EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

May 17, 2021
(House Rules)

STATEMENT OF ADMINISTRATION POLICY

H.R. 1629 – Fairness in Orphan Drug Exclusivity Act

(Rep. Dean, D-Pennsylvania, and two cosponsors)

The Administration supports House passage of H.R. 1629, the Fairness in Orphan Drug Exclusivity Act. Orphan drug status is intended to encourage companies to develop promising drugs for rare diseases. Current law provides market exclusivity for drugs that treat any disease or condition which (A) affects fewer than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from that drug's sales in the United States. H.R. 1629 affects only drugs that qualify under the latter provision. Current law allows market exclusivity to be extended for a new version of the same drug without the drug developer having to show a lack of profitability for that new version as well. This legislation would close that loophole, requiring all drugs that obtain seven years of market exclusivity for conditions affecting 200,000 or more people to illustrate that they have no reasonable expectation of recovering R&D costs through U.S. sales.

The Administration applauds these steps to ensure Americans have access to high quality, affordable treatments.

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