

March 14, 2025

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

RE: Comments of the Connected Health Initiative, Request for Information on the Development of an Artificial Intelligence (AI) Action Plan (90 FR 9088)

Dear Mr. D'Souza:

The Connected Health Initiative (CHI) appreciates the opportunity to submit views to the National Science Foundation's Networking and Information Technology Research and Development (NITRD) National Coordination Office (NCO) in response to its request for information on behalf of the Office of Science and Technology Policy (OSTP) to inform the development of an Artificial Intelligence (AI) Action Plan.¹ CHI is committed to accomplishing policy actions needed to sustain and enhance America's AI dominance, and to ensure that unnecessarily burdensome requirements do not hamper private sector AI innovation.

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## I. About the Connected Health Initiative and Statement of Interest

CHI is the leading multistakeholder policy and legal advocacy effort dedicated to connected health technologies that improve health outcomes and reduce costs. We seek to advance responsible pro-digital health policies and laws in areas including reimbursement/payment, privacy/security, effectiveness/quality assurance, U.S. Food and

<sup>&</sup>lt;sup>1</sup> NSF, Request for Information on the Development of an Artificial Intelligence (AI) Action Plan, 90 FR 9088 (2025), available at: <a href="https://www.federalregister.gov/documents/2025/02/06/2025-02305/request-for-information-on-the-development-of-an-artificial-intelligence-ai-action-plan">https://www.federalregister.gov/documents/2025/02/06/2025-02305/request-for-information-on-the-development-of-an-artificial-intelligence-ai-action-plan</a>.

Drug Administration (FDA) regulation of digital health, health data interoperability, and the rising role of artificial/augmented intelligence (AI) in care delivery.

For more information, see <u>www.connectedhi.com</u>.

## II. Artificial Intelligence and its Vital Role in Advancing the *Quadruple Aim* in Healthcare

Today, there are already many examples of AI systems, powered by streams of data and advanced algorithms, improving healthcare by preventing hospitalizations, reducing complications, decreasing administrative burdens, and improving patient engagement. AI offers the promise to rapidly accelerate and scale such results and drive a fundamental transformation of the current disease-based system to one that supports prevention and health maintenance. For example, AI-driven digital therapeutics that deliver clinically-backed interventions to treat patients where they are, saving the patient, provider and others throughout the healthcare value chain immense time and expense.

The CHI finds that one of the most helpful ways to see the value of AI in healthcare is to view the proposition through the lens of the "quadruple aim" framework. Built on the Institute for Healthcare Improvement's "triple aim," a widely accepted compass to optimize health system performance, the quadruple aim focuses on four key areas where health systems need to be improved and acknowledges concerns of key stakeholders. The four areas are (1) enhancing population health; (2) improving patient experience, satisfaction, and health outcomes; (3) better clinician and healthcare team experience and satisfaction; and (4) lowered overall costs of healthcare.

Improving Population Health Management: Al-enabled tools offer great promise in overcoming the challenges faced by clinicians, health systems, health plans, and public health officials working to advance population health management and public health. Al-enabled tools, for example, can process massive and disparate data sources to provide public health officials, health care systems, and providers essential and actionable data rapidly related to assist with more timely and accurate population level disease surveillance and assessments of disparities and health care resource distribution.

<sup>&</sup>lt;sup>2</sup> http://www.ihi.org/engage/initiatives/tripleaim/pages/default.aspx.

<sup>&</sup>lt;sup>3</sup> Thomas Bodenheimer, MD and Christine Sinsky, MDFrom Triple to Quadruple Aim: Care of the Patient Requires Care of the Provider, Ann Fam Med November/December 2014 vol. 12 no. 6 573-576.

Population health<sup>4</sup> management has long been viewed as the essential ingredient to improve overall health outcomes and arrest rising health care costs. Population health management involves aggregation and analysis of huge amounts of data from divergent sources, something that can be potentially streamlined through robust and powerful AI systems. AI-powered tools can collect patient generated health data and also deliver clinically-backed interventions to treat patients where they are.

As more systems are created and deployed, the opportunity for AI to help improve healthcare outcomes is significant, with estimates suggesting outcomes could be improved by 30-40 percent.<sup>5</sup>

Improving Patient Experience, Satisfaction, and Outcomes: One of the more significant critiques of healthcare systems around the world is that they fail in many respects to meet patients' expectations around access to care, ease of use, and care continuity and coordination.

All too often, patients are forced to make multiple visits, shuffling between a general practitioner and a specialist. With the ability to replicate specialist-level expertise at the frontlines of care, Al-enabled tools will reduce paperwork burdens, center care around where the patient is located, and enhance the ability to manage and understand how to sustain health or manage a disease. Services that increasingly can be enhanced and improved with Al systems will provide patients and their health care teams with timely, essential information, and ongoing support that is not currently available.

With people over the age of 65 representing an increasing percentage of the population, AI systems will be essential for human caregivers and clinicians to extend their reach and coverage of an ever-growing population of patients.

Improving Clinician and Healthcare Team Experience and Satisfaction: Among clinicians and the extended health care team, the growing administrative and paperwork demands coupled with compounding rates of new medical knowledge and data generation are driving records levels of burn-out and dissatisfaction. Alenabled tools can and should be deployed to drastically improve clinician and

<sup>&</sup>lt;sup>4</sup> Defined as "an approach [that] focuses on interrelated conditions and factors that influence the health of populations over the life course, identifies systematic variations in their patterns of occurrence, and applies the resulting knowledge to develop and implement policies and actions to improve the health and well-being of those populations." Kindig, D. and Stoddart, G. What Is Population Health? American Journal of Public Health, 93, 380-383 (2003).

<sup>&</sup>lt;sup>5</sup> Nicole Lewis, Artificial Intelligence to play key role in population health, Medical Economics (2017) (available at http://www.medicaleconomics.com/medical-economics-blog/artificial-intelligence-play-key-role-population-health).

healthcare team satisfaction using tools that help clinicians and the health care team to more quickly screen, diagnose, treat, and monitor effectively patients and remove time-consuming and often mundane tasks.

Reducing Healthcare Costs: The U.S. struggles with both rising costs of providing healthcare to citizens. The situation is unsustainable, and, in many countries, the problem will only get more acute as populations age and average life expectancy continues to rise. A huge amount of data is available today for collection and utilization in timely prevention and treatment decisions that would result in massive cost savings, but that data currently usable, but can be found in electronic health record (EHR) systems.

CHI sees enormous promise in AI to more accurately capture and leverage the range of health data available. This savings estimate includes only the top 10 AI scenarios, such as assisted surgery, virtual nursing assistants, and administrative workflow assistance, etc.

Healthcare administrative costs (e.g., billing) are a continuing challenge. The administrative costs of the U. S. health care system are estimated to be 31 percent of total healthcare expenditures.<sup>6</sup> Al's potential to help us address spiraling costs in healthcare is very real, and it is already showing returns today.

Each of the four domains discussed above are already seeing the potential AI systems have to positively impact the current healthcare system, which the AI Action Plan should seek to augment.

Further, CHI has worked with the broader community to develop, and strongly encourage the HHS strategy to align with, healthcare ecosystem-wide consensus recommendations on the use of AI in healthcare:

- CHI's Health AI Policy Principles, a comprehensive set of recommendations on the
  areas that should be addressed by policymakers examining AI's use in healthcare,
  and how they should be addressed (<a href="https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf">https://connectedhi.com/wp-content/uploads/2022/02/Policy-Principles-for-AI.pdf</a>);
- CHI's Health AI Good Machine Learning Practices, a recommended pathway for the FDA to ensure innovation in machine learning-enabled medical devices, including for continuously learning algorithms, while protecting patient safety (https://connectedhi.com/wpcontent/uploads/2022/04/CHIAITaskForceGMLPs.pdf);
- CHI's Advancing Transparency for Artificial Intelligence in the Healthcare Ecosystem, a proposal on ways to increase the transparency of and trust in health

<sup>&</sup>lt;sup>6</sup> http://www.pnhp.org/publications/nejmadmin.pdf.

Al tools, particularly for care teams and patients (<a href="https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf">https://connectedhi.com/wp-content/uploads/2022/02/AdvancingTransparencyforArtificialIntelligenceintheHealthcareEcosystem.pdf</a>); and

 CHI's Health AI Roles & Interdependency Framework, which proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; and suggests roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept (https://connectedhi.com/wpcontent/uploads/2025/03/CHI-Health-AI-Roles.pdf).

# III. Specific Input of the Connected Health Initiative on the Artificial Intelligence Action Plan

We strongly encourage OSTP to align its AI Action Plan with CHI's comprehensive AI policy principles:

## 1. Harmonizing and Coordinating Approaches to Al

A wide range of federal, local, and state laws prohibit harmful conduct regardless of whether the use of AI is involved. For example, the Federal Trade Commission (FTC) Act prohibits unfair or deceptive acts or practices, and states also have versions of these prohibitions in their statutes. The use of AI does not shield companies from these prohibitions. However, federal and state agencies alike must approach the applicability of these laws in AI contexts thoughtfully and with great sensitivity to the novel or evolving risks AI systems present. Congress and other policymakers must first understand how existing frameworks apply to activities involving AI to avoid creating sweeping new authorities or agencies that awkwardly or inconsistently overlap with current the AI Action Plan.

## 2. Quality Assurance and Oversight

The AI Action Plan should utilize risk-based approaches to ensure that the use of AI aligns with any relevant recognized standards of safety, and efficacy. All healthcare stakeholders benefit from understanding the distribution of risk and liability in building, testing, and using AI tools. To the extent, the AI Action Plan addresses liability, it should ensure the appropriate distribution and mitigation of risk and liability. Specifically, those in the value chain with the ability to minimize risks based on their knowledge and ability to mitigate should have appropriate incentives to do so. Some recommended areas of focus include:

- Ensuring Al is safe and efficacious.
- Encouraging AI developers to consistently utilize rigorous procedures and enabling them to document their methods and results.
- Encouraging those developing, offering, or testing AI systems intended for consumer use to provide truthful and easy-to-understand representations regarding intended use and risks that would be reasonably understood by those intended, as well as expected, to use the AI solution.

The AI Action Plan should ensure that agencies apply existing policies to the use of AI prior to advancing new policies to only fill existing gaps; foster a risk-based approach to recognize the diverse and heterogenous use cases for AI; and align to international standards—including ISO42001 life cycle quality management standard.

CHI also urges OSTP to align with our recommendations on the roles and interdependencies in the AI value chain, which support the theme of a shared responsibility for safety and efficacy. In this framework, CHI proposes clear definitions of stakeholders across the healthcare AI value chain, from development to distribution, deployment, and end use; discusses roles for supporting safety, ethical use, and fairness for each of these important stakeholder groups that are intended to illuminate the interdependencies between these actors, thus advancing the shared responsibility concept.

### 3. Thoughtful Design

The AI Action Plan should encourage design of AI systems that are informed by real-world workflows, human-centered design and usability principles, and end-user needs. AI systems should facilitate a transition to changes in the delivery of goods and services that benefit consumers and businesses. The design, development, and success of AI should leverage collaboration and dialogue among users, AI

<sup>&</sup>lt;sup>7</sup> This framework is accessible at: <a href="https://connectedhi.com/wp-content/uploads/2025/03/CHI-Health-Al-Roles.pdf">https://connectedhi.com/wp-content/uploads/2025/03/CHI-Health-Al-Roles.pdf</a>.

technology developers, and other stakeholders to have all perspectives reflected in AI solutions.

## 4. Access, Infrastructure, and Affordability

The AI Action Plan should enable products and services that involve AI systems to be accessible and affordable. Significant resources may be required to scale systems. Policymakers should also ensure that developers can build accessibility features into their AI-driven offerings and avoid policies that limit their accessibility options.

The U.S. government should take proactive measures to strengthen American Al infrastructure to ensure access and affordability. The AI Action Plan should:

- Provide federal agencies with greater authority to site and permit interstate transmission lines deemed critical to national interests. This includes streamlining approvals and, if necessary, leveraging eminent domain.
- Prevent states from imposing regulations that disproportionately burden data centers that are critical for AI processing.
- Accelerate the development of domestic nuclear power, including small modular reactors (SMRs), through streamlined regulations, tax incentives, and loan guarantees. This will provide a stable, low-carbon power source for data centers.

### 5. Data Bias

The errors in datasets used for AI innovation will remain one of the more pressing issues with AI systems that utilize machine learning techniques in particular. Regulatory agencies should examine data provenance and bias issues present in the development and uses of AI solutions to ensure that bias in datasets does not result in harm to users or consumers of products or services involving AI, including through unlawful discrimination.

### 6. Research and Transparency

The AI Action Plan should support and facilitate research and development of AI by prioritizing and providing sufficient funding while also maximizing innovators' and researchers' ability to collect and process data from a wide range of sources. Research on the costs and benefits of transparency in AI should also be a priority and involve collaboration among all affected stakeholders to develop a better understanding of how and under which circumstances transparency mandates would help address risks arising from the use of AI systems.

We appreciate President Trump's acknowledgment, in the January 23 Executive Order establishing the President's Council of Advisors on Science and Technology,

of the critical research and innovation enabled by initiatives such as the National Science Foundation's National Artificial Intelligence Research Resource (NAIRR). Launched in 2024, NAIRR provides researchers with access to datasets, models, training, cloud computing, and AI credits to drive groundbreaking advancements in Al applications across defense, healthcare, energy, and other sectors vital to U.S. competitiveness. However, the technology developer-donated credits that support NAIRR will expire at the end of the two-year pilot. While Congress has allocated some funding for the program's administration, NAIRR's continuation depends on congressional appropriations for researcher technology credits. The NAIRR Task Force—formed under the National AI Initiative Act of 2020, signed into law by President Trump—estimated that sustaining NAIRR requires \$2.25 billion in federal appropriations over six years to ensure researchers have the resources needed to develop transformative AI solutions and address society's most pressing challenges. The task force recommended congressional appropriations of \$750 million every two years, and we urge the Administration to incorporate this essential funding into future budget proposals to Congress.

## 7. Modernized Privacy and Security Frameworks

The many new AI-driven uses for data, including sensitive personal information, raise privacy questions. They also offer the potential for more powerful and granular privacy controls for consumers. Accordingly, any policy framework should address the topics of privacy, consent, and modern technological capabilities as a part of the policy development process. Requirements created pursuant to the AI Action Plan must be scalable and assure that an individual's data is properly protected, while also allowing the flow of information and responsible evolution of AI. A balanced framework should avoid undue barriers to data processing and collection while imposing reasonable data minimization, consent, and consumer rights frameworks.

#### 8. Standards

The advantages of industry-led standardization in AI development are well established and have been reinforced by the first Trump Administration in Executive Order 13859, which emphasized the need for the United States to drive the development of technical standards, reduce barriers to AI testing and deployment, and enable both new AI-driven industries and AI adoption across existing sectors. A key benefit of private sector and stakeholder participation in AI development is the flexibility it provides to adapt to the rapid evolution of the technology. American companies have been at the forefront of AI innovation, and the United States must continue to harness and support their leadership. The most effective approach is to sustain a private-sector-driven model, with strong government support.

While private industry should lead AI standardization efforts, the U.S. government plays a vital role in supporting and participating in these initiatives. This includes providing resources, investing in research to sustain America's AI dominance, and facilitating contributions to global standards. Additionally, the Trump Administration should take proactive steps to prevent AI standardization from being undermined by standard-essential patent (SEP) challenges that have affected other technologies, such as cellular and Wi-Fi. The longstanding U.S. model—where the government promotes and backs private, voluntary, and consensus-based standard setting—remains the best path forward. CHI has developed a detailed issue brief on the growing risks SEP abuses pose to the healthcare sector, which we urge OSTP to consider as it proceeds with putting its AI Action Plan together.

The United States has the leading global patent system due to its strong emphasis on developing mechanisms that support innovation and foster competition and technological progress. When patent holders choose to contribute their technologies to a technical standard, they understand and agree that their patents may be needed to enable reasonable access to the standard and provide standardsetting organizations (SSOs) with a commitment that they will license their SEPs on fair, reasonable, and non-discriminatory (FRAND) terms to balance the anticompetitive risks associated with standard setting. The SEP holder understands and agrees that, by contributing to the standardization process, it cannot unduly exclude competitors from a standard past requiring a license on FRAND terms. Opportunistic SEP holders have distorted this system by taking advantage of SSO policies that have ambiguous definitions of FRAND to manipulate a fair licensing negotiation process by, for example, overcharging or refusing to license to certain entities in a supply chain. Since SSOs facilitate access to technical standards that touch various industries, these opportunistic SEP holders plague many verticals, always looking for the next market to extract additional and unrelated value for their SEP. The anticompetitive harms experienced in the SEP licensing ecosystem disrupt fair usage of technical standards that support efficient innovation.

The AI Action Plan should position the U.S. government to:

- Restrict the ability of foreign SEP holders to impose injunctions on U.S. companies in foreign jurisdictions.
- Leverage diplomatic influence to pressure foreign governments to prevent their courts from enabling SEP-related hold-ups that disadvantage American businesses.
- Implement domestic safeguards to curb SEP hold-up, including reforming the U.S. International Trade Commission (ITC) to limit foreign entities from leveraging costly SEP exclusion orders against U.S. companies; and

<sup>&</sup>lt;sup>8</sup> This issue paper is accessible at: <a href="https://connectedhi.com/wp-content/uploads/2025/03/CHI-Issue-Paper-Healthcare-and-Standard-Essential-Patents-Feb-202568.pdf">https://connectedhi.com/wp-content/uploads/2025/03/CHI-Issue-Paper-Healthcare-and-Standard-Essential-Patents-Feb-202568.pdf</a>.

defending the Supreme Court's *eBay* decision, which eliminated the automatic presumption of injunctions in patent disputes.

## 9. Global Leadership and Trade

To maintain America's AI leadership, the AI Action Plan must include a strong international strategy that keeps foreign markets open to U.S. AI. To achieve this and strengthen both economic and national security, we urge you to advance a U.S.-led vision of innovation-driven AI governance, protect critical AI assets, and prevent foreign governments from obstructing U.S. AI innovators and deployers. We encourage the AI Action Plan to address the U.S. role as a global leader that advocates for a holistic vision of trustworthy AI rooted in American values, designed to empower workers, and drive global economic growth. The AI Action Plan should enable the U.S. government to:

- Proactively engage with foreign governments to prevent harmful AI policies that undermine U.S. leadership, restrict commercial AI deployment, or block significant U.S. AI investments.
- Refine and enforce export control policies to restrict adversaries' access to critical technologies.
- Reinforce core U.S. digital trade policies to uphold cross-border data flows, resist forced data localization, and protect AI's algorithmic integrity (including model weights) from exploitation or coercive transfers, ensuring AI's full potential is realized.
- Aggressively safeguard U.S. digital market access from policies that erode competitiveness, seek unauthorized access to trade secrets, or impose excessive taxes and regulatory burdens on American companies, such as the European Union's (EU's) AI Act and the EU's Digital Markets Act.
- Strengthen a trusted AI ecosystem that secures national and economic interests, including critical infrastructure, by enhancing cybersecurity measures.
- Embed AI priorities into the negotiating framework of future trade agreements, including free trade agreements and industry-specific accords.
- Lead the AI and digital agenda across key international forums (UN, G7, WTO, G20, OECD), ensuring the United States remains at the forefront of global AI governance.
- Proactively engage with foreign governments shaping AI regulations to safeguard U.S. market access and champion an innovation-driven approach—advocating for adherence to global technical standards, leveraging existing regulatory frameworks where applicable, and promoting pro-innovation policies like open government data.

#### 10. Education

The AI Action plan should support education for the advancement of AI in healthcare, promote examples that demonstrate the success of AI in healthcare, and encourage stakeholder engagements to keep frameworks responsive to emerging opportunities and challenges.

- Consumers should be educated as to the use of AI in the service(s) they are using.
- Academic education should include curriculum that will advance the understanding of and ability to use AI solutions.

## 11. Intellectual Property

The protection of intellectual property (IP) rights is critical to the evolution of AI in healthcare. In developing approaches and frameworks for AI governance, policymakers should ensure that compliance measures and requirements do not undercut safeguards for IP or trade secrets.

Al is an important tool for innovators and authors of creative works to use in their process to develop IP protected works. Similarly, Al as we know it is constantly evolving, and its capability is not fully realized at this time. In order to continue incenting innovative and creative works within the Al space and through the assistance of Al, the U.S. Patent and Trademark Office and the U.S. Copyright Office must focus their IP issuance and registration analysis on the amount of human involvement rather than Al involvement.

While promoting transparency, we advise against disclosing proprietary information, such as training data. The mere fact that a model was trained on specific data does not guarantee its effectiveness for a given use case. Instead, the scientifically sound and industry-standard approach to assessing performance is testing the model in its intended environment using data representative of the target population.

CHI appreciates OSTP's consideration of the above views.

Sincerely,

Brian Scarpelli Executive Director

> Chapin Gregor Policy Counsel

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