COUNCIL FOR AFFORDABLE
HEALTH COVERAGE

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October 31, 2018

The Honorable Scott Gottlieb, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Gottlieb:

I write to share our strong concerns regarding importation in light of the U.S. Food and Drug Administration's (FDA) recently formed work group tasked with developing "focused drug importation policy options."[1]

The Council for Affordable Health Coverage (CAHC) is a broad-based alliance with a singular focus: bringing down the cost of health care for all Americans. Our membership reflects a broad range of interests—organizations representing insurers, PBMs, drug manufacturers, small and large employers, patient groups, consumers, and physician organizations.

While CAHC appreciates the work group's aim of addressing access challenges related to certain sole-source medicines, we encourage the administration to identify ways to achieve this goal without taking a gamble on patient safety and compromising the integrity of our nation's medication supply. As Secretary of Health and Human Services (HHS) Alex Azar has warned before, "There can be no guarantee of safety" [2] under drug importation. Past administrations have echoed these concerns. A task force on drug importation convened by the George W. Bush administration's HHS in 2005 concluded that, "There is no realistic level of resources that could ensure that personally imported drugs are adequately inspected to assure their safety," while adding "Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities."[3]

We know these challenges are formidable and are well-documented. We are unaware of significant changes in either the integrity of or improvements to the distribution chain that would significantly address these safety concerns. Likewise, no data we have seen would result in lower costs for consumers. These two bars – safety and cost savings – are essential elements in any new system. Absent any new data, we see little reason to roll the dice on a risky scheme when other solutions are at hand.

To improve prescription drug affordability and access, we urge FDA and its counterparts across the administration to instead return to a focus on rewarding value. The administration has already made important strides towards this goal through many of the policies in its "American Patients First" agenda.

CAHC has proposed[4] additional steps that policymakers could take to aid the system-wide shift toward value-based care, such as codifying FDA's recently issued guidance allowing pre-approval communication between manufacturers and health plans, creating clear exceptions to Medicaid "best price" for value-based arrangements,

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[1] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613931.htm
[2] https://www.statnews.com/2017/11/14/drug-importation-trump-azar/
[3] https://www.aging.senate.gov/imo/media/doc/hr135rc.pdf
[4] https://www.cahc.net/newsroom/2018/7/17/cahc-outlines-solutions-to-reward-value-save-costs-in-american-patients-first-rfi-response

and establishing a safe harbor from Anti-Kickback regulations for value-based and coordinated care models. Such policies would improve prescription drug access while offering up to $47 billion in annual savings to the healthcare system, according to our internal projections.[5] Conversely, the Congressional Budget Office has found that savings from risky drug importation would be minimal at best.[6]

Media reports indicate that the work group has not released guidelines and will not identify individual members.[7] Additionally, it is not clear whether the work group's findings will be subject to public review and comment. Such opaqueness – particularly on a subject as controversial as this – risks marring the agency's otherwise praiseworthy record in recent years.

We applaud the FDA's efforts to reduce regulatory barriers and increase efficiency in generic drug approvals and CAHC supports the agency's progress in increasing competition and improving pathways to innovation for the benefit of consumers and our healthcare marketplace.

We maintain, however, that consumers would be well served by FDA disbanding the drug importation work group and instead convening stakeholders and administration personnel to continue a conversation on value-based solutions that do not threaten patient safety. If FDA cannot take risky drug importation policies off the table altogether, the agency should act quickly to ensure ample opportunities for public review and comment.

CAHC appreciates your careful consideration of our comments. We stand ready to serve as a resource to you and your staff as you seek to improve prescription drug affordability and access for all Americans.

Sincerely,

Joel White
President

cc: Dr. Rachel Sherman, Principal Deputy Commissioner

[5] https://www.cahc.net/newsroom/2018/7/17/cahc-outlines-solutions-to-reward-value-save-costs-in-american-patients-first-rfi-response
[6] https://www.cbo.gov/sites/default/files/109th-congress-2005-2006/costestimate/s13920.pdf
[7] https://www.statnews.com/2018/08/20/fda-working-group-importation/