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Faisal D'Souza
Technical Coordinator
National Coordination Office
Networking and Information Technology Research and Development Program
National Science Foundation
2415 Eisenhower Avenue
Alexandria, VA 22314

Re: Request for Information on the Development of an Artificial Intelligence (AI) Action Plan

Dear Mr. D'Souza:

The Pharmaceutical Research and Manufacturers of America (PhRMA) appreciates the opportunity to provide comments in response to the Office of Science and Technology Policy Networking and Information Technology Research and Development National Coordination Office's *Request for Information on the Development of an Artificial Intelligence (AI) Action Plan*.[1] PhRMA represents the country's leading innovative biopharmaceutical research companies, which are laser focused on developing innovative medicines that transform lives and create a healthier world. Together, we are fighting for solutions to ensure patients can access and afford medicines that prevent, treat and cure disease. Over the last decade, PhRMA member companies have invested more than $800 billion in the search for new treatments and cures, and they support nearly five million jobs in the United States.

As the Administration considers the development of the *Artificial Intelligence (AI) Action Plan*, it is important to emphasize that the application of AI in drug development and health care is distinct from applications in other sectors, and different cases will require nuance in differing policy and regulatory considerations. The American biopharmaceutical industry relies on a unique foundation of scientific research investment, strong intellectual property (IP) protections, and a flexible regulatory framework, which, in turn, allows life-saving innovation to flourish in the United States. As the use of AI in health care, including in drug development, advances, it is critical that AI-enabled solutions are used responsibly and are trustworthy. Therefore, it is crucial that future policies on the use of AI impacting

[1] National Science Foundation. (2025). *Request for Information on the Development of an Artificial Intelligence (AI) Action Plan.* Available at: https://www.federalregister.gov/documents/2025/02/06/2025-02305/request-for-information-on-the-development-of-an-artificial-intelligence-ai-action-plan.

the biopharmaceutical industry preserve this foundation and take industry-specific considerations into account. By the same token, the industry recognizes the need to use AI in a thoughtful and responsible manner, with careful consideration given to advancing biopharmaceutical innovation, supply chain resiliency and emerging AI-generated biosecurity threats.

This letter contains our detailed recommendations for policy actions that should be included in the new "AI Action Plan." A summary is as follows:

I. **Intellectual Property:** It is imperative that U.S. law and policy apply the same standards to granting IP protections whether an invention is made using AI or not, as AI is a tool that can be used to facilitate biopharmaceutical research and development (R&D). Such law and policy should facilitate and protect the patenting of AI technologies, as well as inventions created using AI, and provide private industry with certainty in the ownership rights for such inventions. PhRMA and our member companies look forward to partnering with the Administration in developing prudent patent and other IP policies that maintain America's innovation advantage as the capabilities of AI continue to change.

II. **Regulatory Framework:** The U.S. must ensure it remains a global leader in AI-enabled biopharmaceutical innovation by fostering a competitive environment that promotes innovation with a flexible, risk-based regulatory approach. PhRMA believes the current U.S. regulatory framework is sufficiently flexible to allow such an environment to flourish. Such an approach is necessary to help ensure that the U.S. does not lose its competitive edge to foreign developers and to avoid delays due to regulatory uncertainty.

III. **Ethical and Responsible Use:** America's biopharmaceutical companies are committed to appropriate, transparent, accountable and responsible use of AI, prioritizing the health and well-being of patients. Trustworthy, transparent use of AI is critical to the application of AI in patient-centered care. The biopharmaceutical industry has a long history of conducting ethical and responsible drug development, both due to the industry's ethical standards and commitment to holding itself accountable as well as regulatory requirements, that also extends to its use of AI. Future policies must allow the industry to operate efficiently while upholding these standards.

American biopharmaceutical companies far exceed the rest of the world in their R&D investments, accounting for over 52% of global biopharmaceutical R&D spending.[2] Additionally, the biopharmaceutical industry is expected to invest more than $3 billion on AI by the end of 2025, a marked increase from $463 million invested in 2019.[3] This significant investment emphasizes the industry's commitment to utilizing AI as a tool to transform processes throughout drug discovery and

[2] T.Long and R.D.Atkinson. (2023). *Innovation Wars: How China Is Gaining on the United States in Corporate R&D*. Information Technology & Innovation Foundation. Retrieved from https://www2.itif.org/2023-us-china-corporate-rd.pdf.
[3] Global Data. (2022). *Pharma industry's spending on artificial intelligence could reach over $3 billion by 2025, says GlobalData*. Retrieved from https://www.globaldata.com/media/pharma/pharma-industrys-spending-artificial-intelligence-reach-3-billion-2025-says-globaldata/.

development and throughout the supply chain and manufacturing, in addition to the promising impact AI will continue to have in getting therapies and cures to Americans faster.

AI has the potential to transform drug discovery, development and manufacturing by significantly increasing efficiencies, improving quality of research, and facilitating novel approaches to develop and deliver new medicines. A recent study shows that there has been an increasing number of submissions to the U.S. Food and Drug Administration (FDA) that incorporated AI elements in recent years.[4] AI is a tool leveraged by the biopharmaceutical industry to enhance a variety of tasks, including, but not limited to, nonclinical and clinical research, post-market activities (e.g., safety monitoring/pharmacovigilance, analysis of real-world data), manufacturing, and submissions to regulatory agencies.[5] Altogether, with the right policies, AI has significant promise to help enhance U.S. manufacturing and supply and improve access to current and future medicines for patients.

To regulate AI technology in a way that continues to support the biopharmaceutical industry's adoption of AI technologies across the drug lifecycle, it is necessary to provide companies with regulatory certainty by developing a federally driven, flexible, risk-based approach. While the continued growth in the use of AI across the drug lifecycle brings promise to patients by supporting the development of hard-to-find therapies and decreasing development timelines, it is crucial that regulatory review ensures that new technologies are properly validated, monitored, and utilized. Furthermore, in recognizing AI as a tool, the biopharmaceutical industry believes that human oversight of AI tools and involvement is paramount throughout the drug lifecycle and should also remain an essential aspect of regulatory oversight.

Beyond drug discovery, development, and manufacturing, AI is transforming management of chronic health conditions and rare diseases by enabling earlier detection and more effective treatment strategies, as well as improving patient outcomes. These advancements are shifting health care from a costly, reactive model to one that emphasizes prevention, early intervention and personalized care. We encourage any future policy efforts to prioritize AI's potential to foster efficient biopharmaceutical innovation, bolster American leadership in innovation, and improve health outcomes.

In recent years, America's biopharmaceutical industry has proven that responsible utilization of AI can:

- Help quickly, efficiently, and accurately analyze massive amounts of data to inform drug development and identify potential drug benefits and safety risks;

[4] Liu Q, Huang R, Hsieh J, et al. (2022). Landscape Analysis of the Application of Artificial Intelligence and Machine Learning in Regulatory Submissions for Drug Development From 2016 to 2021. *Clinical pharmacology and therapeutics*, *113*(4), 771-774.
[5] PhRMA. Artificial Intelligence and Biopharmaceutical Innovation. March 2025.Available at: https://phrma.org/resources/artificial-intelligence-and-biopharmaceutical-innovation

- Assist in discovering and developing new drugs and treatment for the over 5,000 rare diseases that currently have limited treatment options; and
- Accelerate the discovery, design, testing, and delivery of new medicines and therapies that will help treat and cure patients with potentially life-threatening illnesses.

Examples of how the biopharmaceutical industry has leveraged AI to advance R&D and facilitate real world data/evidence collection include:

- AI can be used to screen and test drug candidates and analyze digitized cell images so that promising leads can be identified more quickly and accurately amongst millions of compounds within in-house libraries, and to identify promising biomarkers.[6]
- AI can be used to assist in the design of antibodies for medicines that may interact with a known biological target or pathway.[7]
- Computational modeling can be used to determine personalized cancer treatments by reviewing data including patient genetic makeup, biopsy information, and diagnostic tests and scans.[8]
- AI can be used to perform a differential diagnosis between two similar diseases, allowing general practitioners to diagnose a condition that could otherwise only be reliably diagnosed by specialists, to differentiate disease and non-disease conditions (e.g., a patient with heart disease versus a healthy individual) or to determine the status of a disease (e.g., a particular stage of cancer).[9]
- AI may be used in clinical trial design to streamline and expedite drug development. It can also be used to monitor hundreds of ongoing worldwide clinical trials across thousands of sites in real time to help anticipate, identify, and resolve issues that slow or compromise clinical testing.[10]
- AI can be used post-approval to monitor clinical outcomes and safety of a medicine taken by a number of patients, an exercise that would take far too large for a single human to monitor.[11]

[6] *Hacking R&D*, *id.*; Godinez et al. (2022). *Design of potent antimalarials with generative chemistry.* Retrieved from https://www.researchgate.net/publication/358815282_Design_of_potent_antimalarials_with_generative_chemistry ; Cáceres et al. (2022). *Deep learning approaches in predicting ADMET properties.* Retrieved from https://pubmed.ncbi.nlm.nih.gov/33124448/ ; Comment of Novartis, USPTO Request for Comments on Patenting Artificial Intelligence Inventions, Docket No. PTO-C-2019-0029, 84 Fed. Reg. 44889 (Aug. 27, 2019).
[7] Prihoda et al. (2022). *BioPhi: A platform for antibody design, humanization, and humanness evaluation based on natural antibody repertoires and deep learning.* Retrieved from https://www.tandfonline.com/doi/full/10.1080/19420862.2021.2020203 ; Struble et al. (2020). *Current and Future Roles of Artificial Intelligence in Medicinal Chemistry Synthesis.* Retrieved from https://pubs.acs.org/doi/10.1021/acs.jmedchem.9b02120 ; BRISTOL MYERS SQUIBB, *supra* note 3.
[8] Comment of Genentech, Inc., USPTO Request for Comments on Patenting Artificial Intelligence Inventions, Docket No. PTO-C-2019-0029, 84 Fed. Reg. 44889 (Aug. 27, 2019).
[9] Comment of Novartis, *supra* note 4; Comment of Genentech, Inc., *supra* note 6.
[10] Comment of Novartis, *supra* note 4*; From numbers to knowledge*, *supra* note 3.
[11] Comment of Genentech, Inc., *supra* note 6.

I. Strong and Predictable Intellectual Property Protections for AI Technologies and Inventions Created Using AI Technologies Are Necessary to Secure America's Innovation Dominance

A robust and reliable patent and broader IP system in the United States promotes the biomedical R&D ecosystem and PhRMA members' decisions to invest billions of dollars into R&D each year. Likewise, strong and predictable IP protection for inventions related to AI are critical to not only encourage the use of such technologies in R&D, but also in securing American leadership and dominance in this domain. Accordingly, it is important for U.S. law and policy to facilitate and protect the patenting of AI technologies as well as inventions created using AI and provide private industry with certainty in the ownership rights for such inventions. As this field continues to evolve and the capabilities and definition of AI change, robust discussion with stakeholders, including the biopharmaceutical industry, will be key to the development of prudent patent and other IP policies that maintain America's innovation advantage. PhRMA has previously submitted comments to the U.S. Patent and Trademark Office on issues relating to IP and AI[12] and looks forward to working with this Administration as issues related to AI develop in the future.

II. Securing and Maintaining U.S. Competitiveness and Leadership in AI Requires a Flexible, Risk-Based Regulatory Environment

The increasing use of AI in drug development and throughout the drug lifecycle holds enormous promise for patients. AI tools speed the pace of innovation while also enabling new approaches to help ensure safety, effectiveness, and quality of medicines. PhRMA believes the current U.S. regulatory framework is sufficiently flexible to enable the use of AI as a reliable tool across drug development. As the Administration formulates its AI Action Plan, the continued application of a flexible, risk-based approach to regulatory oversight of AI use will allow the U.S. to maintain its competitive advantage.

Employing a risk-based regulatory framework is essential to fostering innovation, given that AI applications vary significantly and should be evaluated based on their intended use and risk profile. For example, the Federal Food, Drug, and Cosmetic Act enables FDA's risk-based approach to regulatory oversight of AI within its purview.

While PhRMA believes FDA's current regulatory framework is sufficiently flexible, guidance from FDA should build upon the strong foundation that already exists for developing and evaluating uses of

[12] PhRMA, Comment in Response to the USPTO's Request for Comments Regarding Artificial Intelligence and Inventorship, Docket No. PTO-P-2022-0045 (May 15, 2023); PhRMA, Comment in Response to the USPTO's Request for Comments Regarding the Impact of the Proliferation of Artificial Intelligence on Prior Art, the Knowledge of a Person Having Ordinary Skill in the Art, and Determinations of Patentability Made in View of the Foregoing, Docket No. PTO–P–2023–0044 (July 29, 2024); PhRMA, Comment in Response to the USPTO's 2024 Guidance Update on Patent Subject Matter Eligibility, Including on Artificial Intelligence, Docket No. PTO-P-2024-0026 (Oct. 16, 2024).

AI models. For the biopharmaceutical industry, FDA guidance generally reduces uncertainty regarding new technologies and plays an important role in encouraging investment. The Agency's recent draft guidance on the use of AI to support regulatory decision-making in drug development[13] provides insight into the approach FDA intends to apply, which will help enhance confidence in the application of this technology by stakeholders. PhRMA looks forward to providing comments on this draft guidance and FDA's continued work in this area.

In addition, given the global nature of drug development, U.S. leadership in AI-enabled innovation can help drive alignment across global regulators to achieve harmonization, where feasible. This would help foster innovation by minimizing duplicative, overlapping, or inconsistent approaches to regulation. Venues such as the International Council for Harmonisation (ICH), the International Coalition of Medicines Regulatory Authorities (ICMRA), the International Medical Device Regulators Forum (IMDRF), Pharmaceutical Inspection Co-operation Scheme (PIC/S), or other nimble regulator to regulator discussions are useful avenues as regulators work towards global alignment on regulatory expectations. In an increasingly interconnected biopharmaceutical landscape, reducing regulatory divergence fosters innovation and increases efficiencies in drug development.

An Agile Approach to Regulatory Oversight of AI Use Is Paramount

A responsive and agile approach regarding the oversight of AI is needed, as the use of AI tools in drug research and development is evolving. Ongoing dialogue with stakeholders can help ensure that regulatory approaches remain informed by practical implementation to address challenges, while maintaining opportunities to promote transparency and innovation. We ask that the AI Action Plan include sufficient opportunities for the biopharmaceutical industry, AI developers and FDA to collaborate and share best practices, thereby helping the U.S. lead in innovation and bring treatments to patients faster.

FDA's ability to review AI-generated data and associated algorithms will also require an integrated approach across FDA centers and a robust infrastructure. As FDA continues to develop AI-related policy, establishing a common vocabulary will be important. As such, we commend FDA on its recently published digital health and AI glossary,[14] and encourage its use to facilitate harmonization across FDA centers, other U.S. agencies, as well as across regulators. PhRMA also encourages the National Institute of Standards and Technology (NIST) and other U.S. Government entities, including FDA, to work together in developing and/or adopting best practices and standards that can be used to facilitate

[13] U.S. Food and Drug Administration. (2025). *Draft Guidance for Industry: Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products*. Retrieved from https://www.fda.gov/media/184830/download.
[14] U.S. Food and Drug Administration. (2025). *FDA Digital Health and Artificial Intelligence Glossary – Educational Resource* (accessed Feb. 20, 2025). Retrieved from https://www.fda.gov/science-research/artificial-intelligence-and-medical-products/fda-digital-health-and-artificial-intelligence-glossary-educational-resource.

understanding and share case studies across industries.

Regulator Adoption of AI Can Increase Efficiency and Help Spur Innovation

PhRMA encourages FDA to incorporate AI tools where feasible to gain efficiencies in its own operations. For example, AI-based approaches can help to streamline workflows and enable FDA to make decisions more efficiently and consistently in its routine practices. Sharing lessons learned with stakeholders, as appropriate, including what criteria FDA uses to assess AI model credibility and trustworthiness, what specific AI models it uses, and how FDA uses human-in-the-loop to ensure appropriate oversight and accuracy of AI models, can help provide additional assurance to biopharmaceutical companies as they continue to utilize and incorporate AI in drug development. Furthermore, continuing to build and maintain an internal workforce that has the expertise to review drug submissions that incorporate AI elements will be critical to ensure the regulatory environment keeps pace with this rapidly evolving field.

III. Appropriate Safeguards Are Needed to Ensure Transparent, Responsible use of AI

The promise AI presents for the U.S. health care system is immense. When appropriately leveraged through a commitment to principles such as appropriate human oversight and accountability, ethical and responsible use, and a patient focus, there is significant potential for AI to contribute to incredible scientific advancements and patient access. However, as with any new technology, AI tools could also be used to impede access to care if not used responsibly. Certain safeguards are important to prevent egregious misapplications of AI in health care.

Development of consensus-based, sector-specific guardrails

Any guardrails should consider sector-specific needs and factors such as end users and impact and calibrate the level of enforcement to both the specific levels of risk and benefits the use may impose. The Administration and regulators should align with the policies and practices that reflect industry-wide input, including national and international standards. Due to the rapidly evolving nature of this technology, any guardrails should also be developed in partnership with the private sector to ensure policies are robust, flexible, and reflect the expertise and experience of all stakeholders.

Data is increasingly important to increasing the efficiency of biopharma innovation, including in the next wave of personalized medicine. Robust, reliable use of AI requires large, representative use of protected data sets that are representative of the applicable patient population. To stay competitive, the United States should develop a national strategy to expand data interoperability, including training AI models, as appropriate. These efforts would provide a springboard for private sector investment to harness these technologies and drive future innovation. As the Administration considers new policies to

address the growing use of AI across sectors, it should take extra care to avoid policies that would undermine U.S. AI leadership. Broad stakeholder input from private sector entities that are leading the development of these tools will ensure that any policy solutions are balanced and informed.

AI tools should be responsibly deployed and not further impede access to care

In addition to establishing guardrails and a robust data infrastructure, we encourage the Administration to consider increased transparency into the extent to which AI tools are used in health care decision-making. Greater insight into the role of algorithms in utilization management tools is important to ensuring responsible, patient-centered deployment of AI tools. A U.S. Senate report outlined examples of how AI and predictive technologies may have contributed to higher volumes of prior authorization denial rates for post-acute care by insurers.[15] Utilization management tools, which health plans sometimes use to inappropriately bar patients' access to services and medicines, may present increased burdens if AI is utilized for decision-making processes without guardrails, which is why it is critical that the Administration implements safeguards and accountability measures to protect against impediments to health care access.

PhRMA supports the use of AI as a tool with the shared goal of using AI and deploying AI tools in a safe, responsible manner that supports early care interventions and disease prevention; fosters well-informed, shared patient-clinician decision-making; and enables patients to obtain access to the care and medicines they need more quickly. AI tools should not interfere with care decisions that have been made between a provider and patient. The application of AI tools should be consistent with usual course of care and held to the same policies and standards that ensure patient access to services are protected – irrespective of care delivery method, whether with sole human involvement or AI was a component.

Conclusion

PhRMA and our member companies stand ready to serve as a resource on the development of AI policies. As this Administration develops an AI Action Plan, we encourage the consideration of the following policies to leverage AI tools across the health care delivery system.

An AI policy framework should:

- **Be sector-specific and not take a one-size-fits-all approach.** The biopharmaceutical industry diverges from other industries in that it is already highly regulated therefore, new AI policies should be mindful of existing regulations that guide the industry, including those that impact the use of AI.

[15] U.S. Senate Permanent Subcommittee on Investigations. (2024). *Refusal of Recovery: How Medicare Advantage Insurers have Denied Patients Access to Post-Acute Care.* Retrieved from https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf.

- **Leverage existing regulations that already encourage innovation and protect patients.** The current risk-based approach to AI regulation will allow the U.S. to continue to be a leader in drug development.
- **Apply the same standards when determining IP protections whether or not AI was used during the inventive process.** AI can be a tool used in the discovery of new medicines, and inventions resulting from the use of this tool should be able to be patent protected.

Supporting the biopharmaceutical industry through a flexible, risk-based regulatory framework would maintain our nation's global reputation as the leader in biopharmaceutical development and innovation and significantly enhance American leadership in AI. This is due to the substantial investment the industry has made and the exemplary ethical use of AI systems it demonstrates. As the industry that accounts for the single largest share of all U.S. business R&D, representing about 20 percent of domestic R&D by U.S. businesses in 2022, the biopharmaceutical industry is particularly well suited to help lead efforts to promote American leadership in AI on a global scale.[16]

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PhRMA appreciates your consideration of these comments, and we look forward to continuing dialogue with the Administration and other stakeholders on these important issues.

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[16] National Science Foundation. (2022). *Business Enterprise Research and Development (BERD) Survey*. Table 32. Retrieved from https://ncses.nsf.gov/surveys/business-enterprise-research-development/2022#data.