December 20, 2024

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Office of Management and Budget (OMB)
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Attention: OMB Desk Officer

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**RE: Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR) (CMS-10849, OMB 0938-1452)**

To The OMB Desk Officer,

Eli Lilly and Company (Lilly) appreciates the opportunity to respond to submit these comments in response to the Centers for Medicare & Medicaid Services' (CMS) Negotiation Data Elements and Drug Price Negotiation Process for Initial Price Applicability Year 2027 under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) Information Collection Request (ICR), including the Federal Register Notice, Supporting Statement – Part A, ICR Form (CMS-10849, OMB, 0938-1452).[1]

In advance of Initial Price Applicability Year (IPAY) 2026, Lilly offered several suggestions to lower the burden of data collection and reporting while maintaining or improving the consistency and reliability of data reported to CMS. We appreciate CMS' inclusion of some of our recommendations (such as incorporating certain (albeit limited) real-world evidence spending in Question 5 and adjusting the time period for data collection in Section D). However, we remain concerned that CMS has underestimated the time, effort, and seniority level required to develop and implement this new data reporting framework.

As we have previously highlighted, CMS is proposing to require that manufacturers provide extensive and unnecessary data, and at a level of detail and categorization that is not required by the authorizing statute and that is inconsistent with the manufacturer's audited financial statements, generally accepted accounting principles (U.S. GAAP), and/or U.S. Securities and Exchange Commission (SEC) reporting standards.[2] Because the ICR proposals go beyond U.S. GAAP and SEC requirements, the burden they impose on manufacturers is specific to the Program and the time and resources needed to comply, described previously, would be in addition to existing manufacturer obligations to track and monitor product R&D, production, distribution, and other costs. And for IPAY 2027, CMS is proposing to request even more data and/or categorization, not less. This high data collection burden is not necessary to ensure the "proper performance of the agency's functions." Moreover, it is unclear whether and to what extent CMS used the vast amounts of data collected from manufacturers in the first year of the "Medicare Drug Price Negotiation Program" (Program). It is incumbent on CMS to right-size the ICR to reduce the data requested to only those subjects and formats reasonably necessary to support the Program and as provided for by the statute.

Ultimately, the proposed ICR is inconsistent with the Paperwork Reduction Act (PRA),[3] which requires that agencies collect data in the least burdensome way necessary – that enables the agency's function, complies with the authorizing statute, and achieves the

[1] Available: https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-10849.
[2] As we highlighted in our comments to the Draft Guidance, the U.S. SEC and other governmental bodies do not require external reporting of costs (including research and development costs) or profits at a product-specific level, and manufacturers may not prepare standard financial statements with this data at a product-specific level.
[3] *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").

applicable agency objectives – and ensures practical utility.[4] The ICR sets up an excessively burdensome reporting regime that exceeds the needs of, and offers limited utility to, the Program.

Below we reiterate several suggestions to lower the burden of data collection and reporting while maintaining or improving the consistency and reliability of data reported to CMS. We implore CMS to carefully consider these and other comments as it modifies the data reporting requirements for the Program.

## General Comments

### 1. CMS Should Further Expand Word Limits to Allow Manufacturers to Fully Explain the Values Reported.

Throughout the ICR, CMS proposes to require that manufacturers describe or explain the reported financial values in great detail, "including any calculations or conversions and any assumptions made."[5] In addition (and as we highlight in more detail below), the proposed ICR requirements are often inconsistent with U.S. GAAP or other existing financial data calculation or reporting requirements, and CMS states that manufacturers must "[d]escribe the policies and methodologies used in the calculations . . . , as well as the standard used if it is inconsistent with GAAP."[6] Certain questions require even more specificity.

While CMS expanded the word character limits for some questions, there are others that remain too restrictive where manufacturers should be free to elaborate fully, given the extensive explanation requirements. We recommend that CMS further expand the word limits of all fields to allow for a fulsome explanation of the reported values, helping ensure the data can be meaningfully understood.

### 2. CMS Should Provide Clear Explanations of Evidence Used and Give Stakeholders Adequate Time to Understand Prior to ICR Submission

To give meaning to the agency's stated goal of promoting transparency, we urge CMS to commit to including timely and meaningful explanations as to how the evidence on alternative treatments were utilized, how such factors (and any other information) were weighed and considered, and any non-manufacturer sources of information relied upon. We additionally ask CMS to release the explanation of MFPs, including drugs identified as therapeutic alternatives for negotiations, and any non-proprietary evidence before the ICR data collection process concludes for IPAY 2027 selected medicines. Today, CMS is required to publish their explanation of MFP by March 1, 2025 for IPAY2026, the same day stakeholders are required to submit data on the ICR form.[7,8] This creates a scenario where stakeholders are submitting information before understanding what CMS evaluates in their price-setting process. The lack of transparency limits all stakeholders' ability to provide the most impactful information to the agency.

## Section C. Research and Development (R&D) Costs and Recoupment – General Comments

### 1. CMS Should Allow Manufacturers to Stipulate to R&D Recoupment. Alternatively, CMS Should Streamline R&D Reporting to Ensure its Approach is the Least Burdensome Necessary to Achieve the Statutory and Program Objectives.

[4] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).
[5] ICR at 11
[6] *Id.* at 5
[7] Centers for Medicare and Medicaid Services (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. Available: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf.
[8] ICR at 2.

In the Draft Guidance[9] and the ICR, CMS proposes to continue to require that manufacturers identify R&D expenses for a selected drug, determine whether such expenses should be reported in one of five categories defined by CMS, determine whether such expenses are "direct" or "indirect" or are "incurred for an a [Food and Drug Administration (FDA)] approved indication," and perform various ad hoc calculations to include, exclude, or allocate such expenses pursuant to CMS's specific and novel instructions. This collection goes well beyond the statutory requirement to submit information on "research and development costs of the manufacturer for the drug," which does not require manufacturers to subdivide and categorize this information as proposed in the ICR.[10] The statute merely requires manufacturers to report on "the extent to which the manufacturer has recouped research and development costs," which requires neither the proposed strict categorization of R&D data nor the reporting of global or U.S. lifetime net revenue.[11] And, as we have described previously, neither U.S. GAAP nor SEC require external reporting of R&D costs at a product-specific level, nor are manufacturers otherwise required to categorize and calculate R&D data in this way. Manufacturers will incur meaningful data collection burden to generate the data in the manner that CMS proposes.

CMS indicates in the Draft Guidance that it will use R&D costs to determine whether to adjust the preliminary price upward or downward; it does not specify whether or how it will use the breakdown of R&D into five distinct categories as distinct from total R&D costs.[12] CMS can achieve these purposes without requiring that manufacturers 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) and develop new and manual methodologies to categorize, calculate, and allocate the requested data across CMS' five R&D data categories, in the way CMS prescribes, solely for the purposes of the Program. Simply, CMS does not need all the information it is requesting, and it is requesting an unprecedented amount of information.

For the purposes of drastically reducing the reporting burden on manufacturers and improving consistency of manufacturer data submissions, we recommend that CMS amend its reporting requirement 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, either as to R&D costs or global and U.S. lifetime net revenue. If a manufacturer does not or cannot certify that it has recouped its R&D costs, then the manufacturer can provide additional information.

Alternatively, CMS should significantly streamline the R&D reporting requirement to better align with how manufacturers capture and report R&D data in their financial systems today. Specifically, CMS should collect R&D data in two 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. Such approach would both materially reduce reporting burden on manufacturers and improve consistency of manufacturer data submissions.

Either approach would comply with the statute and enable CMS to achieve its purposes under the Program but would do so in a way that is more consistent with the PRA.

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[9] CMS, *Medicare Drug Price Negotiation Program: Draft Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2027 and Manufacturer Effectuation of the Maximum Fair Price (MFP) in 2026 and 2027* (May 3, 2024) [hereinafter Draft Guidance].

[10] Social Security Act (SSA) §§ 1193(a)(4), 1194(e)(1)(A).

[11] *Id.*

[12] Draft Guidance at 87 ("[I]f a Primary Manufacturer has not recouped its R&D costs, CMS may consider adjusting the preliminary price upward. Conversely, if a Primary Manufacturer has recouped its R&D costs, CMS may consider adjusting the preliminary price downward or apply no adjustment.").

### 2. CMS Should Not Limit the Definition of R&D Costs to Costs Associated with "All FDA-Approved Indications of a Drug."

CMS proposes to limit the definitions of R&D costs to those incurred "for all FDA-approved indications of a drug." First, this definition risks excluding costs that are necessary to the R&D process and that are otherwise included in the manufacturer's audited and publicly disclosed financial statements and U.S. GAAP. It also risks excluding material costs incurred by manufacturers (e.g., to conduct trials that further the understanding of approved molecules, to invest in R&D for indications approved in non-U.S. markets – indications that may be approved by the U.S. FDA at a later time).[13]

Moreover, manufacturer systems generally are not configured to assign costs to a specific indication, particularly in early stages where research is indication-agnostic and focused on the molecule safety, toxicity and general efficacy. Additionally, late phase research efforts may support a portion of or the entirety of a manufacturer's portfolio and would not be assigned to a specific molecule or indication. As a result, manufacturers will likely need to develop assumptions and customize their calculations in a manner inconsistent with current financial reporting, solely for the purposes of the Program, to determine whether and to what extent expenses (particularly those not associated with a specific clinical trial) are reasonably associated with an FDA-approved indication.

To further standardize and improve consistency of submitted information, aid in CMS's interpretation of the submitted information, and significantly reduce the reporting burden on Primary Manufacturers, we recommend that CMS define R&D costs without limiting those costs to those incurred for FDA-approved indications. Alternatively, we recommend that CMS specify that certain categories of research, e.g., basic pre-clinical research, is assumed to be for FDA approved indications.

### 3. CMS Should Not Exclude "Costs Associated with Ongoing Basic Pre-Clinical Research, Clinical Trials, and Pending Approvals" from the Definition of R&D Costs.

CMS proposes to exclude "costs associated with *ongoing* basic pre-clinical research, clinical trials, and pending approvals" from the definition of R&D costs. As we previously noted, this definition excludes costs that are otherwise included in the manufacturer's audited and publicly disclosed financial statements and U.S. GAAP. It also ignores meaningful expenses incurred by manufacturers to research and seek approval of innovative therapies, for example, when manufacturers continue to conduct trials to gain approval for additional indications of a drug.

Importantly, under CMS guidance, once a selected drug is subject to an MFP, such MFP applies to all *future* indications of the drug unless a new MFP is established through the renegotiation process at some future point. Renegotiation of the MFP in the event a new indication is required by statute only where CMS "expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated."[14] CMS has not yet committed to renegotiate whenever a new indication is approved. This means material R&D costs for these future indications (e.g., costs that may have been *ongoing* at the time of the drug's selection) may never be reported to CMS by a manufacturer in support of the negotiation or renegotiation of the MFP, and the drug's MFP – which will apply to all indications of that drug – will be determined without consideration of such costs.

Moreover, manufacturers may need to manually identify and exclude these costs from the data they report to CMS, in a manner inconsistent with their reporting under U.S. GAAP and to the SEC. To further standardize and improve consistency of submitted information, aid in CMS's interpretation of the submitted information, and significantly reduce the reporting burden on Primary

[13] CMS's proposed limitation of certain R&D costs to FDA-approved indications is also inconsistent with CMS's proposal regarding how to identify therapeutic alternatives to a selected drug; there, the ICR indicates that CMS will look to on- and off-label indications. Manufacturers may be in the process of incurring R&D expenses for indications not yet approved by FDA and should be able to include those costs in reported R&D, consistent with the identification of therapeutic alternatives.

[14] SSA § 1194(f)(3)(C).

Manufacturers, we recommend that CMS define R&D costs to include ongoing costs. Such approach better reflects the treatment of these expenses under existing financial reporting requirements, results in a more appropriate R&D cost recoupment calculation (i.e., the comparison of lifetime revenue to lifetime costs, which include ongoing costs), and better aligns with the underlying structure of the Program (e.g., which applies the MFP to all future indications).

### 4. CMS Should Not Exclude Indirect Costs from the Calculation of Various R&D Costs

In Questions 3-5 of the ICR, CMS proposes to limit manufacturer calculations of R&D costs to direct expenses only. As above, this limitation not only *excludes* costs that are otherwise included in the manufacturer's audited and publicly disclosed financial statements and U.S. GAAP but also ignores material costs incurred by manufacturers. This adds to manufacturer data calculation burden but offers limited utility to the Program.

To further standardize and improve consistency of submitted information, aid in CMS's interpretation of the submitted information, and significantly reduce the reporting burden on Primary Manufacturers, we recommend that CMS define all R&D costs to *include* indirect costs.

### 5. CMS Should Not Require that Manufacturers Deduct Federal Funding from the Final Calculated Numerical Amounts in Questions 2-5.

The ICR instructs manufacturers as follows:

> If [a] Primary Manufacturer received any prior Federal financial support, as defined in Section E, for any of the costs listed in Questions 2 through 5 (e.g., basic pre-clinical research, clinical trials, etc.), deduct such funding from the final calculated numerical amount before answering the relevant question and note that deduction in the applicable free response field. CMS will be collecting additional information on prior Federal financial support in Questions 9, 10, and 11.[15]

This requirement is unduly burdensome as it is inconsistent with U.S. GAAP, ambiguous, and largely duplicative to another CMS reporting requirement.

Specifically, this requirement creates another new and material reporting burden inconsistent with U.S. GAAP and other financial reporting requirements. Manufacturers are not required to carve out federal funding from their financial statements or disclosures. Moreover, CMS provides no guidance as to how such funding should be deducted or allocated. For example, manufacturers may make different assumptions with respect to how to proportionally deduct tax credits across the various numeric responses, which will create inconsistency in the data that is submitted to CMS. Finally, CMS already requires manufacturers calculate and extensively describe federal financial support in a separate question in Section E (i.e., Questions 9 and 10), such that CMS will already know what portion of reported manufacturer R&D costs were offset by federal financial support, regardless of whether manufacturers take on the additional burden of deducting these costs from R&D and with no guidance from CMS on how to do so across the distinct R&D cost categories to be reported.

Thus, this requirement is unnecessarily burdensome while providing no utility to the Program: it is inconsistent with U.S. GAAP, ambiguous for manufacturers to implement consistently, and largely duplicative to information CMS requests in a different question of the ICR. Consistent with the PRA, we recommend that CMS adopt the "least burdensome approach necessary" and not require that manufacturers exclude federal research from R&D costs, particularly since federal financial support must be reported and fully explained in a different section of the ICR.

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[15] ICR at 11. CMS defines "Federal financial support" as including "tax credits, direct financial support, grants or contracts, in-kind contributions (e.g., support in the form of office/laboratory space or equipment), and any other funds provided by the federal government that support discovery, research, and/or development related to the selected drug." *Id.* at 24.

Section C. Research and Development (R&D) Costs and Recoupment – Specific Comments

### 1. Question 2: Basic Pre-Clinical Research for All FDA-Approved Indications of the Selected Drug

CMS proposes to define basic pre-clinical research costs 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."[16] CMS's definitions and instructions in this section create meaningful data collection burden and may result in inconsistency in manufacturer submissions.

*First*, the overwhelming majority of – if not all – pre-clinical research costs are reasonably associated with or are "for" an FDA approved indication, as these early costs provide an understanding of toxicity and safety of a potential medicine. Ultimately, many of the pre-clinical expenses result in information that is submitted to FDA when seeking drug approval. Also, 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, and there is no "flag" in manufacturer financial systems that links pre-clinical R&D costs to an FDA approved indication.

Accordingly, to help drive consistency in manufacturer submissions and reduce manufacturer reporting burden, we recommend that CMS allow all relevant pre-clinical expenses to be reported, regardless of whether those expenses are explicitly tied to an FDA-approved indication. Alternatively, we recommend CMS explicitly acknowledge that pre-clinical research costs are presumed to be for an FDA-approved indication.

*Second*, in the ICR for Program year IPAY 2027, CMS has increased the manufacturer reporting burden by asking additional questions, including requiring a "list of the direct research expenses and indirect research expenses for the selected drug" in Question 2b, separate and distinct from CMS's request for a detailed explanation of preclinical expenses (including "an explanation of the values used in the direct and indirect cost calculation") in Question 2c.[17] This requirement creates redundancy in manufacturing reporting with no clear benefit to CMS- particularly given that, here too, the proposed ICR is unclear as to how CMS intends to use this information. Thus, we recommend that CMS combine questions 2b and 2c and allow manufacturers to describe their methodologies holistically.

### 2. Question 3: Post-IND Costs for All FDA-Approved Indications of the Selected Drug

The definitions in this R&D cost category are also limited to only those expenses "for each FDA-approved indication."[18] In addition, CMS does not allow reporting of indirect expenses or any "ongoing" research. These limitations exclude transactions that are otherwise included in manufacturers' financial statements and meaningfully limit the data that can be reported to CMS. If CMS does not accept our recommendation to allow reporting of "ongoing" research in all R&D cost categories, we recommend that CMS allow the reporting of "ongoing" research in this category specifically. This would reduce reporting burden and facilitate a better understanding and interpretation by CMS of the research and development costs of a selected drug that will be subject to an MFP for all future indications.

### 3. Question 4: Costs of Failed or Abandoned Products Related to the Selected Drug

The definitions in this R&D cost category are also limited to only direct expenses. We recommend that CMS allow reporting of indirect expenses to reduce manufacturer reporting burden and better depict the expenses incurred.

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[16] *Id.* at 13.
[17] *Id.* at *14.*
[18] *Id.* at 15.

### 4. Question 5: Direct Costs of Other R&D for the Selected Drug Not Accounted for Above

We again encourage CMS to allow reporting of ongoing direct and indirect costs in this category to reduce data collection burden. Also, CMS has *added* to the reporting burden in this question by requiring additional responses and itemization that create redundancy in manufacturer responses without providing any practical utility to CMS. We recommend that CMS combine questions 5b and 5c to remove redundancy, lessen burden, and offer more utility to the Program by allowing manufacturers to describe their methodologies holistically.

### 5. Question 6: Global and U.S. Total Lifetime Net Revenue for the Selected Drug

CMS continues to meaningfully increase the burden of reporting in this question. Instead of seeking the lifetime net revenue as a single response, CMS is now requiring manufacturers report both "the *per calendar year revenue* for the global total lifetime net revenue" and the total lifetime revenue. Some products selected for the Program have been on the market for many years, and CMS has no need for revenue by calendar year to evaluate R&D cost recoupment. This new requirement adds to the reporting burden of manufacturers but does not provide any practical utility. Thus, if CMS does not accept our recommendation to allow manufacturers to certify to R&D expense recoupment, we recommend CMS revert to the prior requirement for a single response of global, total lifetime net revenue and U.S. lifetime net revenue, without adding a requirement for per-calendar year revenue.

## Section I. Evidence on Alternative Treatments – General Comments

### 1. Organizations Submitting Evidence Should Meet Thorough Standards to Ensure Organizational Independence, Patient-Centered Procedures, and Methodological Rigor

When determining therapeutic alternatives for a selected drug, CMS should rely on external organizations for purposes of evidence synthesis or technology assessment only if such organizations meet specified standards. Such standards should ensure organizational independence, patient-centered procedures, methodological rigor, and transparency. CMS should apply these same rigor and transparency standards to its internal "claims analysis" and review when adjusting the MFP starting point based on clinical evidence.

### 2. CMS Should Specify That Manufacturers Will Not Be Penalized if a Dossier is Not Submitted

Lilly appreciates the opportunity for manufacturers to submit an optional dossier in Question 36.[19] While we support allowing manufacturers to submit relevant supplementary information in their responses, like a dossier, a supplementary response may not always be necessary. Given the breadth of potentially excessive information in these documents and that these are not always kept up to date, a manufacturer should not be penalized for choosing not to submit if the answers are otherwise sufficient.

[19] ICR at 49.

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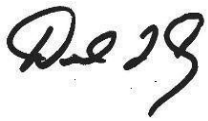
Lilly appreciates the opportunity to comment on this revised ICR. We reserve the right to submit additional comments on other issues to IRARebateandNegotiation@cms.hhs.gov. We urge you to thoughtfully consider the issues discussed in this letter and would be happy to speak with you regarding any of the letter's content. Please do not hesitate to contact Derek Asay at Asay_Derek_L@Lilly.com with any questions.

Sincerely,



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