

[PRESS RELEASE](#)

BIO Statement on New PDUFA Package

May 4, 2022



Media Contact



[Jacy Gomez](#)

2027471281

jgomez@bio.org

The House Energy & Commerce Committee today unveiled a new package for the Prescription Drug User Fee Act (PDUFA). After the release, BIO's Chief Science Officer, Cartier Esham, made the following remarks:

"For more than thirty years, the FDA user fee programs have shown tremendous results in delivering life-saving medicines to patients who urgently need them. These agreements between the industry and FDA include important provisions to improve the use of real-world evidence, modernize, streamline, and diversify clinical trials, and ensure that the Agency has the resources necessary to support the world-leading innovation our companies bring to patients every day.

"While we are still analyzing the bill, we are pleased to see bipartisan support from the Energy & Commerce Committee for these critical public health programs. We are further encouraged that the Committee recognizes the importance of a timely reauthorization and has worked together to develop a bill that will continue the shared goal of transforming and improving patients' lives for years to come. We look forward to working with the Committee on in the coming weeks to achieve that goal."

Discover More

CMS Decision is an Enormous Setback for Alzheimer...

Dr. Michelle McMurry-Heath, President and CEO of the Biotechnology Innovation Organization (BIO), released the following statement in response to the Centers for Medicare and Medicaid Services' (CMS's) National Coverage Determination (NCD) to...

[Learn more →](#)

BIO Statement on Reports of a Proposed Deal on...

John Murphy, Chief Policy Officer at the Biotechnology Innovation Organization (BIO), released the following statement regarding reports of a proposed deal on a Covid-19 vaccine intellectual property rights waiver: "While we have seen the reported...

[Learn more →](#)

BIO Joins Efforts to Aid in Humanitarian Relief...

The following statement can be attributed to BIO's President and CEO Dr. Michelle McMurry-Heath in response to the ongoing conflict in Ukraine and the organization's efforts to help in humanitarian relief: "The conflict in Ukraine and violence...

[Learn more →](#)