July 31, 2023

VIA ELECTRONIC FILING - REGINFO.GOV

Lilly USA, LLC

Lilly Corporate Center
Indianapolis, Indiana 46285
U.S.A.
+1.317.276.2000
www.lilly.com

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

RE: 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)

To The OMB Desk Officer:

Eli Lilly and Company (Lilly) appreciates the opportunity to respond to certain sections of the *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).*[1] CMS has requested stakeholder feedback "regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions [and the] the accuracy of the estimated burden."

In the ICR, as well as the June 30, 2023 Revised Guidance (Revised Guidance),[2] CMS made minor changes to its proposed data reporting requirements under sections 1193(a)(4) and 1194(e) of the Social Security Act (SSA),[3] applicable to manufacturers with drugs selected for the "Medicare Drug Price Negotiation Program" (Program) under the IRA. Notwithstanding these changes, we continue to have significant concern that CMS is requiring manufacturers to provide extensive and unnecessary data, and at a level of prescribed detail and categorization that is inconsistent with the manufacturer's audited financial statements, generally accepted accounting principles (U.S. GAAP), and/or U.S. SEC reporting standards.

As we describe below, the proposal will require manufacturers to mine their financial systems and other books and records to attempt to identify transactions (some of which could be decades-old and captured in since-retired systems) for "reconstruction" purposes and to develop new and manual methodologies to allocate or calculate the requested data, solely for the purposes of the Program. CMS has estimated the "burden" for each responding manufacturer as follows:

> [I]t will take a business operations specialist or team of business operations specialists, on average, 100 hours, at a cost of $77.28 per hour, to gather cost data and compile required information. . . . After the relevant data have been gathered and compiled, it is estimated that it will take an economist or team of economists, on average, 300 hours, at a cost of $116.18 per hour, to perform necessary economic analyses, including the R&D costs of the manufacturer for the drug and the extent to which the manufacturer has

[1] 88 Fed. Reg. 42722 (July 3, 2023).
[2] *See* CMS, Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026 (June 30, 2023).
[3] As implemented by Section 11001 of the Inflation Reduction Act of 2022 (P.L. 117-169).

> recouped R&D costs, the selected drug's cost of production and distribution, and other data elements specified in the data element instructions.[4]

In response to CMS's request for feedback on the "burden estimate," we believe CMS has meaningfully underestimated the time, effort, and level of seniority of the individuals required to develop and implement this novel data reporting framework – a framework that is inconsistent with any other existing data reporting paradigm, including U.S. GAAP and SEC reporting requirements. We estimate the number of personnel-hours needed will likely exceed 1000 in the first year of the Program and will include time and effort from key finance and legal resources, including mid-level and senior financial leaders, in order to understand whether and to what extent sufficiently reliable data is available, develop methodologies to allocate data in new ways, and develop assumptions (including in circumstances in which data is not reproducible). This burden is exacerbated by the extremely compressed timeline for data submission in the first year of the Program.

Not only does CMS request that manufacturers identify, analyze, and potentially reclassify or recharacterize their data in new ways, but such detailed data analysis offers limited – to no – benefit to CMS in the Program. As CMS articulated in the Revised Guidance, manufacturer data serves two purposes: (1) to understand "the extent to which the manufacturer has recouped" its research and development (R&D) costs,[5] and (2) to adjust the preliminary price that will serve as the basis for the "Maximum Fair Price" (MFP) in the Program.[6] To serve these purposes, CMS does *not* need for manufacturers to mine all R&D transactions, determine whether such transactions are "direct" or "indirect" costs based on a novel paradigm, determine whether such transactions are "for FDA-approved indications" of the selected drug, divide R&D data into five categories, and perform various other adjustments (e.g., removing federal funding) or allocations inconsistent with U.S. GAAP. But that is what CMS is proposing here. And we are skeptical that understanding, for example, how much of a manufacturer's R&D spend was split between preclinical vs. clinical research will result in any meaningful difference in how CMS approaches its recoupment calculation or price adjustments. Simply, CMS does not need all of the information it is requesting, and it is requesting an unprecedented amount of information.

Most problematic, however, is the following: CMS has the authority to impose on a manufacturer a civil monetary penalty (CMP) equal to $1,000,000 for each day the manufacturer is "in violation"[7] of a data submission requirement. Notwithstanding the remaining complexity and ambiguity of the ICR's data definitions, CMS has explicitly stated that it will not allow manufacturers to submit a statement of "reasonable assumptions" because CMS believes the existing guidance is sufficient to, among other things, "permit . . . enforcement actions, as warranted."[8] In other words, although multiple stakeholders requested that manufacturers be able to describe the underlying rationale for the methodologies used in

---

[4] CMS, Information Collection Request for Negotiation Data Elements under Section 11001 and 11002 of the Inflation Reduction Act, Supporting Statement – Part A (CMS-10847, OMB 0938-NEW).
[5] *See* SSA § 1194(e)(1)(A).
[6] *See*, e.g., Revised Guidance at 150 ("The adjustment to the preliminary price applied on the basis of these data, if any, may be upward or downward, as needed to account for these manufacturer-specific data elements. These data elements are: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs.").
[7] SSA § 1197(b).
[8] See, e.g., Revised Guidance at 86.

their calculations, CMS has said "no," in part because it believes its guidance is clear enough to impose significant penalties.

Ultimately, the ICR is inconsistent with the Paperwork Reduction Act (PRA),[9] which requires that agencies collect data in the least burdensome way necessary (that still enables the agency's function, complies with the authorizing statute, and achieves the applicable agency objectives) and ensures practical utility.[10] As described below, the ICR sets up an excessively burdensome reporting regime that is not only inconsistent with, or additive to, existing manufacturer obligations under U.S. GAAP and/or SEC requirements, but also exceeds the needs of, and offers limited utility to, the Program. We implore CMS to carefully consider these and other comments as it finalizes the data reporting requirements under the IRA.

Our comments are organized into three sections: Section I includes comments regarding the ICR generally, Section II includes comments on the burden of collecting and reporting research and development (R&D) costs as proposed, and Section III includes comments on the burden of collecting and reporting unit production and distribution costs as proposed.

I. GENERAL COMMENTS

A. CMS's Refusal to Accept Manufacturers' Reasonable Assumptions Could Impact the "Quality, Utility, and Clarity of the Information to Be Collected" by the Program.

In the Revised Guidance, CMS noted that several commenters raised concern regarding the potential for significant financial penalties associated with unintended misreporting of the required data. These commenters, including Lilly, requested that CMS allow submission of reasonable assumptions to explain the basis for their answers to various questions. In response to these requests, CMS indicated that although it "appreciates commenters' feedback regarding the perceived potential for CMP liability:"[11]

> CMS is not adopting the recommendation that Primary Manufacturers submit a statement of reasonable assumptions with submissions under section 1194(e)(1) of the [SSA] or *otherwise use* reasonable assumptions. CMS believes it is important that data submissions reflect the application of consistent standards and definitions to *permit appropriate consideration of such data, timely execution of the negotiation process, and enforcement actions, as warranted*. As such, data submitted in response to this revised guidance must be based on consistent definitions and scope, as reflected in Appendix C of this revised guidance.[12]

In other words, CMS seems to suggest that the ICR is sufficiently clear and reflects "application of consistent standards and definitions" such that reasonable assumptions are unwarranted.

---

[9] *See United States v. Ionia Mgmt. S.A.*, 498 F. Supp. 2d 477, 487 (D. Conn. 2007), *citing Dole v. United Steelworkers of America,* 494 U.S. 26, 32 (1990) (explaining that the PRA was enacted in response to the "enormous growth of our federal bureaucracy" and "its seemingly insatiable appetite for data").
[10] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).
[11] Revised Guidance at 81.
[12] Revised Guidance at 86 (emphasis added).

We respectfully disagree. Notwithstanding the ICR's proposed definitions, manufacturers will need to make certain assumptions and ultimately make substantial adjustments to their financial systems and controls to provide the level of detail requested. For example, under U.S. GAAP, different manufacturers might use different methodologies related to product costing. These methodologies may result in one company defining a cost to be a "direct cost" whereas another manufacturer may define the same cost as an "indirect cost," both of which would be Cost of Goods Sold or inventory and allowable under US GAAP, but which would require different allocations to arrive at consistent reporting under the ICR. Further, depending on a manufacturer's accounting policies, the manufacturer may track and apply certain manufacturing costs directly at the SKU level while other costs may be appropriately allocated to products at a higher level. This difference in assumption over a finite time period and a specific product set could create meaningful distortions in the figures reported to CMS, depending on how allocations are performed. Given the above examples, it is important that manufacturers be allowed to explain their assumptions.

We note that the ICR contemplates that manufacturers may include certain assumptions in response to specific questions in their submission. However, we are concerned that this proposal is somewhat in conflict with the statements in the Revised Guidance. Moreover, we are concerned that the proposal in the ICR to prescribe such assumptions to the word-limited response fields could impact the "quality, utility, and clarity of the information collected."

We request that CMS explicitly resolve the tension between the Revised Guidance and the ICR and acknowledge that manufacturers may submit reasonable assumptions. To the extent CMS desires to limit such assumptions to the four-corners of a manufacturer's submission, we request that CMS remove the word limit and add a "general comments or assumptions" response to allow manufacturers to disclose assumptions not otherwise captured in the specific response fields. If CMS will not allow reasonable assumptions, we urge the agency to establish a process for receiving, reviewing, and responding to manufacturer requests (visible to all stakeholders) so that the parties have clarity, consistency and predictability.

B. Several of the ICR Proposals Require Data Capture and Reporting in a Manner that Is Inconsistent with U.S. GAAP and Adds Unnecessary Burden Without Providing Meaningful Benefit to the Program.

The ICR specifies that manufacturers must calculate and report data "using the methodologies described throughout the [ICR] and consistent with generally accepted accounting principles (GAAP), when applicable."[13] Notwithstanding this instruction, and as we note in more detail below, the ICR includes several examples of data delineation and classification that differ from, or are additive to, U.S. GAAP and that create new and material burden on manufacturers (e.g., by requiring new data storage methodologies and systems). These burdens are unnecessary as the incremental data CMS will receive provides limited utility to the Program.

[13] ICR at 4.

We note that in the ICR Supporting Statement,[14] CMS states that some manufacturer-specific data may not result in a "duplication of effort" because it "may already be collected from manufacturers by CMS or other federal agencies." As an example, CMS highlights that "drug manufacturers currently submit data related to manufacturer financials, such as total net revenue (e.g., 10-K filings with the Securities and Exchange Commission)." Importantly, the SEC does not require external reporting of costs at a product-specific level, nor is such reporting required under U.S. GAAP. Therefore, Lilly does not prepare standard financial statements with R&D costs or manufacturing and distribution costs at a product-specific level, nor does it have such data stored in its financial and accounting systems in the way CMS proposes. This means that Lilly will need to determine product-specific costs specifically for the purposes of the Program.

We acknowledge that CMS may choose to collect data in a manner inconsistent with U.S. GAAP or SEC reporting requirements. Indeed, CMS has explicitly done so in other contexts.[15] However, consistent with the PRA, CMS's proposals in this ICR should follow *the least burdensome necessary approach* that allows CMS to operate the Program. In our examples below, we highlight where CMS should adopt alternatives that are *considerably less resource intensive* (indeed, some of CMS's proposals may not even be workable). These alternatives are unlikely to yield materially different results, yet they will still provide the necessary data utility. Ultimately, we urge CMS to carefully consider when it is deviating from U.S. GAAP – a well-known and understood standard that serves as the basis for companies' audited financial statements – to ensure the right balance between adding manufacturer burden and Program data utility.

C. CMS's Proposed Methodology for Foreign Exchange Rate Calculation Is Unduly Burdensome and Inconsistent with U.S. GAAP.

In its instructions for reporting monetary amounts, CMS proposes requiring that manufacturers convert foreign currency to USD using the "exchange rate applicable at the time the costs were incurred" by referencing the daily rate maintained on the Internal Revenue Services website, or if the exact date is not known "the yearly average exchange rate" for the year the costs were incurred.[16] This proposal creates an extraordinary burden that offers limited to no value to the Program. For example, the number of transactions necessary to calculate and respond to the R&D questions in the ICR could exceed 10 million records. Particularly in the context of R&D, some of these expenses will be decades old. Manufacturers do not have systems in place that would allow for the conversion of this data on a daily – or even annual – basis, and CMS's proposal would require manual data conversion. In fact, in some cases, R&D and manufacturing cost data is converted to USD before it is stored in our systems, and *there is no way* to recreate the transaction in the original currency to allow "re-calculation" into USD as CMS proposes.

We request that CMS modify its proposal to be consistent with U.S. GAAP, which sets forth rules for translating foreign currencies in Accounting Standard Codification (ASC) 830. Such approach would *materially alleviate* the burden on reporting manufacturers and enable manufacturers to comply by

---

[14] CMS, Information Collection Request for Negotiation Data Elements under Section 11001 and 11002 of the Inflation Reduction Act, Supporting Statement – Part A (CMS-10847, OMB 0938-NEW).
[15] *See, e.g.*, 71 Fed. Reg. at 69669. ("Fees that meet our definition of bona fide service fees are not considered price concessions for purposes of the ASP calculation, regardless of how they are treated for financial accounting purposes.").
[16] ICR at 4.

aligning to existing accounting standards. This approach also would yield a data result that would not be materially different to CMS's current proposal.

D. CMS's Proposal for Reporting Monetary Values Implies a Level of Precision that Does Not Exist.

In its instructions for reporting monetary amounts, CMS proposes requiring that manufacturers report to two decimal places.[17] This proposal suggests that the data reported to CMS will be precise and ignores the inherent assumptions, estimates, and allocations that will be required to calculate these new data. Moreover, annual revenue that is multiple decades old may not be accessible anywhere but historical Form-10Ks, which may have been rounded according to manufacturer policies and consistent with SEC requirements. We request that CMS modify its proposal to allow manufacturers to be consistent with the standards used for SEC reporting purposes.

E. In Year 1 of the Program, the Timeline for Data Submission Is Incredibly Short and Burdensome, Particularly Given the Newness and Complexity of the Requirements.

As noted throughout our comments, the ICR prescribes data capture, categorization, and analyses in new and novel ways, in some cases inconsistent with any existing manufacturer reporting requirements. To alleviate manufacturer reporting burden and help ensure consistency and reliability of data submitted, particularly in Year 1 of the Program, we recommend that CMS dramatically simplify reporting requirements and categories, consistent with the recommendations in this letter, other manufacturer feedback, and the requirements of the PRA.

II. Comments Related to Section C: Research and Development (R&D) Costs and Recoupment

As a threshold matter, we reiterate that the SEC does not require external reporting of R&D costs at a product-specific level, nor is such data capture and reporting required under U.S. GAAP. Therefore, Lilly does not prepare standard financial statements with this data at a product-specific, package-specific, or indication-specific level. As a result, Lilly believes manufacturers will need to make reasonable assumptions for the purposes of calculating the values required to be submitted, which may be prepared solely for purposes of complying with Program requirements.

A. CMS's Proposal for Reporting R&D Costs and Revenue Is Inconsistent with U.S. GAAP. As a Result, R&D Cost Data May Not Be Available or Reliable – Negatively Impacting Data Utility. CMS Should Allow Manufacturers to Stipulate to R&D Recoupment. Alternatively, CMS Should Streamline R&D and Revenue Reporting to Ensure its Approach is the Least Burdensome Necessary to Achieve the Statutory and Program Objectives.

We appreciate that CMS has reduced the number of R&D cost reporting categories in this ICR. However, the ICR continues to require data categorization and allocation in a manner that is not required or

[17] ICR at 4.

contemplated under U.S. GAAP and that will require manufacturers like Lilly to develop new, or modify existing, data capture methodologies and systems.[18]

Specifically, the ICR requires that manufacturers identify and classify R&D expenses in one of five different categories, identify such expenses as "direct" or "indirect" (with limitations on whether indirect expenses may be reported), identify such expenses as "incurred for an FDA approved indication" or not (with limitations on whether such expenses may be reported), identify "any prior Federal funding support" and "deduct such funding" from each proposed R&D category, etc. We have described many of the challenges associated with the specific questions in the ICR in other sections of these comments. In general, however, neither U.S. GAAP, nor any other existing reporting paradigm, require data capture and categorization in this way. There are not "indicators" in financial systems that identify "Federal funding" or identify costs as for "FDA-approved indications" or "direct/indirect," as CMS proposes.

In fact, Lilly engaged with the SEC on this very issue several years ago. The SEC accepted our position, and – since 2010 – Lilly has included a statement similar to the following in its annual financial statements:

> We manage research and development spending across our portfolio of potential new medicines. A delay in, or termination of, any one project will not necessarily cause a significant change in our total research and development spending. Due to the risks and uncertainties involved in the research and development process, we cannot reliably estimate the nature, timing, and costs of the efforts necessary to complete the development of our research and development projects, nor can we reliably estimate the future potential revenue that will be generated from any successful research and development project. Each project represents only a portion of the overall pipeline, and none is individually material to our consolidated research and development expense. ***While we do accumulate certain research and development costs on a project level for internal reporting purposes, we must make significant cost estimations and allocations, some of which rely on data that are neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to report on total research and development costs by project, by preclinical versus clinical spend, or by therapeutic category.***[19]

The circumstances described above and discussed with the SEC remain true. Namely, Lilly does not have sufficiently reliable data – and never will in some circumstances – to capture R&D costs in the manner in which CMS is proposing. **Manufacturers will need to develop new methodologies and data classification systems and assumptions** – solely for this purpose – to *exclude* R&D costs that are otherwise *included* in the manufacturer's audited and publicly disclosed financial statements and to allocate costs as CMS has proposed. We estimate more than 500 hundred personnel-hours will be required for R&D alone, as well as analysis of millions of lines of data and meaningful data integration

[18] In the Revised Guidance, CMS stated that in defining R&D costs, it "considered a multitude of sources including government reports, literature searches, the FDA website, and discussions with experts" and concluded "[t]he definition is intended to be sufficiently broad to accommodate differences in accounting policies and cost allocations across different manufacturers." Revised Guidance at 88. We respectfully disagree for the reasons described herein.

[19] Eli Lilly and Company Form 10-K (2022) (emphasis added), available at: https://investor.lilly.com/static-files/4c0f30f8-6e49-41c9-8859-24618c1b3785.

or system reconfiguration costs, a herculean task to complete by October 2. (In fact, Lilly has already invested extensive time, in excess of 200 hours from key financial and legal resources, to understand the proposal and begin building a framework.) This material burden far outweighs any data utility. CMS is able to: (1) understand "the extent to which the manufacturer has recouped" its costs,[20] and (2) adjust the preliminary price that will serve as the basis for the MFP,[21] ***without*** the categorization and delineation required in the current proposal.

By deviating from U.S. GAAP in this way, we are concerned that the ICR creates three separate data challenges, all of which not only add to the burden (and, in some cases, impossibility) of data collection and reporting, but also threaten the usefulness of the data to CMS.

<u>*First*</u>, much of the data that CMS is requesting may not be available. The R&D costs associated with many of the products that may be subject to the Program may have been incurred more than 20 years ago. CMS's proposed structure presumes that manufacturers will be able to access data that was never required to be captured or retained in perpetuity. As a result, CMS may receive inconsistent depictions of manufacturers' R&D expenses – those without access to historical data will be unable to fully reflect the R&D costs associated with a selected drug, whereas those with new products may be able to – ultimately jeopardizing the usefulness of the data to the Program.

<u>*Second*</u>, if such historical data *does* exist, manufacturers will need to decode, translate, integrate, and/or analyze data from retired systems or data archives, adding to the number of personnel hours and resources – i.e., the burden – associated with data collection and reporting. Because such archived data may not include all necessary data elements to classify it into one of CMS's proposed categories, manufacturers may make different judgment calls as to whether to include the data or how to categorize it. In addition, because the data elements CMS presumes are tied to R&D transaction records are not required to be maintained for accounting or external reporting purposes, manufacturers may need to integrate their financial data with data from *yet other* systems (e.g., project management, HR) – systems that likely have been changed or reconfigured multiple times in the relevant period. Ultimately, these challenges could impact the reliability of the data submitted.

<u>*Third*</u>, there is meaningful inconsistency in CMS's R&D cost and revenue data collection instructions. Although CMS has revised the ICR to consider both global and U.S. revenue, the underlying tension in CMS's proposal is unresolved. Specifically, the ICR states that CMS will calculate "recoupment of R&D costs using both the *global* and U.S. *total lifetime* net revenue for the selected drug."[22] CMS indicated it will also consider global and U.S. revenue "when determining whether to *adjust the preliminary price*."[23] However, the ICR instructions continue to propose generally limiting R&D costs to those incurred "for all FDA-approved indications"[24] and explicitly *excluding* "costs associated with

---

[20] *See* SSA § 1194(e)(1)(A).
[21] *See*, e.g., Revised Guidance at 150 ("The adjustment to the preliminary price applied on the basis of these data, if any, may be upward or downward, as needed to account for these manufacturer-specific data elements. These data elements are: (1) R&D costs of the manufacturer for the drug and the extent to which the manufacturer has recouped R&D costs.").
[22] ICR at 8 (emphasis added).
[23] *See* Revised Guidance at 88.
[24] *See, e.g.*, ICR at 10. *See also* ICR at 8 ("All costs in this Section C are for FDA-approved indications of the selected drug, unless otherwise specified. Do not report any costs for indications that are not labeled indications.").

ongoing basic pre-clinical research, clinical trials, and pending approvals"[25] and "costs associated with applying for and receiving foreign approvals."[26]

In other words, CMS has asked manufacturers to *limit* reporting of R&D costs[27] to *exclude* costs that are otherwise included in the manufacturer's audited and publicly disclosed financial statements (e.g., R&D costs not associated with FDA approved indications). Yet, CMS does not impose the same limitations on revenue calculations (and such limitations are likely not possible). This approach to exclude certain R&D costs is unlikely to meaningfully impact the data's utility or CMS's approach to preliminary price adjustments. In fact, such incongruence between costs and revenues could negatively impact the Program – it could result in misleading recoupment calculations and could lead to arbitrary decision making with respect to adjustments of the preliminary price.

Taken together, the ICR creates materially new requirements on manufacturers,[28] and poses data availability, reliability, and consistency challenges. To address these challenges and reduce manufacturer burden, we support the recommendations that Pharmaceutical Research and Manufacturers of America (PhRMA) put forth in their comments to the original ICR, dated May 22, 2023. Specifically, PhRMA recommended that CMS amend the ICR to allow a single global response in which a manufacturer can attest whether it has recouped its R&D costs. If a manufacturer certifies that it has recouped its R&D costs, then CMS need not gather any additional information. If a manufacturer does not or cannot certify that it has recouped its R&D costs, then the manufacturer can provide additional information.

PhRMA proposed two alternatives, both of which we also support as they address the burden/utility imbalance described above:

- Alternative Option 1: Allow manufacturers to allocate a percentage of total R&D to the MFP-selected drug (e.g., 20% of total R&D spending to the selected drug) and a free text box to explain how that calculation was derived.

- Alternative Option 2: Propose collecting data in two broader categories: (1) costs of R&D before initial FDA approval (an aggregate way to gather all basic/preclinical and clinical development), and (2) costs of R&D after FDA approval, which would include Phase IV costs.

All three of these options (i.e., stipulation, allocation, or broadened categories) better align to the objectives of the PRA, as they are a materially less burdensome way for manufacturers to collect and

[25] ICR at 8.
[26] ICR at 8.
[27] CMS "believes that for the purpose of the Negotiation Program, the definition of R&D costs is sufficiently broad, as reflected in the additional revisions and clarifications made to Appendix C." Revised Guidance at 68. We respectfully disagree. As we noted in our comments to the Initial Guidance, dated April 14, 2023, the proposal ignores meaningful expenses incurred by manufacturers to advance and seek approval of innovative therapies. For example, manufacturers may continue to execute trials to further the understanding of approved molecules and to gain approval for additional indications of that molecule that will further benefit patients. However, these additional trial costs may be for indications that are not yet, and may not ever be, approved by FDA.
[28] We note, again, that such burden is exacerbated by CMS's authority to impose significant financial penalties on manufacturers who adopt reasonable assumptions that CMS – post hoc – may disagree with.

report data to CMS – data that still would enable CMS's function, comply with the IRA, and achieve the Program objectives. If CMS declines to adopt any of the three above proposals, we implore CMS to carefully consider our other recommendations in this section to ensure a prudent balance of stakeholder burden relative to the incremental utility of preparing the required data.

B. CMS's Proposal to Exclude Federal Financial Support from R&D Costs is Unnecessarily Burdensome.

The ICR continues to require that manufacturers deduct "Federal financial support" from the determination of R&D costs.[29] CMS defines "Federal financial support" as including "*tax credits*, direct financial support, grants or contracts, and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug."[30]

This expansive definition raises a number of concerns. First, this requirement creates another new and material data capture and reporting burden inconsistent with U.S. GAAP. Manufacturers are not required to carve out – proportionally – federal funding from their financial statements or disclosures. And federal funding of preclinical research (like much of preclinical research) may not be product specific. As a result, such funding would need to be allocated.

Further, while manufacturer accounting systems may be able to identify *direct* federal funding (e.g., grants or contracts), they are highly unlikely to capture indirect funding, and CMS leaves open the question of whether and to what extent indirect funding must be considered. For example, if a manufacturer engaged – twenty years ago – a vendor to help with some aspect of the discovery process, and the vendor received some amount of federal funding, what obligation does the manufacturer have under the ICR? It is impractical and near impossible for manufacturers to track every dollar of federal funding that may have indirectly touched the research process for an asset that was discovered decades ago.

Not only does CMS *not need* such information to serve the Program purposes, it *should not use* some of this information in the Program. We disagree with CMS that "the definition of prior Federal financial support appropriately captures industry and/or government standards in a manner that is consistent with the statutory requirements to use such information."[31] Tax credits, in particular, are a function of a *separate* statutory structure in which the federal government has incentivized specific activities or innovations.[32] It is wholly inconsistent with these federal tax provisions to later *penalize* the manufacturer, as CMS contemplates: "For example, CMS may consider adjusting the preliminary price downward if funding for the discovery and development of the drug was received from Federal sources,"[33] including tax credits.

Consistent with the PRA, we request CMS adopt the "least burdensome approach necessary" and not require that manufacturers exclude federal research from R&D costs. To the extent CMS continues to

[29] ICR at 8.
[30] ICR at 20 (emphasis added).
[31] Revised Guidance at 89.
[32] Revised Guidance at 88. ("The federal government supports drug research through tax incentives.").
[33] Revised Guidance at 88.

require reporting of "Prior Federal Financial Support" in Section E of manufacturer responses, we request that CMS explicitly exclude tax credits and indirect funding.

C. The ICR proposal related to "Question 2: Basic Pre-Clinical Research for All Approved Indications of the Selected Drug" imposes material and unnecessary data collection and analysis requirements on manufacturers.

Per the ICR, manufacturers must report basic pre-clinical research costs, which are defined as "all discovery and pre-clinical developmental costs incurred by the Primary Manufacturer with respect to the selected drug during the basic pre-clinical research period and are the sum of (1) direct research expenses and (2) the appropriate proportion of indirect research expenses."[34] The ICR indicates that manufacturers should limit their responses to "R&D costs . . . for all FDA-approved indications for the selected drug related to pre-clinical research."[35] As we have noted, classification of pre-clinical R&D costs as "direct" vs. "indirect," or "incurred for an FDA approved indication" vs. not, is not required for U.S. GAAP, SEC, IRS, or any other external reporting purpose. Accordingly, our financial systems do not differentiate our R&D costs in the way CMS proposes. In this category of research in particular, the data elements necessary to enable such categorization may not even exist, particularly for aged transactions.

We raise three specific issues related to this "Question 2" for CMS's consideration. *First*, in this category of R&D costs in particular, the nature of the costs are such that identifying each transaction *by FDA approved indication* is unduly burdensome. In most cases, a manufacturer will not know the expected FDA label until the end of the R&D cycle, well after pre-clinical costs were incurred. Even when a manufacturer has a list of FDA approved indications, there is no "flag" in manufacturer financial systems that links R&D costs to an FDA approved indication.

Second, in its instructions related to "basic pre-clinical research," CMS indicates that manufacturers must, "[i]n the free response field, identify the length of the basic pre-clinical research period, which runs from: the *date of initial discovery* . . . to the day before the last IND application for an FDA-approved indication of the selected drug went into effect."[36] This proposal creates a meaningfully new requirement for manufacturers, as there is no current requirement to precisely identify the "date of discovery." Moreover, this requirement ignores material basic pre-clinical research costs, which is: (1) counter to CMS's primary purposes for collecting the data, and (2) inconsistent with CMS's definition of "basic preclinical research," as well as the realities of scientific discovery.

Specifically, the IRA charges CMS with determining "the extent to which the manufacturer has recouped research and development costs."[37] But the proposal described in the instruction for Question 2 contemplates carving off a meaningful portion of such R&D costs, ultimately impacting the reliability of the data in CMS's recoupment analysis. Also, CMS defines "basic pre-clinical research" to include "*all* discovery and pre-clinical" costs, including, for example, "costs of in vivo and in vitro studies on

[34] ICR at 10.
[35] ICR at 10 (emphasis in original).
[36] ICR at 10 (emphasis added).
[37] Codified at Section 1194(e)(1)(A) of the SSA.

the selected drug."[38] To capture "*all*" discovery and pre-clinical development costs necessarily involves capturing the costs of experimentation before the elusive "moment" of discovery. In fact, that is when most in vitro studies of an asset occur.

Third, in this R&D category alone, CMS proposes to allow manufacturers to capture a portion of "indirect" research costs. CMS defines "indirect basic pre-clinical research costs and relevant general and administrative expenses" as "operating costs for basic pre-clinical research beyond the basic pre-clinical research costs for the selected drug, including administrative personnel and overhead costs (expenses for clinical facilities and equipment) that are shared across multiple potential drugs or biologics."[39] CMS instructs manufacturers to "use proportional allocation, whereby the same proportion of spending allocated for direct research on the selected drug is used to estimate the proportional spending for indirect research."[40]

CMS appears to assume that manufacturer financial systems are configured to classify all expenses as direct v. indirect; that all direct expenses are assigned to a particular asset;[41] and that manufacturers can – with relative ease – add up all direct costs to determine the proportion of such direct costs associated with the selected drug. [42]

U.S. GAAP does not require delineation of R&D expenses in this way. *Even if* manufacturers have otherwise assigned "direct" and "indirect" labels to costs in their financial systems, such labels would be for internal management reporting purposes only, and – because not required for any other purpose – the methodologies for such assignment will likely have evolved over the decades in which the manufacturer incurred expenses. As a result, to comply with this novel allocation requirement, manufacturers will need to re-evaluate their approach (both current and historic) in light of the definitions in the ICR. This necessarily will entail manual data review and analysis of historical transactions, as well as potential system updates. In attempting to update their systems and processes, manufacturers may inadvertently fail to capture some direct costs or allocate certain indirect costs – ultimately impacting the utility of the data to CMS's analysis.

The requirements of this "Question 2" are prominent examples of where the ICR has gone beyond U.S. GAAP in a manner that adds substantial burden but that offers limited benefit to CMS. We estimate at least two hundred people-hours, in addition to meaningful system time and expenses, will be required to attempt to retrofit our "basic pre-clinical research" data in this way. We request that CMS reconsider its approach to reporting R&D expenses and adopt instead one of the three alternative proposals described above in Section II.A. These proposals more appropriately balance the incremental data capture and reporting burden with the practical usefulness of the data for *all* categories of R&D costs. Alternatively,

---

[38] ICR at 10.
[39] ICR at 10-11.
[40] ICR at 11.
[41] As described, CMS also seems to assume that manufacturer systems identify a cost as clearly "pre-clinical" vs. not, or "incurred for an FDA approved indication" vs. not. As explained, this is just not accurate.
[42] We note that CMS expects manufacturers to include extensive discussion of this topic in their responses: "In the free response field, list the direct research expenses and the indirect research expenses for the selected drug, the percentage of direct and indirect spending on the selected drug out of the total direct and indirect basic pre-clinical research costs, an explanation of the values used in the indirect cost calculation, and a list of the activities the Primary Manufacturer included in the direct research expenses and the indirect research expenses." ICR at 11.

we request that CMS specifically update its instructions for reporting basic pre-clinical research costs to remove the requirement to report only costs incurred "for all FDA-approved indications."

D. CMS's Instructions on "Question 6: Global and U.S. Total Lifetime Net Revenue for the Selected Drug" Will Require that Manufacturers Implement New Control Systems to Ensure Accurate Reporting. This Burden Does Not Improve the Data Utility.

The ICR defines the "global, total lifetime net revenue period" as "the date the drug or biologic was first sold anywhere globally through the date of the publication of the [selected drug on the selected drug list]. If global, total lifetime net revenue for the selected drug is not available through the date of the publication of the selected drug list that includes the drug as a selected drug for an initial price applicability year, calculate net revenue through the most recent quarter for which such data are available."[43]

As CMS seems to contemplate, most manufacturers, particularly those who are also publicly traded companies, have systems, processes, and controls that are performed on a quarterly basis to help ensure accurate external reporting. These quarterly processes will not be completed by the date of publication of the selected drug, and any estimates of revenue as of such date may be incomplete and unaudited. As a result, manufacturers may need to implement redundant and off-cycle controls to assess the completeness and accuracy of revenue data as of the publication date. Or, CMS may end up with inconsistent depictions of lifetime revenue (e.g., if some manufacturers report revenue as of most recent quarter close and others report as of the date of publication). To alleviate this potential burden and drive consistency in data collection, we recommend that CMS request revenue as of the most recent quarter close, assuming such close is at least 15 days before the publication date. In the first year of the Program, we recommend CMS request revenue as of June 30, 2023.

III. Comments Related to Section D: Current Unit Costs of Production and Distribution

We reiterate that the SEC does not require external reporting of costs at a product-specific level, nor is such reporting required under U.S. GAAP. Therefore, Lilly does not prepare standard financial statements with this data at a product-specific or package-specific level. As a result, manufacturers will need to make reasonable assumptions for the purposes of calculating the values required to be submitted, which may be prepared solely for purposes of complying with Program requirements.

A. CMS proposes to calculate a "unit cost of production and distribution" based on a date range that is inconsistent with SEC reporting periods.

The ICR indicates that manufacturers must provide "[a]verage unit costs during the 12-month period ending May 31, 2023 (for selected drugs for initial price applicability year)."[44] As noted above, most manufacturers, particularly those who are also publicly traded companies, have systems, processes, and controls that are performed on a quarterly or annual basis to help ensure accurate external reporting.

[43] ICR at 15.
[44] ICR at 18.

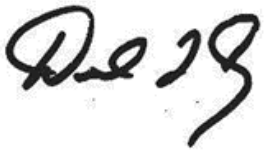
Under the ICR proposal, manufacturers will need to implement additional controls to assess the completeness and accuracy of manufacturing and distribution cost data on an off-cycle basis. To alleviate this burden, and assuming CMS continues to want a 12-month average cost, we recommend that CMS request production and distribution data as of the close of the company's most recent fiscal year to align with the company's external financial reporting. Alternatively, we propose CMS align its request date to a quarter close, e.g., June 30, 2023.

* * *

Lilly appreciates the opportunity to comment on certain sections of the ICR. Given the short timeline for commenting and the significance of these issues, we have limited our comments to the issues above. We reserve the right to submit additional comments on other issues to IRARebateandNegotiation@cms.hhs.gov.

We urge you to thoughtfully consider the issues discussed in this letter and would be happy to speak with you regarding any of the letter's content. Please do not hesitate to contact Derek Asay at derek.asay@lilly.com with any questions.

Sincerely,



Derek L. Asay
Senior Vice President, Government Strategy

Shawn O'Neail
Senior Vice President, Government Affairs