Bristol Myers Squibb™

VIA ELECTRONIC DELIVERY

July 31, 2023

Office of Management and Budget (OMB)
725 17th St NW
Washington, DC 20503
Attention: OMB Desk Officer

Re: Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)

Dear OMB,

Bristol Myers Squibb (BMS) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) *Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA)* ("Negotiation Data Elements ICR" or "ICR").[1]

At BMS, we are inspired by a single vision—transforming patients' lives through science. We are in the business of breakthroughs—the kind that transform patients' lives through lifesaving, innovative medicines. Our talented employees come to work every day dedicated to the mission of discovering, developing, and delivering innovative medicines that help patients prevail over serious diseases. We combine the agility of a biotech with the reach and resources of an established pharmaceutical company to create a global leading biopharma company. In oncology, hematology, immunology, and cardiovascular disease—with one of the most diverse and promising pipelines in the industry—we focus on innovations that drive meaningful change.

BMS supports Medicare policies that promote beneficiary access to new and effective medical treatments and help ensure Medicare patients benefit from the innovation that defines the U.S. health care system. That is why we do not support the Medicare "negotiation" and price setting policies contained in the *Inflation Reduction Act (IRA)*. We are extremely concerned by the impact that these policies will have on clinical research and future innovation for patients. For these reasons, BMS has filed a federal lawsuit asking a court to declare the IRA unconstitutional. BMS believes that, in the absence of full repeal of the IRA's drug pricing provisions, significant clarity and reforms are necessary in several critical areas. Although our comments are designed to help CMS in these areas as it implements the process that Congress established in the IRA, nothing we say in this comment letter should be construed as suggesting that CMS can cure the constitutional flaws in the statute that Congress wrote.

[1] 88 Fed. Reg. 42,722 (July 3, 2023); CMS, "Agency Information Collection Activities: Submission for OMB Review; Comment Request," *available at* https://www.federalregister.gov/documents/2023/07/03/2023-14176/agency-information-collection-activities-submission-for-omb-review-comment-request#addresses.

The IRA will have vast ramifications for patients, providers, manufacturers, and other stakeholders across the country. BMS is concerned that CMS' implementation of the IRA could have sweeping negative repercussions with respect to Medicare beneficiary access to needed medicines, and, indeed, for all patients. It is vital for CMS to give meaningful consideration of and response to stakeholder feedback on its proposals.

BMS believes that it is essential for CMS to develop and finalize a process that allows stakeholders to reasonably predict how price setting will operate in practice. Any "negotiation" under the IRA should include full transparency regarding stakeholders' comments and CMS' interpretation and evaluation of such comments. BMS urges CMS to commit to a process without arbitrary limitation on the scope of such dialogue (*e.g.*, through limitation of meetings and/or limitations on dossier submission length). Not only is such commitment necessary to effectuate Congress's intent, but it will also promote greater transparency and information sharing. We also believe it will be readily manageable for the Agency, given the limited number of drugs subject to "negotiation" in any given year.

BMS appreciates the opportunity to provide the following comments on the Negotiation Data Elements ICR. As with our comments on the initial Medicare "Negotiation" Guidance[2] and initial Negotiation Data Elements ICR,[3] our recommendations reflect and are driven by our deep expertise in pharmaceutical innovation and global value assessment processes, and we offer them to help mitigate against the unintended and negative consequences the Guidance and ICR would have on innovation and, most importantly, patients.

Key comments include:

- **Inappropriateness of Methodology:** BMS strongly asserts that CMS should place more emphasis on the clinical, societal, and therapeutic value of a selected drug, which are true indicators of innovation, and not engage in an unclear, burdensome, and arbitrary approach based on historical manufacturer-specific information. The statute lists basic categories of manufacturer-specific information (also known as the 1194(e)(1) factors) that CMS can require from manufacturers for the determination of the "Maximum Fair Price" ("MFP"), as well as evidence about alternative treatments, as applicable (also known as the 1194(e)(2) factors). We are concerned that CMS incorrectly and inappropriately places significantly greater emphasis on the former, without much consideration of the latter. BMS does not support this approach. In fact, the World Health Organization (WHO) cautions against countries using cost-plus pricing as a primary policy for setting the price of pharmaceutical products, and notes that the method has not been widely used.[4] Yet CMS states it will adjust the preliminary price of a selected drug on the basis of these manufacturer-specific data described in 1194(e)(1) "… in totality and apply an upward adjustment, downward adjustment, or no adjustment… and may consider each factor in isolation or in combination with other factors."[5] Further, CMS deviates from the Paperwork Reduction Act regulations, which require an Agency to take "every reasonable step to ensure that the proposed collection of information… has practical utility…"[6] among other tenets. The lack of specificity and unclear explanation in CMS' methodology for adjusting pricing based on the data described in 1194(e)(1) exposes its purported cost-based methodology as

[2] CMS, "Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments" (March 15, 2023), *available at* https://www.cms.gov/files/document/medicare-drug-price-negotiation-program-initial-guidance.pdf; CMS, "Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026" (June 30, 2023), *available at* https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.

[3] 88 Fed. Reg. 16,983 (March 21, 2023); CMS, "Information Collection Request (ICR) Form for Negotiation Data Elements under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB 0938-NEW)," *available at* https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10847.

[4] WHO, "WHO guideline on country pharmaceutical pricing policies" (Sept. 2020), *available at* https://www.who.int/publications/i/item/9789240011878.

[5] Medicare "Negotiation" Guidance at 150.

[6] 5 C.F.R. §1320.5(d)(1)(i)-(iii).

merely conceptual without practical utility. Data used in an arbitrary and variable manner will result in setting prices that are equally arbitrary and random. For these reasons, CMS should place greater emphasis on metrics which approximate the value that these medicines provide (the 1194(e)(2) factors).

- **Scope, Burden, and Confidentiality of Information:** BMS is concerned with the scope, burden, and confidentiality of information CMS will require. While CMS is directed to seek basic manufacturer-specific data for the purposes of determining an MFP, the Agency has greatly expanded its reach and added extraordinarily complicated and intrusive data elements that appear unnecessary for the determination of this MFP. In addition, manufacturers will have exceedingly short timeframes for completing and submitting the manufacturer-specific data and optional evidence about alternative treatments (at most, 31 days from the date of selection on September 1, 2023, and the submission date on October 2, 2023). Some of the requested data, such as government price reporting information, are already available to CMS, while others are publicly available, creating additional and unnecessary burden on manufacturers. It is also not clear what CMS' legitimate need is for pricing metrics beyond non-FAMP, which is the only pricing metric explicitly listed in the IRA statute, and/or those that approximate the Medicare market (as this is a Medicare pricing scheme only). Even for the data elements that manufacturers *can* provide, the breadth of information coupled with the strict timelines will make the burden exceptionally high and the submission perhaps impossible to complete and submit on time. Moreover, there may be information to which manufacturers do not reasonably have access or cannot provide with reasonable efforts. We urge CMS to critically consider which data elements are actually necessary for determining the MFP and compile said elements in the least burdensome way.
- **Value Assessment and Evidence About Alternative Treatments:** While we appreciate CMS' willingness to make several positive changes to the value assessment process—including, but not limited to, an additional manufacturer meeting in Fall 2023 and flexibilities related to evidence submission format—we strongly urge the Agency to make additional clarifications as well. BMS would like the Agency to clarify that supporting text included in the accepted tables/charts/graphs, such as chart titles, labels, legends, and footnotes related to the visual representation, will be considered and reviewed by CMS as necessary contextual components. It is also critical for CMS to ensure that manufacturers are permitted to receive redacted evidence submitted by other stakeholders in advance of the Fall 2023 meeting to facilitate an important dialogue prior to an "offer" exchange, or plan for one additional meeting before an initial offer to allow for discussion regarding redacted evidence submissions. While CMS stated in its Medicare "Negotiation" Guidance that it will "strive to share the section 1194(e)(2) data submitted by the public with the Primary Manufacturer of a selected drug during the negotiation period…"[7] CMS should ensure that the manufacturer receives it with adequate time to respond and engage with CMS about it. BMS also recommends that unmet need be considered from initial approval to the time of assessment. Additional value should be particularly considered for those medications that treat serious medical conditions, including those that make incremental steps toward curative goals. Further, unmet need should be viewed from the perspective of patients and providers. Unmet need should accordingly encompass a spectrum of characteristics, such as: alternative dosing regimens; route of administration; reduction of side effects; and shorter treatment periods.

General Instructions

- Transparency and Clarity: In response to stakeholder feedback in both the Medicare "Negotiation" Guidance and initial Negotiation Data Elements ICR seeking additional detail on how negotiation factors would be weighted and how evidence would be evaluated and prioritized, CMS notes that it "believes it is important to maintain flexibility when considering how each negotiation factor contributes" as "unique characteristics" and other

[7] Medicare "Negotiation" Guidance at 67.

information may impact these negotiation factors.[8] Yet, elsewhere in the Medicare "Negotiation" Guidance, in response to stakeholders seeking flexibility when submitting highly detailed and complex data elements, the Agency notes it will *not* permit reasonable assumptions as submissions must be "based on consistent definitions and scope."[9] CMS has seemingly chosen to inconsistently apply flexibility related to the Negotiation Data Elements ICR process. For example, while we appreciate that each drug and patient population is unique, we believe that the lack of methodology and transparency in how the data elements will be weighted is a significant limiting factor that does not allow manufacturers to adequately prepare for the "negotiation" process. And while we appreciate that CMS has provided some instructions and definitions related to the data submission, we note that CMS has not considered every necessary detail of that submission, including but not limited to factors such as cost of capital and lifetime net revenues. BMS strongly supports the need for additional transparency and clarity, but in the absence of such necessary detail, manufacturers must be able to make reasonable assumptions when submitting data elements to CMS. This becomes even more critical when, despite reasonable and good-faith efforts to comply with CMS' new and detailed requirements under short timelines, manufacturers could be subject to significant civil monetary penalties (CMPs) should there be an error or miscalculation in submitting these data elements. While our comments seek to highlight key areas where CMS has not provided critical clarity and transparency, we note that our comments are not exhaustive in that regard.

- "Primary Manufacturers": The Medicare "Negotiation" Guidance introduced the concept of "Primary Manufacturers" and "Secondary Manufacturers." The Negotiation Data Elements ICR affirms such terms, noting that the Primary Manufacturer is "responsible for aggregating and reporting all necessary data on its selected drug(s) from other parties, as applicable."[10] BMS does not agree with this approach, which is found nowhere in the statute and, at the very least, could not be imposed without proper rulemaking procedures. Primary Manufacturers may not have the legal authority to obtain such information from Secondary Manufacturers, as CMS has recognized in other contexts. And Primary Manufacturers have no ability to attest to, nor would it be appropriate for them to opine on, the data of another manufacturer. It is also impractical and unnecessary. **CMS should not require manufacturers to report information that is practically and legally unavailable to them.**

- Confidentiality of Submitted Information: While not explicitly discussed in the ICR, we agree with CMS that the Agency should ensure confidential commercial information submitted by manufacturers during the "negotiation" process is protected from disclosure and wish to reiterate several specific considerations. **We believe it is imperative that CMS ensure adequate safeguards to protect manufacturers' trade secret, proprietary, and other confidential commercial information from disclosure, including the opportunity for manufacturers to receive notice of potential disclosure and the opportunity to object to such disclosure.** One suggestion to aid in facilitating the identification of proprietary information, which is utilized by certain states for price transparency reporting, is for CMS to allow manufacturers to proactively designate which data are confidential and proprietary, and therefore not subject to public disclosure. This would help remove potential ambiguity from CMS determinations that information is "already publicly available."[11] BMS also asks CMS to carefully consider how the Agency intends to keep such information confidential within the Agency itself. CMS notes that manufacturers will submit the data dossier via the Health Plan Management System (HPMS) but does

[8] *Id.* at 57.
[9] *Id*. at 81-82.
[10] Negotiation Data Elements at 2.
[11] In the Medicare "Negotiation" Guidance, at p. 123, CMS notes that it will "will treat research and development costs and recoupment, unit costs of production and distribution, pending patent applications, market data, revenue, and sales volume data as proprietary, unless the information that is provided to CMS is already publicly available, in which case it would be considered non-proprietary."

not detail the safeguards for ensuring data security and confidentiality, and accordingly, we ask the Agency to consider measures to ensure the confidentiality of proprietary information.

- Instructions for Reporting Monetary Amounts: CMS is finalizing its policy that when calculating monetary values, manufacturers should assume at most an 8.1 percent annual cost of capital.[12] While BMS appreciates CMS acknowledging our concerns with this metric in the revised Medicare Negotiation "Guidance,"[13] we wish to reiterate our belief that the Agency inadequately considers a manufacturer's capital costs, and the cap on that cost appears to be arbitrary and uninformed. This approach further penalizes manufacturers as CMS does not seem to allow for any adjustments in future interest or inflation rate changes. In fact, in the "Research and Development in the Pharmaceutical Industry" report, in which CMS cites as supporting rationale, the Congressional Budget Office (CBO) notes that R&D costs "have increased by about *8.5 percent* per year over roughly the past decade."[14] In addition, when adjusted for inflation, pharmaceutical industry spend on R&D has increased over 10 times since the 1980s.[15] **Therefore, we strongly urge CMS to apply flexibility in its approach and remove the cap on the cost of capital or, at a minimum, allow manufacturers to adjust that cap appropriately based on interest and inflation rate levels in any given year.**

Research and Development Costs and Recoupment

BMS continues to remain highly concerned that the data elements that CMS will use to establish the MFP do not adequately capture the value and benefit of a drug to patients and the broader health care system. CMS should balance these factors such that the Agency prioritizes rewarding innovation and preserving advancements in patient care. In contrast, placing a greater emphasis on R&D recoupment, as the Agency seeks to do, is a flawed approach that ignores certain biopharmaceutical realities—such as the high risk-reward of pharmaceutical innovation and the wide range of costs incurred beyond R&D. CMS must consider metrics that provide a more complete picture of the drug development and commercialization process to contextualize this broader investment. **BMS strongly urges CMS to place a lesser emphasis on R&D recoupment, and more emphasis on the selected drug's therapeutic and clinical attributes which is the true measure of innovation.**

While BMS appreciates CMS' acknowledgement of our recommendation to establish a uniform starting point across data collections,[16] we are disappointed that the Agency has not adopted this standard. **We continue to encourage CMS to establish a more thoughtful, forward-looking framework (*i.e.,* not retrospective) and tie reporting to the nearest month or quarterly cutoff in the future as we believe it is impossible for manufacturers to comply with reporting dates selected arbitrarily by CMS. We are concerned that if CMS were to use an arbitrary look-back period, it could disadvantage and unfairly penalize manufacturers for previous pricing practices and data collection before the law went into effect.** We want to emphasize the difficulty of obtaining pre-clinical and post-investigational new drug (IND) spend which could be for timeframes occurring more than 15 years ago. At that time, there was no way to foresee that the federal government would have mandated data reporting, so the record-keeping was not designed with that end in mind. Manufacturers also need time to establish systems to collect this information and may not be able to retrieve historical data from previous information systems that are no longer utilized, and we ask CMS to consider extending the maximum amount of flexibility in this process.

[12] Negotiation Data Elements at 4.
[13] Medicare "Negotiation" Guidance at 87-88.
[14] Congressional Budget Office (CBO), "Research and Development in the Pharmaceutical Industry" (April 2021), p. 16 (emphasis added), *available at* https://www.cbo.gov/publication/57126#footnote-055.
[15] *Id*. at 5.
[16] Medicare "Negotiation" Guidance at 86.

Our specific comments on the "Research and Development Costs and Recoupment" elements follow.

- Primary Manufacturer Acquisition Costs of the Selected Drug: BMS agrees with CMS' approach to considering primary manufacturer acquisition costs of the selected drug and thanks the Agency for acknowledging that these costs most appropriately fall under the definition of R&D and not market data, revenue, and sales volume data. Costs associated with one manufacturer acquiring another is a common practice of unlocking innovation and should be viewed as inseparable from total R&D costs. In addition to acquisition costs, it is also critical that CMS considers costs of in-licensing, joint ventures, co-commercialization agreements, partnerships, and other forms of acquisition as each contributes individually but significantly to a manufacturer's R&D capabilities and results in innovative medicines being delivered to patients who need them.

- Basic Pre-Clinical Research for All Approved Indications of the Selected Drug: While we appreciate that CMS has revised its guidance to clarify that the relevant reporting period for basic pre-clinical research costs begins on the later of the date of initial discovery or the date the Primary Manufacturer acquired the right to hold the New Drug Applications (NDAs)/Biologic License Applications (BLAs) of a selected drug,[17] we note that other critical concerns have not been addressed. For example, we believe that the Agency has not communicated a data request that considers a full and complete perspective of pharmaceutical development and has instead identified irrelevant and inappropriate factors for consideration. Compiling and calculating R&D costs for a drug that has been on the market for over a decade is a complicated process that is not easily reduced to a finite set of specific considerations, factors, or other items. We note that it is inappropriate to create a framework that not only considers historical or lifetime data reflective of early research but also assumes that the manufacturer can access information that was not required to be captured and reported previously. Furthermore, requesting manufacturers to retrospectively collect asset-level pre-clinical data is not feasible. We urge CMS to consider a more precise method: the Agency should invest the time in establishing forward-looking reporting requirements that start on a future date. We request that CMS utilize an individual calendar year as a starting point for all manufacturers' selected drug information.

- Post-IND Costs for All Approved Indications of the Selected Drug: BMS wishes to reiterate that manufacturers need clarification on the data elements that would satisfy CMS' inquiry on costs associated with "preparing the selected drug for clinical trials."[18] Additional context is needed to determine if this requirement refers to manufacturing costs or costs associated with the drug development process, as CMS' request is vague. CMS repeatedly refers to "personnel" in this question and elsewhere in the Negation Data Elements ICR. BMS requests that CMS define "personnel" and explicitly consider both the internal and external function service providers that support and are directly associated with the study. It is vital that CMS assess these costs in totality when determining the initial MFP price and consider all direct and indirect costs that the manufacturer incurs throughout the life cycle of the selected drug.

  In addition, BMS recognizes that CMS has removed the "Costs of All Post-Marketing Trials for the Selected Drug" Question and intends to include that information in "Post-IND Costs" Question.[19] We urge CMS to clarify the scope of post-marketing trials and specifically state that CMS will include investigator sponsored studies (ISR) and real-world data gathering. Typically, these are under the purview of medical generation evidence, also referred to as "post-marketing trials," and BMS encourages CMS to further clarify its intent. Additionally, CMS

[17] *Id.* at 87.
[18] Negotiation Data Elements at 12.
[19] Medicare "Negotiation" Guidance at 87.

must recognize and consider scenarios in which the manufacturer does not operate the study. BMS also asks CMS to provide guidance on how the Agency will consider alliances or co-development arrangements, and subsequently, how it intends for the manufacturer to consider this for reporting purposes. BMS notes that CMS does not appear to fully recognize the additional costs directly associated with running clinical trials, and BMS urges CMS to explicitly identify and consider these costs, specifically the purchase of third-party assets, such as combination or comparator assets. BMS urges CMS to recognize and consider ongoing expenses post approval; for certain therapeutic areas, often oncology and hematology, there are costs related to continued follow-up and data generation. CMS must recognize the ongoing investment in and value of these products. Another factor that CMS should consider is the sales and marketing costs that are essential for providers and patients to understand the availability of new therapies.

- Costs of Failed or Abandoned Products Related to the Selected Drug: BMS strongly asserts that *all* clinicals trials conducted by the manufacturer need to be considered by CMS, not only those that were approved. "Failed" clinical trials require significant capital from manufacturers and frequently contribute to new discoveries—simply because a trial did not have a successful readout does not mean that the manufacturer did not incur expenses to develop the asset or make important scientific discoveries along the way. Manufacturers will also incur a tremendous financial burden if the overwhelming number of molecules and targets that do not proceed to Phase I or IND are not reflected in reporting. Ongoing drug development and discovery is reliant on the commercial success of a minority of medications, compounded by the extremely low drug development success rate across all therapeutic areas, measuring at less than 7% in 2022.[20] In addition, limiting failed and abandoned drugs to the same therapeutic class as the selected drug overlooks the many drugs that switch therapeutic classes during their development or span across, and have uses in, different therapeutic classes. BMS urges CMS to consider the totality of the investment, including failed and approved clinical trials.

- Direct Costs of Other R&D for the Selected Drug Not Accounted for Above: BMS seeks clarity from CMS on what is meant by "other R&D" costs[21] for the purposes of this question.

- Global and U.S. Total Lifetime Manufacturer Net Revenue for the Selected Drug: As discussed in our initial Negotiation Data Elements ICR comments, BMS strongly opposed CMS' intent to use global, total lifetime manufacturer net revenue for the selected drug. This requirement would include net sales information from countries outside of the U.S. and has no place in price negotiation that is specifically based on a U.S. policy change intended for the U.S. market—and even then, is intended for the Medicare market *only*, which is a subset of the U.S. market. While CMS noted that it only intended to include R&D costs for FDA-approved indications, which is a U.S. cost and regulatory metric, the Agency seemed to be calculating the "recoupment" of these U.S. costs by comparing them to global total lifetime net revenues, thereby violating a matching principle of expenses incurred and revenues earned, which would likely unfairly disadvantage manufacturers. In addition, the total net revenues earned in countries outside of the U.S. are already subject to manufacturer-payer agreements; inclusion of those agreements (by virtue of capturing global net sales) in the CMS initial offer development is a double dip that further penalizes manufacturers. BMS noted in our initial comments that if CMS were set on its approach and intended to utilize global, total lifetime manufacturer net revenue, then, at a minimum, the Agency should recognize the costs of ongoing research and significant, necessary expenditure incurred for international product launches and line extensions or limit the collection of sales data to U.S. market only. In the revised Negotiation Data Elements ICR, and in response to public comments, CMS notes that it will consider both global and U.S. revenue when determining whether to adjust the preliminary price based on

[20] IQVIA Institute, "IQVIA Pipeline Intelligence, Dec 2022" (Jan. 2023).
[21] Negotiation Data Elements at 14.

manufacturer-submitted data.[22] **While BMS can appreciate CMS acknowledging our concerns regarding the comparison of global, lifetime net revenue with R&D costs attributable to FDA-approved indications of the selected drug, we disagree with CMS' finalized approach. BMS strongly urges CMS to *only* consider U.S.-based information, as Medicare prices are U.S. specific.** Additionally, by including costs from ex-U.S. countries, CMS could push pharmaceutical companies to reconsider investment outside the U.S. to the extent CMS' expansive methodology risks inappropriately influencing U.S. pricing.

Current Unit Costs of Production and Distribution

In general, BMS notes that there are several challenges with obtaining CMS' requested information about current unit costs of production and distribution at the drug-specific level. Primary Manufacturers will be responsible for submitting certain data that will serve as the basis for "offers" and "counteroffers," and these costs and data inputs should be determined and reported in accordance with generally accepted accounting principles. We offer several specific suggestions for CMS to consider below.

- Limitations on Reporting Timelines: Similar to how CMS revised its policy to clarify that reporting for basic pre-clinical research costs begins on the later of the date of initial discovery or the date the Primary Manufacturer acquired the right to hold the NDA(s)/BLA(s) of a selected drug,[23] BMS urges CMS to consider removing data reporting elements for product and development costs at the asset level prior to a specific date. There may be instances (*e.g.*, prior acquisitions, divestitures, and collaborations) where the manufacturer does not possess nor have access to such information due to previous reporting and tracking guidelines.

- Need for Inclusion of Channel Fees: CMS declines to explicitly include channel fees in its definition of costs of distribution and notes that the definition generally refers to all (direct and allocation of indirect) costs related to packaging, labeling, and shipping operating costs for facilities and transportation.[24] We ask the Agency to explicitly include channel fees in the definition of costs of distribution.

- Broadening of the Current Unit Costs of Production and Distribution Definition: Additionally, CMS requires the reporting of "allocated shared operating and other indirect costs (such as capitalized production facility costs, benefits, generalized and administrative costs, and overhead expenses) specific to each NDC-11 based on unit volume,"[25] but needs to also consider the other overhead expenses that are not allocated, like freight, global quality, and the supply chain organization. BMS also requests that CMS consider expenses associated with non-manufacturing facilities that contribute to the cost of developing and marketing a selected drug.

Prior Federal Financial Support

BMS continues to maintain that the only prior federal financial support that should be reported is funding that directly resulted in a patent application containing a Government Interest Statement and/or research where a patent assignee was a U.S. government agency. Accordingly, we disagree with CMS' decision not to narrow this definition.[26]

[22] Medicare "Negotiation" Guidance at 88.
[23] *Id.*
[24] *Id*. at 89.
[25] Negotiation Data Elements at 19.
[26] Medicare "Negotiation" Guidance at 88-89.

Patents, Exclusivities, and Approvals

As we have noted in previous comments, BMS strongly supports protection of intellectual property (IP) rights and believes that an effective IP framework is essential for the viability of the biopharmaceutical industry and efforts to deliver innovation that addresses unmet patient needs. The discovery and development of new medicines is a long, complex, and rigorous process. BMS is concerned that CMS' proposals could contradict the framework that was intended to protect and encourage innovation and is highly disappointed with CMS maintaining its position in the Medicare "Negotiation" Guidance that the Agency may use existing patents or exclusivities on the selected drug to adjust the MFP.[27] **BMS firmly believes that CMS should not set the MFP for selected drugs below the MFP ceiling price into which patent protection extends.**

In response to stakeholder comments, we appreciate the fact that CMS removed certain definitions and provided additional clarification related to Patents, Exclusivities, and Approvals.[28] However, BMS strongly urges CMS to consider the following modifications.

- Limitations on Patent Scope Information: CMS is requiring, among other items, that manufacturers submit "all patents… as of September 1, 2023, both expired and unexpired…" and "all patents related to the selected drug, both expired and unexpired, where the Primary Manufacturer is not listed as the assignee/applicant (for example, for a joint venture product or if any patents related to the selected drug are held by a federal agency)."[29] **BMS maintains that any request for patent information should be limited to information that pertains to U.S patents or applications submitted, licensed, and/or acquired directly by the Primary Manufacturer that claim or cover the selected drug as it is currently used in the commercial product.** Additionally, BMS recommends that the Agency remove "expired" approved patents as this does not pertain to the selected drug. Complying with these requirements would be burdensome and unfair for Primary Manufacturers.

- Submission Burdens: The ICR requests that manufacturers list all active and pending applications and approvals for selected drugs under 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act or section 351(a) of the Public Health Services (PHS) Act.[30] A drug manufacturer would not have insight into another sponsor's pending applications with the FDA, so this data request is operationally impractical. And FDA itself notes that it does not report on pending applications.[31] Given these parameters, we request again that CMS remove this requirement. In addition, to limit manufacturer burden, we urge CMS to utilize FDA's publicly available resources (*e.g.,* Orange Book, Purple Book, and Drugs@FDA) to procure patent information and disagree with CMS' justification for maintaining these requirements.[32]

[27] *Id.* at 59.
[28] *Id*. at 90.
[29] Negotiation Data Elements at 23.
[30] *Id*. at 24.
[31] FDA, "Frequently Asked Questions about CDER," *available at* https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/frequently-asked-questions-about-cder; FDA states: "due to confidentiality rules, FDA is prohibited from releasing information on any drug under development, review or pending approval unless the information has been made public. You may contact the manufacturer directly to ask about products under development."
[32] Medicare "Negotiation" Guidance at 90.

Market Data and Revenue and Sales Volume Data

BMS continues to have serious concerns with the "Market Data, Revenue, and Sales Volume Data" section of the ICR. In compelling a manufacturer to "agree" to the disclosure of certain information, the Agency is bound by constitutional and statutory requirements, and should otherwise seek only to gather what is required for anticipated "negotiation" of the MFP. Yet the Agency appears to read "market data and revenue and sales volume data for the drug in the United States" in an exceedingly broad way. **The Agency cannot, and should not, impose an obligation to divulge virtually *all* pricing information for the drug, including proprietary, otherwise reported, and irrelevant information. BMS objects to CMS' proposed information collection in this section based on appropriateness, relevance, duplication, excessive scope, and undue burden.**

- Duplicative Reporting Requirements: BMS appreciates CMS removing several reporting requirements in the ICR, including but not limited to 340B Ceiling Price.[33] Similar to our arguments related to removing 340B Ceiling Price from this submission, we note that the Secretary of Health and Human Services already has access to the Medicaid Best Price through existing government price reporting. Manufacturers should not be required to re-report this information to the Agency, which should have easy access to such information within its own Department. Furthermore, requiring five years' worth of data on Medicaid Best Price is unduly burdensome for a manufacturer to provide, not to mention seemingly irrelevant for determining an MFP in the *Medicare* market. We also note that Federal Supply Schedule (FSS) and Wholesale Acquisition Cost (WAC) prices are already publicly available and do not need to be re-compiled by manufacturers.

- Appropriateness and Relevance of Reporting Requirements: BMS strongly objects to CMS requesting data on pricing metrics that do not reflect an actual Medicare price and therefore have no bearing on a Medicare-"negotiated" price. By creating a Medicare "negotiation" scheme, Congress has directed CMS to use market data, revenue, and sales volume data to come up with a new pricing metric reflective of the Medicare market. And by referring to final FSS and Big Four prices, for example, CMS would be capturing complexities of those calculations that should not apply to IRA price setting. While we recognize that CMS considers FSS and Big Four prices to be included in the definition of market data and revenue and sales data,[34] BMS strongly reiterates that reference to FSS and Big Four prices could have the unintended consequence of reducing or eliminating manufacturers' voluntary discounts that lead to lower prices for those government channels. Such pricing may be inherently short-term and thus would serve as an inappropriate benchmark for setting a longer-term price. CMS inappropriately requests utilization data which is not necessary for the purpose of MFP negotiation. CMS also seeks to create new methodologies, such as multiple variations of U.S. commercial unit prices. Not only are these methodologies not relevant in determining a Medicare-based price, but they would be near impossible for manufacturers to develop and validate within a 30-day timeframe. If Congress had wanted CMS to base the MFP on commercial "best" price or similar metric, it would have required disclosure of such a proprietary metric.

Consistent with our comments in other sections and in previous letters, BMS is also concerned with how vague CMS' phrasing of timeframes is portrayed throughout the ICR, and particularly so in the "Market Data and Revenue and Sales Volume Date" section. BMS believes that the lack of consistency, coupled with broad time ranges, could inadvertently lead to discrepancies in data reporting—and despite reasonable efforts to comply with CMS' newly-created, extremely-detailed requirements within incredibly short timeframes, manufacturers could be subject to severe CMPs should there be an error or miscalculation in submitting these data elements.

[33] Negotiation Data Elements at 7.
[34] Medicare "Negotiation" Guidance at 90-91.

BMS asserts that only information germane to determining an MFP for the Medicare market should be included in the manufacturer's data submission (*i.e.,* commercial and/or non-Medicare government pricing information should not form the basis of a Medicare price). We question the legitimacy of CMS' request for this pricing information as it relates to the purpose of this ICR. **The IRA statute only refers to submission of manufacturer non-FAMP, and not the other pricing metrics proposed in the ICR, and BMS urges CMS to remove these extraneous reporting requirements. We also ask CMS to only finalize submission requirements that are essential for operationalizing the Medicare price setting process and to do so in the least burdensome way possible.**

Evidence About Alternative Treatments

BMS appreciates CMS' modification to accept manufacturer evidence in the form of tables/charts/graphs to visually represent evidence in a more meaningful and clear way. As CMS has reiterated its unwillingness to review additional text within stakeholder responses, BMS would like the Agency to clarify that supporting text included in the accepted tables/charts/graphs, such as chart titles, labels, legends, and footnotes related to the visual representation, will be considered and reviewed by CMS as necessary contextual components.

We remain concerned by CMS' decision to allow stakeholders discretion over which cost effectiveness measures to submit given the lack of consensus on which measures do not treat the value of elderly, disabled, or terminally ill lives differentially. This is very likely to result in individual stakeholders submitting different measures based on their singular perspectives and increases the chance of an arbitrary decision that could disadvantage vulnerable populations.

BMS is disappointed with CMS' decision to consider unmet need only up until the time of evidence submission rather than throughout the entire lifecycle of the selected drug, which seems at odds with the Agency's potential consideration of clinical trial comparators that may have been popular prior to launch but have been supplanted over time by both the selected drug and other newer therapies. Older therapeutic alternatives, including clinical trial comparators, are no longer the standard of care and are inappropriate to consider for establishing a starting point for MFP, especially if CMS is not considering the unmet need demonstrated by the selected drug compared to the therapeutic alternatives. As stated in earlier comments, BMS recommends that unmet need be considered across the product's lifecycle and comparators should be chosen accordingly based on an assessment of unmet need. Additional value should be particularly considered for those medications that treat serious medical conditions, including those that make incremental steps toward curative goals. Further, unmet need should be viewed from the perspective of patients and providers. Unmet need should accordingly encompass a spectrum of characteristics, such as: alternative dosing regimens; route of administration; reduction of side effects; and shorter treatment periods.

BMS applauds CMS' decision to add an additional meeting with selected drug manufacturers following drug selection and evidence package submissions as well as the opportunity for manufacturers to review redacted evidence submissions from other parties. **It is critical for CMS to ensure that manufacturers are permitted to receive this redacted evidence in advance of the fall meeting to facilitate an important dialogue prior to an offer exchange, or plan for one additional meeting before an initial offer to allow for discussion regarding redacted evidence submissions.**

While CMS has appropriately agreed to consider various outcomes in addition to health outcomes, it is crucial for the Agency to consider novel elements of value (*e.g.*, adherence, convenience, caregiver burden, independence, productivity/wages) in stakeholder submissions for new patient and caregiver experience questions. Selected drug manufacturers should also be given the opportunity to submit comments for those questions based on feedback

collected from patients and caregivers throughout the drug's lifecycle. BMS requests that CMS provide further detail and commitment within the ICR to incorporate societal and novel value elements into the Agency's assessment.

Given the significant ramifications of what CMS has proposed, BMS encourages CMS to correct these inadequacies before initiating the first ICR data collection.

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BMS appreciates the opportunity to comment on the Negotiation Data Elements ICR. We would be pleased to discuss these comments in further detail. Should you have any questions or concerns, please contact Caroline Tucker, Director, Executive Branch Strategy, at caroline.tucker@bms.com.

Sincerely,

/s/

Amy Demske
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