Gillibrand-Braun #1065 – the 9/11 Responder and Survivor Health Funding Correction Act (Sponsored by Senators Gillibrand, Braun, Schumer)

Summary of NDAA Amendment

HELP majority has cleared Gillibrand-Braun #1065.

This NDAA version of this bill is a bipartisan, scaled-down version of the 9/11 Responder and Survivor Health Funding Correction Act using a new payfor - the "citizen's petition payfor" which streamlines the Citizen Petition process at the FDA to reduce administrative costs.

In this new version, we have taken out the technical policy changes and reduced the total cost from \$2 billion to \$676 million. The Amendment:

- Provides \$444 million which partially addresses the funding shortfall set for FY29.
- Provides \$232 million to expand eligibility to 9/11 responders at the Pentagon and Shanksville sites
 who were active-duty DOD military or civilians, along with other Federal employees currently
 excluded from the program.
- <u>Total Cost:</u> **Total of \$676 million = Pentagon/Shanksville Fund:** \$232 million + **Correction fund:** \$444,000,000

What is the "Citizen's Petition Pay-For"?

The "Citizen's Petition Pay-For" streamlines the Citizen Petition process at the FDA to reduce administrative costs

The citizen petition process is available so stakeholders may express concerns about pending drug applications to the FDA, who is required to respond to the petitions. Some disingenuous actors, however, submit citizen petitions with the sole intention of delaying generic competition to brand-name prescription drugs. This Pay-For allows the FDA to reject citizen petitions if its primary purpose is to delay the approval of a pending drug application. The amendment allows the FDA to deny a citizen petition if it believes that the petition was submitted with the primary purpose of delaying the approval of a pending drug application or the petition does not on its face raise valid scientific or regulatory issues. Previously, both conditions needed to be met for the FDA to deny the petition up front.

This will lead to greater access to generic drugs and more competition in the prescription drug marketplace. The calculated saving from reducing the administrative cost of going through these petitions is about \$676 million.

Background

The World Trade Center Health Program (WTCHP) provides medical treatment and monitoring for approximately 124,000 9/11 responders and survivors from the World Trade Center and lower Manhattan, the Pentagon, and the Shanksville crash site, who live in every State and 434 out of 435 Congressional Districts. Since the 2015 reauthorization with the current set funding amounts (and longer-term formula), the Program has seen a significant increase in enrollment. Part of this is because cancers take time to develop and be diagnosed.

Why Now?

Thank you to many of your boss' support on the 9/11 health <u>Omni amendment</u>. The \$1 billion helped delay the program funding shortfall from FY27 to FY29 – but, unfortunately, didn't solve the long-term funding problem.

The **Gillibrand-Braun** #1065 will partially address the funding issue and allow currently excluded DoD Pentagon and Shanksville, PA responders to participate in the WTCHP.