

Congress of the United States
Washington, DC 20515

June 12, 2015

Stephen Ostroff, M.D.
Acting Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Acting Commissioner Ostroff:

We are writing to express our concerns regarding the Food and Drug Administration's (FDA) implementation of the *Drug Quality and Security Act* (DQSA). While we recognize the agency for its work to implement the law, we are concerned that recently released guidance documents may unnecessarily impact patient access to some compounded and repackaged drugs, which would run counter to assurances made during negotiation of DQSA. The safety of compounded and repackaged drugs is our top concern, but we must ensure that critical treatments are still available to patients who need them.

We are specifically concerned about provisions in the February 2015 draft guidance *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. We appreciate the agency's recognition of the important role these products play in the treatment of patients such as pediatric and ophthalmology patients. However, certain provisions, specifically the beyond use dates (BUD) for products covered in this guidance, could severely impact physicians' and patients' ability to access and use these products. This is especially true for biological products repackaged for office use, such as repackaged bevacizumab, for use in treating ophthalmology patients.


Unnecessarily restrictive BUDs, particularly when there is strong evidence showing the biological products can be safely mixed, diluted, or repackaged for use with longer BUDs, will essentially eliminate these products as treatment options for many patients. Physician offices will be unable to receive shipment of the products from a compounding facility before the expiration of the BUD in many cases, causing problems for physicians and patients alike. This is especially problematic for rural practices and patients. Further, we are concerned that the proposed BUDs may not allow for the required sterility testing for compounded and repackaged sterile drug products.


We urge the FDA to adhere to Congressional intent and abandon this one-size-fits-all approach to compounded and repackaged biological products and, where the evidence shows the products can be safely compounded or repackaged outside the proposed parameters, allow those products to be compounded or repackaged within parameters appropriate for that particular drug.

While we support reasonable safety measures to ensure compounded and repackaged drugs are safe and sterile, the agency must also ensure that access to essential treatments is not unnecessarily limited, as strict limitations on the compounding and repackaging process may make some treatments essentially unavailable to patients who need them.

Sincerely,


H. Morgan Griffith
Member of Congress

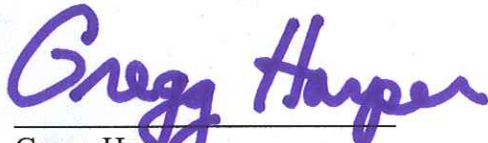

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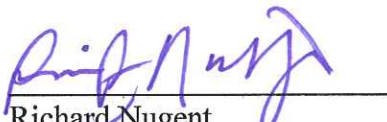

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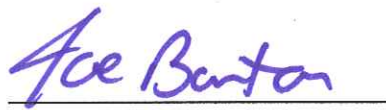

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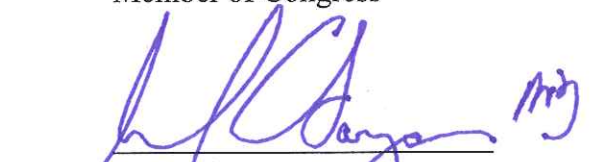

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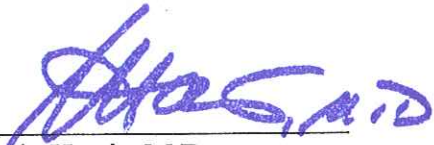

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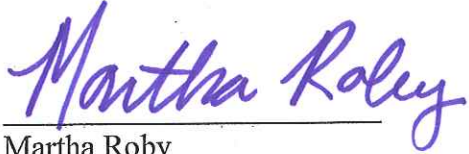

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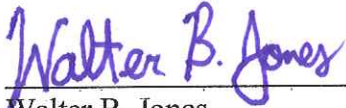
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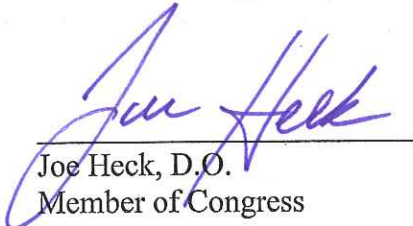
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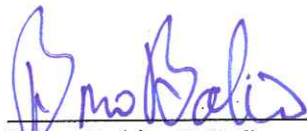
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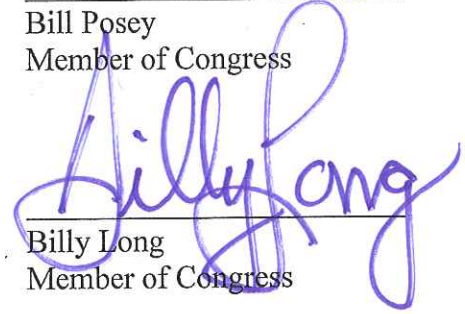
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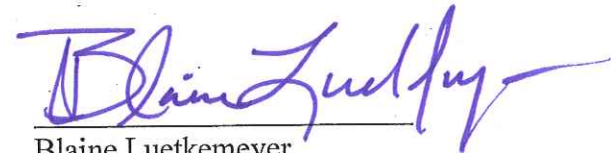
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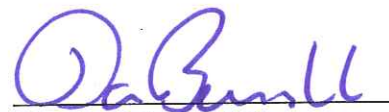
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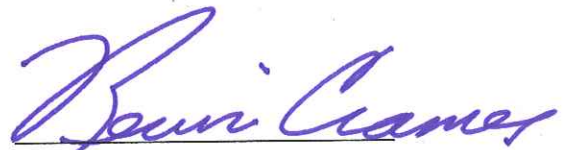
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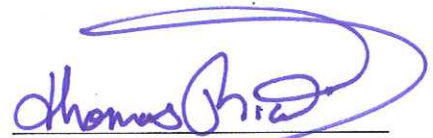
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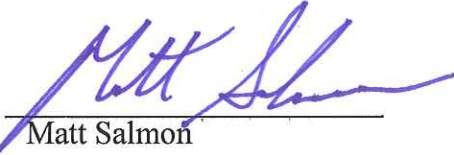
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