

May 20, 2022

The Honorable Patty Murray
Chair, Senate Committee on Health,
Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

The Honorable Richard Burr
Ranking Member, Senate Committee on
Health, Education, Labor & Pensions
428 Senate Dirksen Office Building
Washington, D.C. 20510

The Honorable Frank Pallone, Jr.
Chair, House Committee on Energy and
Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member, House Committee on
Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Members of the Conference Committee for
H.R. 4521

RE: Comments Regarding H.R. 4521, the America COMPETES Act of 2022/United States Innovation and Competition Act; in Support of Section 20402 - Notification, Nondistribution and Recall of Drugs

Dear Chairperson Murray, Ranking Member Burr, Chairperson Pallone, Ranking Member McMorris Rodgers, and Other Conferees:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, respectfully urges you to include Section 20402 (Notification, nondistribution and recall of drugs) — which was a provision of the version of H.R. 4521 engrossed in the House of Representatives on February 4, 2022, but not in the version engrossed in the Senate on March 28, 2022 — in the final version of H.R. 4521 negotiated by your conference committee.

The Food and Drug Administration (FDA) can require manufacturers to recall medical devices, biological products, controlled substances, tobacco, and food. Yet shockingly, when it comes to drugs that are not controlled substances, the FDA can only ask drug producers to issue recalls voluntarily. Over the past decade, there have been numerous examples of drug producers — including traditional compounding pharmacies, outsourcing facilities engaged in the production of sterile compounded drugs, manufacturers of over-the-counter drugs, and manufacturers of homeopathic drug products — disregarding FDA requests for voluntary recalls of tainted or potentially tainted drug products that posed a serious threat to the health of patients and consumers.

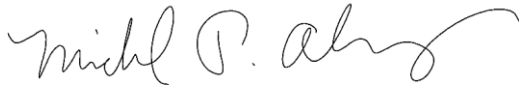
Inclusion of section 20402 from the version of H.R. 4521 that was engrossed in the House in the final version of the legislation negotiated by your conference committee would finally close this dangerous loophole by granting the FDA mandatory recall authority for all drugs.

Thank you for considering our views on this important public health issue.

Sincerely,



Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group



Michael T. Abrams, M.P.H., Ph.D.
Senior Health Researcher
Public Citizen's Health Research Group

Cc: The Honorable Nancy Pelosi, Speaker, United States House of Representatives
The Honorable Chuck Schumer, Majority Leader, United States Senate
The Honorable Kevin McCarthy, Minority Leader, United States House of Representatives
The Honorable Mitch McConnell, Minority Leader, United States Senate