

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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March 8, 2016

Mr. Sean Cavanaugh  
Deputy Administrator and Director  
Centers for Medicare and Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Mr. Cavanaugh:

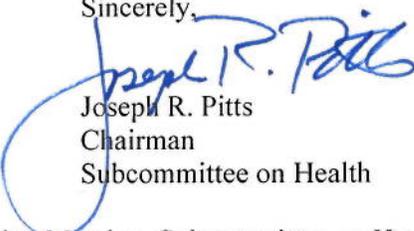
Thank you for appearing before the Subcommittee on Health on February 4, 2016, to testify at the hearing entitled "Examining Implementation of the Biologics Price Competition and Innovation Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on March 22, 2016. Your responses should be mailed to Graham Pittman, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to [graham.pittman@mail.house.gov](mailto:graham.pittman@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,



Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Gene Green, Ranking Member, Subcommittee on Health

Attachment

## Attachment — Additional Questions for the Record

### The Honorable Joseph R. Pitts

1. In its draft naming guidance, FDA seems to make the case that distinguishing biosimilars from their reference product and other biosimilars is critical to patient safety. If this is the case, why did CMS not share this view and take the opportunity to have different J-codes for biosimilars?
2. There appears to be a disconnect between what the FDA may do in this space and CMS reimbursement policy. For example, the FDA may approve a product for a subset of indications of its reference product with interchangeability. However, combining all products into 1 code inherently removes the incentive for innovation and the development of biosimilars with multiple indications and interchangeability with the reference product. This could potentially reduce ultimate savings by decreasing the amount of products that could be interchangeable with the reference product? Did CMS consider these impacts to innovation and Medicare program costs?
3. Do you fear that physicians will be confused with a payment policy that equalizes payment among biosimilars when even those with the same reference product, may have different indications and thus are not clinically interchangeable?
4. How will CMS ensure that patients receive the most clinically appropriate biosimilar therapy if the biosimilar best for that patient is reimbursed potentially below the provider acquisition cost because CMS's payment policy does not differentiate these important clinical differences?
5. How will CMS ensure that the policy does not result in a shift in the site of care from physicians' offices to more expensive settings (thereby also increasing patient cost-sharing obligations), given that hospitals are more capable of absorbing losses on drug reimbursement?
6. Did CMS consider that despite the potential uniqueness of future biosimilars within a class, all being grouped under the same code, cause confusion among patients?
7. What role could pharmacy benefit managers (PBMs) play in tracking adverse events if products share the same code? What role would insurers play in tracking product-specific biosimilar adverse events?

### The Honorable Michael Burgess

1. In a letter to the Senate HELP committee dated June 26, 2007, the Secretary of HHS stated that companies seeking interchangeability determinations should be required to provide clinical evidence for every indication of use approved for the reference product. The Secretary expressed concern that otherwise a patient might be switched to a product that hadn't been shown to be interchangeable for the patient's disease. Does this still reflect the agency's thinking on interchangeability? If not, why? If so, please explain why the agency

has selected a reimbursement model that treats all biosimilars of a single reference product the same, regardless of the number of indications for which a biosimilar has produced clinical evidence?

2. Did CMS have any discussions with FDA regarding the potential effects the reimbursement policy could have on the biosimilars marketplace? If not, why? If so, please describe what factors were addressed in those discussions.

### **The Honorable Gus Bilirakis**

1. Mr. Cavanagh, as you have heard in this hearing and from outside stakeholders, there has been a lot of concern about grouping biosimilars together for the purposes of coding and payment. In the final regulations for Medicare's Part B biosimilar regulations, CMS wrote: "We also note that the proposed revised regulation text would not preclude CMS from separating some, or all, of a group of biosimilars for payments – and the creation of one or more separate HCPCS codes – should a program need to do so arise."
  - a. What type of incident, complication, need, or problem, would have to happen for CMS to change its position?
  - b. Shouldn't we determine how the biosimilar marketplace will look, and see how biosimilars are integrated into clinical practices, based on actual experience, before setting a policy that you admit may need refinement?
2. Mr. Cavanagh, as I understand it, Medicaid is covering biosimilars as a single source drug, something used for brand name drugs, rather than covering biosimilars as a generic drug. Yet, the Medicare regulations for biosimilars have CMS using a template based on generics. Why does CMS have two different lines of thinking on biosimilars?

### **The Honorable Chris Collins**

CMS recently determined that biosimilar medicines to a single reference product will have the same billing code. However, in many clinical care settings, the use of unique HCPCS (Healthcare Common Procedure Code System) codes are essential to facilitate accurate attribution of adverse events. As more biosimilar medicines are approved, this issue will become larger.

1. How will CMS ensure that proper, adverse event tracking is not compromised by this payment policy?

### **The Honorable Frank Pallone**

Biosimilars are an exciting new frontier in American medicine. Because this is a new, emerging marketplace, we need to make sure we do everything possible to incentivize manufacturers to enter the market. For this to happen, it is important that the Administration has a clear and coherent position on biosimilars.

1. Please describe the extent to which CMS has collaborated with FDA on implementing biosimilars policy?
2. Did CMS seek FDA guidance when drafting its Part B reimbursement policy?

When CMS published the final rule on Part B payments, the agency noted that many commenters were concerned that the proposed payment approach may make it more difficult to track safety monitoring of codes because individual biologic products could not be distinguished on claims. Historically, post-approval drug safety surveillance has been a difficult endeavor. I'm concerned that due to differences between biosimilars and regular generics, that safety tracking *may be even more difficult* for biosimilars.

3. Prior to release of the Rule, did CMS consult with FDA about the potential effects of the proposed approach on their ability to track drug safety?
4. Please discuss CMS' efforts to address this issue.

One of the most difficult decisions to make in payment policy for prescription drugs is the balance between patient access and spurring innovation. Not unexpectedly, CMS indicated in the Part B Payment Final Rule that the agency received considerable comment on this topic. Several stakeholders have indicated that they are concerned that grouping biosimilar products for payment purposes would discourage innovation.

5. Can you comment on how the agency addressed these concerns in the final payment rule?

FDA has been very explicit that biosimilars are not the same as generics. However, CMS has indicated that because of the degree of similarity of biosimilars to their reference products, that the agency believes it is appropriate to price biosimilars in a similar manner to generics.

6. Can you discuss this apparent difference in opinions?

The FDA has taken the approach of having two differing levels of biologic drugs: Biosimilars and interchangeable biologics.

7. Although there are currently no interchangeables at this time, has CMS considered developing a future payment structure that reflects these differences?

### **The Honorable Lois Capps**

It's incredibly important for patients to be engaged in their care, but that doesn't mean anything if they cannot afford the treatments that are best suited for them. Biosimilars offer great promise in bringing these costs down and helping patients afford the treatments they need, when they need them. But there seems to be great concern about how they will be paid for. Dr. Cavanaugh, CMS has recently laid out its framework for how biosimilars will be treated in Medicare Part B. My understanding is that Medicare Part D and Medicaid have set up systems that treat

biosimilars as a unique drug, whereas Part B treats biosimilars more like a traditional small molecule generic drug.

1. Can you explain these different approaches to reimbursement and why the Part B rule treats biosimilars different than in these other federal programs?