CONGRESSIONAL BUDGET OFFICE
U.S. Congress
Washington, DC 20515

Phillip L. Swagel, Director

December 10, 2019

Honorable Frank Pallone Jr.
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington DC 20515

Re: *Budgetary Effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act*

Dear Mr. Chairman:

The Congressional Budget Office and the staff of the Joint Committee on Taxation (JCT) have completed an analysis of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act, as posted by the House Committee on Rules on December 6, 2019 (Rules Committee Print 116-41), and including modifications discussed with staff.[1]

Summary

CBO and JCT estimate that enacting the current version of H.R. 3 would increase direct spending by about $40 billion and increase revenues by about $46 billion over the 2020-2029 period (see Table 1). The net effect would be to reduce unified federal deficits by about $5 billion over that 10-year period.

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1. In October, CBO released an analysis of an earlier version of H.R. 3, concerning the effects of title I on federal spending for Medicare's Part D (the outpatient prescription drug benefit). See Congressional Budget Office, letter to the Honorable Frank Pallone concerning the effects of drug price negotiation stemming from title I of H.R. 3, the Lower Drug Costs Now Act of 2019, on spending and revenues related to Part D of Medicare (October 11, 2019), www.cbo.gov/publication/55722. Modifications to the Rules Print include changing the implementation date to 2022 for sections 501 through 507, and changing the implementation date to 2023 for sections 602 and 603.

The largest effects on spending over that period would result from two sets of provisions, CBO and JCT estimate:

- The price negotiation provisions would lower spending by about $456 billion, and

- The provisions providing dental, vision, and hearing coverage under the Medicare program would raise spending by approximately $358 billion.

The estimates are uncertain. For example, the price negotiation process could be implemented in ways that differ from CBO's interpretation, and manufacturers might respond to it differently from what CBO has projected.

The estimates in Table 1 account for interactions among various provisions of the bill. Specifically, the estimates of title II reflect the impact of title I; the estimate of title III reflects the impact of titles I and II; and the estimate of titles V, VII, and VIII reflects the impact of the first three titles. CBO has not estimated the effects of H.R. 3 on spending subject to appropriation; but those effects could be substantial.

Title I, Lowering Prices Through Fair Drug Price Negotiation

In their October 2019 analysis of title I, CBO and JCT noted that the Secretary of Health and Human Services (HHS) would be required to negotiate prices for selected drugs so that, in general, prices did not exceed 120 percent of the average in a reference group of six foreign countries (Australia, Canada, France, Germany, Japan, and the United Kingdom). Negotiated prices would be used by plans participating in Part D of Medicare (the outpatient drug benefit) and would be available to insurers in the commercial market. Insurers could opt out of using those prices. Drug manufacturers that do not agree to participate in negotiations or that fail to agree to a negotiated price would be subject to an excise tax.[2] Manufacturers would be prohibited from deducting the excise tax payments in determining their income taxes. Thus, the combination of income taxes

2. The methodology for estimating the effects of title I on Medicare Part D is described in the October 11, 2019, estimate. CBO used a consistent methodology for estimating the effects on spending for drugs by other federal programs and in the commercial market. CBO's October estimate included the effects of title I on Medicare Part D. The estimates in this letter include the effects on Part D, as well as on other federal programs and the commercial market.

and excise taxes on the sales could cause the drug manufacturer to lose money if the drug was sold in the United States.

CBO and JCT estimate that enacting Title I would reduce direct spending by about $456 billion over the 2020-2029 period, the net effect of:

- A reduction of about $448 billion in direct spending for Medicare;
- An increase in direct spending of about $1 billion for Medicaid, on net (negotiated prices in the commercial market would lower estimated net prices paid by Medicaid for some drugs currently on the market, but those lower prices would be more than offset by an increase in launch prices for new drugs);
- A reduction in direct spending of $12 billion for subsidized plans purchased through the marketplaces established by the Affordable Care Act and the Federal Employees Health Benefits program;
- An increase in direct spending of $1 billion for TRICARE, the result of increases in the launch prices of new drugs; and
- A direct appropriation of $3 billion to HHS to implement and administer the program of drug price negotiation.

Title I would increase revenues by about $45 billion, primarily because the availability of lower drug prices would reduce the estimated cost of health insurance offered by employers. CBO and JCT estimate that employment-based insurance premiums would decline as a result. Relative to current law, that reduction in premiums would increase revenues because a larger share of total compensation for workers would take the form of taxable wages and salaries.

As noted in the October 11, 2019, letter, JCT does not estimate any increase in revenues from the excise tax.

Title II, Medicare Parts B and D Prescription Drug Inflation Rebates

Title II would limit annual price increases for drugs covered under Medicare Part B (the Medical Insurance component) and under Part D to the rate of inflation, as measured by the consumer price index for all urban consumers. If price increases outpaced that index, manufacturers would pay a rebate to the federal government. Rebates would not apply to drugs selected for negotiation under title I because annual price increases for those drugs would be subject to an inflation cap.

CBO estimates that title II would reduce direct spending by about $36 billion over the 2020-2029 period—the net effect of a reduction of about $37 billion in spending for Medicare and an increase of about $1 billion for Medicaid. Title II also would increase revenues by about $500 million over the 2020-2029 period because a reduction in the net price of some drugs in the commercial market relative to estimated prices under current law would result in a larger share of total compensation for workers taking the form of taxable wages and salaries.

Title III, Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries

Title III would modify the benefit design of Medicare Part D to eliminate cost sharing for beneficiaries who reach the catastrophic phase of the benefit, eliminate the coverage gap (the doughnut hole), modify beneficiary cost sharing, and increase plan liability for drug spending. The current manufacturer discount program in the coverage gap would be replaced by separate discounts above and below the catastrophic threshold. Title III would increase direct spending by about $9 billion over the 2020-2029 period, CBO estimates.

Title IV, Drug Price Transparency

Title IV would require drug manufacturers to explain increases in drug prices that exceed threshold amounts established in the bill. A manufacturer also would be obliged to report how much it had spent on manufacturing the drug, its overall investments in research and development, and its net profits for the drug from the time of introduction to the market. Requiring manufacturers to report on drug discounts and investments in research and development would not affect Medicare spending or spending by other payers. Although H.R. 3 provides for the imposition of civil monetary penalties on manufacturers who fail to meet new reporting requirements, CBO expects that no manufacturers would do so. CBO does not estimate any budgetary effect from title IV.

Title V, Program Improvements for Medicare Low-Income Beneficiaries

Title V would make more beneficiaries eligible for Medicare Part D's low-income subsidies, which pay for beneficiaries' premiums and cost sharing, and would make those subsidies more generous for some beneficiaries. The title also would increase eligibility for the Qualified Medicare Beneficiary Program, under which Medicaid pays for Medicare premiums and cost

sharing. The modifications to both programs would increase spending by about $105 billion over the 2020-2029 period. About $55 billion of the estimated increase in direct spending from title V would occur in the Medicaid program.

Title VI, Providing for Dental, Vision, and Hearing Coverage Under the Medicare Program

Title VI would add new benefits for dental, vision, and hearing care (including dentures, glasses, hearing aids, and preventive services) to the Medicare program. CBO estimates that those provisions would increase direct spending by about $358 billion over the 2020-2029 period. Of that amount, almost $238 billion would pay for dental care, $30 billion would pay for vision care, and $89 billion would pay for hearing services.

Title VII, NIH, FDA, and Opioids Funding

H.R. 3 would appropriate funding for activities at the National Institutes of Health and the Food and Drug Administration to support activities related to medical research and the development of new drugs. Based on historical spending patterns for those agencies' activities, CBO estimates that H.R. 3 would increase direct spending by almost $9 billion over the 2020-2029 period.

Title VII also would appropriate funding related to federal responses to opioid use disorder. The bill would create an Opioid Epidemic Response Fund to support activities at six federal agencies, including the Substance Abuse and Mental Health Services Administration and the Centers for Disease Control and Prevention. Based on historical spending patterns for those agencies and similar activities, CBO estimates that the bill would increase direct spending by almost $10 billion over the 2020-2029 period.

Title VIII, Miscellaneous

Title VIII would make many changes to Medicare, as well as fund or reauthorize several programs. CBO estimates that title VIII would increase direct spending by almost $42 billion over the 2020-2029 period, mostly for the following provisions:

- Guaranteed issue of certain Medicare supplemental insurance policies ($14 billion),
- Increased Medicare payments to physicians ($11 billion),

- Additional funding for Community Health Centers ($10 billion), and
- Elimination of beneficiary cost sharing for colorectal cancer screening ($3 billion).

Effect on Pharmaceutical Research and Development

CBO estimates that under the bill, approximately 8 fewer drugs would be introduced to the U.S. market over the 2020-2029 period, and about 30 fewer drugs over the subsequent decade. (Under current law, the Food and Drug Administration approves, on average, about 30 new drugs annually, suggesting that about 300 drugs might be approved over the next 10 years.) The estimates are in the middle of the distribution of possible outcomes, in CBO's assessment, and are uncertain.

Those effects would occur because the potential global revenues for a new drug over its lifetime would decline as a result of enactment, and in some cases the prospect of lower revenues would make investments in research and development less attractive to pharmaceutical companies. The result would be fewer new drug products developed and coming to market. The effects would be larger in the 2030s because of the considerable time needed to develop new drugs and because of the larger effects that would occur when more phases of development are affected. Later in the 2030s, the size of the effects would stabilize at an annual reduction of roughly 10 percent. CBO estimates that the effects on new drug introductions from increased federal spending under the bill on biomedical research would be modest and would almost all occur more than 20 years in the future.

The introduction of new drugs would tend to be delayed in the six reference countries: Australia, Canada, France, Germany, Japan, and the United Kingdom. Prices of new drugs in those countries would rise somewhat. The drugs not introduced in the United States as a result of the legislation also would not be introduced in those countries. CBO did not predict what kind of drugs would be affected or analyze the effects of forgone innovation on public health.

To estimate the bill's effects on innovation, CBO first projected the effects of H.R. 3 on manufacturers' revenue from new drugs in the United States and in other countries, considering when drugs would be introduced and their prices over time. CBO estimates that future global revenue from new

drugs would be reduced by about 19 percent.[3] CBO estimated changes in the number of new drugs that would be developed and marketed in part on the basis of a review of the research literature on the relationship between future revenue and innovation.[4] CBO also modeled manufacturers' decisionmaking about whether to move a drug through the phases of development.[5]

Mandates

H.R. 3 would impose private-sector mandates as defined in the Unfunded Mandates Reform Act (UMRA). CBO estimates that the cost of the mandates would greatly exceed the annual threshold established in UMRA ($164 million in 2019, adjusted annually for inflation) in each year.

Title I would require drug manufacturers to negotiate the prices of selected drugs with the HHS Secretary and to provide those drugs at the negotiated prices to plans participating in Part D of Medicare and to insurers in the commercial market. Because participation in Medicare is voluntary, the duty to sell at negotiated prices to Medicare plans would not impose a mandate as defined in UMRA. However, that duty also would apply to sales made to group and individual health plans, which would impose a private-sector mandate because the sales do not occur within a voluntary federal program. The cost of the mandate would include the value of forgone revenue from commercial sales at the reduced prices that would result from the mandatory negotiation. CBO estimates that the aggregate cost would average about $45 billion annually in each of the first five years

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3. Future global revenue was calculated as the sum of the present values of streams of lifetime revenue for groups of new drugs. Each present value was a single number that expressed the flow of future revenue in terms of an equivalent lump sum received in 2020.

4. See Pierre Dubois and others, "Market Size and Pharmaceutical Innovation," *RAND Journal of Economics*, vol. 46, no. 4 (Winter 2015), pp. 844-871, https://doi.org/10.1111/1756-2171.12113; Margaret E. Blume-Kohout and Neeraj Sood, "Market Size and Innovation: Effects of Medicare Part D on Pharmaceutical Research and Development," *Journal of Public Economics*, vol. 97 (January 2013), pp. 327-336, https://doi.org/10.1016/j.jpubeco.2012.10.003; and Daron Acemoglu and Joshua Linn, "Market Size in Innovation: Theory and Evidence From the Pharmaceutical Industry," *Quarterly Journal of Economics*, vol. 119, no. 3 (August 2004), pp. 1049-1090, https://www.jstor.org/stable/25098709.

5. CBO's modeling drew on research from several sources, including Joseph A. DiMasi, Henry G. Grabowski, and Ronald W. Hansen, "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs," *Journal of Heath Economics*, vol. 47 (May 2016), pp. 20-33, https://doi.org/10.1016/j.jhealeco.2016.01.012; and Christopher P. Adams and Van V. Brantner, "Estimating the Cost of New Drug Development: Is It Really $802 Million?" *Health Affairs*, vol. 25, no. 2 (March/April 2006), pp. 420-428, https://doi.org/10.1377/hlthaff.25.2.420.

that the mandate is in effect. That cost includes two components: the cost to the manufacturers whose drugs would be selected for negotiation and the cost to other manufacturers who would face competition from lower-priced alternatives.

Titles I and II also would require drug manufacturers and group health plans to submit pricing, sales, rebate, and other information to the Congress and the Secretary to facilitate negotiations. CBO estimates the cost to meet the new reporting requirements would be small.

The duties in title II for drug manufacturers to provide rebates for price increases above the rate of inflation are not mandates because manufacturers voluntarily participate in those programs, subject to the terms set by the federal government. H.R. 3 would not impose any intergovernmental mandates as defined in UMRA.

Contributors

The estimates were prepared by Christopher Adams, Colin Baker, Tom Bradley, Alice Burns, Jennifer Gray, Stuart Hammond, Philippa Haven, Tamara Hayford, Lori Housman, Evan Herrnstadt, Jamease Kowalczyk, Andrew Laughlin, Lara Robillard, Sarah Sajewski, Ellen Werble, Rebecca Yip, and Katherine Young. This letter was also reviewed by Theresa Gullo, Jeffrey Kling, Leo Lex, and Susan Willie.

I hope this information is useful to the Congress in its deliberations. If you have any questions, please contact me or the primary staff contacts, Chad Chirico and Paul Masi.

Sincerely,

Phillip L. Swagel
Director

Enclosure

cc: Honorable Greg Walden
Ranking Member
Honorable Richard Neal

Chairman
Committee on Ways and Means

Honorable Kevin Brady
Ranking Member

Honorable Bobby Scott
Chairman
Committee on Education and Labor

Honorable Virginia Foxx
Ranking Member

H.R. 3, The Elijah E. Cummings Lower Drug Costs Now Act

As posted by the House Committee on Rules on December 6, 2019 (Rules Committee Print 116-41), and including modifications discussed with staff

	By Fiscal Year, Millions of Dollars										2020-2024	2020-2029
	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029		
	Increases or Decreases (-) in Direct Spending Outlays[a]											
Title I, Lowering Prices Through Fair Drug Price Negotiation[b]												
On-budget												
Medicare	0	0	0	-11,000	-20,400	-27,100	-74,500	-94,300	-122,500	-98,400	-31,400	-448,200
Medicaid	20	114	266	-27	157	412	-343	-127	101	632	531	1,205
Private Health Insurance	0	6	7	-372	-604	-758	-2,147	-2,645	-3,091	-2,647	-963	-12,251
Other	582	620	650	670	700	148	130	160	190	240	3,222	4,090
Subtotal, title I on-budget outlays	602	740	923	-10,728	-20,147	-27,298	-76,860	-96,912	-125,300	-100,175	-28,610	-455,156
Off-budget												
Other	0	1	2	-27	-39	-47	-137	-166	-193	-165	-63	-771
Subtotal, title I off-budget outlays	0	1	2	-27	-39	-47	-137	-166	-193	-165	-63	-771
Total, title I unified-budget direct spending	602	742	924	-10,755	-20,186	-27,345	-76,997	-97,078	-125,493	-100,341	-28,673	-455,927
Title II, Medicare Parts B and D Prescription Drug Inflation Rebates[b]												
On-budget												
Medicare	0	-400	-5,700	-3,300	-10,800	-5,000	-4,200	-3,400	-2,600	-1,800	-20,200	-37,200
Medicaid	0	0	0	0	100	100	200	200	300	400	100	1,300
Other[c]	0	0	-60	-30	-19	-15	-13	-8	-6	-3	-109	-154
Subtotal, title II on-budget outlays	0	-400	-5,760	-3,330	-10,719	-4,915	-4,013	-3,208	-2,306	-1,403	-20,209	-36,054
Off-budget												
Other	0	0	-4	-1	-1	-1	-1	0	0	0	-6	-8
Subtotal, title II off-budget outlays	0	0	-4	-1	-1	-1	-1	0	0	0	-6	-8
Total, title II unified-budget direct spending	0	-400	-5,764	-3,331	-10,720	-4,916	-4,014	-3,208	-2,306	-1,403	-20,215	-36,062
Title III, Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries												
Medicare	0	0	10	-1,233	-883	-106	913	2,122	3,789	4,850	-2,106	9,461
Subtotal, title III on-budget outlays	0	0	10	-1,233	-883	-106	913	2,122	3,789	4,850	-2,106	9,461
Title IV, Drug Price Transparency												
Medicare	0	0	0	0	0	0	0	0	0	0	0	0
Subtotal, title IV on-budget outlays	0	0	0	0	0	0	0	0	0	0	0	0
Title V, Program Improvements for Medicare Low-Income Beneficiaries[d]												
Medicare	0	0	2,360	4,658	6,666	7,465	6,841	6,780	7,031	7,960	13,684	49,762
Medicaid	0	0	2,063	4,363	6,967	7,373	7,779	8,252	8,760	9,335	13,393	54,892
Subtotal, title V on-budget outlays	0	0	4,423	9,021	13,634	14,838	14,620	15,033	15,790	17,295	27,077	104,654
Title VI, Providing for Dental, Vision, and Hearing Coverage Under the Medicare Program[d, e]												
Medicare	56	96	101	7,885	14,598	40,792	58,392	66,701	78,503	81,372	22,736	348,497
Medicaid	0	0	0	0	0	946	1,610	1,899	2,297	2,428	0	9,179
Subtotal, title VI on-budget outlays	56	96	101	7,885	14,598	41,738	60,002	68,600	80,800	83,800	22,736	357,676
Title VII, NIH, FDA, and Opioids Funding												
National Institutes of Health	0	128	439	674	754	938	1,095	1,055	1,022	1,083	1,995	7,190
Food and Drug Administration	21	78	238	282	220	161	169	189	198	203	838	1,757
Other	0	231	1,138	2,414	2,277	2,049	1,331	325	76	0	6,059	9,840
Subtotal, title VII on-budget outlays	21	438	1,814	3,369	3,250	3,148	2,595	1,569	1,295	1,286	8,892	18,786
Title VIII, Miscellaneous												
Medicare	240	910	1,350	1,400	2,000	2,820	3,630	4,560	5,830	6,300	5,900	29,040
Other	2	621	1,460	2,526	3,104	2,734	1,368	633	138	51	7,713	12,637
Subtotal, title VIII on-budget outlays	242	1,531	2,810	3,926	5,104	5,554	4,998	5,193	5,968	6,351	13,613	41,677
Total Estimated Changes												
On-Budget Direct Spending	**921**	**2,405**	**4,321**	**8,910**	**4,837**	**32,959**	**2,255**	**-7,603**	**-19,964**	**12,003**	**21,393**	**41,044**
Unified-Budget Direct Spending	**921**	**2,406**	**4,319**	**8,882**	**4,797**	**32,911**	**2,118**	**-7,769**	**-20,157**	**11,838**	**21,325**	**40,265**

Continued

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	By Fiscal Year, Millions of Dollars										2020-2024	2020-2029
	2020	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**		
Increases or Decreases (-) in Revenues												
Title I, Lowering Prices Through Fair Drug Price Negotiation[b]												
On-budget	0	-22	-31	759	1,432	1,833	5,558	7,204	8,550	7,756	2,139	33,040
Off-budget	0	-9	-13	311	581	741	2,066	2,623	3,103	2,717	870	12,119
Total, title I unified-budget revenues	0	-30	-44	1,070	2,013	2,573	7,624	9,827	11,653	10,473	3,009	45,159
Title II, Medicare Parts B and D Prescription Drug Inflation Rebates[b]												
On-budget	0	0	112	81	46	37	32	26	18	10	239	362
Off-budget	0	0	46	34	19	15	12	9	6	3	99	144
Total, title II unified-budget revenues	0	0	158	115	65	52	44	35	24	13	338	506
Total Estimated Changes												
On-Budget Revenues	**0**	**-22**	**81**	**840**	**1,478**	**1,870**	**5,590**	**7,230**	**8,568**	**7,766**	**2,378**	**33,402**
Unified-Budget Revenues	**0**	**-30**	**114**	**1,185**	**2,078**	**2,625**	**7,668**	**9,862**	**11,677**	**10,486**	**3,347**	**45,665**
Net Increase or Decrease (-) in the Deficit From Direct Spending and Revenues												
Effect on the On-Budget Deficit	**921**	**2,427**	**4,240**	**8,069**	**3,358**	**31,089**	**-3,335**	**-14,833**	**-28,532**	**4,237**	**19,015**	**7,642**
Effect on the Unified-Budget Deficit	**921**	**2,437**	**4,205**	**7,696**	**2,719**	**30,286**	**-5,550**	**-17,631**	**-31,835**	**1,352**	**17,977**	**-5,401**

Sources: Congressional Budget Office; staff of the Joint Committee on Taxation.
Components may not sum to totals because of rounding. Outlays are on-budget unless specified.

a. Medicare provisions include interactions with MA payments, the effect on Medicare Part A and Part B premiums, and TRICARE; other spending is for the health programs of the Department of Defense and for the Federal Employees Health Benefits program.
b. Proposal would affect direct spending and revenues, which are shown separately.
c. "Other" also includes private health insurance for title II only.
d. These provisions were estimated based on H.R. 3 as posted by the House Committee on Rules on December 6, 2019, and include modifications discussed with staff. Those modifications include changing the implementation date to 2022 for sections 501 through 507, and changing the implementation date to 2023 for sections 602 and 603.
e. Title VI, Providing for Dental, Vision, and Hearing Coverage Under the Medicare Programs[d]

Dental and oral health care	0	0	0	0	0	24,500	41,700	49,200	59,500	62,900	0	237,800
Hearing care	0	0	0	7,025	11,200	12,400	13,300	14,200	15,700	15,500	18,225	89,325
Vision care	0	0	0	760	3,300	4,800	5,000	5,200	5,600	5,400	4,060	30,060
Implementation funding	56	96	101	100	98	38	2	0	0	0	451	491
Subtotal, title VI on-budget outlays	56	96	101	7,885	14,598	41,738	60,002	68,600	80,800	83,800	22,736	357,676

FDA = Food and Drug Administration; MA = Medicare Advantage; NIH = National Institutes of Health; TRICARE = the health care program operated by the Department of Defense.