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William N. Parham, III, Director
Paperwork Reduction Staff
Office of Strategic Operations and Regulatory Affairs
Centers for Medicare & Medicaid Services
7500 Security Boulevard Baltimore, Maryland 21244

Richard Revesz
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th NW Washington, DC 20503

Sent via electronic mail

Re: Comments on 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)

Dear Mr. Parham and Mr. Revesz:

Genentech appreciates the opportunity to submit comments on the *Information Collection Request for Negotiation Data Elements under Section 11001 and 11002 of the Inflation Reduction Act (CMS-10847, OMB, 0938-NEW)* (the "ICR"). We agree with CMS' stated goal of the ICR to ensure that the collection of information specific to the negotiation factors under the Inflation Reduction Act ("IRA") is clear, reduces burden and duplicative reporting, and collects only relevant information needed for the proper implementation of the IRA's Medicare Drug Price Negotiation Program (the "Program"). We appreciate CMS' consideration of the comments received during the 60-day comment period and the modifications made to the ICR to date. However, as outlined in our prior comment letter, we believe there are additional opportunities for CMS to reduce burden, reduce duplicate reporting, and to collect only relevant information

needed for the proper implementation of the Program. Below we also provide further comment on additional ways CMS could best achieve their stated goals.

Genentech is a leading biotechnology company dedicated to pursuing groundbreaking science to discover and develop medicines for people with serious and life-threatening illnesses. We are committed to improving patients' lives through new innovations. To this end, in 2022 we, under the Roche umbrella, invested over $15 billion globally in research and development – more than any other health care company in the world. In the past ten years, we have delivered to patients 20 new medicines that treat devastating diseases like cancer, multiple sclerosis, and hemophilia. In addition to our over 40 approved medicines, we have 70 potential new medicines in clinical or preclinical development and have been granted 39 FDA Breakthrough Therapy Designations for medicines with the potential to provide substantial improvement over currently available treatments. It is this commitment to innovation and treatment advances we feel should be incentivized through the IRA process. Because collecting information from manufacturers regarding the negotiation factors is a critical step in the Program, it is essential that this ICR collect information that is clear and useful for the purposes set forth in statute, while also reducing the burden of reporting.

We appreciate the changes CMS has made to the ICR thus far, which simplify the reporting of R&D costs, remove data collection of certain unnecessary data points, and take steps to reduce burden on manufacturers (e.g., pre-populating NDC numbers). We also appreciate the changes to broaden the scope of information considered in assessing comparative effectiveness (e.g., more expansive view of clinical and non-clinical benefits). These clarifications will result in the collection of clearer and more useful information by CMS. However, many of our original concerns from the 60-day notice remain.[1] Indeed, despite the modifications CMS made to the ICR, there remain additional opportunities that can still be addressed to ensure the proper function of the Program while aligning with the requirements of the Paperwork Reduction Act ("PRA"). Specifically, CMS should:

- Take additional steps to reduce reporting burden on manufacturers by pre-populating additional data elements, namely those elements that are already reported to the government and within the government's possession;
- Increase the word limits for text fields to improve the utility of the information collection by ensuring the submission of all relevant information;
- Allow for rolling data submissions to reduce reporting burden while ensuring that the information collection does not omit information necessary to the proper functioning of the Program, particularly during the first year of implementation;

[1] Please also see Appendix A for our full comment letter submitted in response to the 60-day notice for a more detailed review of those concerns.

- Reduce the burden associated with the reporting of R&D recoupment and federal financial support while better aligning the relevant reporting requirements with the statute; and
- For consistency with the statute, request one single number for federal financial support.

We discuss each of these recommendations, in turn, below.

A. *CMS Should Pre-populate all Data Fields Where the Requested Data are Already Reported to or Otherwise in the Possession of the Government.*

Under sections 1193(a)(4) and 1194(b)(2) of the Social Security Act, CMS is collecting certain manufacturer-specific data as part of the Program. We continue to recommend that **CMS reduce the burden of this reporting requirement for manufacturers by pre-populating the manufacturer-specific version of the ICR Form using data already available to the government.** The PRA prohibits "any federal agency from adopting regulations which impose paperwork requirements on the public unless the information is not available to the agency from another source within the Federal Government," and requires each agency to "manage information resources to…reduce information collection burdens on the public." Although we believe that CMS is erroneously concluding that manufacturers must affirmatively "submit" all section 1194(e)(1) information already in the possession of the government, there remains further opportunity for CMS to reduce the burden of such reporting while maintaining its interpretation around manufacturer submission of information.

In this 30-day ICR, CMS has decided to pre-populate "Section A. Selected Drug Information" for manufacturers, where it previously instructed manufacturers to gather and submit this information. This change will unquestionably reduce manufacturer burden and represents an acknowledgement by CMS that it already has certain data and is able to pre-populate this information on the version of the ICR Form sent to manufacturers. Yet, it is unclear why CMS has decided to narrowly pick and choose which data are pre-populated and which data are still left for manufacturers to duplicatively report. **Using data already reported to or otherwise in the possession of the government, CMS should similarly pre-populate:**

- Question 14: Regulatory Exclusivity Periods
- Question 16: Wholesale Acquisition Cost Unit Price
- Question 18: Medicaid Best Price
- Question 20: Federal Supply Schedule Price
- Question 22: Big Four Price

All of the data necessary to answer these questions are already reported to the government or in the government's possession. Pre-populating this information would help to reduce the burden of

reporting the large amount of information that is collected in the ICR while still aligning with CMS' interpretation that manufacturers must affirmatively submit the required data under the Program.

B. CMS Should Increase Text Box Word Limitations to Improve the Utility of the Information Collected.

As with our comments submitted in response to the 60-day notice, **we continue to ask that CMS increase the free text word limitations for text boxes throughout the ICR.** CMS did in fact increase the word limit for "Question 3: Post IND-Costs for All Approved Indications of the Selected Drug." However, this change appears to have been motivated by CMS's consolidation of two data categories into a single question. This change thus did not address our concern that the text box word limits will hamper manufacturers' ability to fully report all relevant information, limiting the utility of the information CMS collects.

Due to the unprecedented nature of the Program and numerous new processes and procedures being established, CMS should lean towards more flexibility in the initial years rather than needlessly limiting the collection of relevant information necessary for the proper implementation of the Program. Increasing the word limitations of the text boxes for IPAY 2026 would ensure that relevant information was collected with little risk to CMS. Indeed, if the IPAY 2026 implementation experience indicates that the text fields were too large, CMS has the opportunity to reevaluate this aspect of the ICR when the agency seeks approval for similar ICRs for future years.

C. CMS Should Allow Rolling Submissions to Reduce Reporting Burden and Ensure the Collection of Relevant Information.

We are deeply concerned that the data submission deadline of October 2—just one month after publication of the selected drug list—will not give manufacturers sufficient time to collect the data necessary to inform the negotiation of a maximum fair price ("MFP") under the Program and will significantly increase the burden on manufacturers by providing very little time to collect, review, verify, and report the necessary to CMS. We continue to **urge CMS to establish a data submission process that allows manufacturers to supplement the information reported by the submission deadline on a rolling basis.** We note there is precedent for this approach: CMS already instructs manufacturers to notify the agency if submitted information has changed, which indicates that CMS is capable of receiving additional information after the submission deadline and prepared to do so. Allowing rolling submissions would improve the quality, utility, and clarity of the information collected by allowing manufacturers ample time to submit responsive information and the opportunity to supplement that information as needed.

This will be particularly important for the first IPAY of the Program, for which both CMS and manufacturers will be implementing the Program's reporting requirements for the first time.

D. CMS Should Reduce the Reporting Burden While Better Aligning R&D Cost Recoupment Data Collection With Statute.

Although CMS chose to simplify some of the reporting requirements regarding R&D costs, CMS can still take additional steps to reduce reporting burden by better aligning data collection of R&D cost recoupment information with statute. In the current version of the ICR, CMS is requesting unnecessary information regarding recouped R&D expenditures. Specifically, CMS is collecting the Primary Manufacturer's global, total lifetime net revenue and U.S. total lifetime net revenue for the selected drug to determine the extent to which the Primary Manufacturer has recouped R&D costs for the selected drug. Not only did CMS miss the opportunity to simplify reporting, they requested more information from manufacturers than required by statute. **Specifically, information on whether a manufacturer recouped its R&D costs can be most simply accomplished with the least burden by replacing Questions 6 & 6a with a single attestation (YES/NO) on whether a manufacturer has recouped their R&D costs.** We note that this approach is also consistent with the statute, which does not specifically reference information regarding global or U.S. revenues, and instead merely refers to "[r]esearch and development costs of the manufacturer for the drug *and the extent to which the manufacturer has recouped research and development costs*."[2] Only if a manufacturer answers "NO" should it be necessary for the manufacturer to report the extent to which its R&D costs were not fully recouped.

E. For Consistency with the Statute, CMS Should Request One Single Number for Federal Financial Support and Strike Question 10.

In Section E of the current version of the ICR, CMS proposes to require manufacturers to disaggregate data for Prior Federal Financial Support. As we commented previously, this information collection exceeds the statute, which refers only to prior federal financial support as one line item. CMS appears to have responded to this and similar comments by revising "Question 9: Federal Funding Support Amount" such that it is now a single line item. But, in the very next question CMS undoes this simplification by continuing to require manufacturers to disaggregate the sources of federal financial support. Requiring manufacturers to sub-divide the data in the way CMS proposes does not enhance the utility of the data and serves only to increase burden on manufacturers in a manner not contemplated by statute. **CMS should delete Question 10 and instead rely on the information that will be collected in Question 9.**

[2] SSA § 1194(e)(1)(A) (emphasis added).

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Thank you for considering our comments on the revised ICR. As the manufacturer of products that may be selected drugs under the Program in the future, we are invested in ensuring that the Program is implemented in a manner that reduces burden on manufacturers while ensuring that CMS relies on the most accurate, complete, and useful information in negotiating the MFP for each selected drug. We welcome the opportunity to discuss these comments with you further and address any questions you may have. Please reach out to me or Valerie Reynolds (reynolds.valerie@gene.com) at any time.

Sincerely,

David Burt
Executive Director
Federal Government Affairs
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