To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of prescription drugs furnished under part D of the Medicare program.

IN THE HOUSE OF REPRESENTATIVES

Mr. Doggett introduced the following bill; which was referred to the Committee on ______________________

A BILL

To amend title XVIII of the Social Security Act to require the Secretary of Health and Human Services to negotiate prices of prescription drugs furnished under part D of the Medicare program.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Medicare Negotiation and Competitive Licensing Act of 2018”.
SEC. 2. REQUIRING THE SECRETARY OF HEALTH AND
HUMAN SERVICES TO NEGOTIATE PRICES OF
PRESCRIPTION DRUGS FURNISHED UNDER
PART D OF THE MEDICARE PROGRAM.

Section 1860D–11 of the Social Security Act (42
U.S.C. 1395w–111) is amended by striking subsection (i)
and inserting the following new subsection:

“(i) NEGOTIATION OF LOWER DRUG PRICES.—

“(1) IN GENERAL.—Notwithstanding any other
provision of law, the Secretary shall, for plan years
beginning on or after the date of the enactment of
this subsection, negotiate with pharmaceutical manu-
facturers the prices (including discounts, rebates,
and other price concessions) that may be charged to
PDP sponsors and MA organizations during a nego-
tiated price period (as specified by the Secretary) for
covered part D drugs for part D eligible individuals
who are enrolled under a prescription drug plan or
under an MA-PD plan. In negotiating such prices
under this section, the Secretary shall take into ac-
count the following factors:

“(A) The comparative clinical effectiveness
and cost effectiveness, when available from an
impartial source, of such drug.

“(B) The budgetary impact of providing
coverage of such drug.
“(C) The number of similarly effective drugs or alternative treatment regimens for each approved use of such drug.

“(D) The associated financial burden on patients that utilize such drug.

“(E) The associated unmet patient need for such drug.

“(F) The total revenues from global sales obtained by the manufacturer for such drug.

“(2) Finalization of Negotiated Price.—

The negotiated price of each covered part D drug for a negotiated price period shall be finalized not later than 30 days before a PDP sponsor is required to submit information described in subsection (b)(2) for the first plan year in such negotiated price period.

“(3) Competitive Licensing Authority.—

“(A) In General.—Notwithstanding any exclusivity under clause (iii) or (iv) of section 505(j)(5)(F) of the Federal Food, Drug, and Cosmetic Act, clause (iii) or (iv) of section 505(c)(3)(E) of such Act, section 351(k)(7)(A) of the Public Health Service Act, or section 527(a) of the Federal Food, Drug, and Cosmetic Act, or by an extension of such exclusivity
under section 505A of such Act or section 505E of such Act, and any other provision of law that provides for market exclusivity (or extension of market exclusivity) with respect to a drug, in the case that the Secretary is unable to successfully negotiate an appropriate price for a covered part D drug for a negotiated price period, the Secretary shall authorize the use of any patent, clinical trial data, or other exclusivity granted by the Federal government with respect to such drug as the Secretary determines appropriate for purposes of manufacturing such drug for sale under a prescription drug plan or MA-PD plan. Any entity making use of a competitive license to use patent, clinical trial data, or other exclusivity under this section shall provide to the manufacturer holding such exclusivity reasonable compensation, as determined by the Secretary based on the following factors:

“(i) The risk-adjusted value of any Federal government subsidies and investments in research and development used to support the development of such drug.

“(ii) The risk-adjusted value of any investment made by such manufacturer in
the research and development of such
drug.

“(iii) The impact of the price, includ-
ing license compensation payments, on
meeting the medical need of all patients.

“(iv) The relationship between the
price of such drug, including compensation
payments, and the health benefits of such
drug.

“(v) Other relevant factors determined
appropriate by the Secretary to provide
reasonable compensation.

“(B) REASONABLE COMPENSATION.—The
manufacturer described in subparagraph (A)
may seek recovery against the United States in
the United States Court of Federal Claims.

“(C) INTERIM PERIOD.—

“(i) IN GENERAL.—Until 1 year after
a drug described in subparagraph (A) is
approved under section 505(j) of the Fed-
eral Food, Drug, and Cosmetic Act or sec-
tion 351(k) of the Public Health Service
Act and is provided under license issued by
the Secretary under such subparagraph,
PDP plans and MA-PD plans shall not
pay more for such drug than the average of the prices available, during the most recent 12-month period for which data is available prior to the beginning of such negotiated price period, from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the ten OECD (Organization for Economic Cooperation and Development) countries that have the largest gross domestic product with a per capita income that is not less than half the per capita income of the United States, as reported by the manufacturer to the Secretary.

“(ii) Federal program licensing.—If such drug is not made available at the price determined, the Secretary shall authorize such entities to use any patent, clinical trial data, or other exclusivity granted by the Federal government with respect to such drug as the Secretary determines appropriate for purposes of manufacturing such drug for sale under any Federal program, including those provided
by Medicare, Medicaid, Veterans Affairs, the Department of Defense, and the Coast Guard.

“(4) FDA EXPEDITED REVIEW OF LICENSED DRUG APPLICATIONS.—The Secretary shall prioritize review of applications under section 505(j) of the Federal Food, Drug, and Cosmetic Act for drugs licensed under paragraph (3)(A).

“(5) PROHIBITION OF ANTICOMPETITIVE BEHAVIOR.—No drug manufacturer may engage in anticompetitive behavior with another manufacturer that may interfere with the issuance and implementation of a competitive license or run contrary to public policy.

“(6) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan or an organization offering an MA-PD plan from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated by the Secretary.”.