

Congress of the United States
Washington, DC 20515

February 3, 2016

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

Dear Dr. Ostroff,

In light of recent high-profile examples of price spikes for certain generic drugs, we are extremely concerned about the public health implications of such significant price increases for common medications. We understand it is not within the jurisdiction of the Food and Drug Administration (FDA) to set or regulate drug prices. However, it appears that certain regulatory barriers and practices at FDA may be hindering price competition in some circumstances, enabling a few bad actors to dramatically increase prices, prioritizing profits over care without adverse consequences. Therefore, we ask for FDA's support to ensure an efficient process for approving generic drugs that will encourage vigorous price competition. Specifically, we have identified two actions that we feel can lead to meaningfully lower drug prices.

A functioning market requires many competitors to foster price competition for the benefit of patients. However, a slow review and long approval time for generic drug applications is delaying a number of competitor drugs from reaching the market. While the pathway to approve generic drugs is intended to be expedited, the approval rate has not kept pace with applications. In 2014, more than 1,400 generic drug applications were submitted for approval and not a single one was approved. With the current backlog of generic drug applications now numbering near 4,000 applications, the median approval time for a generic drug has ballooned to 3.5 years. Addressing this backlog should be a priority for the FDA, particularly the review of generic drug applications in cases like proposed generic competitors to Daraprim (the HIV treatment which was subject to a more than 4,000% price increase after it was acquired by Turing), where there is now no other competitor on the market. We seek your immediate action on the backlog in generic approvals. We are also interested in your input on whether and how Congress could provide the agency with additional authorities to expedite review of generic applications for drugs that no longer have patent protection or data exclusivity, but that treat a small number of patients, providing a weak incentive for generic entry.

Second, an examination of the Unapproved Drugs Initiative is needed to ensure it is meeting its intended goals. This initiative, to bring all drugs that were on the market prior to FDA regulation under the current approval process, seeks to ensure drug safety and incentivize production of rare treatments. However, it appears that current enforcement efforts have pushed commonly used old treatments, which offered downward price pressure on new treatments, off the market. Thus, this initiative may have unintentionally contributed to increased prices for some drugs. Given the new dynamic in the generic drug market, implementation of the initiative deserves a reevaluation. We applaud FDA efforts to ensure the safety and efficacy of all medications, and urge you to focus enforcement efforts on drugs that demonstrate legitimate safety risks or lack evidence of effectiveness.

In the ever evolving pharmaceutical ecosystem, it is critical that there is a fair and efficient path for the approval of generic medications. With generic drugs comprising more than 80 percent of all filled prescriptions, a competitive marketplace is necessary for maintaining access to affordable medication. We urge you to take immediate action to reduce the generic drug application backlog and to prioritize enforcement of unapproved drugs that pose serious safety risks. Thank you for your prompt attention, we look forward to working with you to ensure Americans have consistent access to affordable medication.

Sincerely,



Ami Bera, M.D.
Member of Congress



Scott Peters
Member of Congress



Ron Kind
Member of Congress



Juan Vargas
Member of Congress



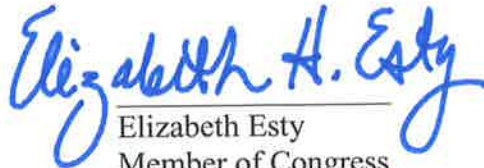
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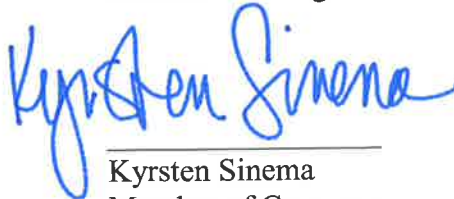
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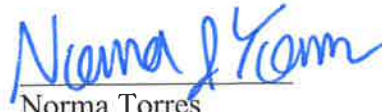
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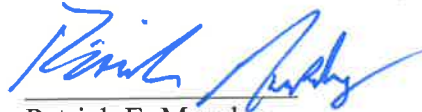
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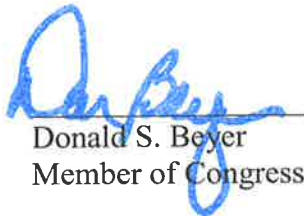
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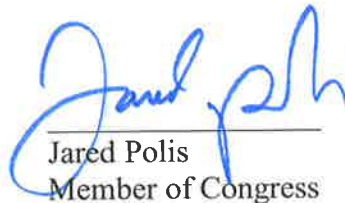
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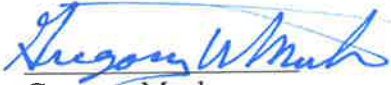
Bill Foster
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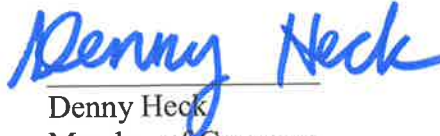
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