July 31, 2023

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CMS Deputy Administrator and Director of the Center for Medicare
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8016
Attn: PO Box 8016

**RE: (Updated) Information Collection Request (ICR) Form for Negotiation Data Elements Under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB0938-NEW)**

Dear Administrator, Seshamani:

On behalf of Johnson & Johnson (J&J), we submit the following comments in response to the Centers for Medicare & Medicaid Services (CMS, the agency) and the Office of Management and Budget's (OMB) Updated *Information Collection Request (ICR) Form for Negotiation Data Elements Under Sections 11001 and 11002 of the Inflation Reduction Act (IRA) (CMS-10847, OMB0938-NEW)*.[1] J&J is the world's most comprehensive and broadly-based manufacturer of healthcare products for pharmaceutical, medical devices, and diagnostics markets. For nearly 130 years, we have led the way in innovation and are continuing this heritage today by bringing important new pharmaceutical products to market in a range of therapeutic areas on behalf of all our current and future patients, including Medicare, Medicaid, and Marketplace beneficiaries.

J&J remains very concerned by the significant volume and scope of information required under this updated ICR that is not expressly required to implement the Drug Negotiation Program (or the Program) as required within the IRA). In response to the Initial ICR, J&J expressed this concern and recommended CMS 1) align reporting requirements directly with, and not exceeding, the statute; 2) prioritize operational feasibility and simplicity, including leveraging data already required for federal reporting programs, utilizing information and resources otherwise available within the Government, and delaying requests for information that are not critical for year-one operations; and 3) commit to prioritizing those factors that emphasize value to the Medicare beneficiary.

The updated ICR does not sufficiently address our three primary recommendations, and therefore we remain significantly concerned that certain elements of the data request(s) are fundamentally misaligned with standard business practices, requesting data that often does not exist, or has not been collected and/or retained in such a format that would enable manufacturers to respond and certify accuracy compliantly. Other data elements are poorly defined, allowing for inconsistent interpretation and application to the Program's implementation.

Further, the Form for Negotiation Data Elements outlined in this updated ICR fails to comply with the criteria outlined within the Paperwork Reduction Act (PRA).[1] These criteria require that information collection:

[1] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

"(i) Is the least burdensome necessary for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives;

(ii) Is not duplicative of information otherwise accessible to the agency; and

(iii) Has practical utility. The agency shall also seek to minimize the cost to itself of collecting, processing, and using the information, but shall not do so by means of shifting disproportionate costs or burdens onto the public." [2]

In addition to our comments offered below, we refer CMS back to the J&J response to the initial ICR submitted on May 22, 2023. We again strongly recommend CMS, in coordination with OMB, reduce unnecessary reporting burden by removing reporting requirements that exceed statutory requirements or duplicate submission of data already available to the Agency and provide flexibility in the form and format of data reported, including removal of word limitations, and to prioritize value to beneficiaries.

**Instructions for Reporting Monetary Amounts**

*Additional Flexibility In Reporting Format and Detail Is Needed*

In the updated ICR, CMS states, "When calculating and reporting monetary values, the information must be determined using the methodologies described throughout the document and consistent with generally accepted accounting principles (GAAP), when applicable." CMS also clarifies that manufacturers should provide an explanation of the standard used if it is inconsistent with GAAP. J&J agrees with and supports this clarification, as alignment with GAAP is consistent with our internal accounting practices. However, we are concerned with the rigid format and detail required for reporting monetary amounts that will lead to a significant reporting burden on manufacturers. Therefore, we reiterate our previous ask for CMS to limit the data required for submission to that data outlined in the statute and to provide flexibility in reporting detail and format with the opportunity for manufacturers to explain values reported. Specifically for monetary amounts, we encourage CMS to provide manufacturers with the ability to report a range of estimates with the ability to explain rather than an exact figure. This format would better align with the PRA requirement to ensure the collection of information "is the least burdensome for the proper performance of the agency's functions to comply with legal requirements and achieve program objectives".

Regarding inflation, CMS specifically states "Do not make any adjustments for inflation to any dollar amounts reported. As applicable, in the free response field, specify the applicable time period for a specific question (e.g., calendar quarter, calendar year) and report the cost and revenue per each applicable time period. CMS will make the relevant inflation adjustments, as necessary." We ask CMS to provide additional transparency around the methodology it intends to use to make relevant inflation adjustments.

In addition, we note that some costs (lifetime research and development (R&D), revenue), are cumulative, and as indicated above, CMS will require manufacturers to provide the amounts by year within the free response field. However, given the word restrictions, this would be problematic, and therefore, we reiterate our request for CMS to remove the word restrictions which impose unnecessary reporting burden and limit the ability to provide complete responses on the Form. As another example, regarding foreign currency conversions, CMS states, "When converting another currency to USD, use the exchange rate

[2] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

applicable at the time the costs were incurred. The Internal Revenue Service (IRS) website lists government and external sources where historical exchange rates can be found to the day. If the exact date of a sale or conversion is not known, use the yearly average exchange rate for that currency for the year the costs were incurred. In the free response field, report the amount, the currency, the exchange rate, and time period(s) used in this calculation." We are concerned that when there is a foreign currency conversion, for example when reporting R&D costs and worldwide revenue, the word limitations will be problematic given the conversion information that CMS is requiring for submission and reiterate our ask for CMS to remove the restrictive word limitations.

**A: Selected Drug Information**

*Request CMS Provide Clarity on Its Inclusion of Discontinued NDC-11s*

In the updated ICR, CMS outlines its intent to prepopulate the HPMS system with NDC-11s and associated dosage form, strength, unit, and labeler code for selected drugs and provide manufactures with the ability to list any missing NDCs, note when an NDC is not controlled by the primary or secondary manufacturer, or if any of the NDCs have been discontinued. J&J appreciates that CMS seeks to leverage information available to the agency and prepopulate this information in the HPMS system. However, we are concerned that CMS states it will prepopulate this information for any NDC-11s that are marked as "discontinued". Primarily, we are not clear on what CMS means by discontinued. Discontinued could be interpreted to mean NCD-11s that are no longer in production or have been replaced. By this definition, we do not see the value or goal of listing discontinued NDC-11s in the HPMS, given that the intent of the program is to negotiate future prices for drugs. Under the PRA, information collected by an agency "must have practical utility[3]." Therefore, we ask CMS to clarify what it means by discontinued and explain its need for information on discontinued NDC-11s in order to negotiate future prices for selected products.

**B: Non-FAMP Data Collection**

*Urge CMS to Leverage its Statutory Authority to Align Non-FAMP Reporting with VHCA*

We are concerned that CMS did not update the Non-Federal Average Manufacturer Price (Non-FAMP) reporting requirement to align with the Non-FAMP reporting requirements under the Veterans Health Care Act (VHCA). The proposed approach places a significant burden on manufacturers and is unnecessary given that Non-FAMP data is already calculated by the manufacturer under the VHCA based on the fiscal year. We disagree that CMS is limited by statute, and we respectfully point out that CMS interprets the statute broadly in its proposals of other sections of this ICR. Again, we reiterate that the VHCA does not require manufacturers to submit Non-FAMP calculated units. While Non-FAMP units are embedded within the calculation logic, we are not required to and do not store that information in reporting the final Non-FAMP in the format and based on annual calendar quarters needed for this new requirement. To meet this new reporting requirement, we would have to manually extract and verify the units by calendar quarter for the past five years based on calendar quarters. We reiterate our previous ask for CMS to revise this section to align with Non-FAMP calculated under the VHCA and ask OMB to work with CMS to better align this reporting requirement.

*Support Clarity Provided in Definition for Market Entry*

J&J appreciates CMS' update to clarify the definition for "market entry." For drugs where there is no non-FAMP data in 2021, CMS clarified its intent to require the Primary Manufacturer to submit data on

[3] 5 C.F.R. § 1320.5(d)(1)(i)-(iii).

the Non-FAMP unit type and total unit volume for each NDC-11 of the selected drug for the first full year following market entry for such drug and provide manufacturers with the opportunity describe assumptions, methodological steps, and other information needed to interpret reported non-FAMP prices when there is no Non-FAMP data in 2021. Furthermore, CMS outlines the process for determining temporary Non-FAMP predicted upon the first 30 days of commercial sales data in cases where there is 30 days but not a full calendar quarter of data available. J&J appreciates this added clarity provided in the updated ICR.

CMS should clarify that for as long as there is an NDC with at least 30 days of sale (Temporary Price), the Primary Manufacturer does not need to submit Non-FAMP data for subsequent NDCs that do not have at least 30 days of sale in 2021, where the 30 days fall in 1Q2023 (also the first full quarter). In the example below, the Primary Manufacturer would submit Non-FAMP data for NDC1 of a selected drug that has four calendar quarters of 2021 Non-FAMP. The manufacturer does not need to submit Non-FAMP data for the subsequent NDC2 because NDC2 does not have at least 30 days of sales in 2021.

Example:
Key: T (Temporary Non-FAMP); F (First Full Quarter Non-FAMP); Q (Quarterly Non-FAMP)

| | | 2021 | | | | 2022 | | | |
|---|---|---|---|---|---|---|---|---|---|
| NDC | Market Date | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 |
| NDC1 | 1/1/2019 | Q | Q | Q | Q | | | | |
| NDC2 | 12/15/2021 | | | | | T | F | Q | Q |

**C: Research and Development Costs and Recoupment:**

*The Outlined R&D Reporting Requirements Are Operationally Infeasible*

J&J remains concerned by the approach CMS has adopted in determining R&D costs and manufacturer recoupment. In its updates to the ICR, CMS collapsed certain categories under the Research & Development Costs section, allowed for the inclusion of acquisition costs, and collection of both worldwide and well as U.S. net revenue. These minor improvements, however, do not address our primary concerns regarding the agency's violation with the PRA, the high degree of operational burden associated with the reporting requirements for this section, and the overly narrow view of R&D.

In the updated ICR, CMS modified its approach to require manufacturers to break down and report R&D costs into five categories and two categories of recoupment despite these changes the magnitude of data and way in which the data is requested is especially burdensome, as reporting in this manner and level of detail does not align with our current business or financial practices. This level of detail is not required by statute and is unnecessary for CMS to meet its statutory obligations. We again raise our concern that the reporting requirements are in conflict with the PRA because CMS is requesting collection of information exceeding what is necessary for CMS to perform its function to assess R&D costs and if drug developers have recouped these costs. Further, CMS does not provide an explanation regarding the utility of this data in this manner and why it is essential to implementing the Program.

As we previously stated in our past comments, we encourage CMS to simplify the R&D reporting requirements outlined in the ICR to allow the Primary Manufacturer to offer an attestation in instances where the manufacturer believes it has fully recouped R&D costs for the selected drug. In instances where the manufacturer indicates that R&D costs have been recouped, then CMS does not need additional

information. However, in instances where the manufacturer has not recouped costs, manufacturers should provide more information to the Agency. In those cases, CMS should allow increased flexibility in manufacturers' responses to this question to allow for the appropriate cost determination that aligns with internal and/or industry financial practices. Additionally, in these instances, we ask CMS to allow manufacturers to include indirect R&D costs after pre-clinical development (Questions 3 -5). These are true costs to the manufacturer and are currently not accounted for under the details that CMS provided for R&D.

The burden associated with the historical data gathering that will be required to satisfy the reporting requirements under this section is significant, and CMS should not impose such significant burden in instances where manufacturers indicate they have recouped R&D costs.

**D: Current Unit Costs of Production and Distribution**

*CMS Should Remove Its Overly Prescriptive Methodology for Determining Production and Distribution Costs*

J&J appreciates CMS' update to require reporting for this section at the NDC-11 rather than NDC-9. This level of reporting better aligns with the Non-FAMP reporting requirements, and we agree with this revision. However, as we previously commented, we are concerned with the burden that is being imposed on manufacturers stemming from CMS' prescriptive methodology for determining production and distribution costs. This methodology is not outlined in statute and relies on data that may not be available to manufacturers. For example, certain costs may not be available at the product level, such as various overhead functions. While CMS does allow manufacturers to explain methodology, it will require substantial time and resources to perform the needed calculations and allocations that are not typical in our current operations, which is burdensome to manufacturers.

We also ask CMS to clarify or define unit volume, as included in Question 7 of the form, specifically if it is intended to account for unit volume produced or sold.

**E: Prior Federal Financial Support**

*CMS Should Increase Flexibility In Reporting Format for Prior Federal Financial Support*

Unfortunately, the updates made for this section do not address our previously stated concerns related to burden of reporting for federal financial support information resulting from the prescriptive reporting format. While CMS attempted to simplify the reporting format in Question 9 by requiring reporting of a single total value for Federal Financial Support, in Question 10, CMS is requiring manufacturers to disaggregate that reported value by category, which is similar to the level of detail required by the table in the initial ICR. We continue to ask CMS to reduce burden of reporting by leveraging the flexibility afforded to the agency in statute and require reporting of a single value accompanied by an explanation of the reported information.

*Requirement to Report R&D Tax Credits Should be Removed from Prior Federal Financial Support Reporting*

We again recommend CMS remove R&D tax credits from this section. As explained in our previous comments, the CMS requirement to submit information on R&D tax credits exceeds the statutory requirements, and it is aggregated and thus cannot be directly correlated between dollars spent and credit

received for any single product. For example, for J&J, the R&D credit is based on the consolidated filing of all J&J legal entities included in the filings, which spans beyond pharmaceuticals and includes consumer goods, medical technology, etc. Therefore, these tax credits which are not product-specific and not required by the IRA should not be considered for this section as it is impossible to allocate the credit at a product-specific, or even sector-specific level.

**F: Patents, Exclusivities, and Approvals**

J&J agrees with and appreciates the Agency's decision to revise certain language within its updated guidanceSpecifically, we agree with the revision from "if the selected drug has patents and exclusivities that will last for a number of years, CMS may consider adjusting the preliminary price downward" to "CMS will review the patents and exclusivities reported as it develops its initial offer."[4,5] We continue to stress the important role of patents and exclusivities in the protection of intellectual property and incentives allowed for drug developers to introduce innovations that enhance patient outcomes.

*Requirements to Report on Expired Patent Information and Exclusivities Are Not Necessary for the Negotiation and Should Be Removed*

J&J is concerned that the Updated ICR includes increased and unnecessary reporting requirements for patent and exclusivity information for a selected drug. Specifically, we oppose the new requirements under Questions 12 and 14 for Primary Manufacturers to submit information for expired patents and regulatory exclusivities. Given that under CMS' definition, a product is aggregated based upon active moiety (e.g., across dosage forms and strengths), the required reporting of *expired* patent information and exclusivities is overly burdensome in view of this information's limited for value the drug price negotiation process. The utility of such information to the negotiation is unclear, and therefore we again raise our concern regarding the conflict of requiring submission of this data with IRA requirements, and PRA regulations, which require a clear utility for the collected data.

Moreover, Question 12, which is directed to patent information for a selected drug, was expanded to include patents that claim metabolites or intermediaries of a selected drug. Again, this reporting requirement is overly burdensome in view of its value to the negotiation process. Instead, submission of this information should be discretionary.

In addition, the word limitations imposed for Questions 13-15 should be removed as they restrict the ability to provide complete information.

**G: Market Data and Revenue and Sales Volume Data (Questions 16 – 25)**

*CMS Should Align with Statute and Remove Required Reporting of Pricing Data Beyond non-FAMP*

We reiterate our primary concern with this section that CMS is requiring submission of data exceeding what is outlined and intended by statute. While we agree with CMS' removal of Part D price reporting and 340B Ceiling from the reporting requirements under this section in the updated ICR, we continue to urge CMS to remove reporting requirements related to Best Price, FSS, Big Four and Average Manufacturer Price (AMP) units, and commercial price points. We again emphasize that CMS does not have the authority to require submission of pricing data aside from Non-FAMP, as Non-FAMP is the only

[4] Initial Guidance pg 53

[5] Revised guidance pg 151

pricing metric specified in the IRA, and is the only information needed to establish the maximum fair price (MFP) at the ceiling price. J&J does not support mandatory reporting of additional pricing data points from other federal and commercial programs which are proprietary and unnecessary for Program implementation. This pricing data is not required for the Program, as they are reflected in prices from separate and distinct programs which should have no bearing on the determination of the MFP. The statute does not require the submission of this data, and therefore J&J urges CMS to remove questions in this section requiring the submission of pricing data beyond Non-FAMP.

In addition to our primary concern that CMS lacks the authority to require submission of this data, we are also concerned with the significant and unnecessary burden imposed on manufacturers by the required reporting of data points included under this section that already reported to federal agencies (including Best Price, FSS price, Big Four price). Because these data are already available to CMS from within the Government, under the PRA, it is inappropriate to impose reporting burden when the data is already available to the Agency.

Furthermore, CMS cannot expect manufacturers to comply with this section without providing clarity on the vague and confusing submission requirements and definitions outlined in the updated ICR. Specifically, we recommend the following, and refer the Agency to our past comment letter on these points:

1. CMS Should Align Reporting Requirements to the Most Recent Five Full Calendar Years
   J&J recommends that CMS aligns the reporting requirements to the most recent five full calendar years (e.g. 2018-2022) to be consistent with other government pricing reporting requirements included in the ICR

2. CMS Should Adopt Package Size for Unit Type Submission Requirements
   Prices at the lowest unit of measure are not consistent with the price that is typically reported and published for certain data sets, such as FSS and Big Four Price, which are all at package size, and we suggest that CMS adopt package size price where appropriate. CMS should also confirm that manufacturers should exclude returns in the requested volume data set.

3. CMS Should Remove Monthly Reporting Requirement Under the Definition for WAC Unit Price (WAC unit price definition and Questions 16 & 17)
   CMS introduces Section G by providing definitions for the data points required for submission, including WAC unit price. The definition provided for Wholesale Acquisition Cost (WAC) unit price introduces significant confusion as it seems to conflict with the reporting requirement under Question 16. While Question 16 calls for the submission of WAC unit price by quarter for the most recent five years, the definition refers to "most recent month." Given this discrepancy, it is not clear what level of reporting is required for submission of WAC unit price. We ask CMS to remove the reference to "most recent month" under the definition of WAC unit price or further clarify this definition in updated guidance. In the absence of further clarity from CMS, we believe for Question 16 that reporting the weighted average to be a reasonable interpretation.

4. Opposition to FSS and Big Four Submission Requirements (Questions 20 – 23):
   In the updated ICR, CMS states its belief that use of FSS / Big Four prices is appropriate in situations where the selected drug has no therapeutic alternative, or the price of the therapeutic alternative exceeds the ceiling. However, J&J continues to contend that CMS does not have the authority to require submission of this pricing data. Moreover, the reporting requirements are unclear. Specifically, CMS describes the requirement to report the total unit volume, defined as the total number of units for each NDC-11 sold to direct federal purchasers. However, as we

previously noted, federal agencies do not typically purchase directly from the manufacturer, as they typically purchase through wholesalers. Therefore, these questions are not logical, and they should be removed.

5. Clarity for Commercial Average Net Unit Price Definition (Questions 24 & 25)
   The definition for commercial average net unit price - best is contradictory, as it states the lowest price to any commercial payer in the U.S., but then specifies that it is net of discounts, chargebacks, rebates, etc. These does not make sense, as these are costs that we would not consider part of sales revenue although they may represent operating costs. We ask CMS to clarify this definition or recognize that manufacturers will need to make reasonable assumptions when submitting the data required for these questions. J&J underscores that these questions represent new and significant reporting requirements not already calculated or reported by manufacturers for any other programs and will result in reasonable differences in reporting across manufacturers. For this and other reasons noted above, we urge CMS to remove these reporting requirements.

## H: Certification of Submission of Sections A through G

*Ask CMS to Update the Certification to Recognize the Need for Reasonable Assumptions and Account for the Restrictive Word Limitations*

J&J continues to have concerns with the certification statement. As we previously commented, given the word limitations, which we oppose, it is not reasonable to require certification that information is "complete," and therefore we ask CMS to remove this from the certification statement, similar to the update CMS made to the certification statement in Section J, which we support, or remove all word limitations. Furthermore, while we agree that the information submitted should be accurate, we re-emphasize our ask for CMS to explicitly acknowledge that manufacturers will have made reasonable assumptions given CMS' vague requirements and the significant challenges stemming from conflicts between the requirements outlined in ICR and manufacturer and industry accounting practices.

## I. Evidence About Alternative Treatments

*Urge CMS to Avoid Any and All Use of Overly Simplified and Problematic Cost-Utility Analyses*

We appreciate that CMS' revised guidance forgoes a "formulaic quantitative approach" for a "qualitative approach" to evidence evaluation that preserves the "ability to consider nuanced differences between different drugs that might not be captured in a more thoroughly pre-specified quantitative approach".[6] However, we remain concerned that the Updated ICR continues to embrace measures of cost-utility analysis, which are in direct contradiction with the Agency's intention. Specifically, CMS still encourages submitters to articulate the relevance of these measures to the selected therapies. We strongly urge that CMS unequivocally dismiss any analysis that in part depends on such metrics known to fail the FDA's guidance of patient involvement. Irrespective of the ICR submitter's opinion, the integrity of these measures and their value to CMS is questionable, as they have demonstrated a deficiency in comprehensively and reliably assessing patients' health.[7] Given well-known conceptual limitations,

[6] https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf
[7] Browne J, Cryer D, Stevens W. Is the QALY Fit for Purpose? Am J Accountable Care. 2021;9(2):8-13 https://www.ajmc.com/view/is-the-qaly-fit-for-purpose-

estimates may present a false sense of accuracy while being inherently incomplete, and they may even be downright misleading indicators of value. [8,9]

We urge CMS to recall, in the process of making therapeutic value determination, that no such standardized cost-utility approach be considered obligatory or even useful. The Agency should rely on meaningful disease-specific and patient-centric instruments that more accurately capture the impact of treatments on patients and their caregivers to aid in understanding the full value of selected therapies for each population in each individual case.[10] We strongly encourage the Agency to apply methods that allow for comprehensive understanding of patient value by refusing to adopt generic, one-size-fits-all metrics that are measured against cost-effectiveness thresholds which are still subject to debate and variation, as well as considerable underlying ethical challenges. [11,12,13]

*Ask CMS to Recognize Methodological Challenges to Metrics Specifically Listed in the ICR and Concerns over Self-Attestation*

We agree with and appreciate the Agency's acknowledgement in the revised Guidance that "QALYs will not be used in the Negotiation Program". We strongly encourage the Agency to maintain a similar stance towards recent iterations of similar one-size-fits-all-summary-metrics, such the evLYG (Equal Value of Life Years Gained) or HYT (Health Years in Total). Modifications made with these measures to circumvent the discriminatory decision-making associated with QALYs have introduced new fundamental shortcomings. For instance, the evLYG has been proven to be inherently inadequate as it disregards the full impact therapies can have on patients' quality of life.[14] As we highlighted in our initial Guidance comment, this oversight would ignore critical patient-focused considerations like treatment side-effects, a concern specifically raised for cancer patients.[15]

Similarly, the HYT exhibits significant methodological deficiencies and potential discriminatory properties. As a recent academic analysis states, "[w]e identify fundamental flaws in the HYT approach's theoretical foundations, including violations of basic axioms of decision theory", while concluding that,

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[8] Gafni A, Birch S. Preferences for outcomes in economic evaluation: an economic approach to addressing economic problems. Soc Sci Med. 1995; 40:767–76; Phelps CE, Madhavan G. Valuing Health: Evolution, Revolution, Resistance, and Reform. Value Health. 2019 May;22(5):505-510. doi: 10.1016/j.jval.2019.01.010

[9] Browne J, Cryer D, Stevens W. Is the QALY Fit for Purpose? Am J Accountable Care. 2021;9(2):8-13 https://www.ajmc.com/view/is-the-qaly-fit-for-purpose-

[10] Food and Drug Administration. Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims. Guidance for Industry. December 2009. https://www.fda.gov/regulatory-information/search-fda-guidance/documents/patient-reported-outcome-measures-use-medical-product-development-support-labeling-claims

[11] Bilinski A, MacKay E, Salomon JA, Pandya A. Affordability and Value in Decision Rules for Cost-Effectiveness: A Survey of Health Economists. Value in Health. 2022;25(7):1141–7. http://dx.doi.org/10.1016/j.jval.2021.11.1375; Sampson C, Zamora B, Watson S, et al. Supply-Side Cost-Effectiveness Thresholds: Questions for Evidence-Based Policy. Appl Health Econ Health Policy. 2022;20(5):651–67. http://dx.doi.org/10.1007/s40258-022-00730-3

[12] Menzel PT, How Should Willingness-to-Pay Values of Quality-Adjusted Life-Years Be Updated and According to Whom? AMA Journal of Ethics. 2021;23(8):E601-606. Available from: http://dx.doi.org/10.1001/amajethics.2021.601 ; See also: National Council on Disability. Quality-Adjusted Life Years and the Devaluation of Life with Disability. November 2019. https://ncd.gov/sites/default/files/NCD_Quality_Adjusted_Life_Report_508.pdf ; National Council on Disability. Policy Brief: Alternatives to QALY-Based Cost-Effectiveness Analysis for Determining the Value of Prescription Drugs and Other Health Interventions. November 2022 https://ncd.gov/sites/default/files/NCD_Alternatives_to_the_QALY_508.pdf

[13] Solow B, Pezalla EJ. ISPOR's Initiative on US Value Assessment Frameworks: The Use of Cost-Effectiveness Research in Decision Making among US Insurers. Value in Health. 2018;21(2):166–8. http://dx.doi.org/10.1016/j.jval.2017.12.004

[14] https://www.agingresearch.org/news/alliance-advocates-for-equitable-access-for-alzheimers-patients-seeking-new-treatment/

[15] Cohen, J. T., Ollendorf, D. A., Neumann, P. J., Will ICER's Response to Attacks on QALY Quiet the Critics. December 2018. https://cevr.tuftsmedicalcenter.org/news/2018/will-icers-response-to-attacks-on-the-qaly-quiet-the-critics

"[i]n common with the QALY, the HYT approach 'discriminates' on the grounds of baseline HRQoL (Health-Related Quality of Life), although for different reasons and in different circumstances".[16]

J&J values vigorous academic debate as part of a healthy scientific process conducive to hypothesis testing, concept validation, and refinement. At the same time, we strongly believe that the Agency remains acutely aware of its unique responsibilities and influence in weighing such arguments. As such, we encourage that the Agency refrain from analyses that rely on untested or contested measures to make decisions that directly impact millions of beneficiaries' health. We thus express serious concern over the proposed cost-effectiveness attestation in Section I, which still invites submission of analyses tangled in these contested metrics. We are concerned that the Agency is not adequately equipped to consider the many factors that should inform analysis of subjective, non-binding interpretations of such metrics. Therefore, the Agency should not bear the responsibility of making determinations on these factors, particularly within the short window of time between submissions and its final determination of price.

As currently drafted, the proposed attestation does not require submitters to clearly identify which parts of the submitted analysis rely on such measures and would therefore have to be discarded in line with statutory obligations and CMS' qualitative approach. Given the significant consequences of using the aforementioned (and similar metrics), we urge CMS to unequivocally dismiss information associated with them. As it has done with the QALY, CMS should clearly communicate that these instruments will not be considered. This would encourage submitters to focus on providing relevant information on the clinical comparative effectiveness of therapies that not only satisfy the nondiscrimination criterion but that is also not inherently biased and misleading and thus supports CMS stated approach to conduct a qualitative, value-driven and patient-centered evaluation process.

*We offer the following additional comments related to the specific questions:*

- We appreciate that CMS provided a list of outcomes it will consider in its definition section for Question 28, adding important categories such as outcomes relating to productivity. We understand that the Agency cannot exhaustively list all measures it will consider in evaluating the value of the selected therapies, but as noted in our previous comments, we urge the inclusion of a broad and holistic range of impacts on patients, caregivers and the society. Domains of economic impact that matter to patients may include direct medical costs, non-clinical healthcare costs, social impacts, ability to work, education and job attainment or caregiver impacts, and should be understood through the lens of the lived experience of Medicare beneficiaries in the healthcare system.[17]

- We appreciate CMS' adoption of a previous suggestions made by J&J to include health equity considerations in Question 29. This consideration can meaningfully impact diverse beneficiary groups who may derive differential benefits from evaluated therapies. Additionally, we welcome CMS' clarified definition on unmet need in the revised Guidance and ICR (Question 30). In this context, we would similarly emphasize the importance of understanding remaining unmet needs within certain subpopulations from a health equity perspective. Too often the so-called "Myth of the Average" in standardized value assessments can overshadow remaining disparities, and we

[16] https://noahe.ca/events/past/noahe-rounds/health-rounds-iii/hetar-iii-s6; Paulden M, Snowsill T, O'Mahony J, McCabe C. Are the 'Equal Value of Life Years Gained' and 'Health Years in Total' Approaches Viable Alternatives to the QALY? Matters of Logic and Matters of Value. Event: Society for Medical Decision Making (SMDM) 42nd Annual North American Meeting. Recording: https://www.youtube.com/watch?v=MtNKI2VfTJw;

[17] https://thevalueinitiative.org/wp-content/uploads/2023/06/05-2023-Economic-Impacts-Framework-Report_FINAL.pdf

steadfastly uphold that health equity is integral to the concept of value.[18] In preparation for the evaluation process, we would direct CMS's attention to organizations like the Innovation and Value Initiative (IVI) that have pioneered in actively engaging communities to jointly develop criteria and deepen understanding of value assessment needs, with an eye towards eliminating existing disparities across our healthcare system.[19]

- We are heartened to see that CMS has added Question 31 in the Updated ICR that accounts for both the patient and caregiver perspectives directly. However, there is discrepancy in CMS' interpretation of caregiver benefit, which, as it stands in Question 28, is only recognized when there is a direct impact on the individual using the product. This viewpoint is at odds with the definition established in academic literature, its practical application in U.S. payer decision-making, or its understanding by other government agencies.[20,21,22] As acknowledged by the Center of Disease Control and Prevention (CDC), "Caregiving can impact the caregiver's life in myriad ways including his/her ability to work, engage in social interactions and relationships, and maintain good physical and mental health." [23] Recognizing CMS' track record of proactive engagement with caregiver organizations, [24] we ask the Agency to provide needed clarity on its view. Specifically, CMS should affirm that if selected therapies yield benefits impacting these crucial dimensions, such value to caregivers will indeed be recognized and incorporated into the evaluation.

- For responses to questions 27-30 and 32, CMS continues to specify word counts and limits on the number of citations. While we welcome the addition of tables, graphs and other figures for questions 28-30 and 32, we believe the remaining constraints still unduly restrict the presentation of valuable scientific information. This is particularly problematic for products with multiple indications, as the revised ICR requests manufacturers to discuss comparative evidence at the level of each indication of the selected products and their therapeutic alternatives. We urge CMS to also accept tables and charts as response formats for Question 27 as these would be most effective to accurately and thoroughly convey prescribing information across diverse indications.

- For questions 28-30, CMS stated a preference for submission references to be in MLA style (Modern Language Association). While MLA is commonly used in the humanities, we noticed that CMS linked to the different NLM (National Library of Medicine) style guide. Also known as Vancouver style, NLM is commonly used in the field of medicine and health sciences, such as in PubMed. For clarity, we ask CMS to confirm that it indeed requests that submitters adhere to MLA style, and not Vancouver/NLM style.

**J. Certification of Submission of Section I for All Respondents**

[18] https://www.npcnow.org/sites/default/files/2022-01/The_Myth_of_Average_01.2022.pdf
[19] https://thevalueinitiative.org/health-equity-initiative/
[20] Grosse SD, Pike J, Soelaeman R, Tilford JM. Quantifying Family Spillover Effects in Economic Evaluations: Measurement and Valuation of Informal Care Time [Internet]. PharmacoEconomics. 2019;37(4):461–73. Available from: http://dx.doi.org/10.1007/s40273-019-00782-9
[21] https://www.bcbs.com/the-health-of-america/reports/the-impact-of-caregiving-on-mental-and-physical-health
[22] https://www.cdc.gov/aging/caregiving/caregiver-brief.html:
[23] Ibid.
[24] https://www.cms.gov/outreach-and-education/outreach/partnerships/caregiver

J&J appreciates the updates made to this certification statement to remove “complete”, “accurate” and removal of the statement of liability. We welcome these changes and ask CMS to apply similar changes to the Certification Statement in Section H.

We are committed to engaging with CMS to implement a Program that prioritizes operational feasibility, and most importantly recognizes the value to beneficiaries as a foundational aspect of determining the MFP. We encourage CMS and OMB to review our previous comments on the Initial ICR in addition to the comments above, and we would welcome questions and the opportunity to work more closely with the Agency on the ongoing IRA implementation.

Sincerely,

Jacqueline Roche, DrPH
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Johnson & Johnson Worldwide Government Affairs & Policy