



July 31, 2023

Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W. Washington, DC 20201

Dear Administrator Brooks-LaSure:

Arnold Ventures welcomes the opportunity to provide comments to the Office of Management and Budget on the Information Collection Request:

Information Collection Request for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (CMS-10847)

Arnold Ventures (AV) is a philanthropy dedicated to investing in evidence-based policy solutions that maximize opportunity and minimize injustice. Our work within the health care sector is driven by the recognition that the system costs too much and fails to adequately care for the people it serves. Our work spans a range of issues including commercial-sector prices, provider payment incentives, prescription drug prices, clinical trials, Medicare sustainability, and complex care.

Under the Inflation Reduction Act (IRA), manufacturers are required to report certain data to the Secretary to support the negotiations process, including the non-Federal Average Manufacturer Price, research and development (R&D) costs, unit costs, prior federal financial support for research and development, US and worldwide net sales of the selected drug, and patents and exclusivity periods that cover the selected drug. CMS requires these data to implement the negotiations process as directed by the IRA. Manufacturers, academics, clinicians, patients, patient groups and any other interested parties have the option to submit data on therapeutic alternatives to the selected drug and studies on comparative effectiveness.

We thank you for the opportunity to provide comments about CMS's data collection requirements. This letter focuses on the following categories of data: (I) data to assess recoupment of R&D Costs, (II) patent data, and (III) data on therapeutic alternatives.

I. Data to Assess Recoupment of R&D Costs

Adjusting Monetary Values for the Cost of Capital. CMS plans to use data collected from manufacturers on R&D costs and net revenues to determine whether R&D costs have been recouped at the time of negotiation. This is a factor that CMS will consider when determining its initial offer price.

Many top selling drugs likely to be selected for negotiations have been on the market many years and have worldwide sales in the billions of dollars. This means that it is likely that the profit stream generated from sales of these drugs could far exceed their development costs. In order to determine this, CMS can compare the capitalized costs of R&D to the present discounted value of returns. To facilitate that analysis, CMS should request that the manufacturer use the same cost of capital to adjust both R&D costs and the present value of net revenues. We also recommend that those dollar amounts be adjusted to the same year (such as the date that the drug was first sold in the US). In order to compare R&D costs to the returns, those monetary flows over time must be adjusted by the cost of capital to the same year. If the manufacturer reports



R&D costs capitalized to the current year, CMS will need to adjust those amounts to the date that the drug was first approved in order to make the R&D costs reported by the manufacturer comparable to estimates of R&D costs in the published literature.¹

Reporting Spending on Clinical Trials. CMS should request that spending on clinical trials be separated between clinical trials that took place prior to the drug's approval and those that took place after first marketing of the drug (post marketing clinical trials). Much of the cost of R&D is the cost of capital for investing in the development of the drug *prior* to receiving any revenues from its sales. Isolating spending on clinical trials that took place prior to approval will help CMS better understand the contribution of the cost of capital to total R&D costs as well as the amount of R&D spending that occurred at the riskier stage prior to drug approval.

Reporting Spending on Failed Drug Candidates. CMS should seek additional descriptive information about spending on drug candidates that were never approved to help it assess the share of such spending that should be included in R&D costs. Manufacturer should provide CMS with a brief description of how each failed drug candidate relates therapeutically to the selected drug (such as treating the same disease using a similar mechanism of action) and the timeframe during which the spending occurred.

CMS should limit the amount of time that the manufacturer can reach back to include failed drug candidates in R&D costs—particularly if the manufacturer is allowed to capitalize those costs at a rate of up to 8.1 percent as noted in the final guidance. Since those investments could have begun 10 years or more before the development process began for the selected drug, the manufacturer should also report the share of reported spending on failed projects that can be accounted for by the cost of capital.² This information will help CMS to assess reported spending on failed drug candidates and determine the share of such spending that should be attributed to R&D costs for the selected drug.

Sales Revenues. When collecting sales data, CMS should request net sales data for the US and worldwide for a single recent year. That information should not be difficult for the manufacturer to provide and will help CMS to assess the size of the Medicare market relative to US and worldwide sales. This could help CMS to understand the potential relative impact of negotiations on the manufacturer's profits. For example, if Medicare sales are small relative to worldwide sales, then it may be easier for the manufacturer to absorb a lower Maximum Fair Price (MFP) because a smaller share of profits from the drug's sales would be affected by the MFP.

Taxes and R&D Costs. Some studies of R&D costs have accounted for the fact that if the company had not invested in R&D, then those earnings would have been taxed as profits. Most R&D spending by large pharmaceutical companies is financed from the revenues of drug sales.³ For large pharmaceutical companies that finance R&D in this way, their marginal tax rate should also

¹ [Estimating the Cost of Industry Investment in Drug Research and Development: A Review of Methods and Results - Stephanie Rennane, Lawrence Baker, Andrew Mulcahy, 2021 \(sagepub.com\)](#)

² Monetary values double after 10 years using a cost of capital of 8.1 percent.

³ [Research and Development in the Pharmaceutical Industry \(cbo.gov\)](#)



be considered when estimating R&D costs.⁴ For example, if a company spent \$1 billion on R&D but their corporate tax rate was 20%, then the actual cost to the company was \$800 million.

II. Patent Data

When collecting data from the manufacturer on patents that cover the selected drug, the manufacturer should be required to report all patents that were applied for or issued as of the date the drug was selected for negotiations. The form currently asks for patents that were issued or applied for prior to the NDA approval date. But we know that many drugs are covered by patents that were applied for after the drug was approved by the FDA.⁵

In addition, CMS should request that the manufacturer flag those patents where a generic or biosimilar manufacturer has obtained a court decision that the patent is not valid or not infringed. This would help CMS to better understand the extent to which the manufacturer has attempted to limit competition through excessive patenting.

III. Data on Therapeutic Alternatives

Patient Reported Data. AV strongly supports CMS's decision to collect information from individual patients and their caregivers on patient experience with the drug or its therapeutic alternatives, impacts on health, side effects, impact on quality of life, and any challenges accessing the drug, for example, because of issues with affordability.

Academics and Patient Groups. AV strongly supports the ability of academics, patient groups, health care providers and other interested parties to submit data on therapeutic alternatives and comparative effectiveness to CMS by October 1, 2023 to strengthen the information available to CMS during the negotiation process.

Conclusion

AV is prepared to assist with any additional information needed. Comments were prepared by Anna Anderson-Cook Ph.D. with assistance from Andrea Noda, MPP, Vice President of Health Care at Arnold Ventures and Mark E. Miller, Ph.D. Executive Vice President of Health Care at Arnold Ventures.

Please contact Andrea Noda at anoda@arnoldventures.org or Mark E. Miller, Ph.D. at mmiller@arnoldventures.org with any questions.

Sincerely,

Andrea Noda
Vice President of Health Care
Arnold Ventures

⁴ For example, if the company spent \$1 billion on R&D but their corporate tax rate during the drug's development was 20%, then the actual cost to the company was \$800 million (because they would have paid \$200 million more in taxes had they not invested those funds in R&D).

⁵ See for example the work by IMAK [Overpatented, Overpriced – I-MAK](#) and also by Robin Feldman [Evergreen Drug Patent Database - UC College of the Law \(uclawsf.edu\)](#)