February 15, 2024

The Honorable Mike Bost
Chair
House Committee on Veterans' Affairs
364 Cannon House Office Building
Washington, DC 20003

The Honorable Mark Takano
Ranking Member
House Committee on Veterans' Affairs
550 Cannon House Office Building
Washington, DC 20515

The Honorable Mariannette Miller-Meeks
Chair, Subcommittee on Health
House Committee on Veterans' Affairs
364 Cannon House Office Building
Washington, DC 20003

The Honorable Julia Brownley
Ranking Member, Subcommittee on Health
House Committee on Veterans' Affairs
550 Cannon House Office Building
Washington, DC 20515

Re: Johnson & Johnson Statement for the Record for House Committee on Veterans' Affairs Subcommittee on Health Hearing on Artificial Intelligence at VA: Exploring its Current State and Future Possibilities

Dear Chair Bost, Chair Miller-Meeks, Ranking Member Takano, and Ranking Member Brownley:

On behalf of Johnson & Johnson, we would like to thank you for holding the hearing titled "Artificial Intelligence at VA: Exploring its Current State and Future Possibilities." We commend the Subcommittee on Health for focusing on this transformative technology in the healthcare sector. We look forward to bipartisan action and your partnership with the Department of Veterans Affairs on this crucial issue for patients, healthcare providers, the Veterans Health Administration, and innovators across the healthcare ecosystem.

Johnson & Johnson (J&J) is the world's largest and most diversified healthcare products company, and we are committed to using our reach and size for good. Innovation has been an essential part of the fabric of Johnson & Johnson for more than 135 years. Thanks to the incredible efforts of tens of thousands of scientists, researchers, engineers, designers, and clinicians, we have pioneered multiple breakthroughs and are building a world where complex diseases are prevented and cured, treatments are smarter and less invasive – and solutions are personal.

Leader in the Military Connected Community

Johnson & Johnson is proud to lead in support of the United States military-connected community: from military service members to veterans to military families & spouses and veteran caregivers – we are committed to keeping this community healthy and enabling them to bring their unique experiences and strengths to the world. J&J's long and proud history of supporting military service members dates back to the Spanish-American War in 1898, when the company held positions for employees and paid their salaries while they served. That obligation continues today as we continue to grow our support for the military community, including by being a signatory to the United States Department of Defense Initiatives for Guard & Reserve military members and military spouses.

As we look to the future of health care for veterans and military communities, we believe artificial intelligence (AI) holds tremendous potential to advance human health on a global scale. By combining the power of artificial intelligence (AI) with our scientific expertise, we find answers to some of the most pressing questions in healthcare. We accelerate breakthroughs – in understanding and treating diseases, discovering and developing therapies, equipping healthcare providers (HCPs) with insights, and personalizing care for patients, including veterans.

Artificial Intelligence at Johnson & Johnson

AI and machine learning play an increasingly important role in delivering excellence at Johnson & Johnson. AI is helping to drive socially beneficial innovations and new ways of helping those we serve live healthier lives. For instance, it is used in drug development, robotic-assisted surgery, commercial activities, chatbots and smart manufacturing in our supply chain. We are applying AI across our business, focusing on finding solutions to big questions and advancing our impact on patients. For example, we are driving the development of technology that utilizes AI and machine learning (ML) to potentially help with earlier diagnosis and treatment of pulmonary hypertension and lung cancer, two disease states that have an outsized impact on veterans.

In pulmonary hypertension (PH) and cardiac amyloidosis, two progressive and often-fatal diseases, despite the existence of treatments, both diseases are commonly misdiagnosed early on, given that their respective symptoms mimic those of other more common diseases. To help diagnose these diseases, Johnson & Johnson has teamed up with collaborators Anumana and Mayo Clinic for pulmonary hypertension, and Ultromics Ltd. and Atman Health for cardiac amyloidosis to develop AI algorithms aimed at helping detect these diseases early on. The PH algorithm and Ultromics' cardiac amyloidosis algorithm have both received Breakthrough Device Designation from the U.S. Food and Drug Administration and, if approved, could help facilitate earlier, more accurate diagnoses, leading to patients receiving treatment sooner.

Beyond early detection algorithms, medical devices, including connected devices, robotic platforms and digital solutions are also evolving with AI to enhance their capabilities. For example, Johnson & Johnson MedTech's Monarch™ Platform for bronchoscopy lets physicians examine areas of the lung that are more difficult to access with conventional bronchoscopes– and that can aid in earlier lung cancer diagnosis. The flexible robotics system uses preoperative CT scans of the lung to inform the procedure, but tracking objects in such a dynamic environment in real time can be complex. The Monarch™ R&D team uses AI and ML algorithms to develop and refine the Monarch™ Platform's navigation, which helps physicians guide the bronchoscope during lung biopsy procedures and allows them to locate a potential tumor more accurately. This leads to more accurate diagnosis and treatment, positively impacting patients served by VA Medical Systems where the Monarch™ system is in active use.

Supporting Medical Innovation and the Deployment of Artificial Intelligence

The use of AI in healthcare needs to be built on a foundation of trust. To provide clarity and certainty in the development and deployment of AI, we believe that any framework should leverage risk-based mechanisms and existing research and ethics standards, practices, and guidelines. Consideration of new regulation should begin with an assessment of existing authorities and regulatory systems that can be adapted and applied to AI. We encourage a

whole of government approach that looks across agencies and branches to maximize coordination, avoid redundancies, and streamline efforts to harness the enormous potential of AI.

Any policy regarding AI should have a clear scope and framework, facilitating implementation and avoiding complexity, to build trust between citizens, developers, deployers and users and create a favorable environment that fosters medical innovation. Policy development should begin with an assessment of existing policies and regulations, including applicable sector-specific laws and guidelines, such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Highly regulated sectors, like the healthcare industry, have existing frameworks for addressing relevant risks (e.g., safety, security, privacy), and these frameworks should be evaluated for their contribution and applicability to AI.

Recognizing the accelerated speed of AI continuous development, it is crucial to promote consensus-based standardization to assure a thriving and innovative ecosystem, avoiding a fragmented system that could hinder investment in innovation in the long term. Regulatory efforts should focus on a risk-based approach, a transparent framework for compliance and enforcement and versality of regulation to promote innovation with the aim to pursue fair, responsible, secure, and transparent use of AI.

As AI and machine learning are increasingly used in healthcare (e.g., drug development, robotic assisted surgery, smart manufacturing, etc.), there is opportunity to provide additional clarity on existing regulations. It is essential that innovators and developers know as early as possible the information, for example metrics and endpoints, that document the development and performance of AI/ML models will be required by regulators to approve and/or license an AI model. It is also important to establish monitoring processes, as ongoing assessment of usage of AI models is key to assure transparency, accountability, safety, and interpretability. Some examples of use cases for which additional clarification could be beneficial include:

- Instances where predictions are being made about patients that may influence their subsequent treatment, cases such a medical decision support, prediction of future events, risk prediction, AI/ML as medical devices and use within medical devices.
- Deployment of AI/ML in clinical practice.
- Potential use of AI to support molecular discovery efforts to predict the clinical performance of a drug in development.
- Use of AI/ML models for patient selection, stratification, and endpoint evaluation, which may have potential to directly impact patient care and labeling claims.

Ethics in AI and Protecting Patients

We believe ethical considerations should be at the forefront of how we are applying AI models and that regulation has a key role to promote the responsible and transparent usage of AI. Well-established practices and standards exist for demonstrating clinical validity and utility and connecting these efforts to meaningful outcomes for patients[1]. It is important to start by

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7909857/

assessing the existing research practices used for creation of treatment guidelines and approvals of new therapies to assess any AI-related gaps.

- Although AI/ML developers are developing methodologies and good practices for bias identification and management, regulators should be at the forefront of assuring AI decision making is following an agreed-upon set of social values and not perpetuating biases. It will be critical to address the propensity of AI applications to express bias based on the data on which they are trained, especially in the health care space where disparities in health outcomes are a disappointingly persistent reality.
- Diversity, equity and inclusion must be considered in all aspects of AI (e.g., selecting the issues to address/problems to solve using AI, training and hiring a diverse workforce from the data scientists to programmers, attorneys, and program managers).
- Not all data is created equal, and data that is not reflective of the population it intends to help or the unbiased problem it intends to solve does not have the proper level of quality upon which society can rely. Fostering participation by diverse populations, including veterans and those who live in rural settings, will help enable data generation that simultaneously improves the authenticity of data sets and the inclusivity of data-driven insights.
- AI systems must continually be monitored, and models must be adjusted for fitness for purpose, accuracy and resilience, in addition to monitoring and testing datasets for accuracy and to avoid unfair bias.

Stakeholders are currently utilizing certain practices to help assure the integrity of AI/ML or to address issues such as bias, missing data, and other data quality considerations. Any frameworks should consider existing standards of conduct and practices, such as:

- Investigating the source of missingness, ensuring models are tested on representative and diverse populations, thorough review of features used in modelling.
- Testing model performance on patient subpopulations, understanding the data ingestion/data structuring process used for ML methodology.
- Development and implementation of Post-Training Fairness metrics and assessments and constant monitoring of deployed ML solutions to detect drift.
- Development of methods to aid interpretability and transparency.
- Contrast and comparison with more traditional approaches and previous scientific research.
- Incorporating Human in the Loop (HITL) workflows.

Data as an Enabler of AI

Another key element for safe, ethical, and transparent AI use is privacy. We operate in a highly regulated industry where we use a variety of types of data, including administrative and claims data, clinical data, genomic data, patient-generated data, and social determinants of health data that move through a variety of transmission networks. This data is essential to continued innovation, discovery, evaluation, and speed for the delivery of healthcare products and services to patients and consumers. We use data to enable greater precision in medicine, expand the range and application of effective therapies, and empower and support patients. It serves a critical role in new and innovative healthcare models by flagging potential safety

concerns, promoting adherence to treatment, personalizing care, or connecting an extended healthcare and support team. Many of these innovations can also contribute to overall lower costs for healthcare and greater access.

Innovation in the healthcare industry and effective treatment of patients are heavily dependent on appropriate access to, and use of, patient and consumer data. We support adoption of a comprehensive national privacy law and associated standards to help ensure a more consumer- and patient friendly approach to managing personal information while ensuring consistent privacy protections, reducing variability across multiple governments and government agencies, allowing a greater flow of data, and maintaining adequate protections.

Workforce and Digital Literacy in AI

Healthcare professionals, including those who serve veterans, need to have a thorough understanding of digital technologies for healthcare systems to effectively guide patients. We support policies to empower and diversify both the data science and provider workforce, support educational advancement, and drive access to the full range of healthcare providers to reduce health inequities and ensure that all have access to innovations, such as:

- Training diverse healthcare professionals to read, analyze, and interpret data is essential to increase efficiency of care, achieve better outcomes, increase equity, and help patients understand and consider their care options. Healthcare workforce planning and education are important tools for policymakers to anticipate future skills shortages and take remedial action in education and training policies early on.
- Diversifying the AI and technology workforce and increasing training in the field for underrepresented minorities is critical for bias reduction and inclusivity in data ecosystems. We also need more life science education and training programs to improve the application and customization of technologies like AI to healthcare needs.
- Digital access and literacy are critical to ensure citizens and patients are empowered to manage their own data, understand the benefits of AI, and have the tools to make informed decisions.
- Workforce skilling via lifelong learning programs and university education, equipping the workforce with the reskilling and continued learning opportunities required to embrace ongoing technological developments to maximize the positive impact of AI. For example, investments to enhance the digital skills of HCPs could be done through pre-certification by medical societies and advancement of AI curricula for both HCPs and hospital managers.

If we include healthcare workers as a critical group when designing, deploying, and assessing AI solutions, and have broad, sustainable funding from government, we can use AI to support the healthcare workforce, including their work experience and resiliency, and improve outcomes for all members of the ecosystem.

Conclusion

We recognize the power and promise of AI in healthcare and believe this is a collective effort. We value our role as collaborator and innovator in healthcare, contributing new ideas, solutions, technology, partnerships, and perspectives on AI policy. We are focused on increasing

engagement and cocreation with patients, providers, and policymakers to raise the understanding on how harnessing the potential of AI in healthcare can help everyone.

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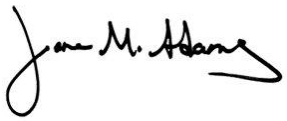
Johnson & Johnson looks forward to serving as a resource and providing additional thoughts about policies to assure AI is ethically, safely, and efficiently integrated into our society. Thank you for your attention to this critically important issue. If you have any questions or we can provide any assistance to the Committee, please email Leif Brierley at LBrierl1@its.jnj.com.

Sincerely,

Jane M. Adams
Vice President, Federal Affairs



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