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## **CBO’s Model of Drug Price Negotiations Under the Elijah E. Cummings Lower Drug Costs Now Act**

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## Abstract

One of the inputs that the Congressional Budget Office used to estimate the budgetary effects of the Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3) is a simulation model of price negotiations. CBO modeled those negotiations using a Nash bargaining framework, which was based on the gains to each party—the government and the manufacturer—from a successful negotiation. The gain to the government was estimated to be the avoided cost of purchasing the next-best alternative treatment, plus the incremental clinical value of using the drug of interest instead of the alternative (measured in dollars), minus the agreed-upon price of the drug. The manufacturer's gain was estimated to be the revenue from selling the drug in the United States. This working paper describes the simulation model in detail, including its data sources and parameter values, and the sensitivity of the results.

In CBO's analysis, the average resulting drug price would be close to the specified upper bound of 120 percent of the index of international drug prices. Negotiations would reduce prices by 57 percent to 75 percent, relative to current prices, depending on the data and parameters that were used in the calculations. H.R. 3 specified upper and lower bounds on the prices resulting from the negotiations; in CBO's estimation, changes to the upper bound would significantly affect the prices of the drugs the agency examined.

*Keywords:* pharmaceutical prices, Nash bargaining, negotiation

*JEL Classification:* I11, I18

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## Introduction

The Congressional Budget Office developed a model of price negotiations to estimate the budgetary effects of the Elijah E. Cummings Lower Drug Costs Now Act.<sup>1</sup> That legislation—also known as H.R. 3—would require that the Secretary of Health and Human Services (HHS) negotiate maximum fair prices (MFPs) for a selected set of drugs, which then would be available at those prices to insurers participating in Medicare Part D (the prescription drug program), insurers in the commercial market, and other providers who directly administer prescription drugs to individuals (such as through infusion or injection).

CBO's model, which is based on the widely used Nash bargaining framework, informed its estimate of the effect of negotiation on pharmaceutical prices in the presence of international price data. That effect fed into the remainder of the estimate. This paper describes the model, the data and parameters used to calibrate it, and the sensitivity of the results to those decisions. In general, the results were similar using different data sources and parameter values, but the structure of the negotiations stipulated by H.R. 3 played a major role in constraining the results. The model described below is for the introduced version of H.R. 3; the version that passed the House was amended in several ways, including to expand the number of drugs subject to negotiation. CBO has not analyzed the effects of that proposal.

The legislation would not allow MFPs to exceed 120 percent of the average of the prices—called the average international market, or AIM, price—for a given drug in six reference countries: Australia, Canada, France, Germany, Japan, and the United Kingdom. H.R. 3 would also establish a target price for each drug equal to the lowest price available in any of those countries. If a manufacturer offered a price at or below the target amount during the negotiation process, that amount would become the MFP.

The Secretary would choose at least 25 drugs for MFP negotiation each year beginning in 2021, and those prices would be used in Part D beginning in 2023. The set of drugs would be drawn from the 125 single-source drugs with the highest federal spending in Part D and with the highest net spending (excluding any rebates provided by drug manufacturers) in the United States overall. Single-source drugs have no generic or biosimilar competitors; only the company that made the drug holds the patent and has the exclusive right to sell the drug. The Secretary must select the 25 drugs that he or she projects will result in the greatest savings to the federal

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<sup>1</sup> For additional information, see Congressional Budget Office, letter to the Honorable Frank Pallone Jr. on the effects of drug price negotiations stemming from Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on spending and revenues in Part D of Medicare (October 11, 2019), [www.cbo.gov/publication/55722](http://www.cbo.gov/publication/55722); and letter to the Honorable Frank Pallone Jr. regarding the budgetary effects of H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act (December 10, 2019), [www.cbo.gov/publication/55936](http://www.cbo.gov/publication/55936).

government or to individuals who are eligible for the maximum fair price.<sup>2</sup> The Secretary also would negotiate prices for all insulin products in the first year (2021).

Pharmaceutical manufacturers that did not comply with certain requirements of title I would be subject to an excise tax on all sales of the selected drug. The amount of the tax would be a percentage of the price of each sale: It would start at 65 percent, would increase by 10 percentage points for each 90 days of noncompliance, and would be capped at 95 percent. Manufacturers would be prohibited from deducting the excise tax payments from their income taxes. Thus, the combination of income taxes and excise taxes on the sales could cause the drug manufacturer to lose money if the drug was sold in the United States. The legislation also includes civil monetary penalties for manufacturers that sell drugs at prices higher than the maximum fair price. CBO and the staff of the Joint Committee on Taxation (JCT) expect that a manufacturer would remove its drug from the U.S. market rather than pay the excise tax.

Because CBO does not know which drugs the Secretary would select for the set each year and because the necessary data are available only for certain existing drugs, CBO's bargaining model estimated the effect of negotiations on the prices for a "proxy cohort" of drugs. For those estimates, the agency used existing data on Medicare spending, international prices, and relative therapeutic benefits of those drugs relative to their likely alternatives. The model applies most directly to drugs that are already on the market when they are selected for negotiations and for which international price data are available.

CBO's full analysis of the budgetary effects of H.R. 3 used the savings implied by the bargaining model as only one of many inputs.<sup>3</sup> The agency translated the output from that model into reductions in prices for future cohorts of drugs that could be subject to negotiations and then determined the overall effects on the federal budget. For example, CBO's estimate accounted for changes in the nature of those cohorts over time relative to the proxy cohort, and it modeled manufacturers' ability to adjust the availability and price of the drug in foreign markets to affect the international price data on which the negotiations are based.

## **Overview of Nash Bargaining**

Economists use bargaining models to predict the outcome of a transaction when buyers and sellers both possess some degree of market power. In such cases, there is typically no single market price; instead, the price is agreed upon jointly by the two parties. Because the potential transaction would create value for both parties, an agreement is the mutually preferred outcome.

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<sup>2</sup> Sec. 1192(b) of the Elijah E. Cummings Lower Drug Costs Now Act, H.R. 3, 116th Congress.

<sup>3</sup>See Congressional Budget Office, letter to the Honorable Frank Pallone Jr. on the effects of drug price negotiations stemming from Title I of H.R. 3, the Lower Drug Costs Now Act of 2019, on spending and revenues in Part D of Medicare (October 11, 2019), p. 8, [www.cbo.gov/publication/55722](http://www.cbo.gov/publication/55722).

However, even though neither party would want negotiations to fail, it is unclear which party would dictate the terms of the agreement. Indeed, the point of the bargaining model is to predict how a price would be set under such circumstances.

CBO used a Nash bargaining framework in its analysis of H.R. 3. Although that framework does not explicitly model the strategic behavior of the two negotiating parties, it is consistent with several models of negotiations in which the parties do behave strategically, such as Rubinstein (1982).<sup>4</sup> As such, the Nash bargaining framework is a standard approach to analyzing negotiations and is used extensively in antitrust enforcement and regulatory review.<sup>5</sup>

Multiple recent academic papers have specifically used a Nash bargaining framework to model pharmaceutical price negotiations.<sup>6</sup> Ganapati and McKibbin (2019) used it to model the prices of generic and off-patent drugs across various countries outside the United States; Dubois, Gandhi, and Vasserman (2019) used it to model drug price setting in Canada and simulate how prices in the United States and Canada would change if the United States adopted a form of reference pricing. Finally, Ladkawalla and Yin (2015) used a Nash bargaining framework to model negotiations among drug manufacturers, insurers, and pharmacies. In its analysis of H.R. 3, CBO applied the Nash bargaining model to the negotiation of prices for on-patent drugs in the United States that is described in the proposed legislation.

The prediction of the Nash bargaining framework, known as the Nash bargaining solution, is determined by two factors: the parties' relative bargaining leverage and the parties' relative bargaining weights. In the Nash bargaining framework (and as it is defined here), leverage is

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<sup>4</sup> See Ken Binmore, Ariel Rubinstein, and Asher Wolinsky, "The Nash Bargaining Solution in Economic Modelling," *RAND Journal of Economics*, vol. 17, no. 2 (Summer 1986), pp. 176–188. [www.jstor.org/stable/2555382](http://www.jstor.org/stable/2555382); and Ariel Rubinstein, "Perfect Equilibrium in a Bargaining Model," *Econometrica*, vol. 50 (1982), pp. 97–110.

<sup>5</sup> The Department of Justice, Federal Communications Commission, and Federal Trade Commission have used Nash bargaining models to litigate and evaluate mergers. For example, see *United States v. AT&T, Inc.*, 916 F.3d 1029 (D.C. Cir. 2019); Jonathan B. Baker and others, "Year in Economics at the FCC, 2010–11: Protecting Competition Online," *Review of Industrial Organization*, vol. 39, no. 4 (December 2011), pp. 297–309, <https://doi.org/10.1007/s11151-011-9319-3>; and Joseph Farrell and others, "Economics at the FTC: Hospital Mergers, Authorized Generic Drugs, and Consumer Credit Markets," *Review of Industrial Organization*, vol. 39, no. 4 (December 2011), pp. 271–296, <https://doi.org/10.1007/s11151-011-9320-x>. One recent analysis used a Nash bargaining model to predict whether a merger is likely to be anticompetitive and finds that the approach outperforms traditional methods; see Christopher Garmon, "The Accuracy of Hospital Merger Screening Methods," *RAND Journal of Economics*, vol. 48, no. 4 (Winter 2017), pp. 1068–1102, <https://doi.org/10.1111/1756-2171.12215>.

<sup>6</sup> See Sharat Ganapati and Rebecca McKibbin, "Non-Tariff Barriers and Bargaining in Generic and Off-Patent Pharmaceuticals" (draft, Georgetown University, March 2019), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3313630](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3313630); Pierre Dubois, Ashvin Gandhi, and Shoshana Vasserman, "Bargaining and International Reference Pricing in the Pharmaceutical Industry" (draft, Harvard University, May 2019), <https://scholar.harvard.edu/files/vasserman/files/dgv.pdf>; and Darius Ladkawalla and Wesley Yin, "Insurers' Negotiating Leverage and the External Effects of Medicare Part D," *Review of Economics and Statistics*, vol. 97, no. 2 (May 2015), pp. 314–331, [https://doi.org/10.1162/REST\\_a\\_00463](https://doi.org/10.1162/REST_a_00463).

determined by the net gain to a party from a successful negotiation relative to a failed negotiation, not including any payments between the two parties. If that net gain is large, that party will be able to obtain less favorable terms because a failed negotiation would result in a large loss for the party. A party with less to gain from a successful negotiation (or, equivalently, with less to lose from a failed one) has more “leverage” in a colloquial sense. The bargaining weights encompass any other factors—including the party’s patience, the cost of capital, and bargaining skill—that affect the division of the total gains from an agreement.

The Nash bargaining solution is the price that “splits the surplus” from a successful negotiation proportional to the parties’ relative bargaining weights. If the parties have equal bargaining weights, once the price is paid the parties will have gained the same amount, on net, from a successful negotiation relative to a failed negotiation.

The Nash bargaining framework can incorporate constraints on the possible outcomes of the negotiations, an aspect that is particularly relevant to CBO’s analysis of H.R. 3. Although the constraints do not directly affect CBO’s analysis of the bargaining leverage or the bargaining weights, they ensure that the outcome is restricted to a certain range. If the negotiations would otherwise fall outside that range, the constraints may effectively “pull” the resulting outcome back to the boundary of the acceptable range of outcomes.

### **Modeling the Maximum Fair Price Negotiations in H.R. 3**

There are two steps to the model that CBO used to estimate the MFPs that would result from negotiating the net prices of selected drugs under H.R. 3. In the first step, CBO computes the negotiated price, which is determined on the basis of the gains from a successful negotiation relative to a failed negotiation and the relative bargaining weights of the two parties. In the second step, CBO determines the MFP by comparing the negotiated price to bounds defined in the legislation. Specifically, the MFP is equal to the negotiated price if it falls between the upper and lower bounds. If the negotiated price exceeds the upper bound, the MFP is equal to the upper bound. If the negotiated price is less than the lower bound, the MFP is equal to the lower bound.

#### **Failed Negotiations**

The consequences of a failed negotiation are an important determinant of the MFP. If drug manufacturers faced no meaningful consequences from a failed negotiation, the Secretary would have very little bargaining leverage.<sup>7</sup> Under H.R. 3, 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 on the drug’s sales, in addition to income taxes. CBO and JCT expect that a manufacturer would take its drug off the U.S. market rather than pay the excise tax, so that tax would have the

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<sup>7</sup> See Congressional Budget Office, letter to the Honorable Chuck Grassley concerning negotiation over drug prices in Medicare (May 17, 2019), [www.cbo.gov/publication/55270](http://www.cbo.gov/publication/55270).

same effect as if the drug had not been approved for sale or as if the drug was excluded from a national list of drugs (that is, a formulary) that any insurer could cover. The potential use of the excise tax and anticipated removal of the drug from the United States would serve as a source of pressure on both parties to reach an agreement.

In a onetime interaction, both the Secretary and the manufacturer would prefer any agreement to a failed negotiation. So how can the excise tax act affect the negotiation? It can be understood in two ways. First, such questions of strategic decisionmaking can be understood through the Rubinstein model, in which the parties alternate offers until one is accepted; if they persistently reject one another's offers, the negotiation fails.<sup>8</sup> However, that never happens in the equilibrium of the model; instead, the parties immediately agree on the Nash bargaining solution. So even though the parties always come to an agreement, the spectre of protracted disagreement and failure disciplines the outcome.

Second, one can appeal to the intuition of a repeated negotiation in which the manufacturer and Secretary will negotiate over many drugs over time.<sup>9</sup> The manufacturer would not want to reveal a willingness to accept a very low price regardless of the benefit conferred by the drug, lest it encourage similarly low offers in the future; thus, the threat of disagreement remains an option as a response to an unreasonably low offer. Conversely, the Secretary would not want to reveal a willingness to pay a very high price regardless of the benefit conferred by the drug; thus, the threat of disagreement remains an option as a response to an unreasonably high offer.

### **Determining the Negotiated Price**

In the absence of bounds on the MFP, the negotiated price is the solution to the bargaining model that CBO used to estimate H.R. 3. Formally, that solution is the price that maximizes the weighted product of the two parties' gains from coming to an agreement.

In the model, the manufacturer's benefit from an agreement is equal to its revenue from selling the drug, which is calculated as the negotiated price multiplied by the quantity sold. The manufacturer's benefit from a failed negotiation is zero because the manufacturer is expected to remove the drug from the U.S. market in that case. Therefore, the net gain to the manufacturer from a successful negotiation is equal to the negotiated price multiplied by the quantity sold in the U.S. market.

In addition, the Secretary's per-beneficiary, per-year benefit from an agreement is equal to the average per-beneficiary, per-year value of the drug to a beneficiary taking the drug, minus the

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<sup>8</sup> See the [Appendix](#) for a full characterization of the Rubinstein model in the context of MFP negotiations.

<sup>9</sup> Although CBO does not explicitly model each MFP negotiation as part of a series of bargains, such a framework provides another intuitive reason that the excise tax could encourage an agreement.



negotiated price.<sup>10</sup> That value is the clinical benefit of the drug (as measured in dollars), and it is multiplied by the quantity sold to Medicare beneficiaries. The benefit from a failed negotiation is the clinical benefit of the next-best alternative treatment (which might be a different drug or even a nonpharmaceutical treatment) minus the price of that treatment. Therefore, the gain to the Secretary from a successful negotiation is the incremental clinical benefit of the drug minus the incremental price of the drug, relative to the alternative treatment.<sup>11</sup>

The model reflects two technical assumptions about the payoffs to the parties. First, the cost of producing, distributing, and marketing the drug in the United States is assumed to be zero. Although that may be a reasonable approximation for some drugs, it overstates the gain to the manufacturer from an agreement. Incorporating nonzero costs to manufacturers would result in higher negotiated prices. Second, use of the drug does not change with the negotiated price (or neither party accounts for such a change while negotiating). To the extent that there is a change in use and it is a factor in the negotiations, a lower price generates more surplus, which creates a mutual incentive to settle on a lower price than the parties otherwise would. In CBO’s simulation, the negotiated prices for most drugs are predicted to lie above 120 percent of the AIM price, so small deviations from these assumptions would probably have little effect on the overall estimate of reduced federal spending.

The Nash bargaining problem is expressed mathematically as:

$$\max_p [q_m(e - p) - q_m(e_a - p_a)]^\lambda [(q_m + q_o)p - 0]^{1-\lambda}$$

The gain for each party is its payoff from a completed negotiation minus its payoff from a failed negotiation. The first term in brackets is the Secretary’s gain from a completed negotiation relative to a failed negotiation:

- The health benefit to a Medicare beneficiary from receiving that drug ( $e$ ), minus the amount of money paid for the drug under the potential negotiated price ( $p$ ), times the number of Medicare beneficiaries receiving treatment ( $q_m$ ), minus

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<sup>10</sup> The model does not account for possible spillover benefits to other beneficiaries, such as benefits associated with vaccines.

<sup>11</sup> When CBO estimates the budgetary effects of a policy that changes the number of prescriptions filled, the agency typically applies a “medical offset” that captures associated changes in other medical expenditures. The bargaining model does not account for that medical offset to the drug being negotiated or the relevant alternative treatments. Instead, CBO applies the medical offset to the changes in future drug spending as computed in the main budgetary analysis, to which the bargaining model is one input. For more details about the medical offset, see Congressional Budget Office, *Offsetting Effects of Prescription Drug Use on Medicare’s Spending for Medical Services* (November 2012), [www.cbo.gov/publication/43741](http://www.cbo.gov/publication/43741).

- The health benefit to a Medicare beneficiary from receiving the alternative treatment ( $e_a$ ), minus the amount of money paid for the alternative treatment ( $p_a$ ), times the number of Medicare beneficiaries receiving treatment ( $q_m$ ).

The second term in brackets is the manufacturer's gain from a successful negotiation relative to a failed negotiation:

- The revenue from selling the drug to the entire U.S. market, minus the number of Medicare beneficiaries using the drug ( $q_m$ ), plus the number of other fair-price-eligible individuals taking the drug ( $q_o$ ), times the potential negotiated price ( $p$ ), minus
- Zero U.S. revenue from the drug it is taken off the market.

The exponents  $\lambda$  and  $(1 - \lambda)$  represent the relative bargaining weights of the Secretary and manufacturer, respectively. In this context, those bargaining weights succinctly capture a number of factors, including the Secretary's preference to hold out for low prices, potential political ramifications for the Secretary if negotiations are delayed, the public relations consequences for the manufacturer if it is perceived as being unwilling to negotiate, and the relative costs of capital between the parties.

The negotiated price solves the Nash bargaining model above and is equal to  $(1 - \lambda)(e - e_a + p_a)$ . That is, the parties split the incremental clinical benefit of the drug plus the avoided price of purchasing the alternative treatment. The negotiated price has a sensible relationship to the opportunity cost of the drug from the Secretary's perspective. If the drug provides a large therapeutic benefit over the existing alternative, the negotiated price would tend to be high. If the drug is used in place of an expensive alternative treatment, the negotiated price would also tend to be high. Those are both cases in which the Secretary would receive large gains from access to the drug, so his or her leverage would be low. The bargaining weight  $\lambda$  determines how the negotiated price would divide the net benefit of the drug between the two parties. If the bargaining weights are 50-50 (that is, if  $\lambda = 0.5$ ), the split would be even. The Secretary would receive the net benefit of the drug but pay half of it to the manufacturer through the negotiated price.<sup>12</sup>

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<sup>12</sup> Because current prices are negotiated between manufacturers and insurers, CBO's model assumes a ceiling on prices that could be negotiated between the Secretary and manufacturers. In the model, the negotiated price is constrained to a range below the current price and above zero. That parameter makes little difference in CBO's analysis of H.R. 3 because the MFP is typically constrained by the target price or 120 percent of the AIM price. In the context of modeling future policies that did not include an AIM-based upper bound or similar constraint, however, that modeling assumption could be more consequential.

In CBO’s model, the cost of the alternative treatment reflects its current-law price. That price could also be negotiated under the legislation, however, so the two negotiations could interact with one another because one drug’s MFP would feed into the negotiation over the other drug’s MFP. In CBO’s full analysis of the budgetary effects of H.R. 3, the agency adjusted its estimate to account for some competitive pressure among drug prices elsewhere in the analysis rather than explicitly characterize it in the bargaining model. Nonetheless, the results are similar using a “Nash-in-Nash” (Nash-equilibrium-in-Nash-bargaining) framework in which the price of an alternative treatment is that treatment’s model-predicted MFP if it is negotiated.<sup>13</sup>

### **Determining the Maximum Fair Price**

H.R. 3 effectively constrains the MFP to lie between the target price and 120 percent of the AIM price. That constraint does not directly affect the negotiated price, but it can prevent the parties from agreeing to an MFP equal to the negotiated price.<sup>14</sup> If the negotiated price was below the target price, the manufacturer would offer the target price and the Secretary would have to accept. That outcome could occur if a drug has a small incremental clinical benefit, an inexpensive alternative, or an especially high target price. Conversely, if the negotiated price exceeded 120 percent of the AIM price, the parties would agree to an MFP equal to 120 percent of the AIM price. That outcome could occur if the drug has a large incremental clinical benefit, an expensive alternative, or an especially low AIM price. Finally, if the negotiated price lies between the target price and 120 percent of the AIM price, the MFP would equal the negotiated price.<sup>15</sup> For a graphical summary of the three cases as applied to a hypothetical drug with a target price of \$800 and an AIM price of \$1,000, see **Figure 1**. In that figure, the target price and 120 percent of the AIM price are shown using dotted lines. Between those lines, the MFP is equal to the negotiated price. Outside those lines, the MFP is equal to one of the bounds.

### **Data Sources**

To model the effect of negotiation on the prices of future cohorts of drugs, CBO analyzed a set of existing drugs for which the necessary data were available. The model’s calculations required four main data series: the current price of each drug and its alternative treatment(s), the incremental clinical benefit of the drug in terms of quality-adjusted life years (QALYs) or life

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<sup>13</sup> For more information on the Nash-in-Nash modeling approach, see Allan Collard-Wexler, Gautam Gowrisankaran, and Robin S. Lee, “‘Nash-in-Nash’ Bargaining: A Microfoundation for Applied Work,” *Journal of Political Economy*, vol. 127, no. 1 (February 2019), pp. 163–195, <https://doi.org/10.1086/700729>.

<sup>14</sup> For an example of a Nash bargaining problem in which the possible outcomes are constrained, see Abhinay Muthoo, *Bargaining Theory With Applications* (Cambridge University Press, 1999), pp. 23–24 and Figure 2.5, <https://doi.org/10.1017/CBO9780511607950>.

<sup>15</sup> For an explanation of how the target price and AIM price upper bound result in this solution (using Rubinstein (1982) as the strategic model that underpins the Nash bargaining solution), see the **Appendix**.

years saved, a value that converts that incremental clinical benefit into dollars, and international prices for each drug.

### **Set of Existing Drugs CBO Analyzed**

Beginning in 2021, H.R. 3 requires the Secretary to choose each year at least 25 drugs for which prices would be negotiated.<sup>16</sup> CBO’s analysis of that legislation modeled multiple future cohorts of negotiated drugs, but it did not project the *exact* drugs that would be included in those cohorts. Instead, the analysis focused on a set of existing drugs—the proxy cohort—which formed the basis for additional modeling of the future cohorts through the 10-year budget period.

The proxy cohort comprises drugs covered by Medicare. Furthermore, because the model requires information on the incremental clinical benefit of the drugs, CBO restricted the proxy cohort to include only those drugs that had been evaluated in an Institute for Clinical and Economic Review (ICER) comparative-effectiveness study at the time of the analysis. That set of drugs provides a convenience sample, and ICER’s studies tend to focus on relatively high-priced, high-expenditure drugs.<sup>17</sup> The proxy cohort includes 28 drugs typically covered by Part D and 10 drugs generally covered by Part B.<sup>18</sup> Five of the drugs in the proxy cohort were purchased by both Part D and Part B in 2017 (the year of analysis).<sup>19</sup> The proxy cohort includes all high-expenditure drugs for which data are available; it is not necessarily the specific set of drugs CBO expects the Secretary would negotiate.

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<sup>16</sup> In the first year of negotiations (2021), all insulin products would also be included.

<sup>17</sup> In 2017, across the 28 drugs in the sample covered by Medicare Part D, the average total expenditure was \$648 million, and the median total expenditure was \$248 million. Across the 10 drugs in the sample covered by Medicare Part B, the average total expenditure was \$767 million, and the median total expenditure was \$540 million. Of all the drugs in the sample, Medicare spent the least on cystic fibrosis drug Orkambi (\$83 million), which ranked 225th among all drugs covered by Part D that had a single manufacturer. For comparison, the 125th-ranked single-manufacturer drug in terms of 2017 Part D spending (Janumet XR, a drug used to control high blood sugar in people with Type 2 diabetes) cost a total of \$223 million. Those total expenditure values and rankings are from the Medicare Part B and Part D spending “dashboards” and do not account for rebates and discounts. However, they provide some sense of the ranking of the drugs in the proxy cohort relative to the likely ranking of negotiation-eligible drugs.

<sup>18</sup> Part D is Medicare’s outpatient drug benefit, in which beneficiaries usually purchase prescription drugs at retail pharmacies. Drugs covered under Part B are generally infused or injected, and beneficiaries receive them in a physician’s office or outpatient hospital setting. Some drugs may be covered by both parts of Medicare. H.R. 3 did not specifically instruct the Secretary to negotiate drugs covered by Part B; rather, the bill directed the Secretary to choose drugs for negotiation that are commonly used in the market as a whole, which included several Part B drugs.

<sup>19</sup> Because alternatives and costs may differ across contexts, CBO separately modeled Part D and Part B negotiations for those drugs when computing the average MFP.

CBO estimated the MFP for each drug in the proxy cohort, expressed as a percentage of the AIM price, and used the simple average across drugs (or MFP index) to inform its broader model of the budgetary effects of negotiations in H.R. 3 on the prices of future cohorts of drugs.

### **Current Prices of Drugs and Alternative Treatments**

For its calculations, CBO started with data from Medicare’s aggregate spending “dashboards” for Part D and Part B.<sup>20</sup> To compute current drug prices, CBO divided the total annual expenditure for a drug in 2017 by the number of beneficiaries receiving the drug in that year. Thus, all prices in CBO’s analysis are in terms of dollars per beneficiary-year. The dashboard prices for Part D do not reflect rebates, which reduce the net price of the drug, so CBO adjusted those prices using confidential Medicare data on the rebates and discounts that insurers participating in Part D obtained from manufacturers in 2017.

### **Incremental Clinical Benefits**

CBO used data from a number of ICER’s reports to quantify the incremental clinical benefit of a drug relative to alternative treatments.<sup>21</sup> ICER produces comparisons of the outcomes that a patient with a given condition can expect under a variety of treatments. Many of those comparisons analyze drugs that would probably be eligible for negotiation.

To measure a drug’s benefit, CBO used either incremental life years or quality-adjusted life years as reported by ICER. (One year spent in a hypothetical state of perfect health is equal to one QALY.) For conditions that are fatal, the incremental change in expected life years may be an appropriate measure of the drug’s effectiveness. For conditions that are rarely fatal but reduce quality of life, QALYs may be a more appropriate measure.<sup>22</sup> Patients with those kinds of conditions (such as plaque psoriasis, an autoinflammatory condition that causes skin lesions) benefit from drugs that improve their quality of life, but they do not necessarily live longer.

Some groups have expressed concerns about the use of QALYs. For example, some argue that the measure potentially discriminates against older or disabled patients and does not reflect patient-specific preferences for quality versus length of life. Despite the limitations of using incremental QALYs and life years to approximate the benefit of a treatment, such an approach

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<sup>20</sup> Centers for Medicare & Medicaid Services, “CMS Drug Spending”, [www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs](http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs).

<sup>21</sup> See Institute for Clinical and Economic Review, “Who We Are,” [www.icer.org/who-we-are](http://www.icer.org/who-we-are).

<sup>22</sup> CBO uses QALYs and life years as proxies to model the value of a drug; however, the model does not require QALYs or life years to be an explicit criterion in the Secretary’s decisionmaking. ICER uses both QALYs and life years (which it refers to as equal value of life years gained) to communicate the incremental clinical benefit of a drug; see Institute for Clinical and Economic Review, “Cost-Effectiveness, the QALY, and the evLYG,” <http://icer.org/our-approach/methods-process/cost-effectiveness-the-qaly-and-the-evlyg>.

was the best available to CBO and is consistent with the approach taken by many countries to negotiate drug prices.<sup>23</sup>

To model the Secretary’s valuation of those clinical benefits, CBO converted the incremental increase in QALYs or life years to dollar-equivalent units using conversion factors from HHS. The formula for the negotiated price requires that the clinical benefit be expressed in dollar-equivalent units so that it can be compared with the drug price being proposed. CBO used the value of a statistical life year (VSLY) and the willingness to pay for a QALY (WTP-Q) to monetize life years and QALYs, respectively. (VSLY and WTP-Q are standard concepts used in regulatory analysis.)<sup>24</sup> Because the dollar-equivalent measure of the incremental clinical benefit needed to be in annual per-beneficiary terms, CBO divided the total incremental value by the number of remaining life years reported by ICER.

### **International Drug Prices**

For its analysis of H.R. 3, CBO consulted two sources of information on the relationship between U.S. drug prices and international drug prices: an analysis by the staff of the House Committee on Ways and Means and data underlying an analysis by So-Yeon Kang and others.<sup>25</sup> Since that time, the Council of Economic Advisers has released a similar study.<sup>26</sup> Even though the three analyses differ somewhat in the measures and countries they report, their qualitative findings largely agree.

CBO’s analysis used data only from the six countries that were used to determine H.R. 3’s calculation of the AIM price. When using the results of the studies by Ways and Means and So-Yeon Kang and others, CBO calculated the ratio of the foreign price to the Medicare Part B or D

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<sup>23</sup> For example, the United Kingdom’s National Institute for Health and Care Excellence (NICE) uses QALYs to help decide whether to approve drugs for sale to the National Health Service; see NICE, “Who We Are and What We Do”, [www.nice.org.uk/about/who-we-are/our-charter](http://www.nice.org.uk/about/who-we-are/our-charter). For a general summary of the advantages of and concerns with using QALYs in a cost-effectiveness context, see Peter J. Neumann and Joshua T. Cohen, “QALYs in 2018—Advantages and Concerns,” *Journal of the American Medical Association*, vol. 319, no. 24 (June 2018), pp. 2473–2474, <https://doi.org/10.1001/jama.2018.6072>.

<sup>24</sup> HHS recommends using VSLY and WTP-Q in its regulatory impact analyses and has done so in practice. For the department’s recommendations regarding VSLY and WTP-Q, see Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Guidelines for Regulatory Impact Analyses* (January 2017), pp. 15-22, <https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis>. For an example of the department’s use of VSLY in a regulatory benefit calculation (a final rule issued by the Food and Drug Administration), see Use of Materials Derived From Cattle in Food and Cosmetics, 81 Fed. Reg. 14718, 14730 (March 18, 2016), <https://go.usa.gov/xAaEd>.

<sup>25</sup> See staff of the House Committee on Ways and Means, *A Painful Pill to Swallow: U.S. vs. International Prescription Drug Prices* (September 2019), <https://go.usa.gov/xVeff> (PDF, 1.2 MB); and So-Yeon Kang and others, “Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials With Other Countries,” *Health Affairs*, vol. 38, no. 5 (May 2019), pp. 804–811, <http://tinyurl.com/y4eejm6m>.

<sup>26</sup> See Council of Economic Advisers, *Funding the Global Benefits to Biopharmaceutical Innovation* (February 2020), <https://go.usa.gov/xAaP8>.

price, net of rebates and discounts, for each individual drug common to the studies and the proxy cohort. CBO then applied the average of those ratios across drugs and countries to the current U.S. price of the drug to calculate the AIM price. The agency used the average ratio of the lowest foreign price to the U.S. price across drugs to calculate the target price.

Because the report from the Council of Economic Advisers presented only the average price ratios between the United States and various foreign countries across all drugs in its study, CBO applied the average of the price ratios between the United States and the six countries specified by H.R. 3 to compute the AIM price. The agency used the smallest of the six price ratios (from Japan for all drugs and from the United Kingdom for retail drugs only) to compute the target price.

The average price ratios across drugs in the proxy cohort inform the full budgetary analysis of H.R. 3 only through the MFP index. For that full budgetary analysis, CBO used a combination of data underlying the studies by Ways and Means and So-Yeon Kang and others to model the relationship between the AIM price and the U.S. price separately for each future cohort. CBO then applied the MFP index (based on the proxy cohort) to the AIM price of future cohorts of drugs as a starting point for estimating the overall budgetary effects of the legislation.

## **Central Estimate and Sensitivity Analysis**

To test the validity of its analysis, CBO varied some parameters of its model under a range of sensitivity cases. For each drug in the proxy cohort, CBO computed the MFP and the percentage reduction in price. The MFP index and the average price reduction are the simple averages of the MFP relative to the AIM price and of the percentage reduction in price relative to current U.S. prices, respectively, across drugs. Solving the model under those various cases shows that the results were generally similar when CBO used alternative data sources or parameter values. Varying the upper bound on the MFP (which is specified in the legislation) could affect the outcomes substantially, however.

### **Key Parameters of the Model and Legislative Details**

CBO considered a range of values for each of several parameters and legislative details.

**Source of International Prices.** CBO's central estimate uses the analysis by the House Ways and Means Committee. One sensitivity case uses the analysis by So-Yeon Kang and others. The other two sensitivity cases use measures from the analysis by the President's Council of Economic Advisers; one uses a full sample of drugs, and the other limits the analysis to drugs bought in a retail setting.

**Bargaining Weights.** The central estimate assigns equal bargaining weights (0.5 for the Secretary and 0.5 for the manufacturer).<sup>27</sup> The sensitivity cases assign the Secretary a bargaining weight as low as 0.25 and as high as 0.75.<sup>28</sup>

**Secretary’s Valuation of Therapeutic Benefits.** In its central estimate, CBO used willingness-to-pay values suggested by HHS, converted to 2017 dollars.<sup>29</sup> The VSLY was \$388,000 per life year, and the WTP-Q was \$507,000 per QALY.<sup>30</sup> In accordance with guidance from HHS, the sensitivity cases used values that were 50 percent higher and 50 percent lower.<sup>31</sup>

**Identification of the Next-Best Alternative Treatment.** The next-best alternative treatment determines the incremental benefit of a given drug and the price the government would have paid for the alternative if that drug was not available. Predicting exactly which alternative negotiators would have in mind is difficult, however. In CBO’s central estimate, when negotiations fail, the treatment of beneficiaries depends on the alternative. If the proxy cohort has no other treatments, then beneficiaries would be treated using the standard of care identified by ICER. The standard of care might involve a nonpharmaceutical treatment (for example, the best supportive care for multiple sclerosis) or an older pharmaceutical treatment (for example, methotrexate for rheumatoid arthritis). In the central estimate, if there are other treatments for the same condition

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<sup>27</sup> CBO often assigns probabilities of 50 percent to each of two outcomes when it does not have enough information to identify either outcome as more likely than the other. See Congressional Budget Office, *Estimating the Cost of One-Sided Bets: How CBO Analyzes the Effects of Spending Triggers* (October 2020), Box 1, [www.cbo.gov/publication/56698](http://www.cbo.gov/publication/56698). Because the United States does not have experience negotiating drug prices upon which CBO can draw, the agency’s central estimate is that the surplus would be split evenly between the Secretary and the manufacturer.

<sup>28</sup> The manufacturer’s bargaining weight is always one minus the Secretary’s bargaining weight.

<sup>29</sup> CBO previously reported that it used \$400,000 and \$520,000 for the VSLY and the WTP-Q, respectively; those values were expressed in 2018 dollars rather than 2017 dollars. CBO expects that the difference would have had a small effect on the agency’s overall estimate of changes in federal spending under H.R. 3. See Congressional Budget Office, letter to the Honorable Frank Pallone Jr. on the effects of drug price negotiations stemming from Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on spending and revenues in Part D of Medicare (October 11, 2019), [www.cbo.gov/publication/55722](http://www.cbo.gov/publication/55722).

<sup>30</sup> The WTP-Q value (\$507,000) is based on Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Guidelines for Regulatory Impact Analysis* (January 2017), p. 21, <https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis> (PDF, 1.7 MB). The VSLY (\$388,000) is based on the value used by the Food and Drug Administration in *Use of Materials Derived From Cattle in Food and Cosmetics*, 81 Fed. Reg. 14718, 14730 (March 18, 2016), <https://go.usa.gov/xAaEd>. The general guidance from HHS is to use a central estimate of about \$10 million for the value of a statistical life in 2017. To confirm that the VSLY that CBO used is consistent with the HHS guidance, CBO spread the HHS value of a statistical life over 50 remaining years of life and used a discount rate of 3 percent, resulting in an equivalent VSLY of about \$382,000. Other federal agencies use similar values of a statistical life. (All values have been inflated to 2017 dollars.)

<sup>31</sup> See Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Guidelines for Regulatory Impact Analyses* (January 2017), pp. 16–17, <https://aspe.hhs.gov/pdf-report/guidelines-regulatory-impact-analysis> (PDF, 1.7 MB).



in the proxy cohort, then half of the beneficiaries would receive the treatment with the highest total amount of Medicare spending and half would receive the standard of care. Two sensitivity cases vary the share of beneficiaries that would receive an alternative treatment if it was available in the proxy cohort.

- In the first sensitivity case, all beneficiaries would receive the alternative treatment that accounted for the highest Medicare spending.
- In the second sensitivity case, all beneficiaries would receive the standard of care, even if an alternative treatment existed in the proxy cohort.

In some cases, there are multiple alternative treatments in the proxy cohort. In CBO’s central estimate, anyone not receiving the standard of care would receive the alternative treatment with the highest Medicare spending. The following sensitivity cases are instead based on a standard model of consumer demand.<sup>32</sup>

- In the first sensitivity case, beneficiaries would receive the alternative treatment in the proxy cohort in proportion to the share of Medicare beneficiaries that received each alternative treatment in 2017—and no beneficiaries would receive the standard of care when an alternative treatment is available.
- In the second sensitivity case, half of the beneficiaries would receive an alternative treatment in the proxy cohort in proportion to the share of Medicare beneficiaries that received each alternative treatment in 2017, and half of the beneficiaries would receive the standard of care.

**Legislative Details.** H.R. 3 established bounds on the MFP. The sensitivity cases allow for three possibilities: The MFP could be as high as the current price, as low as zero, or both. For a summary of the wide range of sensitivity cases that CBO considered for those parameters, see **Table 1**.

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<sup>32</sup> Share-based substitution is implied by a logit demand model of differentiated products. See Gregory J. Werden and Luke Froeb, “The Effects of Mergers in Differentiated Products Industries: Logit Demand and Merger Policy,” *Journal of Law, Economics, and Organization*, vol. 10, no. 2 (October 1994), pp. 407–426, <https://doi.org/10.1093/oxfordjournals.jleo.a036857>.

### **Sensitivity of the Model to Individual Parameter Choices and Legislative Details**

In CBO's central estimate, the MFP is 116 percent of the AIM price, on average, a result that is largely robust to the choice of single model parameters and data sources (see **Table 2**).<sup>33</sup> The MFP index remains fairly close to the central estimate in most sensitivity cases because the negotiated prices for most of the drugs in the proxy cohort lie well above 120 percent of the AIM price. Thus, even when the model's parameters are varied substantially, most drugs still have an MFP equal to 120 percent.

For example, suppose that 120 percent of the AIM price for a drug is \$1,000, and the central estimate of the negotiated price is \$1,500 (and thus the MFP is \$1,000). If the value used for WTP-Q was the parameter being varied, the MFP would remain at \$1,000 unless the WTP-Q was more than one-third lower. Similarly, if the Secretary's bargaining weight was the parameter being varied, the MFP would remain at \$1,000 unless that bargaining weight increased from 0.5 to 0.67 or more.

CBO's central estimate of the average price reduction from negotiations in H.R. 3 is 68 percent of current prices. But that result changes somewhat depending on the source of the international price data. If the source of that data differs, the same MFP index for a given drug can imply different savings rates. Thus, the model can produce different average savings even if the negotiations are constrained by the upper bound (120 percent of the AIM price), resulting in more variation in the savings rate. Even in that case, though, the range is quite small except when the model uses the CEA's international price ratio that includes nonretail drugs.

As part of its sensitivity analysis, CBO modeled the impact of the legislation without a statutory upper bound on the MFP; in that case, CBO estimates that price negotiations would still result in some reduction in the average drug's price (see the bottom section of **Table 2**). Specifically, prices would be 22 percent lower than under current law, on average, under the legislation.<sup>34</sup> That finding implies that even if firms managed to distort the AIM price by changing their behavior in foreign markets, the MFP negotiations would result in some price reductions nevertheless. In contrast, the presence of the target price (which acts as a lower bound) is much

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<sup>33</sup> CBO previously reported that the MFP was 114 percent of the AIM price, on average. The difference was due to an error in data preparation that has since been corrected, but CBO expects that the difference would have had a small effect on the agency's estimate of changes in federal spending under H.R. 3. See Congressional Budget Office, letter to the Honorable Frank Pallone Jr. on the effects of drug price negotiations stemming from Title 1 of H.R. 3, the Lower Drug Costs Now Act of 2019, on spending and revenues in Part D of Medicare (October 11, 2019), [www.cbo.gov/publication/55722](http://www.cbo.gov/publication/55722).

<sup>34</sup> Estimates of other policies to implement a mechanism that would involve the Secretary negotiating drug prices would depend on the specifics of those proposed policies. Those specifics could affect the structure of the model and the appropriate parameter values.

less important. There are very few drugs in the proxy cohort for which the negotiated price falls below the target price, so it rarely plays a role in determining the MFP.

### **Interactions Among the Model’s Parameter Values**

CBO also performed a sensitivity analysis that accounted for interactions among all possible combinations of the various data sources and parameter values (presented in **Table 1**), holding the upper and lower bounds on the MFP fixed at the legislatively specified values.

The outcomes are similar across all parameter values that CBO examined, although there is some variation (see **Figure 2** and **Figure 3**). The MFP index varies more when the Secretary has more bargaining power. That is the case because the negotiated price is more likely to fall below 120 percent of the AIM price and, therefore, the model’s exact parameters directly affect the value of the MFP index. Even so, considering the full range of possible outcomes, the average price reduction is contained in a reasonably tight range—roughly 57 percent to 75 percent. As was the case for the results in **Table 2**, the spread in the average price reduction is largely driven by differences in the international price data. When the sensitivity cases do not include those using the CEA’s international price comparison that includes retail and nonretail drugs (the blue series in **Figure 2** and **Figure 3**), the spread in savings rates narrows to 67 percent to 75 percent.

The range of outcomes grows as the bargaining weight assigned to the Secretary rises. A higher bargaining weight could indicate that the Secretary drives a harder bargain or is more skilled at negotiating. All else being equal, a given drug’s negotiated price is more likely to fall below 120 percent of the AIM price as the Secretary’s bargaining weight rises. Because the negotiated price is still rarely below the target price, the MFP would then equal the negotiated price. Therefore, changing the exact values of the various parameters is more likely to change the MFP as more drugs move into that range.

### **Role of the MFP Upper Bound in CBO’s Model**

The MFP upper bound had a large effect on CBO’s estimate of the average MFP from negotiations under H.R. 3. The proposed legislation set the MFP upper bound at 120 percent of the AIM price, resulting in MFPs that were 32 percent of current prices, on average. If H.R. 3 had instead specified that the MFPs could be no larger than 100 percent of the AIM prices, the MFPs would have been 27 percent of current prices, on average (see **Figure 4**). The MFPs increase as the upper bound rises, eventually settling at 78 percent of the current price, on average, if the upper bound is at least 360 percent of the AIM price.

Changing the upper bound only affects the MFP of drugs in the proxy cohort with negotiated prices above that bound.<sup>35</sup> Most drugs in the proxy cohort fall into that category when the upper

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<sup>35</sup> For an illustration of how the upper bound and negotiated price interact to determine the MFP, see **Figure 1**. The negotiated price is also constrained to be less than or equal to the current price.

bound is 120 percent of the AIM price. For those drugs, when the upper bound increases slightly, the MFP also rises. Thus, the savings on those drugs decrease. For drugs with negotiated prices already below the AIM price, the MFP and savings are unchanged.

As the upper bound increases (moving from left to right in **Figure 4**), it surpasses the negotiated price of drugs one by one, and the MFPs of those drugs are no longer affected by the upper bound. As the MFPs of fewer drugs are affected, an additional increase in the upper bound has a smaller effect on average savings across all drugs in the proxy cohort, and the line becomes flatter and flatter. At about 360 percent of the AIM price the line becomes horizontal; because there are no drugs in the proxy cohort with a negotiated rate above that value, increasing the upper bound further has no effect on the average savings.

The sensitivity analysis shows that CBO's estimate of the average savings from negotiations in the proxy cohort would have been very similar under a wide range of alternative model parameters. In contrast, changing the legislatively defined bounds on the MFP could have a larger effect on the estimated savings. Specifically, CBO's estimated average price reduction of 68 percent would have been slightly larger if the upper bound was set equal to the AIM price and about two-thirds smaller if the legislation had not specified an upper bound on the MFP.

## **Possible Future Changes to the Model**

CBO continually reviews its models. For future analyses, the agency would consider a number of changes to its framework for modeling drug price negotiations. Four such changes are examined below. It is unclear how incorporating the below changes would affect CBO's estimate of federal savings under the legislation.

### **Allow for Interactions Across Negotiations**

The model used in the cost estimate for H.R. 3 assumed that negotiations are completely independent. CBO's model of a drug price's negotiation uses the alternative treatment's current price as part of the surplus from an agreement, even if the alternative is also likely to be negotiated. That approach could be reasonable if it was unlikely that the prices of multiple drugs targeting the same condition would be negotiated.

To the extent that the assumption of independence is not reasonable, however, the agency could model negotiations as occurring simultaneously in a Nash-in-Nash framework.<sup>36</sup> That framework

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<sup>36</sup> Other researchers use frameworks similar to Nash-in-Nash to model negotiations between governments and pharmaceutical manufacturers. See Sharat Ganapati and Rebecca McKibbin, "Non-Tariff Barriers and Bargaining in Generic and Off-Patent Pharmaceuticals" (draft, Georgetown University, March 2019), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3313630](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3313630); and Pierre Dubois, Ashvin Gandhi, and Shoshana Vasserman, "Bargaining and International Reference Pricing in the Pharmaceutical Industry" (draft, Harvard University, May 2019), <https://scholar.harvard.edu/files/vasserman/files/dgv.pdf>.

finds a full set of MFPs that are self-reinforcing, in the sense that if an alternative treatment is also likely to be negotiated, its MFP is part of the benefit from an agreement, rather than its current price.

### **Model the Manufacturer's Costs**

CBO's model simplifies the manufacturer's objective function by setting marginal costs of production and distribution and the average cost of marketing in the United States at zero. Although that approximation may be reasonable in some cases, future analyses could incorporate central estimates of those cost parameters if the appropriate data were available. For example, manufacturing costs of some specialty drugs could be large enough to affect negotiations. In addition, a drug's marketing costs could be an important component of negotiations. Those costs are typically high, and some share of the costs would not be recoverable by the time a drug's price was negotiated. The manufacturer would avoid incurring any future marketing costs if no agreement was reached, though, and those avoided costs would affect the negotiated price. Estimating incremental future marketing costs for an individual drug that is already on the market in the United States could be very difficult, however.

### **Incorporate a Utilization Response to Changes in Prices**

CBO's model uses a technical assumption that the quantity of a drug sold does not respond to its price. That assumption is reasonable given that beneficiaries (especially Medicare beneficiaries) tend to be insulated from the full cost of a drug through the (usually small) cost-sharing amounts they pay. That said, there is probably some quantity response; in its budgetary analysis of H.R. 3, CBO estimated that beneficiaries would increase their utilization of drugs in response to reductions in drug prices.

Future modeling of price negotiations might incorporate a similar utilization response. Given the potentially large increase in modeling complexity and the likely small magnitude of the response, though, such an effort might not be worthwhile. If future modeling did allow for a utilization response in Medicare Part D, the model also could account for offsetting changes in medical expenditures in keeping with CBO's typical approach.

### **Expand the Secretary's Objective Function**

In CBO's model, the Secretary's objective function includes only Medicare beneficiaries. Because utilization of a drug does not vary with its price in that model, the negotiation can be expressed by accounting only for the per-beneficiary net benefit of the drug. In future analyses, the Secretary might also put weight on the well-being associated with purchases in the commercial market.

Incorporating commercial purchases would raise a number of analytical and empirical questions.

- First, how would the Secretary weight health benefits and savings to enrollees in commercial insurance plans?

- Second, how would the Secretary weight savings to commercial insurers and beneficiaries that would benefit from access to the MFP?
- Third, what prices do beneficiaries actually pay in the commercial market?

If the benefits to commercial beneficiaries were similar to the benefits to Medicare beneficiaries, putting weight on the commercial beneficiaries would have a limited effect on the negotiated price. All told, the analytical complexity and data required might outweigh the benefits of a more detailed model.

## Tables

**Table 1: Full Range of Sensitivity Cases CBO Considered**

Parameter	Possible Values (Value used for central estimate in <b>bold</b> )
Source of international price data	<b>Committee on Ways and Means</b> , So-Yeon Kang and others, CEA, CEA (retail only)
Secretary's bargaining weight	0.25, 0.375, <b>0.5</b> , 0.625, 0.75
Monetary value of incremental clinical benefit	50%, <b>100%</b> , 150% of central VSL/WTP-Q case
Share of beneficiaries receiving standard of care given a failed negotiation (if there is an alternative drug in the proxy cohort, otherwise 100%)	0, <b>50%</b> , 100%
Alternative drug received by beneficiaries given a failed negotiation (if multiple alternatives are present in the proxy cohort)	<b>Alternative with the highest expenditure</b> , weighted average based on beneficiary shares

Data source: Congressional Budget Office.

CEA = Council of Economic Advisers; VSL = value of statistical life; WTP-Q = willingness to pay for an additional quality-adjusted life year.

**Table 2: CBO’s Central Estimate and Its Sensitivity to Parameters**

<b>Case</b>	<b>MFP Index (Percentage of AIM price)</b>	<b>Average Price Reduction (Percentage of current price)</b>
Central Estimate	116	68
International Price Data:		
So-Yeon Kang and others’ international prices	117	71
CEA’s international prices	116	58
CEA’s international prices (retail only)	117	71
Bargaining Weights:		
HHS Secretary’s bargaining weight = 0.25	118	67
HHS Secretary’s bargaining weight = 0.75	109	70
Monetary Value of Incremental Clinical Benefit:		
VSL/WTP-Q 50 percent lower	114	68
VSL/WTP-Q 50 percent higher	117	67
Alternative Treatment If Negotiation Fails:		
All beneficiaries receive highest-spending alternative if one is available	117	67
All beneficiaries receive SOC, even if an alternative is available	116	68
Beneficiaries receive an alternative proportional to Medicare shares	117	67
Half of beneficiaries receive an alternative proportional to Medicare shares, half receive SOC	116	68
Legislative Details:		
MFP lower bound is zero	115	68
MFP upper bound is the current price	281	22
MFP lower bound is zero and upper bound is the current price	280	22

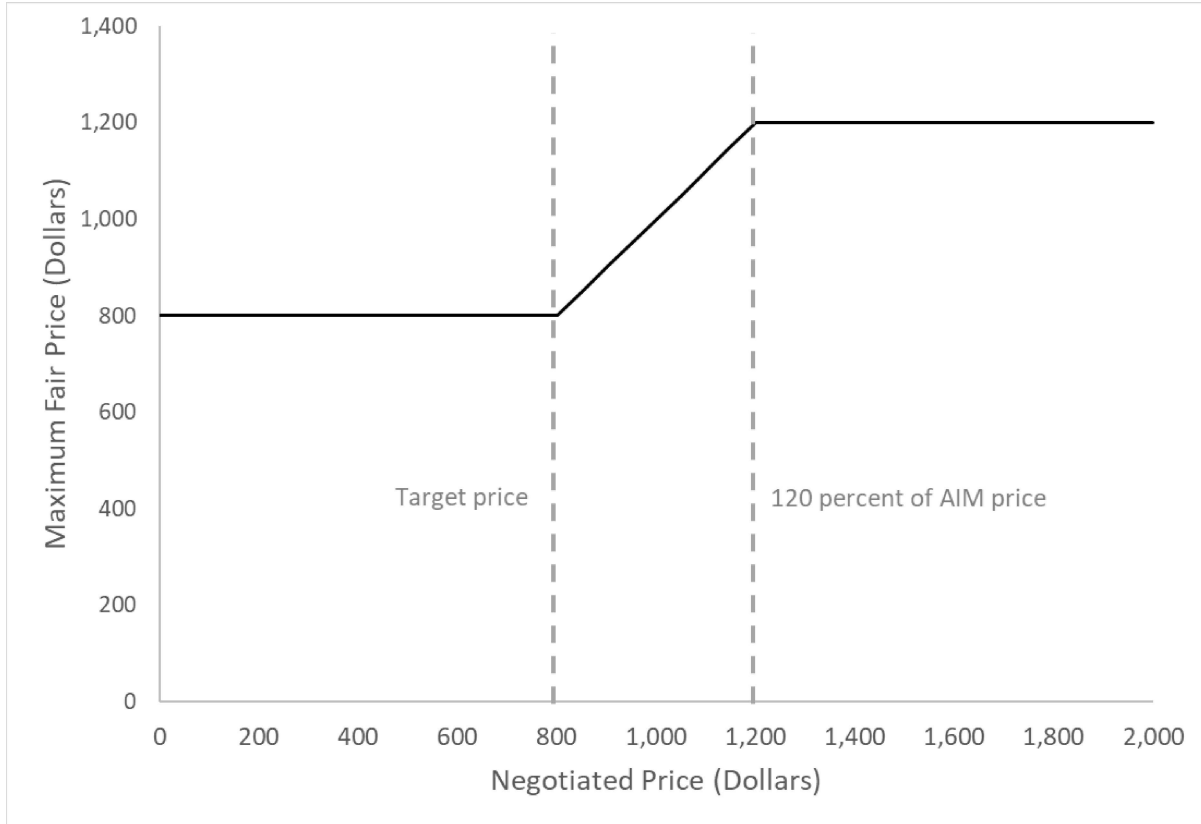
Data source: Congressional Budget Office.

AIM = average international market; CEA = Council of Economic Advisers; HHS = Department of Health and Human Services; MFP = maximum fair price; SOC = standard of care; VSL = value of statistical life; WTP-Q = willingness to pay for an additional quality-adjusted life year.



# Figures

**Figure 1: The Maximum Fair Price As Determined by the Negotiated Price, the Target Price, and the AIM Price**

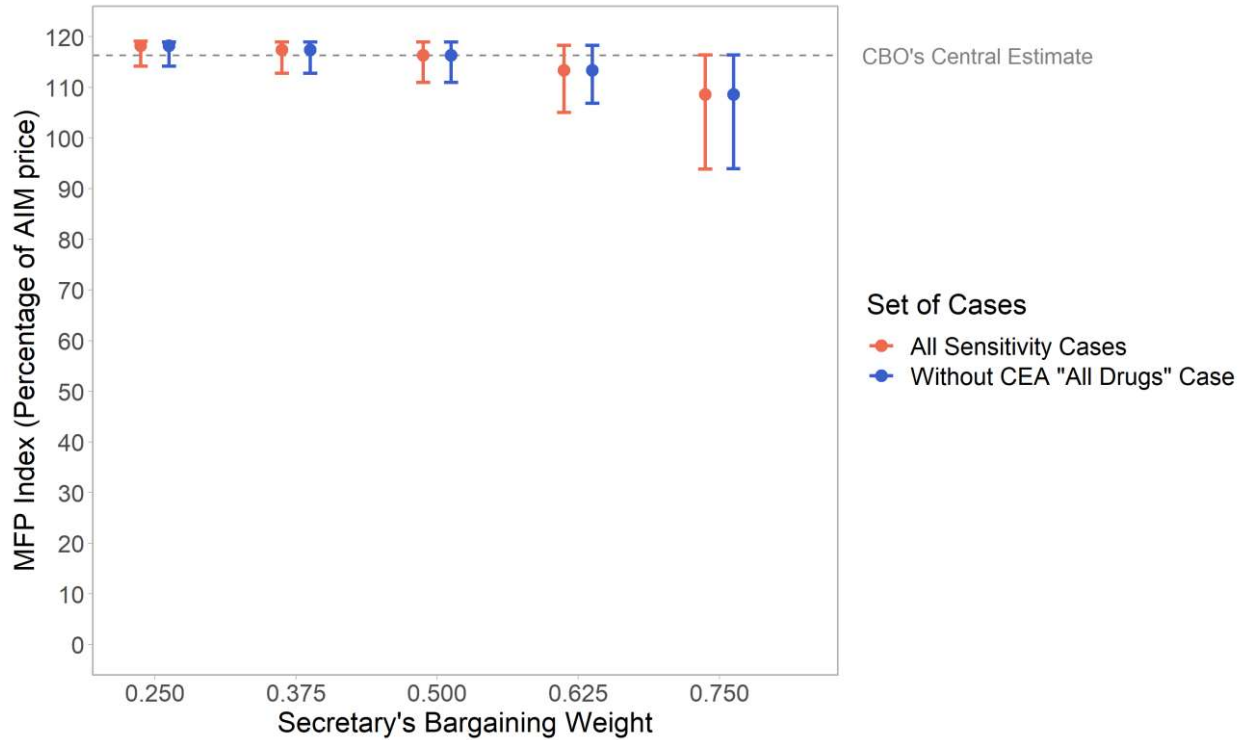


Data source: Congressional Budget Office.

The maximum fair price is plotted as a function of the negotiated price under a hypothetical scenario in which the target price is \$800 and the AIM price is \$1,000.

AIM = average international market.

**Figure 2: Sensitivity Range of the MFP Index As a Percentage of the AIM Price**

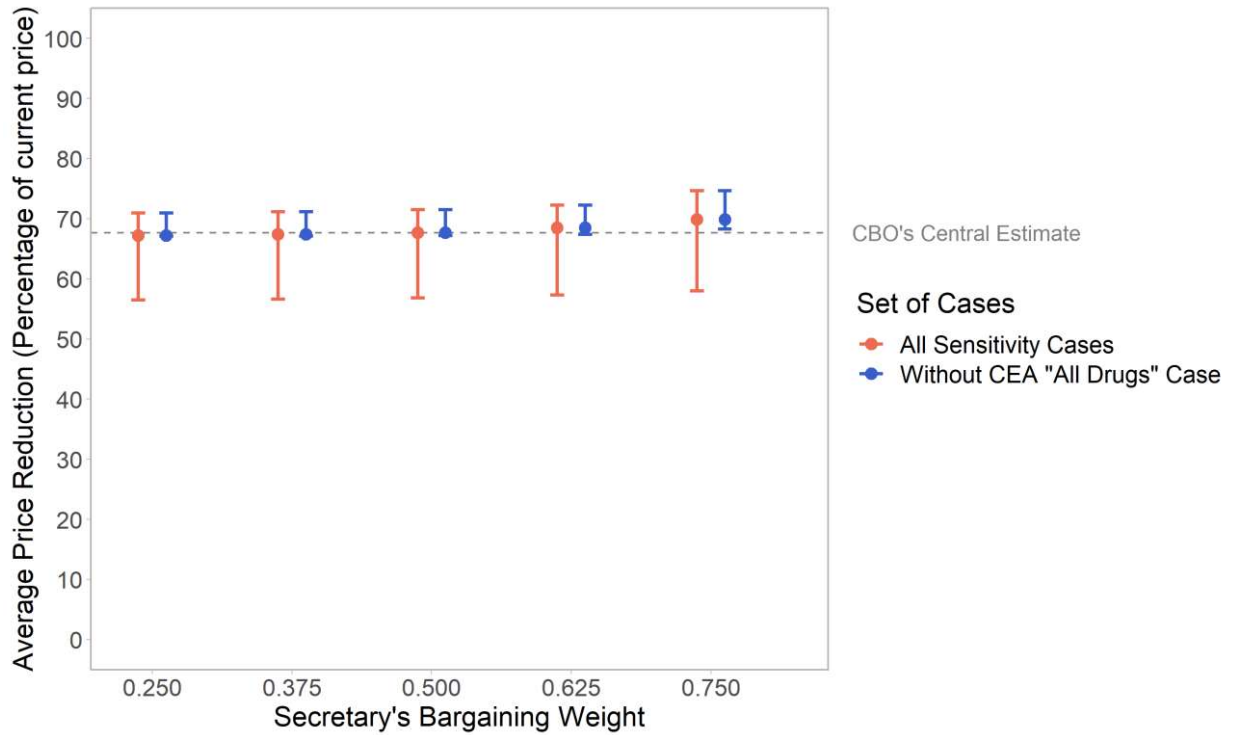


Data source: Congressional Budget Office.

There are a range of MFPs associated with a given value of the Secretary’s bargaining weight. The dot indicates the MFP holding all parameters at their central values, except for the bargaining weight. The orange series includes the full set of sensitivity cases. The blue series omits any sensitivity case for which the international prices were determined using CEA’s price ratio that was calculated using both retail and nonretail drugs.

AIM = average international market; CEA = Council of Economic Advisers; MFP = maximum fair price.

**Figure 3: Sensitivity Range of the Average Price Reduction Relative to Current Prices**

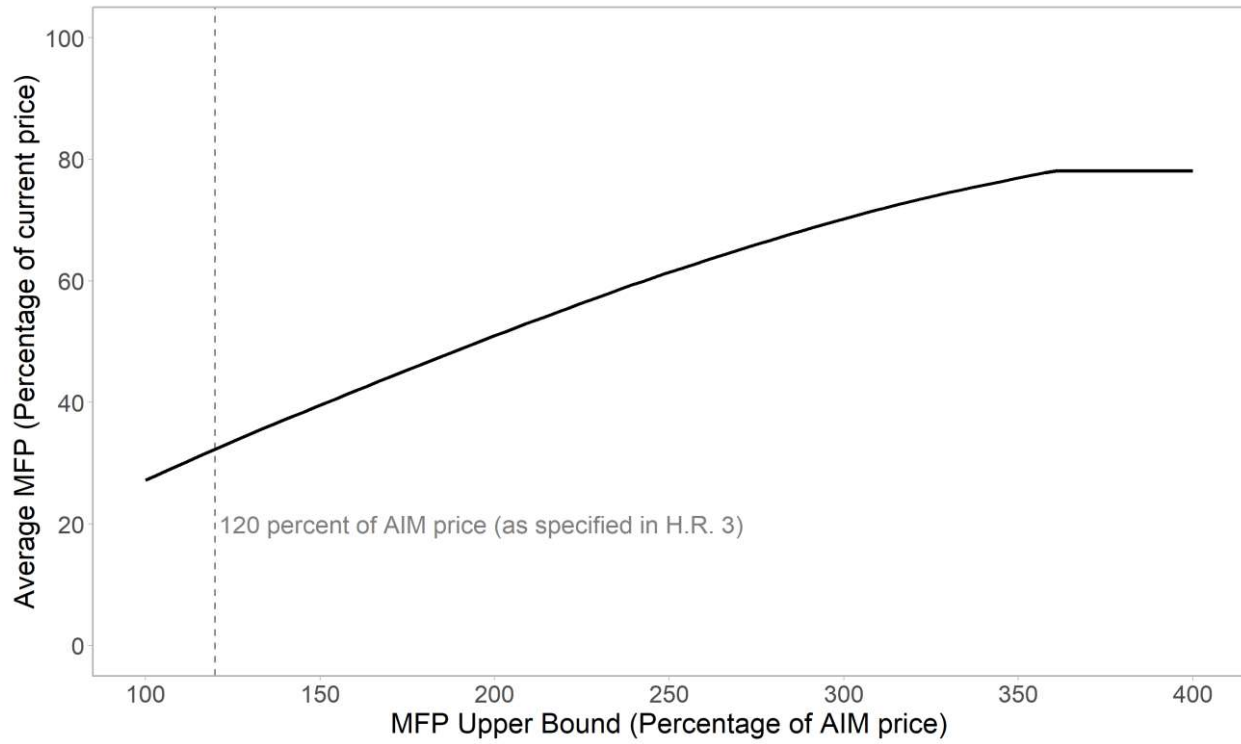


Data source: Congressional Budget Office.

There are a range of prices associated with a given value of the Secretary's bargaining weight. The dot indicates the price holding all parameters at their central values, except for the bargaining weight. The orange series includes the full set of sensitivity cases. The blue series omits any sensitivity case for which the international prices were determined using CEA's price ratio that was calculated using both retail and nonretail drugs.

CEA = Council of Economic Advisers.

**Figure 4: Effect of the MFP Upper Bound on Average MFPs Relative to Current Prices**



Data source: Congressional Budget Office.

AIM = average international market; MFP = maximum fair price.

## Appendix: The Maximum Fair Price in a Rubinstein Alternating-Offers Model

This appendix contains a derivation of the maximum fair price using the strategic bargaining model from Rubinstein (1982).<sup>37</sup> The parties take turns making offers and counteroffers until an agreement is reached. As the length of time between offers gets smaller, the subgame perfect equilibrium (SPE) of the Rubinstein model converges to the solution of an appropriately defined Nash bargaining model.

Suppose, without loss of generality for the final result, that the Secretary of the Department of Health and Human Services makes the first price offer. The drug manufacturer then decides whether to accept that price or make a counteroffer in the next period. That back-and-forth continues for an infinite number of periods, which can be interpreted as the idea that there is always time for another offer. If the parties perpetually reject each other's offers, the drug is taken off the market, and both parties get zero payoff.<sup>38</sup>

The notation for the model is described in **Table A-1**.<sup>39</sup> If an offer  $p$  is accepted in period  $t$ , the Secretary gets  $\delta_s^t(V - p)$  and the manufacturer gets  $\delta_m^t p$ .

**Table A-1: Notation Used in the Rubinstein Model**

Parameter	Description
$p_s, p_m$	Potential offers made by the Secretary ( $s$ ) and the manufacturer ( $m$ ).
$r_i$	The discount rate of party $i$ .
$\Delta$	The amount of time between offers.
$\delta_i$	The discount factor of party $i$ , equal to $\exp(-r_i \Delta)$ .
$\underline{p}, \bar{p}$	The target price and 120 percent of the average international market price, respectively.
$V = e - e_a + p_a$	The surplus from an agreement (the incremental clinical benefit plus the cost of the next-best alternative treatment).

Data source: Congressional Budget Office.

<sup>37</sup> See Ariel Rubinstein, "Perfect Equilibrium in a Bargaining Model," *Econometrica*, vol. 50 (1982), pp. 9–110.

<sup>38</sup> That outcome corresponds to the payoff from a failed negotiation in the Nash bargaining model.

<sup>39</sup> To save on notation, the model is expressed in per-beneficiary, per-year terms. As in the Nash bargaining framework in the main body of the paper, the number of beneficiaries does not affect the MFP if it does not vary with the price.

The SPE is the following: The Secretary always offers  $p_s^*$  and accepts any offer from the manufacturer  $p_m \leq p_m^*$ , whereas the manufacturer always offers  $p_m^*$  and accepts any offer from the Secretary  $p_s \geq p_s^*$ , where:

$$p_m^* = \begin{cases} \underline{p}, & \mu V < \underline{p} \\ \mu V, & \mu V \in [\underline{p}, \bar{p}] \\ \bar{p}, & \mu V > \bar{p} \end{cases}$$

and

$$p_s^* = \begin{cases} \delta_m \underline{p}, & \mu V < \underline{p} \\ \delta_m \mu V, & \mu V \in [\underline{p}, \bar{p}] \\ \delta_m \bar{p}, & \mu V > \bar{p} \end{cases}$$

and  $\mu = \frac{1-\delta_s}{1-\delta_s\delta_m}$ .

Confirming that a set of strategies constitutes an SPE requires checking that both parties are making optimal decisions in each possible period, assuming the other party does not otherwise deviate from its potential equilibrium strategy. The confirmation of the SPE when  $\mu V \in [\underline{p}, \bar{p}]$  closely follows Proposition 3.1 in Muthoo (1999).<sup>40</sup>

If  $\mu V < \underline{p}$ , the target price constrains the offers. If it is the Secretary's turn to make an offer, he or she knows that if that offer is rejected, the manufacturer will offer  $\underline{p}$  and the Secretary will accept it. However, the manufacturer incurs a cost from waiting for a period. From the perspective of this round of offers, the manufacturer's payoff from rejecting the Secretary's offer and offering  $\underline{p}$  is  $\delta_m \underline{p}$ . Thus, if the Secretary offers a price of  $\delta_m \underline{p}$ , the manufacturer will accept it. If the Secretary tries to offer a slightly lower price, the manufacturer will prefer to reject the offer, so the Secretary is making the best possible offer that will be accepted. On the other side, when it is the manufacturer's turn to make an offer and it offers  $\underline{p}$  (the target price), the Secretary must accept the offer as per H.R. 3, which completes the proof.

When  $\mu V > \bar{p}$ , the upper bound (120 percent of the AIM price) constrains the offers. If it is the Secretary's turn to make an offer, he or she knows that if that offer is rejected, the manufacturer will offer  $\bar{p}$ , and the Secretary will accept it. From the perspective of this round of offers, the

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<sup>40</sup> See Abhinay Muthoo, *Bargaining Theory With Applications* (Cambridge University Press, 1999), pp. 45–46, <https://doi.org/10.1017/CBO9780511607950>.

manufacturer's payoff from rejecting the Secretary's offer and offering  $\bar{p}$  is  $\delta_m \bar{p}$ . Thus, if the Secretary offers a price of  $\delta_m \bar{p}$ , the manufacturer will accept it. If the Secretary tries to offer a slightly lower price, the manufacturer will prefer to reject the offer, so the Secretary is making the best possible offer that will be accepted. On the other side, when it is the manufacturer's turn to make an offer and it offers  $\bar{p}$  (120 percent of the AIM price), the Secretary accepts the offer if the payoff from accepting, which is  $V - \bar{p}$ , is at least as large as the discounted payoff from rejecting the offer and having his or her next offer accepted, which is  $\delta_s(V - \delta_m \bar{p})$ . That condition is equivalent to whether  $\frac{(1-\delta_s)}{(1-\delta_m\delta_s)}V = \mu V \geq \bar{p}$ , which it is, since  $\mu V > \bar{p}$ . Because the manufacturer cannot have an offer higher than  $\bar{p}$  accepted (per H.R. 3), the manufacturer cannot do better than offering  $\bar{p}$ , which completes the proof.

The SPE in the standard Rubinstein model corresponds to the standard Nash bargaining solution when the time between offers ( $\Delta$ ) becomes arbitrarily small. In that case,  $\delta_s \rightarrow 1$ ,  $\delta_m \rightarrow 1$ , and  $\mu \rightarrow \frac{r_s}{r_s+r_m}$ . In the case of the MFP negotiation, the outcome of the SPE converges to:

$$p = \begin{cases} \underline{p}, & \text{if } \left(\frac{r_s}{r_s+r_m}\right)V < \underline{p} \\ \left(\frac{r_s}{r_s+r_m}\right)V, & \text{if } \left(\frac{r_s}{r_s+r_m}\right)V \in [\underline{p}, \bar{p}] \\ \bar{p}, & \text{if } \left(\frac{r_s}{r_s+r_m}\right)V > \bar{p} \end{cases}$$

That is the solution to CBO's Nash bargaining model if the manufacturer and the Secretary have bargaining weights equal to  $\frac{r_s}{r_s+r_m}$  and  $\frac{r_m}{r_s+r_m}$ , respectively, and the MFP is bounded by  $\underline{p}$  and  $\bar{p}$ .