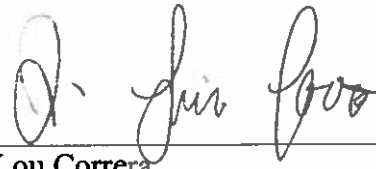
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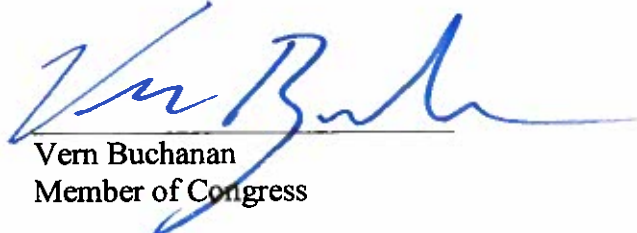
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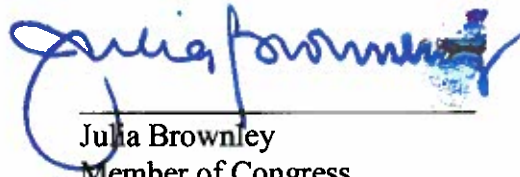
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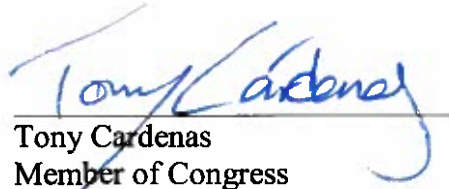
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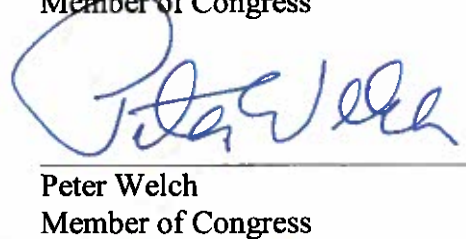
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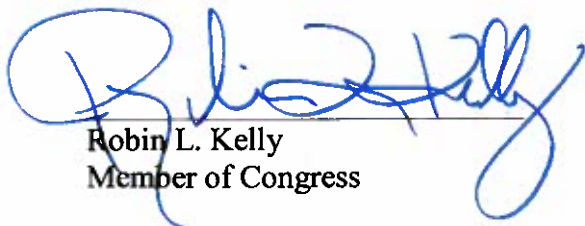
Ron Kind
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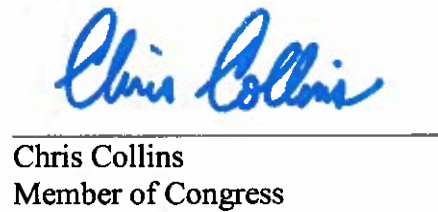
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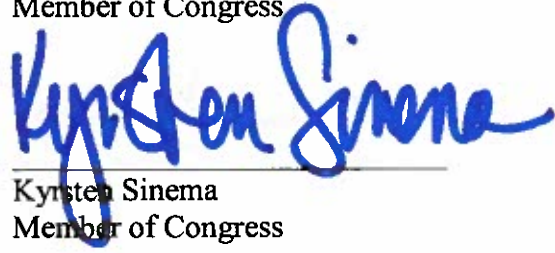
Judy Chu
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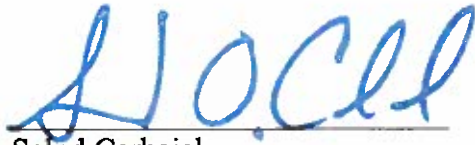
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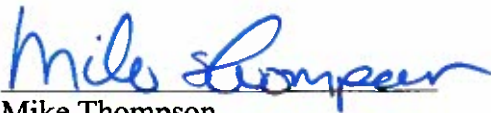
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