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AVOIDING A CAUTIONARY TALE: POLICY CONSIDERATIONS FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE

HEARING

BEFORE THE

SUBCOMMITTEE ON PRIMARY HEALTH AND RETIREMENT SECURITY

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED EIGHTEENTH CONGRESS

FIRST SESSION

ON

EXAMINING POLICY CONSIDERATIONS FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE

NOVEMBER 8, 2023

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C O N T E N T S

STATEMENTS

WEDNESDAY, NOVEMBER 8, 2023

AVOIDING A CAUTIONARY TALE: POLICY CONSIDERATIONS FOR ARTIFICIAL INTELLIGENCE IN HEALTH CARE

Wednesday, November 8, 2023

U.S. SENATE,
SUBCOMMITTEE ON PRIMARY HEALTH AND RETIREMENT SECURITY,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 2:45 p.m., in room 430, Dirksen Senate Office Building, Hon. Edward Markey, Chairman of the Subcommittee, presiding.

Present: Senators Markey [presiding], Baldwin, Murphy, Hassan, Smith, Lujàn, Hickenlooper, Marshall, and Braun.

OPENING STATEMENT OF SENATOR MARKEY

Senator MARKEY. Thank you all so much for being here. The Senate, Health, Education, Labor, and Pensions Subcommittee on Primary Health and Retirement Security will come to order. Thank you all for joining us today for the hearing, "Avoiding a Cautionary Tale, Policy Considerations for Artificial Intelligence in Health Care."

Thank you to Ranking Member Marshall for your continued partnership, your staff's continued partnership on the Subcommittee. We are hearing more and more about the promise of artificial intelligence in health care, the potential for innovation to reduce the red tape facing patients and providers, to identify patterns, improve patient outcomes, and cure disease.

But we have heard grand promises from big tech before. In 2012, Mark Zuckerberg compared social media to the printing press and explained that Facebook was built to make the world more open and more connected.

But here is the unfortunate truth. Big tech made big promises for innovation, democracy, and community, but instead unleashed big problems on the American people without solutions that were attached by big tech. And our young people have suffered the most.

In 2021, 1 in 3 high school girls seriously considered suicide, and at least 1 in 10 high school girls attempted suicide that year, 2021. Among LGBTQ youth, the number was more like one in five attempted suicide in 2021. And as U.S. Surgeon General Dr. Vivek Murthy concluded in a CDC report earlier this year, there is sig-

nificant evidence that big tech's predatory practices contributed significantly to this youth mental health crisis.

That is why I am working to pass my bipartisan Children and Teens Online Privacy Protection Act with Senator Cassidy to ensure children and teenagers and their parents have the tools they need when kids are searching and scrolling and connecting online.

Fast forward 10 years from when Mark Zuckerberg made his rose colored promise and look at our approach to artificial intelligence, and I have concerns, because when we talk about the promises of AI, we need to also talk about its risks.

We have learned time and again that left to self-regulate, big tech puts profit over people almost every time. We cannot afford to repeat that mistake by not regulating artificial intelligence now. The risks are too great.

Unregulated experimentation involving artificial intelligence may fuel our next pandemic. Humans insert human bias and discrimination into algorithms that can supercharge existing inequalities in our health care system, jeopardize our privacy, and misdiagnose or mistreat patients.

Big tech's access to sensitive patient information without guardrails exposes people to their most personal information being shared, or even worse, weaponized back against them. Automated review processes will speed up insurance reviews and denials, leaving patients scrambling to get the health coverage they need to avoid choosing between their care and bankruptcy.

In the middle of all of this, health workers are on the front lines of implementing this powerful technology without proof of safety, reliability, effectiveness, or equity. Workers are seeing health systems replace conversations on retaining and paying the workforce with extending and replacing them using artificial intelligence.

We don't need big tech treating our health care system like a lab to experiment on patients and workers. We need a health care system that prioritizes people over heart rhythms, over bots run by algorithms.

Our artificial intelligence must be paired with a voice for workers in determining their own working conditions, more treatments, and cures for all patients, and better access to health care. Otherwise, we are innovating for the sake of profit, and that isn't really innovation at all. It is greed.

We can act now to prevent the next cautionary tale. We can pass my legislation, the Artificial Intelligence and Biosecurity Risk Assessment Act, with Senator Budd, and the Securing Gene Synthesis Act with Representative Eshoo to require the U.S. Department of Health and Human Services to identify and respond to biosecurity threats involving AI.

We can stop corporations from implementing technologies on patients and workers without their knowledge and without appropriate testing to prevent harm, discrimination, or interference with their clinical judgments. We can guarantee that workers and patients have a voice in whether and how artificial intelligence is used. We can guarantee civil rights protection in the utilization of artificial intelligence.

We can protect young people from big tech's targeting and tracking and pass a comprehensive privacy bill of rights for teenagers and children in our Country. And we have to guarantee that wherever artificial intelligence is used, it prioritizes people over profits.

But I have learned in my many years serving on the telecommunications committee, I was Chairman in the House during, and I am the author of all of the bills moving us from analog to digital America, from narrowband to broadband. Those are all my bills breaking down all the monopolies.

What I learned was the only time you really get things for the little guy is when the big guys want something. So, in AI right now, the big guys want something, and we got to make sure we put in all the protections for the little guys in our society, and we have got to do it simultaneously, not sequentially.

Not after the big guys get what they need. That is what this hearing is really all about in the health care sector. We welcome everyone. And I turn to recognize Ranking Member Marshall for an opening statement.

OPENING STATEMENT OF SENATOR MARSHALL

Senator MARSHALL. Well, thank you, Mr. Chairman. I certainly appreciate those comments. Artificial intelligence and machine learning have great potential to revolutionize health care by developing new cures, improving health care delivery, and reducing administrative burdens, as well as overall health care spending.

We hope someday, someday, very soon, AI and machine learning will allow our clinical workforce to go back to practicing medicine. Those of us in medicine, whether we are a physician, a nurse, a counselor, we all long to spend more face to face time with our patients and less on medical records and administrative burden.

Other opportunities for AI include developing better standards of care, increasing timely access to care, and perhaps most importantly, discovering innovative treatments, which includes monitoring disease progression and the effectiveness of those treatments. But all that being said, my biggest concern we hope to address today is AI's application in biosecurity and how it could be used to enable bioterrorism.

After all, AI can help us prepare or react to the next pandemic, or it could also be used intentionally or unintentionally to develop novel pathogens, viruses, bioweapons, or chemical weapons. As I have always said, those closest to the industry know the challenges. They understand the opportunities and the risks the best.

They also know the most practical and impactful solutions as we look for guardrails that protect Americans, but at the same time promote innovation. Today, we are asking our witnesses to describe these risks and benefits as best they see them. And if we are going to write rules surrounding AI, let's be careful not to destroy innovation or allow those who would harm us to get ahead of us.

After all, artificial intelligence and machine learning have been making remarkable discoveries and improving health care for some five decades without much Government interference.

I would like to quote Ranking Member Cassidy, who has done extensive research and written in a wonderful white paper on this. Senator Cassidy says, "we must strike the right balance for America, from the earliest ages of developing new products through deployment of an AI system or solution solving complex problems."

Mr. Chairman, I have two articles here I would like to submit for the record. First is the white paper from Dr. Cassidy entitled, Exploring Congress Framework for the Future of AI. The Oversight and Legislative Role of Congress Over the Integration of AI in Health, Education, and Labor.

[The following information can be found on page 42 in Additional Material.]

Also, a second document from the American College of Surgeons, a statement to this Committee regarding avoiding—regarding their statement and thoughts on this, Mr. Chair.

Senator MARKEY. Without objection, so ordered.

[The following information can be found on page 60 in Additional Material.]

Senator MARSHALL. Thank you, and I yield back.

Senator MARKEY. Thank you, Ranking Member Marshall. And now I turn to recognize Senator Baldwin, who has a special guest to the Committee who she is going to introduce.

Senator BALDWIN. Thank you so much, Chairman Markey and Ranking Member Marshall. I am so proud to welcome a constituent, Christine Huberty, to our Subcommittee hearing today.

Ms. Huberty comes—currently serves as the Lead Benefits Specialist, Supervising Attorney at the nonprofit Greater Wisconsin Agency on Aging Resources, and it is located in Madison, Wisconsin.

In this role, she provides free legal assistance to Northern Wisconsin residents over the age of 60 who need assistance in accessing their benefits, including Medicare, Medicaid, Social Security, and SNAP. She also provides support related to issues with housing and consumer law.

As you will hear in her testimony, Ms. Huberty has been fighting on behalf of Wisconsinites who have had critical health services denied by big insurance companies using AI.

Ms. Huberty, I want to thank you for your advocacy on behalf of Wisconsin seniors, and for making this trip to Washington, DC. Your testimony highlights the need for us to act to address the use of AI. It is simply not right for patients to have their care dictated by an algorithm.

Welcome to the Subcommittee, and I look forward to your testimony.

Senator MARKEY. Whenever you are comfortable, Ms. Huberty, you may begin with your opening statement.

STATEMENT OF CHRISTINE HUBERTY, SUPERVISING ATTORNEY, GREATER WISCONSIN AGENCY ON AGING RESOURCES, MADISON, WI

Ms. HUBERTY. Thank you, Mr. Chairman, and Members of the Subcommittee. My name is Christine Huberty, and I have served as an Attorney at the Greater Wisconsin Agency on Aging Resources since 2015.

As an advocate for senior residents of Wisconsin, part of my job is to provide legal assistance to those aged 60 and over who are experiencing health care coverage denials. The purpose of my testimony today is to share how the use of AI in health care causes patient harm and administrative burdens.

On May 25th of this year, Jim, age 81, was hospitalized for pneumonia secondary to COVID–19. Jim had a history of COPD and was at the time undergoing chemotherapy for B-cell lymphoma. Jim's doctors recommended that he transfer from the hospital to a skilled nursing facility for short term rehab.

His doctors prescribed at least 30 days of daily therapies in order to return to his prior level of functioning. Jim's insurance provider, however, relied on technology that said he should only need 14.2 to 17.8 days at the rehab facility. Jim received a denial on day 16, with coverage ending 2 days later, just as the algorithm predicted.

Jim went home on day 25, not because he was well enough, but because he feared the mounting out-of-pocket costs. Jim's doctors and therapists did not agree with the algorithm's predicted discharge date, nor did they agree with Jim's own decision to return home. AI directed Jim's care.

The subcontractors using the algorithm argue that the predicted discharge date is used as a guide only, and medical reviewers, humans, make all final denial decisions. If that is the case, then humans who had no contact with Jim ignored the following in his medical records. He was unable to safely swallow by himself and in fact had a choking episode just days after he was admitted. His oxygen saturation remained at unsafe levels.

He was at risk of falling and lacked the strength and activity tolerance to participate in chemotherapy. He could not climb the three stairs necessary to get into his home. He required assistance of at least one, if not two, people with getting in and out of bed toileting, bathing, and dressing.

Most egregiously, they ignored the direct words, currently not safe to return home with wife. Jim's family helped him appeal twice, which was ultimately successful, meaning the algorithm got it wrong and a human did not catch the mistake until it was challenged. In Wisconsin alone, our agency has seen the frequencies of these denials multiply from 1 to 2 per year to 1 to 2 per week.

In 2023, 30.8 million people were enrolled in Jim's type of insurance nationally. This means that use of an algorithm for this one narrow patient experience is churning out hundreds of thousands of incorrect denials that go largely unchallenged. If Jim had stayed in the facility the full length of time that his doctors advised, it would have cost him over $3,600 due to that denial.

Additionally, Jim's health suffered as a result of his early discharge, and members of his family needed to take time off work to provide care. Patients may be reimbursed financially, but they cannot go back in time and get the care that they needed.

Insurance companies bank on patients not appealing, or in many cases with our elderly clients, dying in the process. I am only able to share Jim's story because he had family advocating for him.

On his own, Jim may have remained in the facility, drained his assets on care, and been forced to take Medicaid, which shifts cost to the state. If Jim had returned home on his own, most likely he would have been quickly readmitted to the hospital or died. He certainly would not have been able to navigate the appeals process by himself from his hospital bed.

Using an algorithm to guide discharges also negatively affects the facilities, who must submit almost daily updates to the subcontractors regarding that predicted date and provide hundreds of pages of medical records when a patient appeals. Often, nurses and therapists are called to testify at Federal hearings.

As a result, many facilities are refusing to take patients whose insurance uses this predictive technology due to the administrative burdens it creates. This means that in rural areas, patients need to travel hundreds of miles for the care they need only to be met with network restrictions when they get there.

It is unrealistic to eliminate AI completely from the health care system, I understand. However, this algorithm alone has been used for years to direct patient care with devastating consequences. If the machine itself can't be dismantled, then patients should at a minimum, have a clear view of its moving parts.

When the algorithm gets it wrong, patients need to be compensated, and both the insurance companies and their subcontractors must be penalized. I want to thank you for the opportunity to speak about this important issue, and I welcome any additional questions you have. Thank you.

[The prepared statement of Ms. Huberty follows.]

PREPARED STATEMENT OF CHRISTINE HUBERTY

DEAR MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

My name is Christine J. Huberty and I have served as an attorney at the Greater Wisconsin Agency on Aging Resources (GWAAR) since 2015. The Elder Law and Advocacy Center at GWAAR provides free legal services to adults over age 60 under Title IIIB of the Older Americans Act. As an advocate for senior residents of Wisconsin, part of my job is to provide legal assistance to individuals experiencing healthcare coverage denials. The purpose of my testimony today is to share how the use of Artificial Intelligence (AI) in healthcare causes patient harm and administrative burdens.

On May 25, 2023, Jim, age 81, was hospitalized for pneumonia secondary to COVID–19. Jim had a history of COPD, and was at the time undergoing chemotherapy for B-cell lymphoma. Prior to getting COVID–19, Jim lived with his spouse, was independent in all activities of daily living, and did not need supplemental oxygen. Therefore, Jim's doctors recommended that he transfer from the hospital to a Skilled Nursing Facility (SNF) for short-term rehabilitation. His doctors and therapists recommended daily skilled therapies for 30 days.

Jim's insurance provider contracts with a company that used proprietary technology to compare his care needs with millions of other patients. This technology

said Jim should only need 14.2–17.8 days at a SNF.[1] Jim received a denial on day 16, with coverage ending 2 days later, just as the algorithm predicted. Jim went home on day 25 not because he was well enough, but because he was afraid of the mounting out-of-pocket costs. Jim's doctors and therapists did not agree with the algorithm's predicted discharge date, nor did they agree with Jim's own decision to return home so soon. *AI directed Jim's care.*

The subcontractors using the algorithm argue that the predicted length of stay is used as a guide only, and medical reviewers (humans) make all final denial decisions. This may be the case, but if so, these humans ignored things in Jim's medical records such as:

- He was unable to safely swallow by himself, and in fact had a choking episode just days after he was admitted;
- His oxygen saturation remained at unsafe levels;
- He was at risk of falling and lacked the strength and activity tolerance to participate in chemotherapy;
- He could not climb the three stairs required to get into his home;
- He required assistance of at least one if not two people with getting in and out of bed, toileting, bathing, and dressing; and
- The direct words: "Currently not safe to return home with wife."

Throughout Jim's medical records, the reasoning for discharge was not because it was medically appropriate, but because his insurance denied coverage based on the algorithm. Jim's family helped him appeal twice, which was ultimately successful. Meaning, the algorithm got it wrong, and a human did not catch the mistake until it was challenged.

Some reports show that only 1 percent of denials are appealed, with 75 percent of those overturned.[2] Our agency, which serves Wisconsin only, has seen the number of these denials increase from 1–2 per year to 1–2 per week, with a 90 percent success rate with appeals. In 2023, 30.8 million people were enrolled in Jim's type of insurance nationally.[3] This means that use of an algorithm for this one narrow patient experience is churning out hundreds of thousands of incorrect denials that go largely unchallenged, leaving patients and their families to suffer. When I called Jim's family for permission to share his story, they told me they knew of four other individuals this had happened to in the past 2 years. None of those cases reached our agency.

If Jim had stayed in the SNF the full length of time his doctors advised, it would have cost him over $3,600 due to the denial. Even more troubling is that Jim's health suffered as a result of his early discharge, and several members of his family needed to take time off from their own jobs to help provide care.

I am only able to share Jim's story because he had family advocating for him. On his own, Jim may have remained in the facility, drained his assets, and been forced to take Medicaid, which then shifts the costs to the state. Insurance providers often cite potential eligibility for Medicaid as a reason for a denial in medical records. It is not unrealistic to imagine that if Jim had returned home on his own when he did, he would have been quickly readmitted to the hospital or died. He certainly would not have been able to navigate the appeals process by himself from his hospital bed.

The effects of the use of the algorithm to guide discharges not only causes patient harm, but also negatively affects the facilities, which must submit near daily updates to the subcontractors regarding the predicted discharge date, and provide hundreds of pages of medical records when a patient appeals. Often, nurses and therapists are called to testify at Federal hearings. This is on top of an already understaffed, overworked, and underpaid care system. As a result, many facilities are refusing to take patients whose insurance uses this predictive technology due to the administrative burdens it creates. This means that in rural areas, patients need to travel hundreds of miles for the care they need, only to be met with network restric-

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[1] naviHealth nH Predict Outcome Tool (attached).

[2] Office of Inspector General, Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials (Sept. 2018). *https://oig.hhs.gov/oei/reports/oei-16-00410.pdf*

[3] KFF, Medicare Advantage in 2023: Enrollment Update and Key Trends (Aug. 2023). *https://www.kff.org/Medicare/issue-brief/Medicare-advantage-in—2023-enrollment-update-and-key-trends/*

tions when they get there. Also, if a patient is readmitted to the hospital after being discharged from the SNF too soon, the *facility* is the one penalized. [4]

Meanwhile, neither the insurance provider nor its subcontractors suffer negative consequences. The burden is on the patient to prove why the algorithm got it wrong. If the appeal makes it to the Federal hearing stage, a judge will order the insurance company pay what it was supposed to pay in the first place, and the practice continues. Insurance companies rely on patients not appealing, or in many of our cases with elderly clients, dying in the process.

It is unrealistic to eliminate AI from the healthcare system. However, this algorithm has been used for years to direct patient care with devastating effects. If the machine itself cannot be dismantled, then patients should have, at a minimum, a clear view of its moving parts. Additionally, when it is obvious that the algorithm got it wrong and issued an incorrect denial, patients need to be compensated, and insurance companies and their subcontractors must be penalized.

I want to thank you for the opportunity to speak about this important issue and I welcome any additional questions you may have.

Senator MARKEY. Thank you very much. Our next witness is Dr. Thomas Inglesby. Dr. Inglesby is a Professor at Johns Hopkins University and the Director of the Johns Hopkins Center for Health Security.

Dr. Inglesby chaired the Centers for Disease Control and Prevention Center for Preparedness and Response's Board of Scientific Counselors.

He has advised the Department of Health and Human Services, and he has also a—served as a Senior Adviser on the White House COVID–19 Rapid Response Team. Welcome, Dr. Inglesby. Whenever you feel comfortable, please begin.

STATEMENT OF THOMAS INGLESBY, DIRECTOR, JOHNS HOPKINS CENTER FOR HEALTH SECURITY, BALTIMORE, MD

Dr. INGLESBY. Thank you. Chairman Markey, Ranking Member Marshall, and distinguished Members of the Subcommittee, it is my pleasure to appear before you to discuss the use of artificial intelligence in health care.

My name is Tom Inglesby. I am Director of the Johns Hopkins Center for Health Security and Professor in the Department of Environmental Health and Engineering in the Johns Hopkins Bloomberg School of Public Health.

I am also a medical doctor with a background of providing care for patients with HIV, and the opinions expressed here are my own and do not necessarily reflect the views of Johns Hopkins University.

AI offers great potential benefits for health care and public health. In health care, it could drive earlier disease diagnosis. It could reduce medical errors, lead to more efficient, less invasive surgeries.

In public health, it could improve disease surveillance and perhaps provide earlier indicators of outbreaks, even making it possible to contain smaller outbreaks before they become epidemics.

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[4] JAMA Network, Skilled Nursing Facility Performance and Readmission Rates Under Value-Based Purchasing (Feb. 2022). *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789442*; CMS, The Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program. *https://www.cms.gov/Medicare/quality/nursing-home-improvement/value-based-purchasing*

However, to realize these benefits, it is vital to address potentially very serious risks.

AI developers could inadvertently introduce biases into health care related models. Models could fail to protect privacy, leading to the public sharing of patients' sensitive health care data. Training data could include serious inaccuracies, leading to misleading results that are difficult to detect.

These are among important risks that Congress will need to assess, and where needed, create legislative remedies. My testimony focuses on two high consequence risks related to AI and the biological sciences that I believe deserve top priority for attention and strong governance.

First, the potential for AI to accelerate or simplify the creation of dangerous viruses that are now extinct, or dangerous viruses that only exist within research laboratories. And second, the potential for AI to enable, accelerate, or simplify the creation of entirely new biological constructs that could start a new pandemic.

The Executive Order on AI signed last week launched a series of important strong actions to address and minimize biosecurity risks posed by AI. In addition, several foundational AI and protein design model developers have already taken important steps to reduce biosecurity risks, which I highly commend, but more action is needed.

To that end, I recommend Congress take three immediate steps to further protect against possible high consequence biological risks emanating from future generation AI models. First, Congress should provide HHS with the authority and resources to require anyone purchasing synthetic nucleic acids in the U.S. to purchase only from a nucleic acid provider that conducts sequence and customer screening irrespective of funding source.

This would go—this would build on but go further than the requirements of the Executive Order that was signed last week, which covered only federally funded entities. And this would help establish uniform protection against the risks of synthesizing highly dangerous viruses in the U.S. and give the U.S. a platform to advocate for strong international screening standards.

Second, Congress should commission a rapid risk assessment to identify whether the Executive Order signed last week will adequately address high end biological risks or whether additional Congressional action is needed to prevent those threats.

I want to commend Chairman Markey and Senator Budd for their leadership on the Artificial Intelligence and Biosecurity Risk Assessment Act and recommend taking this additional step in light of the Executive Order.

Third, Congress should require entities developing products with significant dual use risks to evaluate and red team their models, identify significant risks, and address them. Congress should also task an agency with auditing these high risk dual use models and submitting a report to Congress with recommendations for new authorities that will be needed by the agency to take any appropriate remedial actions.

It will be important to conduct red teaming evaluations and audits before future dual use, high end risk bio models are made wholly open source on the internet, because once that occurs, they cannot be recalled. We only have one chance to get things right for each new open source model release.

If taken now, these measures taken together will reduce the risk of high consequence, malicious, and accidental events derived from AI that could trigger future pandemics, which would likely also broadly derail the beneficial uses of powerful AI models.

Congress should pursue these measures in a manner that will allow AI developers and scientists to continue to vigorously to pursue the many very positive uses of AI to improve human health. Thank you again for the opportunity to testify, and I look forward to your questions.

[The prepared statement of Dr. Inglesby follows.]

PREPARED STATEMENT OF TOM INGLESBY

Introduction

Chairman Markey, Ranking Member Marshall, and distinguished Members of the Committee, it is my pleasure to appear before you today to discuss the potential benefits and challenges related to artificial intelligence (AI) use in health care and public health. In order to harness the great promise that AI holds for benefits in health care and public health, AI risks (including privacy, data integrity, and bias) all need to be rigorously addressed.

Within the realm of AI models working in the biological sciences, I want to urge this Committee to place high priority on establishing strong governance over the highest potential dual-use risks of AI and biosecurity (AIxBio), which I judge to be: (1) the potential for AI to accelerate or simplify the reintroduction of particularly dangerous extinct viruses or dangerous viruses that only exist now within research labs; and (2) the potential for AI to enable, accelerate, or simplify the creation of entirely new biological constructs that could start a new pandemic. Taken together, AI foundation models like large language models (LLMs), and AI biological design tools (BDTs), such as models focused on protein design or immune evasion, could now or in the foreseeable future be misused to purposefully create such threats. We should start working to guard against these risks today.

My name is Tom Inglesby. I am Director of the Johns Hopkins Center for Health Security and Professor in the Department of Environmental Health and Engineering in the Johns Hopkins Bloomberg School of Public Health, with a Joint Appointment in the Johns Hopkins School of Medicine. I'm also a medical doctor with a background caring for patients with HIV, and I worked on the COVID pandemic response, including on resolving challenges around access to diagnostic testing for COVID. The opinions expressed herein are my own and do not necessarily reflect the views of Johns Hopkins University.

For 25 years, our Center's mission has been to protect people's health from major epidemics and disasters and build resilience to those challenges. Our Center is comprised of researchers and experts in science, medicine, public health, law, social sciences, economics, and national security—all focused on our mission to protect people's health from epidemics and disasters and ensure that communities are resilient to major challenges. Our team conducts independent research and analyzes how scientific and technological innovations can strengthen health security. Our Center founded the bipartisan Capitol Hill Steering Committee on Pandemic Preparedness and Health Security in 2020, in collaboration with Members of the House and Senate, as well as former Administration officials, as an educational forum to discuss new topics, technologies, and ideas that can improve domestic health security now and in the future. The Steering Committee has held over 20 sessions in the last 3 years intended to be of value to congressional offices working on pandemic and biosecurity challenges.

Today, I was asked to provide comments on how we can guard against potential harms of AI while at the same time working to ensure that AI, where implemented, is done so in ways that will improve patient experience and outcomes. In my testimony below, I provide my views on the enormous potential benefits of AI in health

care and the substantial potential risks that need to be addressed before and while realizing those benefits. Prior to offering those views, I want to give my top line recommendations as to what Congress should be doing at this time to address the greatest AIxBio risks.

To that end, I recommend that Congress now build on the strong foundation provided by the October 30 Executive Order titled: Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (EO no.14110). I recommend that congressional actions related to this include:

(1) Providing the Department of Health and Human Services (HHS) with the authority and resources to require anyone purchasing synthesized nucleic acids, regardless of the funding source, to purchase only from a provider or manufacturer that screens both orders and customers in a way that reduces the highest potential dual-use risks of AIxBio. [1]

(2) Commissioning a rapid risk assessment to identify whether EO #14110 as written will adequately address high-end biological risks or whether congressional action is needed in the near-term to ensure prevention of those threats.

(3) Requiring entities developing models with significant dual-use risks to red-team and evaluate their models, and task an agency with: (1) auditing those models; and (2) submitting a report to Congress with recommendations for new authorities that will be needed by the agency to take any appropriate remedial action should red-teaming, evaluations, or audits fail.

If taken now, these measures will reduce the risk of malicious and consequential misuse of AI-enabled biology while allowing AI developers and scientists to pursue beneficial uses of AI to improve the human condition.

Medical and Public Health Benefits of AI and Recognition of Other Risks in Health Care

AI holds great promise for benefits in health care and public health. Potential benefits include earlier disease diagnoses, allowing doctors to intervene earlier in the course of an illness; reduced medical errors; more efficient or less invasive surgeries; lowering of administrative burdens on clinicians to allow more time with patients; and faster response times to patient questions. Researchers and companies may be able to create or use AI tools to help them accelerate development of vaccines and medicines and to significantly advance personalized medicine. AI may be able to improve disease surveillance and perhaps even provide earlier indicators of new outbreaks or epidemics. It will place stronger diagnostic and clinical tools in the hands of providers in the field or those in clinics far from more advanced health care systems. [2] AI could also assist with more careful monitoring of drug safety and help to improve, and potentially greatly accelerate, clinical trials of new medicines.

To realize these benefits, policymakers, companies, and health systems will need to take great care in implementing consequential AI systems, and all parties will need to address a series of risks and potentially serious challenges. For instance, developers could inadvertently introduce biases into the models that are being developed in AI health care systems. Policymakers and firms will need to ensure that privacy is protected so that individual patient information is not inappropriately accessed or shared publicly. This includes addressing cybersecurity issues in AI, such as the potential for offensive cyberAI to outstrip cyberAI's defensive capabilities, using lessons learned from cyber governance. [3] The quality and integrity of the training data for AI systems will need to be high - inaccuracies or skews in the data

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[1] (requiring that all federally funded entities conducting life-sciences research purchase synthetic nucleic acids only from providers or manufacturers that adhere to the screening framework developed by NIST). Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence, 88 Fed. Reg. 75191 (Nov. 1, 2023), § 4.4(b)(iii).

[2] World Health Organization (WHO), Ethics and Governance of Artificial Intelligence for Health, WHO (June 28, 2021), *https://www.who.int/publications/i/item/9789240029200*; IBM Education, How Can Artificial Intelligence Benefit Healthcare?, IBM (July 11, 2023), *https://www.ibm.com/blog/the-benefits-of-ai-in-healthcare/*.

[3] Louis Columbus, Defensive Vs. Offensive AI: Why Security Teams are Losing the AI War, VENTUREBEAT (Jan. 3, 2023, 10:07 AM), *https://venturebeat.com/security/defensive-vs-offensive-ai-why-security-teams-are-losing-the-ai-war/*.

that AI systems are being trained on could lead to inaccurate or misleading results that could be damaging and hard to detect. [4]

There are additional legal and ethical risks associated with AI. When implementing the technology, it will be vital to ensure that AI is not used as a substitute for investment in and development of core health functions. [5] Many have identified these and other challenges, and it's good to see that U.S.-based companies are trying to work with the government to find feasible ways of effectively mitigating the range of potential AI risks to health care. It will be important for Congress to regularly assess the extent to which AI developers and health care systems are addressing these risks, and to consider legislative remedies to address any clear gaps.

The Need for Strong AIxBio Governance

One area of risk that deserves special and immediate attention is the potential for AI systems to create high-consequence biosecurity and biosafety risks. Leaders from the AI technology field have identified those risks as among their highest priority concerns, as have government officials and outside research groups focused on the establishment of AI governance systems. [6]

Signed last week, EO #14110 represents the strongest action on AI that any government has taken thus far. It sets out a series of high-level principles and priorities that broadly commit the country's AI path to: developing safe and secure AI systems; responsible innovation and competition; a commitment to supporting workers; advancing equity around AI; the protection of privacy and civil liberties; responsible Federal use of AI; and strong global leadership.

As part of this overall approach, the EO identifies a series of specific risks the executive branch will work to address, including the risk that AI systems could substantially lower the barrier of entry to design, synthesize, acquire, or use biological weapons. It details a series of important steps the executive branch will take in the months ahead to develop guidance, identify new industry norms, and evaluate potential risks in order to protect against AI being deliberately misused for this purpose.

The EO directs the National Institute of Standards and Technology (NIST) to develop guidelines and best practices, with the aim of promoting consensus industry standards for safe and secure systems that include benchmarks for evaluating and auditing AI capabilities to cause harm, as well as guidance for AI developers regarding red-teaming practices and testing processes and environments. It also directs the Department of Energy to implement tools and testbeds for evaluating AIxBio capabilities and to develop guardrails that reduce these risks.

The EO directs the Department of Commerce to require companies with frontier dual-use foundation AI models (models that could potentially lower barriers for designing/synthesizing bioweapons) to report activities related to the production of those models, the protection of key model characteristics, and the results of red-teaming tests.

The EO also directs the Office of Science and Technology Policy (OSTP) to establish a framework that encourages providers of synthetic nucleic acid sequences to implement comprehensive nucleic acid procurement screening mechanisms. As part of that effort, OSTP will need to establish criteria and mechanisms for identifying sequences that pose a risk to national security and determine methodologies for verifying performance of screening, including customer screening approaches. Six

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[4] World Health Organization (WHO), Ethics and Governance of Artificial Intelligence for Health, WHO (June 28, 2021), *https://www.who.int/publications/i/item/9789240029200*.

[5] World Health Organization (WHO), WHO Issues First Global Report on Artificial Intelligence (AI) in Health and Guiding Principles for Its Design and Use, WHO (June 28, 2021), *https://www.who.int/news/item/28–06–2021-who-issues-first-global-report-on-ai-in-health-and-six-guiding-principles-for-its-design-and-use*.

[6] See, e.g., Diane Bartz, U.S. Senators Express Bipartisan Alarm About AI, Focusing on Biological Attack, REUTERS (July 25, 2023,10:23 PM), *https://www.reuters.com/technology/us-senators-express-bipartisan-alarm-about-ai-focusing-biological-attack–2023–07–25/*; Congresswoman Anna G. Eshoo, Eshoo Urges NSA & OSTP to Address Biosecurity Risks Caused by AI, CONGRESSWOMAN ANNA G. ESHOO (Oct. 25, 2022), *https://eshoo.house.gov/media/press-releases/eshoo-urges-nsa-ostp-address-biosecurity-risks-caused-ai*; The White House, Fact Sheet: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence, WHITE HOUSE (Oct. 30, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/*; Nuclear Threat Initiative (NTI), Report Launch: The Convergence of Artificial Intelligence and the Life Sciences, NTI (Oct. 30, 2023), *https://www.nti.org/events/report-launch-the-convergence-of-artificial-intelligence-and-the-life-sciences/*.

months after the creation of this framework, all agencies that fund life sciences work will establish that their funding recipients procure nucleic acid sequences from manufacturers that adhere to this framework.

My Center, along with other biosecurity-focused researchers and experts, as well as industry leaders from the companies that conduct nucleic acid synthesis, have been calling for the development of a framework to require those who procure nucleic acid sequences to purchase them from companies that are verified to be carefully screening orders and customers in order to deter and detect any potentially malicious actors. I'm very glad that the EO makes progress on this issue for those entities receiving Federal funding.

I believe that this series of EO actions, taken together, are appropriate, important, strong actions that are needed to better assess, evaluate, test for, and diminish biological risks posed by new AI models. AI foundation models, LLMs, and AI biological design tools—such as those that help to design and predict structures of proteins, design viral vectors, or predict the properties of pathogens, host-pathogen interactions, or immune-system evasion—could be misused by accelerating the synthesis/manufacture of extinct or eradicated highly transmissible viruses, or by helping to design novel biological constructs capable of epidemic or pandemic spread. While more evaluation and study of these risks are clearly needed, preliminary evidence suggests that AI models could in the foreseeable future accelerate, simplify, or enable the creation of these risks. Early technical studies from nongovernmental research teams that I've been briefed on are quite worrying. As these assessments are ongoing, we need a governance process that will address risks identified during red-teaming exercises and other evaluations.

Beyond this EO, I have been encouraged by other developments to address these risks. I highly commend many of the AI companies for making voluntary commitments to pre-release internal and external security testing of their AI systems, which includes testing by independent experts to guard against biosecurity risks.[7] The first step in addressing risk is to identify it, and many of the companies developing frontier models have made progress in the past year in trying to understand the biosecurity risks that their models may pose and addressing those risks.[8]

I'm also encouraged by the Institute for Protein Design's community-wide effort to develop new voluntary guidelines for researchers to follow as they apply AI to protein research. Such commitments can help establish community standards and encourage ethical behavior on the part of individual scientists by, for example, creating an obligation to report any concerning research practices.[9]

Strong governance will also require international collaboration. That is why I'm very pleased to see that the U.S. and 27 other countries recognized the special risks that AI poses in biotechnology in the recently signed Bletchley Declaration by Countries Attending the AI Safety Summit.[10] I'm further encouraged that at least two Artificial Intelligence Safety Institutes have already been stood up—one in the UK and one at NIST in the U.S. Department of Commerce—to provide testing environments for researchers to evaluate emerging AI risks, such as those at the intersection of AI and biotechnology.

Recommendations

Congress should ensure that as the U.S. government acts to mitigate the risks of AIxBio, it set as its highest priority the reduction of the two most consequential biological risks, which I argue are: (1) the potential for AI to accelerate or simplify

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[7] The White House, Fact Sheet: Biden-.Harris Administration Secures Voluntary Commitments from Leading Artificial Intelligence Companies to Manage the Risks Posed by AI, WHITE HOUSE (July 21, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/21/fact-sheet-biden-harris-administration-secures-voluntary-commitments-from-leading-artificial-intelligence-companies-to-manage-the-risks-posed-by-ai/*.

[8] See, e.g., Diane Bartz, U.S. Senators Express Bipartisan Alarm About AI, Focusing on Biological Attack, REUTERS (July 25, 2023,10:23 PM), *https://www.reuters.com/technology/us-senators-express-bipartisan-alarm-about-ai-focusing-biological—attack–2023–07–25/* (Anthropic warning Senators about biological risks during congressional testimony); Anthropic, Frontier Threats Red Teaming for AI Safety, ANTHROPIC (July 26, 2023), *https://www.anthropic.com/index/frontier-threats-red-teaming-for-ai-safety* (Anthropic developing red-teaming tests to guard against biosecurity risks).

[9] Institute for Protein Design (IPD), Results from our Summit on Responsible AI, IPD (Oct. 31, 2023), *https://www.ipd.uw.edu/2023/10/responsible-ai-summit/*.

[10] The Prime Minister's Office, The Bletchley Declaration by Countries Attending the AI Safety Summit, 1–2 November 2023, PRIME MINISTER'S OFFICE (Nov. 1, 2023), *https://www.gov.uk/government/publications/ai-safety-summit–2023-the-bletchley-declaration/the-bletchley-declaration-by-countries-attending-the-ai-safety-summit—1–2-november—2023*.

the reintroduction of particularly dangerous extinct viruses or dangerous viruses that only exist now within research labs; and (2) the potential for AI to enable, accelerate, or simplify the creation of entirely new biological constructs that could start a pandemic.

While I am encouraged by recent actions being taken by the U.S. government, industry developers of powerful AI technologies, and researchers in the field, there are series of steps that I think will be important for Congress to attend to in the time ahead to ensure that these two most consequential biological risks are addressed. They include:

(1) Providing HHS with the authority and resources to require anyone purchasing synthesized nucleic acids, regardless of the funding source, to purchase only from a provider or manufacturer that screens both orders and customers in a way that reduces the highest potential dual-use risks of AIxBio.

Our increasing ability to automate scientific experiments, cheaply synthesize nucleic acids, and autonomously generate biological constructs will likely speed up development of drugs and devices to protect and prolong human health and allow the advent of enormously powerful medical tools that will protect millions of American lives, such as personalized medicine.[11] But we must ensure at the same time that these new powers are not used maliciously to cause great harm. Certain AI models will likely help to accelerate the transition across the "digital-to-physical" boundary—they may also enable digitally designed threats to turn into physical biological risk. They could be used to help malicious actors create highly dangerous and transmissible pathogens. Without a strong screening framework in place and required of all companies, such actors could exploit companies that do not screen customers or orders, or they could find gaps in screening programs that are weak or insufficient to guard against exploitation.[12]

In order to secure the digital-to-physical frontier, it will be critical to implement mandatory screening policies for gene synthesis providers and manufacturers. EO #14110 requires that all federally funded entities conducting life sciences research must purchase synthetic nucleic acids from gene synthesis providers or manufacturers that adhere to a gene synthesis screening framework to be developed by OSTP.[13] This is an excellent initial step, but Congress should further provide HHS—as by far the largest government funder of life sciences research—with the authority and resources to expand this requirement to all U.S. purchasers of synthetic nucleic acids, not just those receiving Federal funding. There is broad public support for this—a recent poll found that 61 percent of Americans of all political affiliations support such an expansion, while only 12 percent do not.[14] My understanding is that the EO's screening requirements were applied only to federally funded entities because the authority to regulate the purchases by other entities in this manner does not currently exist within the executive branch. That suggests that action by Congress is vital. Congress should also give HHS the authority and resources to set up verification mechanisms to ensure that manufacturers and purchasers comply with screening requirements.

While Congress works to ensure that U.S. gene synthesis providers follow OSTP's framework, the executive branch should focus on promoting the adoption of similar standards internationally. Around 60 percent of the gene synthesis market sits outside of North America.[15] Not only does this mean that malicious actors within the U.S. can access international providers, but as COVID–19 demonstrated, borders are not a protection against disease—a gene synthesis-driven outbreak abroad could have terrible impact in the U.S.. It is therefore crucial that the executive branch works to create a widely adopted international agreement that requires all gene synthesis providers globally to adhere to rigorous screening standards. The frame-

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[11] Kanika Jain, Synthetic Biology and Personalized Medicine, 22 MED. PRINC. PRAC. 209 (2013), *https://doi.org/10.1159/000341794*.

[12] The Hon. Mark Dybul et al., Biosecurity in the Age of AI: Chairperson's Statement, HELENA (July 2023), *https://www.helenabiosecurity.org*.

[13] § 4.4(b)(iii).

[14] Artificial Intelligence Policy Institute (AIPI), Vast Majority of U.S. voters of All Political Affiliations Support President Biden's Executive Order on AI, AIPI (Oct. 30, 2023), *https://theaipi.org/poll-biden-ai-executive-order–10—30/*.

[15] (though the market share of the U.S. is expected to increase in coming years). Global Market Insights (GMI), Gene Synthesis Market—By Method (Solid-phase Synthesis), By Services (Antibody DNA Synthesis), By Application (Vaccine Development) By End-use (Academic and Research Institutes, Biopharmaceutical Companies,) & Forecast 2023—2032, GMI (May 2023), *https://www.gminsights.com/industry-analysis/gene-synthesis-market*.

work that will be developed as part of this EO will provide a vital starting point for such an agreement.

(2) Commissioning a rapid report to identify whether EO #14110 as written will adequately address high-end biological risks or whether congressional action is needed in the near term to prevent those threats.

Although EO #14110 requires studies and reports on AIxBio risks,[16] those studies and reports (1) are not required to be reported to Congress; (2) will not include any new legislative recommendations; and (3) do not clearly prioritize high-end biological risks.

For example, the EO requires the Department of Homeland Security (DHS) to submit a report to the president on the potential for AI to be misused to enable the development or production of chemical, biological, radiological, and nuclear (CBRN) threats. It also requires the Department of Defense (DOD) to commission a report on biosecurity risks from AI. These are important actions for the executive branch to take. However, given the fast-moving nature of this technology and Congress's role in ensuring that the executive branch has the tools and resources it needs to appropriately govern, Congress should commission a rapid report to identify whether EO #14110 as written will adequately address high-end biological risks or whether congressional action is needed in the near term to ensure prevention of those threats.

The need for this focus on high-end risks is akin to the important focus that is warranted around the governance of enhanced potential pandemic pathogen (ePPP) research. The U.S. government should carefully scrutinize research that can reasonably be anticipated to create novel pandemic threats, lest we face the devastating consequences of an accident or deliberate misuse. Similarly, we should advance cautiously—and with full awareness of the relevant risks—as we fund and promote the creation of advanced AI models. In prior work on other issues related to biological threats, I have seen efforts that have neglected or paid insufficient attention to high-end biological risks, and I fear that the same thing could happen in this context.

Commissioning a rapid report on high-end biological risks posed by AI would provide timely clarity to Congress as it considers how to ensure the country is harnessing the incredible transformative power that AI promises in health care, public health, and broader society while guarding against its greatest risks. It would be logical for the Administration for Strategic Preparedness and Response (ASPR) to have responsibility for such a report given its responsibilities around genome synthesis screening and assessment of risks related to ePPP research.

(3) Requiring entities developing models with significant dual-use risks to red-team and evaluate their models, and task an agency with: (1) auditing those models; and (2) submitting a report to Congress with recommendations for new authorities that will be needed by the agency to take any appropriate remedial action should red-teaming, evaluations, or audits fail.

Just as EO #14110 establishes a safety program at HHS that provides for remedial action if it finds harms or unsafe health care practices involving AI,[17] so too should Congress establish a program that provides for remedial action in the event that red-teamers demonstrate AI models enable high-end biological risks, evaluations identify high-end biological risks, or audits find that a company did not provide accurate information regarding high-end biological risks. What is currently required by the EO in the area of high-end biological risks is that companies developing or intending to develop dual-use foundation models must report relevant technical information to the Federal Government, including red-teaming performance related to AIxBio risks.[18] However, the question that Congress should address is: what happens in the event of failures? What can the government do if tests show that a model is too dangerous to release safely?

EO no.14110 does not actually require companies to conduct red-teaming tests, evaluations, or audits. Instead, the EO simply requires that if a company volun-

[16] §§ 4.4(a), 4.6.

[17] The White House, Fact Sheet: President Biden Issues Executive Order on Safe, Secure, and Trustworthy Artificial Intelligence, WHITE HOUSE (Oct. 30, 2023), *https://www.whitehouse.gov/briefing-room/statements-releases/2023/10/30/fact-sheet-president-biden-issues-executive-order-on-safe-secure-and-trustworthy-artificial-intelligence/*.

[18] § 4.2(i).

tarily opts to red-team its dual-use foundation model, the results of those tests must be reported.[19] Moreover, the EO does not require individuals or groups that may develop AI systems in the future to report the same activities required of companies in the EO.[20] Accordingly, Congress should develop legislation to require all entities (not just companies) developing models with high-end, dual-use biological risks[21] to red-team, evaluate, and audit their models.

Additionally, while NIST is tasked with developing auditing standards in the EO, it's unclear whether any U.S. government agency would have the authority to require entities to grant the government permission to audit those models, by which I mean the assessment of developers' red-teaming efforts as well as an evaluation of frontier models by the government itself. Nor is it clear by what authority the U.S. government could take remedial action should its evaluation, or that of the developers, find a model dangerous. Congress should therefore task an agency with: (1) auditing those models as described above, as the agency deems necessary; and (2) submitting a report to Congress with recommendations for new authorities that will be needed by the agency to take any appropriate remedial action such as pausing development until safety measures can be implemented, cessation of development, or directing the developer to face other consequences if red-teaming, evaluations, or audits fail. In conducting these evaluations, agencies should of course consider both the most extreme risks posed by advanced models as well as their potential benefits, both in detecting and flagging pandemic threats and in mitigating them through vaccine and drug design.

One of the most concerning risks of AI models is that if they become wholly open source and available on the internet, they cannot be recalled.[22] That is why red-teaming, evaluations, and audits will be so important to conduct before future dual-use, high-end risk bio models are made open source—we will only have one chance to get it right for each release.

It will also be important for Congress to consider how to support the development of a skilled workforce able to sufficiently red-team frontier dual-use foundation models for the highest-consequence biological risks. Providing these authorities will ensure that the AI systems that could be used to design new effective pharmaceuticals, make breakthroughs in fundamental biology, and give doctors powerful new diagnostic tools do not create new pandemic risks that both endanger the public and threaten to undermine AI's great potential benefit.

Conclusion

In order to harness the great promise that AI holds for benefits in health care and public health, AI risks (including privacy, data integrity, bias) will all need to be rigorously addressed. Within the realm of AI models working in the biological sciences, there are two high-consequence risks that deserve top priority for attention and strong governance: (1) the potential for AI to accelerate or simplify the reintroduction of particularly dangerous extinct viruses or dangerous viruses that only exist now within research labs; and (2) the potential for AI to enable, accelerate, or simplify the creation of entirely new biological constructs that could start a new pandemic.

While I am encouraged by recent actions taken by the U.S. government, industry developers of powerful AI technologies, and researchers in the field, I outline above three steps that I think will be important for Congress to attend to in the time ahead to ensure that these high-consequence risks are addressed. If taken now, these measures will help to reduce the risk of malicious and consequential misuse of AI-enabled biology while allowing AI developers and scientists to pursue beneficial uses of AI to broadly improve medicine, public health, and patient outcomes.

Senator MARKEY. Thank you, doctor. Our next witness is Dr. Kenneth Mandl. He is the Director of the Computational Health

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[19] Id.

[20] Compare § 4.2(i) with § 4.2(ii). I suspect that this is because individuals or groups, such as academic institutions, are not currently developing frontier AI models. However, this could shift in the future, such as if the National AI Research Resource (NAIRR) provides independent AI researchers and students with significantly expanded access to computational resources. Accordingly, a capabilities-based requirement rather than an entity-based requirement seems warranted.

[21] Potentially subject to be defined by the actions taken in the EO. See § 4.2(b).

[22] See, e.g., the leak of Meta's Llama model.

Informatics Program, excuse me, at Boston Children's Hospital, and he is a Professor of Pediatrics and Biometric Informatics at Harvard Medical School.

Dr. Mandl is also, importantly, Co-Chairing the National Academy of Medicine's Digital Health Action Collaborative, which is working to facilitate the adoption of an AI code of conduct to ensure responsible and equitable use of AI in health care and in research. Welcome, doctor. Whenever you are ready, please begin.

STATEMENT OF KENNETH D. MANDL, HARVARD PROFESSOR AND DIRECTOR, COMPUTATIONAL HEALTH INFORMATICS PROGRAM, BOSTON CHILDREN'S HOSPITAL, BOSTON, MD

Dr. MANDL. Thank you, Subcommittee Chairman Markey, and Ranking Member Marshall, and Members of the Subcommittee——

Senator MARKEY. Could you just move in a little closer and move the microphone a little closer, please.

Dr. MANDL. Of course. It is with a deep sense of responsibility and privilege that I offer my testimony, as a Professor of Biomedical Informatics and Pediatrics, and Director of a Computational Health Informatics Program. I do Co-Chair the National Academy of Medicine's Digital Health Action Collaborative, but I am not speaking on behalf of the Academy today.

With the release of sophisticated large language models like ChatGPT, AI will transform health care delivery sooner than anticipated. These emerging intelligences assimilate vast amounts of information and demonstrate remarkable empathy and profound reasoning.

But they are flawed, can produce inaccurate responses, hallucinate, and the precision of their answers changes over time and based on the precise wording of prompts. Consider AI in the doctor's office.

The $48 billion high tech investment in electronic health records digitized medical information. But these systems also introduced complex and distorted clinical workflows, turning MDs into documentation clerks, contributing to physician burnout, and exacerbating the shortage of primary care providers.

An early application of clinical AI attempts to alleviate this self-inflicted problem by placing a microphone in the doctor's office and generating clinical visit notes in real time just from the overheard doctor, patient dialog, allowing doctors to face their patients instead of being turned away and crouched over a computer keyboard.

But soon, AI may produce not only the note, but also recommend diagnostics and treatments. Some AI systems may operate independently of physicians, potentially democratizing health care access and alleviating physician shortages, but as of now, with no oversight.

What if the information is inaccurate? What if a drug company could whisper in the ear of your electronic health record, nudging that AI to favor their pills over a competitors? We must anticipate and manage a recalibration of responsibilities within health care

delivery. How will tasks be allocated between human physicians and their AI colleagues?

Will AI improve care and outcomes? Even as we speak, patients and doctors are tapping away at keyboards, using ChatGPT to navigate health care decisions. But here is the catch, there are no guardrails on this road yet.

As we reshape health care around AI, let's remember that today we don't adequately even measure whether current medical practice is effective. For example, drugs are approved by the FDA with limited data obtained under conditions in a trial.

Those conditions are controlled. But how do approved products fare in the wild, in the real world? Do they work like they are supposed to in the messiness of real life? That COVID test you just took, how accurate is it when you are not in a pristine lab but at your kitchen table? How well did that artificial hip you are about to get work in all the patients who had it before?

The National Academy of Medicine's blueprint for learning health care system envisions not just treatment, but learning, and not just from clinical trials, but from the vast ocean of real world data. Each patient's experience informs the care of the next patient by connecting the dots among every visit, treatment, and outcome, but it has been slow in the making.

The urgency of AI should compel us to accelerate a system that meticulously tracks the real world accuracy, safety, and effectiveness of not just AI, but also drugs, diagnostics, devices, procedures, and models of care. To realize the return on investment on our $48 billion that we have spent, we must demand that the data generated are available to support learning.

Thanks to the highly bipartisan 21st Century Cures Act and a rule from the Office of the National Coordinator of Health Information Technology, all EHRs must this year, for the first time, provide a push button export for their data across what is called an API.

Because each hospital office can produce data in the same format, the care delivery system becomes an interoperable data source in a federated network where the lion's share of data can remain safeguarded at the point of origin.

These data cannot only drive the development of innovative AI, but also help evaluate AI innovations in real time. Let's learn from another cautionary tale. The HIPPA privacy rule passed in 2000, guaranteed patients the right to access their electronic health records, but without focused enforcement, nearly 20 years went by before this became possible at health system scale.

If the CURES Act APIs are fully supported, we can avoid data monopolies and spark a free market of American innovation in AI, while moving us toward a high performing health system. Thank you for the opportunity to testify. I look forward to answering your questions.

[The prepared statement of Dr. Mandl follows.]

PREPARED STATEMENT OF KENNETH D. MANDL

Subcommittee Chairman Markey, Ranking Member Marshall, and HELP Committee Chairman Sanders and Ranking Member Cassidy, thank you for holding this hearing today and for inviting me as a witness. It is with a deep sense of responsibility and privilege that I offer my testimony as a Professor of Biomedical Informatics and Pediatrics, and Director of a program in Computational Health. I also Co-Chair the National Academy of Medicine's Digital Health Action Collaborative.

With the release of sophisticated large language models like ChatGPT, AI will transform health care delivery sooner than anticipated. These emerging intelligences assimilate vast amounts of information and demonstrate remarkable empathy and profound reasoning. But they are flawed, can produce inaccurate responses, hallucinate, and the precision of their answers changes over time and based on the precise wording of prompts.

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But soon, AI may produce not only the note, but also recommend diagnostics and treatments. Some AI systems may operate independently of physicians, potentially democratizing healthcare access and alleviating physician shortages. But as of now, with no oversight. What if the information is inaccurate? What if a drug company could whisper in the ear of your electronic health record, nudging that AI to favor their pills over a competitor's?

We must anticipate and manage a recalibration of responsibilities within healthcare delivery. How will tasks be allocated between human physicians and their AI colleagues? And will using AI improve care and outcomes. As we speak, patients and doctors are tapping away at keyboards, using ChatGPT to navigate healthcare decisions. But here's the catch—there are no guardrails on this road yet.

As we reshape healthcare around AI, let's remember that today we don't adequately measure whether medical practice is effective. For example, drugs are approved by the FDA with limited data obtained under controlled conditions in a trial.

But, how do approved products fare in the wild, the real world? Do they work like they're supposed to in the messiness of real life? That COVID test you just took, how accurate is it when you're not in a pristine lab, but at your kitchen table? How well did that artificial hip you're about to get work in all the patients who had it before?

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Let's learn from another cautionary tale. The HIPAA privacy rule, passed in 2000, guaranteed patients the right to access their electronic health records. But, without focused enforcement, nearly 20 years went by before this became possible at health system scale.

If the Cures Act APIs are fully supported, we can avoid data monopolies and spark a free market of American innovation in AI, while moving us toward a high performing health system.

Thank you for the opportunity to testify. I look forward to answering your questions.

Senator MARKEY. Thank you, doctor. And our next witness will be introduced by Ranking Member Marshall.

Senator MARSHALL. Well, thank you, Mr. Chairman. It is an honor to introduce our next witness here today, is Dr. Keith Sale. Dr. Sale is a practicing physician and currently serves as the Vice President and Chief Physician Executive for Ambulatory Services at the home of the No. 1 ranked basketball program in the Nation and a top 25 football program, as well as a top research institute in the country.

Of course, that would be the University of Kansas Health System in Kansas City, Kansas. Dr. Sale's clinical interests include sinonasal disease, auri and vagus nerve stimulator implantation, though his practice includes the full scope of otolaryngology. When he is not seeing patients, he is a leading—partnership with industry to use AI to write clinician notes with physicians put in the electronic health record.

Dr. Sale is the President-Elect of the American Academy of Oral Laryngeal Allergy. He is a National Physician Specialty Trade Association. He has also served as past President of the Kansas City Society of Otolaryngology and Ophthalmology. Thank you for agreeing to testify, Dr. Sale, and welcome.

STATEMENT OF KEITH SALE, VICE PRESIDENT AND CHIEF PHYSICIAN EXECUTIVE OF AMBULATORY SERVICES, THE UNIVERSITY OF KANSAS HEALTH SYSTEM, KANSAS CITY, KS

Dr. SALE. Thank you for that introduction. Chair Markey, Chair Marshall, Committee Members, thank you for the opportunity to be here because it is truly an honor and a privilege. I would like to focus my testimony on what I think is possibly one of the best impacts that AI can have in health care, and that is addressing one of the most serious concerns that faces physicians.

That is burnout. Burnout has become an increasing problem amongst our physicians and our medical staff, and it can impact us in ways when it comes to our ability to take care of patients and to manage the amount of patients that come through our doors on a daily basis. When you think about burnout and AI, I want to get back a little bit to where documentation started, right.

If you go back 20 odd years or so when we started all of this, we were using tape recorders to dictate our notes about clinic visits. I would go in, I would meet with a patient and have a conversation.

I would walk out of the room. I dictate a note. That note would then go to a transcriptionist at the end of the day who would get that note back to me. I would review the note and edit it and put it in the chart.

That whole process was a two or 3 day process, all right. Fast forward 10 years, we have the EMR, right, so electronic medical

record, the—theoretically the savior of medicine at that time. The challenge was it increased our documentation load because now I am the transcriptionist.

I put in all that information personally at the time of the visit. I type in front of the patient and look at my keyboard and my screen instead of talking to the patient, so patient experience is impacted. At the end of the day, half of the documentation is now done, but I still have the other half to do.

So now I am adding two, three, 4 hours at the end of my clinic day to get my documentation done. Fast forward 10 more years. The introduction of AI in health care and ambient documentation tools.

We have now piloted two different tools in our organization. The current one allows me as a physician to take a device in the room. It records that conversation. It then takes that conversation and takes the history and investment plan and summarizes it based on that conversation.

Puts it into a place where I can then review it within minutes of that encounter ending. I edit that information, and the editing part is really important because that is how the AI tool learns. It learns what my preferences are.

It learns my techniques, my topics, my lingo, if you will, in otolaryngology, and allows that note to be more specific and more—especially specific and patient specific. I then can take that edited note, put it in the EMR, and it is done within minutes of seeing that patient.

Now, fast forward into my clinic day and I, even though I love to say I get all of my notes done as soon as that patient walks through the door, I am usually behind a little bit, as most of us in clinical practice are.

At the end of the day, now I have 30 to 45 minutes of time to go through interview notes and plunk them into the EMR. But as I have gotten more facile with this tool, I have been able to get through my notes faster.

I have less editing, and the notes are better. There is more detail, there is more information, and the content is more effective for what I need, for my future visits, what my colleagues need to see from that visit, and then from what the patient needs, who can also now read those notes.

I think there is a great opportunity for AI technology to assist and remove that burden of documentation and administrative tasks that have become commonplace in health care and are truly challenging our physicians and our health care workers as you try and keep up with the growing demand of patient care.

When you talk about the things that I worry about in AI, and how it impacts health care, first and foremost was mentioned was privacy. And so, how do we make sure that the tool we are using now, much like the EMR tools we have, adhere to the HIPAA guidelines and criteria we have in place now?

I think making sure that anything we build and put in place maintains those privacy standards is paramount. I think as we roll out and develop these tools, AI is a data consumption tool in my

mind. I need as a physician to have the ability to input and guide what that tool uses and what it consumes to drive the decisions that I hopefully arrive from based on what it produces for me.

But it is a tool. It is not something that should replace what I decide for—what I decide in practice or how I make decisions that affect my patients. So, ultimately it is designed to enhance my practice, not replace me in practice. I think there is an issue around data security and—as well.

Making sure that as this information passes between different tools and whether it is my device to the EMR, there are protections in place, again, guided under HIPAA. Last, I think what is really unique about the current tool we are using is the traceability and track ability of the information.

I can see in real time as I am editing my note where the AI tool achieved its information to create the note that it documented. I can go into that then and understand that why it said cholelithiasis instead of tonsillitis in my note, and I don't even do gallbladder surgery, so it doesn't belong there. I can go in and edit that.

I know exactly where it came from because it is transparent, and I can track it through that AI's workflow. Ultimately, I think there is a great opportunity for AI to help us in health care, and to make our lives and our workflows better.

I appreciate the time and your allowing me to testify today, and I look forward to your questions. Thank you.

[The prepared statement of Dr. Sale follows.]

PREPARED STATEMENT OF KEITH SALE

Introduction

Chairman Markey and Ranking Member Marshall, I am Dr. Keith Sale, Vice President and Chief Physician Executive of Ambulatory Services at The University of Kansas Health System and Associate Professor of Otolaryngology-Head and Neck Surgery at The University of Kansas School of Medicine. Located in the Kansas City metro area, The University of Kansas Health System is the only academic health system in Kansas, providing a full range of care to patients from every county in Kansas and Missouri, all 50 states and nearly 30 countries. The health system offers over 140 hospital and clinic locations, including its original campus in Kansas City, Kansas, which includes 1,300 beds and is supported by over 17,000 employees and 1,500 physicians. Thank you for the opportunity to present testimony to you and your colleagues on the Subcommittee on Primary Health and Retirement Security regarding the adoption of AI (Artificial Intelligence) and how it can transform the delivery of healthcare and more importantly, enhance patient care. In a changing healthcare environment, AI is one of many tools available to help the American healthcare system improve access and create better outcomes.

Increasing patient care needs in America are overwhelming the healthcare workforce and persistent nursing and physician shortages continue to challenge our healthcare infrastructure. The Association of American Medical Colleges projects the United States will see a shortage of between 37,800 and 124,000 physicians within the next 12 years[1]. In addition, by 2025 the United States is projected to see a shortage between 200,000 to 450,000 of registered nurses needed for direct patient care[2]. Simultaneously, healthcare systems face increased financial pressures that

[1] Robeznieks, A. (2022, April 13). Doctor shortages are here-and they'll get worse if we don't act fast. American Medical Association. *https://www.ama-assn.org/practice-management/sustainability/doctor-shortages-are-here-and-they-ll-get-worse-if-we-don-t-act*

[2] Gamble, M. (2022, May 12). U.S. faces deficit of 450,000 nurses by 2025. Becker's Hospital Review. *https://www.beckershospitalreview.com/workforce/us-faces-deficit-of-450-000-nurses-by-2025.html-oly—enc—id*

include insurance companies creating more barriers to delivering care like pre-authorizations and paying less for the care we provide and higher costs for medicines and equipment critical to patient care.

The Opportunity of AI

Healthcare systems continually evolve to match the ever-changing patient care environment. Before Electronic Medical Record (EMR) systems were widely implemented and before AI improvements, physicians and providers spent considerable time recording and transcribing notes from patient visits because detailed records from patient encounters maintained continuity for follow up visits and improved patient outcomes. However, each stage was duplicative of the original conversation and added time to the patient encounter completion. Historically, these notes could take days to get back into the patients' records. Today AI technology records the conversation between the doctor and patient during the appointment, summarizes the interaction, and downloads the conversation for review within minutes of patient encounter ending. This technology reduces the steps in documentation and directly captures the conversation in real time. Physicians can then edit notes to ensure accuracy and upload finalized clinical notes into the electronic medical record within minutes of completing a visit.

Patient and Physician Benefits

As the complexity of patient care increases, the administrative burden has exploded, and patients now have unprecedented access to physicians and health care workers through EMR portals. AI automates routine and time-consuming tasks reducing the administrative burden and allowing physicians and providers to spend more time with patients focusing on better outcomes. Finding efficiencies for the administrative and documentation burden of healthcare may also allow physicians to see more patients and help address the capacity challenges resulting from the growing physician shortage. In addition, AI's reduction of administrative tasks and documentation may help mitigate the growing concern of physician burnout, much of which relates directly to documentation and administrative burden. Allowing providers to spend more time with direct patient care will help return the joy of practice to our physicians and providers, reduce administrative burdens, and thereby improve patient outcomes.

Importance of Oversight

While AI holds immense potential, its implementation should be built upon clinical practice guidelines, be compliant with patient privacy standards, and be safeguarded from misuse. Physicians and healthcare professionals must be actively involved in the development and validation of AI tools to ensure they are driven by clinical guidelines and that they enhance rather than replace human expertise. Trained and licensed clinicians develop expertise through direct patient interactions that should not be fully replaced by AI. Rather, AI can be used to help clinicians sort through the growing volumes of healthcare data, present care options based on recommended best practices, and inform physicians about therapeutic options. AI will greatly expedite patient care, but human judgment will still need to determine if a final care plan is appropriate and in line with a patient's condition and expectations. To best utilize AI in healthcare requires access to vast volumes of clinical data, financial data, research data, and patient data, much of which is considered highly sensitive and personal information. Maintaining the privacy standards built around the Health Insurance Portability and Accountability Act (HIPAA) that currently exists to protect our patients' privacy is paramount. Continued observance of these standards will safeguard individual data and ensure that healthcare data is used responsibly and kept secure. While healthcare providers, patients, and technology companies contribute to this data pool, the question of data ownership may not be straightforward. Conversations about data ownership and use are essential to maintaining patient trust and preserving the sanctity of patient privacy. Importantly, HIPAA privacy and security standards will also have to keep up with current technology as well.

In conclusion, the integration of AI and its consumption of healthcare data carries tremendous opportunities for improved patient care and outcomes and reduced physician and clinical team burnout. However, data privacy and management are equally significant and require careful consideration. As Congress navigates this complex landscape, it is essential to balance the promise of AI with safeguards to protect patient privacy and maintain data security. I urge this Committee to support initiatives, such as AI, which promote improved patient care while simultaneously easing

the administrative burdens currently troubling our healthcare teams. Additionally, responsible data management and patient privacy must be at the core of AI integration into healthcare to protect our patients' rights and safeguard their privacy.

Thank you for your attention and I am available to address any questions you may have.

Senator MARKEY. Thank you, doctor, very much, now we will turn to questions from the Subcommittee Senators.

Senator Marshall and I, we are part of a long tradition of partnering between Massachusetts and Kansas, going back to Dr. James Naismith inventing basketball at Springfield College, and then the University of Kansas stealing him away to be their—and his rules to be the first basketball coach at University of Kansas.

This partnership has a long, rich history in medicine and in basketball. And we are good at inventing things, but the application out of the University of Kansas has been much better than any Massachusetts college in the basketball field.

We are hoping here that this partnership that we are creating can help us to get the correct formula, the correct rules, like the Naismith basketball rules, for AI. So let me go to you, Ms. Huberty.

In your testimony, you included a powerful story of AI directing care for a patient by deciding what is covered by insurance, and that there are many more people who are currently experiencing this, who don't know to challenge these decisions. They are being made by AI about their health care.

Ms. Huberty, what do stories like Jim's, that you told us here, tell us about insurance companies and companies developing artificial intelligence, and how they are incorporating patient experience versus their profit motivation? Can you talk about the lesson we should learn from that experience?

Ms. HUBERTY. Sure. I do want to focus first just on the fact that this is not new technology that we are talking about in Jim's case. It has been around since I started as an attorney. I believe it was used beforehand.

A lot of times when we are talking about ChatGPT, that is new innovations. We are just starting to get a sense of how it is affecting us. But the technology that affected Jim and has affected hundreds of residents in Wisconsin is not anything new.

We have a long history of showing that this algorithm, this use of predictive technology, has shown time and time again that it is incorrect. They come to us in our agency. We appeal, we get it overturned.

We see that so often, that number, that computer, that algorithm gets it wrong, and there wasn't enough human oversight.

Senator MARKEY. Yes. And who should bear the burden of proving that the use of artificial intelligence won't harm patients? Where should that burden of proof lie?

Ms. HUBERTY. Right now, I think that should be with those subcontractors that have developed and are using that AI.

Senator MARKEY. Yes. I do agree with you, by the way, in terms of this being an old technology.

When Al Gore was Vice President and I was the chairman of the telecommunications committee, when we were breaking down all of the monopolies in the mid–90's so we could have the digital revolution, the broadband revolution, not one home had broadband in February 1996 in America.

I used to call these new technologies Al-Gore-rhythms, right. So, it is not a new word. It was obviously what the digital revolution was unfolding at that time, and we had to heed those warnings that we were hearing at that point.

Bonnie Castillo, who is Executive Director of the National Nurses United, the Nation's largest union of registered nurses, noted in recent written testimony for an AI Insight forum on workforce that, "health care workers should not be displaced or de-skilled, as this will inevitably come at the expense of both patients and of workers."

That is true, if not carefully implemented with Government oversight and worker input, AI can harm health care workers by making them feel like the art and science of health care is distilled to typing into an iPad, and that is all there will be to it.

Dr. Mandl, your testimony noted how technological advances can contribute to health provider burnout. Can you speak to the danger of using AI in the health care settings to automate both tasks and clinical decisions without Government oversight and worker autonomy and input?

Dr. MANDL. The worker autonomy——

Senator MARKEY. Can you turn on your microphone, please.

Dr. MANDL. The worker autonomy and input is very important. And there has to be early on training and education of our workforce so that they can understand what the issues are and understand how to work alongside AI tools, what their functionalities and limitations are.

There is a risk today of using an AI tool without understanding its limitations, for example. There are ergonomics and workflow integration issues that are key. We heard today that documentation burden ballooned with electronic health record implementations. We have to design AI tools so that they improve the life and the work life of physicians while maintaining safety.

Probably there is mental health support to provide to the workforce as well at a stressful moment when there may be workforce shocks as a result of AI, and the shared responsibility between physicians and AI, and we don't know where that is going to equilibrate. There have to be legal and ethical safeguards to protect health workers from liability associated with AI. It has to be clear who is responsible if the AI makes a decision that is incorrect.

That is going to cause a lot of hesitancy and anxiety otherwise. We have to monitor, as I was talking, we have to have systems that are monitoring the output of AI and the diagnoses that are made, the treatment recommendations that are made, the claims denials that are made. Those can all be automated with data.

We have an opportunity to move forward with getting the data flowing in the health care system so that we can monitor safety.

And again, it is the same safety that we are talking about for devices, drugs, procedures, and AI.

There can be a float all boats. And then of course, there are ethics and transparency. And we really need to understand how the AI algorithms were designed, what they were intended to do, and what they actually are doing.

Senator MARKEY. We have to be able to get under the hood just to understand how there are biases built in. Is there harm that is inside of this ultimately human designed algorithm that then takes on a life of its own? What was that human input that ultimately led to the recommendations that will be made?

Thank you, and I will be coming back again. But at this point, I would like to recognize the Senator from Minnesota, Senator Smith, for a round of questions.

Senator SMITH. Well, thank you very much, Mr. Chair. And thank you, Ranking Member, for deferring. I really appreciate that. And thanks to all of you for your testimony. It is super interesting. There is so many questions I could ask.

Dr. Inglesby, I would like to start with you. Could you talk a bit—we know that AI was important in the way in which we developed the COVID–19 response—or vaccine, how we responded to COVID–19, the historic pace of that, of testing and treatments developed, and vaccines as well.

Could you talk about how—kind of what are the lessons learned from that experience? And are there lessons learned as well for not only advancing treatments like the vaccine, but also preventing biosecurity risks, which we are talking about in this Committee hearing?

Dr. INGLESBY. Yes. Well, thank you so much for that question. I think what we have seen with vaccine development, new drug development, and AI tools is that AI can improve the speed and precision and efficiency of many processes involved in vaccine and drug development.

They can start with the target and work backward to decide what will attack that target on that pathogen most efficiently. They can predict toxicity. They can improve the efficiency of laboratory practices.

AI tools kind of across the board can take on different components of the vaccine drug development process and make them more powerful. But on the same—at the same time, those very processes could conceivably either inadvertently, accidentally, or deliberately be misused to identify things that could harm people on large scale, that could become products that, or kind of biological constructs that could not be controlled.

That is my greatest concern, is that we need to set up guardrails, at least to begin with, that are focused on preventing pandemic risks, risks of things spreading in the environment, not being able to be controlled.

I think the companies themselves have said the same things. If you look at what they are saying in the public in the last year, many of the leading companies have said they are concerned about

setting up guardrails around biological risks, and that is one of the things that they are explicitly talking about.

I think the Executive Order begins to do that and has many steps moving in that direction. What I would do, though, is I think Congress should seriously consider going a bit further than the Executive Order even now, because the role of Government still is setting—in the Executive Order, setting standards, creating a testing process, but in terms of requirements for audits, a Government audit of these companies, that does—it is not yet there.

I think that is the next important step.

Senator SMITH. One of the things that I have been thinking about a lot is how do you overcome sort of the black box phenomenon of these AI models and how you get accountability around bias, for example.

There is lots of questions around accountability. But how do you think about it as you as—from your perspective as a clinician, how do you think about that question of getting accountability in that sort of black box world where we are not exactly sure why or how the model comes up with its answer, let's say.

Dr. INGLESBY. Yes, I mean, I think that gets to the heart of the bias questions that people have been talking about here. And there are many sources of bias. Can be data bias. Can be the model itself and how the model collected the data.

Senator SMITH. Right.

Dr. INGLESBY. But one of the strongest things that people talk about in bias is getting rid of the black box, and the term interpretability is really—is the key concept around that.

I think that is just another way of saying that in health care related AIs that will ultimately drive clinical care, we should be able to look under the hood and understand that process. And right now, with some tools we can and some tools we can't.

Senator SMITH. Some tools we just——

Dr. INGLESBY. But that could be—for health care indications of AI, that could become a standard which the Government insists upon. We have to be able to see how this—go, reverse engineer it. Understand how it came up with its—with process and recommendations.

Senator SMITH. Right. Right. That question of how decisions are made and what is programmed into the model, let's call it gets to the core questions of accountability. Ms. Huberty, I was thinking about your story of the man who was confronted with this prior authorization recommendation algorithm, which clearly was not being made in his—you know, the decision is not being made in his best interests.

I mean, to be clear, I worry about humans and these big insurance companies also not correctly balancing the health risks of an individual with the marginal profit that they may incur by releasing somebody 7 days earlier or whatever it is.

I know I am just out of time, Mr. Chair, but could you—like how do you think about how we kind of get the right balance in these models?

Ms. HUBERTY. Well, I think in these cases, there are humans involved in running those—the algorithms and adhering to those discharge dates.

But even those humans involved have moral issues with those dates and how they are required to adhere to them within their own company. So I also just think the volume of it too.

When you have so many of these denials running through that algorithm, the human oversight is only there when it is challenged. So only when there are appeals, do you have that really detailed and careful human oversight where they are looking at the medical records.

I guess my recommendation is to slow down, to get more of the humans involved, have more of the treating physicians more involved as well, because the humans involved in those pieces never see the patients. They have no contact with them whatsoever.

Senator SMITH. Thank you very much.

Senator MARKEY. Great. Thank you very much, Senator Smith. Senator Marshall is willing to forego his turn at this moment so that I can recognize Senator Hassan from New Hampshire for her round.

Senator HASSAN. Thank you very much. And thank you, Senator Marshall. Thank you, Mr. Chair, for this hearing. And thanks to our witnesses for being here. Dr. Inglesby, I wanted to start with a question for you.

Artificial intelligence can be helpful when designing new tools to combat the threat of antimicrobial resistance. For example, researchers at the NIH have found that machine learning algorithms can quickly analyze patterns in antimicrobial resistance.

This can obviously help public health authorities respond to outbreaks of resistant infections more quickly and efficiently. Artificial intelligence also has the potential to help doctors more precisely diagnose and treat an infection with the right antibiotic at the right dose.

As an expert in health security, can you speak to the role that artificial intelligence plays in our fight against antimicrobial resistance?

Dr. INGLESBY. Yes. Well, thank you very much for the question. Very important set of issues around AMR. I think there are a number of ways that AI could help in the fight against antimicrobial resistance, and you have mentioned many of the major ways. The first is the design of new therapeutic approaches.

We have talked about how new protein design tools, in the category of AI, biological design tools could accelerate the development of new therapies. But also, AI can help us with looking at the combination of therapies in ways that were not necessarily obvious by—through human judgment.

Senator HASSAN. Yes.

Dr. INGLESBY. Combinations of therapies. They can move from interpreting the sequences of pathogens and making predictions about resistance. And we begin to see that in experimental ap-

proaches. We just need kind of a strong data set to be able to move forward on that, but lots of potential.

Senator HASSAN. Well then—as a follow-up, how can Congress help support the use of AI to better predict and combat AMR?

Dr. INGLESBY. Yes, well, I think it depends on—depending on the category of approaches, I think new therapeutic approach is I think making sure that BARDA, HHS, and FDA are oriented around new AMR approaches and have the flexibility to make new therapeutics.

There is a—there are a number of different approaches that BARDA has been pursuing around that. I think making sure that the data sets that are being developed around these microbes is robust.

I think people talked about the federated approach, making sure that institutions across the country can work together, anonymize data, and randomized patient data, and develop the datasets we need to make those predictions.

Senator HASSAN. Well, thank you for that. I am going to move now to doctor—is it Mandl? Dr. Mandl, artificial intelligence has played an integral role in the widespread adoption of electronic health records.

Algorithms can help physicians categorize and structure patient data, making it easier for health care providers to access and use. While this has the potential to boost productivity and allow providers to spend more time with their patients, we need standards in AI for medical settings in order to ensure that patients are receiving the best possible care and that their privacy is protected.

How can Congress support the development and implementation of these kinds of standards?

Dr. MANDL. Thank you very much for that question. The delivery of AI through electronic health records will clearly be a very important channel for how AI gets to the point of care.

For one thing, I think it is very important in that context, so that we optimize innovation and excellence, to be modular in the way we integrate AI with electronic health records, to make sure that innovators can get to the point of care outside of the electronic health record, but within clinician workflows as well.

We want to be sure that the innovation and that the decisions that lead to the kinds of outcomes, good and bad, that you are talking about are not all channeled through a small set of companies, but through the full power of American innovation. I refer to in my testimony application programing interfaces.

Under the 21st Century Cures Act, there are actually methods to integrate outside technology with electronic health records so that we can move the data to where it needs to be and implement those standards widely.

The importance on understanding how AI is working is going to be very heavily placed, I believe, on continuous monitoring. While understanding the algorithms and testing the algorithms is extremely important, until you know how they perform in the real world, you can't fully evaluate them.

These large language models, no one understands. No one understands exactly how they work or exactly how they produce their output. So, we are poking the bear and testing. And so, there has to be interactive testing and measuring, and that is how we will begin to see what emerges.

There has to be collaboration across multiple sectors so that we are all on the same team.

Senator HASSAN. That is very helpful. Thank you. And thank you again to all the witnesses. Thanks, Mr. Chair.

Senator MARKEY. I want to make unanimous consent to enter into the record November 1st written statement for AI insight forum workforce by Bonnie Castillo. Without objection, so ordered.

[The following information can be found on page 62 in Additional Material.]

Senator MARKEY. Now I am going to recognize Senator Hickenlooper from Colorado to Chair. Both Senator Marshall and I now have to run over to make the roll call on the floor, and we will try to run over, make it, and come back. This is again how we get our 10,000 steps in. So, just to turn to Senator Hickenlooper. Thank you.

Senator HICKENLOOPER. Great. Thank you, Mr. Chair. Dr. Inglesby, you spoke about the potential for AI models to assist malicious actors in creating highly transmissible pathogens.

This is obviously all the more possible given that we do not currently require screening for all gene synthesis providers. Senator Budd and I have a bill called the Gene Synthesis Safety and Security Act, which would help us conduct critical oversight of the industry and protect against misuse of these types of products.

If we do not enact Federal guardrails here, how would you assess our level of risk?

Dr. INGLESBY. Senator, first of all, I just want to commend your leadership on that Act and think that is a really crucial step that we need to take to reduce bio security risks.

I think the Executive Order goes some distance toward—in the direction that your Act laid out, but I think Congress could go further in requiring that all of those ordering gene—nucleic acids in the United States abide by the same rule, not just those who are federally funded.

But to your point, I think the problem that your Act and the Executive Order has been trying to solve has been the possibility that malicious actors could order de novo nucleic acid—could order nucleic acids through—from a company in the United States and de novo or create viruses that are now extinct, such as smallpox or something along those lines, which would be, if released into the public, would—could create a pandemic.

It is very clear—the industry is very in favor of regulation in this case, which is obviously quite unusual. But they have been very clear about that. Many of the best actors in the industry are already screening their customers and screening the sequences, but it is not a requirement.

The good actors are at a disadvantage. The bad actors are not paying for that or doing that work. So, thank you for your leadership on that.

Senator HICKENLOOPER. Of course. Thank you. Dr. Mandl, you wrote in your testimony that, and I quote, "each patient's experience informs the care of the next patient by connecting the dots among every visit, treatment, and outcome."

In many ways, this is the highest ideal of how our health system, under the best circumstances, good circumstances, how it should work. And certainly, AI could be a great equalizer in terms of helping us to amass and analyze all and connect all those data points.

How can we seize on this moment with our AI to catapult our ability to utilize real world data, but also building the guardrails that you have all been saying are necessary to ensure the security of the data.

What is the No. 1 concern you have in mind in terms of the use of AI to manage this level of data, this amount of data, and how should we—how should we be working to address it?

Dr. MANDL. Well, I think there is two sides to this. One is the actual use of the AI to look across vast amounts of data that no clinician could integrate in their head, and to do that potentially even in real time in the clinic when a patient is before us.

There, we need the guardrails to make sure that the AI is acting in a way that is accurate and beneficial, that is improving the value of care. And there are multiple levels of that kind of measurement.

The second place where I think AI can help us is simply by being a burning platform of sorts. If you look at the COVID pandemic, there were some failings but there were also some incredible successes at the community coming together and moving data to where it needs to be so that we could monitor the pandemic. And as the pandemic went on, we got better and better at it.

The collaboration and the enthusiasm for it was very different than what happened before. I do think that the COVID pandemic receding, hopefully, permanently—we see some also receding of that enthusiasm for the kind of collaboration.

I think that AI is the burning platform where we can actually try to move the data to where it needs to be to evaluate the health care system and to move toward a learning health care system, not just for AI, but for drugs, devices, procedures, surgeries, and that there is an incredible opportunity there if we seize the moment.

Senator HICKENLOOPER. It would be an amazing concept to go from spending 18 percent of our GDP, down to maybe 8 or 10 percent like the rest of the world. That is one way we could move in that direction.

Dr. MANDL. Absolutely.

Senator HICKENLOOPER. Thank you. I am out of time, but I have got other questions that I will submit to both of you in writing.

Senator Braun.

Senator BRAUN. Thank you, Mister—Senator Hickenlooper subbing in for Senator Markey.

I ran a business for 37 years that had so little technology in it until I finally, after repeated kind of not wanting to spend the money on it, have been such a believer that if you use it practically, it not only makes things more efficient, it makes things a lot less expensive too.

When I look to see that AI had come onto the scene, to me, there are so many practical ways that we can use it to sift through the mundaneness of how you do it without it. And all I can tell you is if you drag your feet on it, you are going to regret it because your competition in the real world is going to use it and you are going to regret it.

Based on that, I want to define something that currently is being done by CMS and give it the tools to do it better. I am introducing on November 16th and looking for a good Democratic lead. We will get one, and I think this bill is going to go to town. It is called the Medicare Transaction Fraud Prevention Act.

It will direct CMS to conduct a pilot program of enhanced oversight for two categories of historically high fraud. That would be diagnostic testing and durable medical equipment. By notifying beneficiaries in real time with suspicious purchase alerts, this bill utilizes a successful technique that is already employed by private industry like our leading credit card companies. It is that simple premise.

I want to ask Dr. Inglesby, what do you think of that idea? We know how much fraud is endemic to so much that Government does. I would like to remind everyone that when we spent nearly $1 trillion on the extended unemployment benefits during the CARES Act, the estimate is anywhere from $100 to $250 billion was stolen by domestic and international fraudsters.

When we are now borrowing $1 trillion every 6 months, and just 5 years ago it was $1 trillion annually, I think we need to start doing some things that give taxpayers a better value. What do you think of this idea as a bill?

Dr. INGLESBY. Well, and from what you have described—I haven't heard of this idea before. From what you described, it sounds like a very, very good idea. I am very in favor of tools we can use to decrease fraud at CMS.

I think we use very sophisticated tools in the private sector to detect indicators of fraud or checks. So, if those tools can be used in a way that allow health care dollars to go to clinical care as opposed to some kind of fraud, I think I would be strongly in favor of that.

Senator BRAUN. Thank you. Ms. Huberty, Hoosiers have been billed up to 20 times for like COVID tests, and this phantom billing of larger durable equipment like powered wheelchairs can involve huge co-payments to boot.

What trends do you see in health care fraud, and how do you think that impacts seniors financially? And again, do you think a bill like mine would be the place to start where you weave it into the system to work and even address the larger stuff down the road?

Ms. HUBERTY. I mean, everything that you have said absolutely is happening in terms of the billing fraud. There are programs. Wisconsin has a senior Medicare patrol program, and those are available nationwide to do just that, is to address those issues of fraud and detect and report those.

A bill that would be—you know, that would focus in on that, extremely. We can avoid the wasteful spending and those fraudsters. I think to my testimony, though, what I am getting at is that the AI, those companies are actually committing fraud on the other end where they are taking Medicare dollars and not putting it back into the pockets of the patients by not offering the coverage that they said they were going to.

Senator BRAUN. Thank you. And one final quick question for Dr. Sale. President Biden's Executive Order encourages innovation in health care services so long as AI models are tested robustly beforehand.

The figure that we have talked about is way up there. What do you think, how would this impact a bill like this, taking into consideration what the Administration has put out there as a caveat to make sure it is robustly tested? Do you think this would be a good place to start?

Dr. SALE. Thank you for the question. I do think robustly testing AI technology is important. I think we have been doing it in our own health system now for the better part of 2 years, trying to figure out how we can make ambient documentation support work and be successful for the rest of our physicians to use and use seamlessly.

I think anything that will allow us to, as clinicians, to make sure that we have input and guidance into new tools that we are deploying with patient care, I think are really important. And in safeguarding how we charge for those resources, I think is also important.

Senator BRAUN. Thank you very much. And like I say, this bill will be introduced here shortly, and we would love for all of you to weigh in on it beyond this kind of brief discussion of it.

I think it is the place to start where we can build in what I think is going to be in areas like this, something that is going to completely change the landscape and it is going to save the Government a ton of money. Thank you. I yield back.

Senator HICKENLOOPER. Great, thank you, now I turn over to Senator Lujàn.

Senator LUJÀN. Thank you, Mr. Chairman. And thank you all for being here today.

The way I am looking at this is we need technology to help improve health outcomes, reduce health disparities, not exacerbate them, and it is clear that AI has the power to do both, which points me to the realization that AI is only as good as its inputs. If it is machine learning, it is going to learn based on what exists and what is done and all the fun stuff that gets put in its way. Well, it seems to me that AI has a diversity problem.

What I want to illustrate here is a recent study from the Journal of the American Medical Association researchers reviewed it and

said that of the 70 publications that compare the diagnostic decisions of doctors against AI models across several areas of medicine, most of the data used to train those AI algorithms came from just three states, California, New York, and Massachusetts.

It seems that there is a diversity of data problem by population, by gender, by geography, and all the rest. Now, Dr. Mandl, do you agree that gathering data from a homogeneous patient population teaches the AI tool to serve only that population?

Dr. MANDL. I do agree. And the ability to get data not just from the highest performing health systems that are wealthy enough to have teams in their IT departments that can extract data and make it available, but from the edges.

We should be able to get data from all of the electronic health records out to the federally qualified health centers. And in order to do that, we need interoperability. And the interoperability should enable us to get data to train algorithms and to monitor algorithms. And there is another area that is a little more hidden where these algorithms are being developed that could limit diversity.

In the large language models, the models are further trained after they are—been developed on the data, which already may lack diversity, they are trained with something called reinforcement learning with human feedback, where people tell the AI whether it was right or wrong when answering certain questions.

We actually need a diversity of staff who are doing the reinforcement learning as well so that we get the right mix across multiple perspectives. So, the issue you bring up is extremely important. It is demonstrated over and again that lack of diversity in the data leads to bias conclusions that do not serve the full population well.

Senator LUJÀN. As a follow-up, Dr. Mandl, is, is it important to include this at early stages or later stages? And if the answer is yes, why?

Dr. MANDL. The early stages is much better so that the models are developed with less bias at the beginning. That bias can become entrenched and harder to fix later.

Technically, far better to try to solve the problem early with diverse data and an appropriately diverse reinforcement learning staff, and—rather than just trying to correct the bias later. Absolutely.

Senator LUJÀN. I appreciate that very much. Other examples that I have found with the help of the team, are that I trained mostly on chest x-rays from men will perform poorly when a clinician applies it to a female patient.

An algorithm for diagnosing skin cancer on dermatologic photos will botch the diagnosis if the patient is dark skinned and most of the training images come from fair skinned. I think these are obvious things that are happening in this space.

That technology, such as what I am wearing as well, has been proven that when you are trying to capture information from someone where those that were in the room developing that technology may have been one skin color versus another, maybe it was not obvious to those in the room that they should have included pigment

awareness and challenges when they were trying to grab this technology.

I am hopeful that we can be smarter about this and that this can be included so that the same problems that have been identified in the lack of diversity when it comes to clinical trials of drug treatments are not replicated now that AI is on the boom and on the build and all the rest.

I have lots of other questions, Mr. Chairman. I will submit them into the record, but I thank you conversation.

Senator HICKENLOOPER. Thank you, Senator Lujàn.

Senator Marshall.

Senator MARSHALL. All right. Thank you, Chairman. Again, welcome to all of our witnesses today. I think the question I am going to start with is, is what should Congress not do right now with AI? What should we not do that would prevent innovation from continuing? What scares you, Dr. Sale?

Dr. SALE. I think when you think about innovation in health care, we do innovation as part of our practice of medicine, and this has been ingrained in what we do, especially in the academic world where I live, right.

It is all about how we move forward patient care and drive—and change and make improvements in patient care, and I think my fear would be if we somehow limit or restrain the ability to utilize this type of technology in health care.

I think as I mentioned earlier in my testimony, there are a tremendous number of applications where AI is beneficial and can be beneficial in patient management, patient throughput, patient access, physician well-being, etcetera.

I think if there is any fear that I have, it is that this technology would be actually removed or limited in some way. I think we want to be actively engaged as clinicians in developing that tool. I think that if there was any way that we would be somehow cut out of that process, I think that makes me nervous.

But I think those are the two areas where if there is anything that the Government would do that would limit our access to or ability to participate in the development of this tool, I think that would be scary for me.

Senator MARSHALL. Thank you. Let's go ahead to Dr. Mandl next.

Dr. MANDL. I will say that I would avoid actions that would promote unregulatable monopolies, and I would be very cautious when designing specific regulations to recognize the extremely rapid change in this technology.

It is not even enough to keep up with the medical literature. You have to be following releases and announcements on Twitter a couple of times a day to understand what is going on in this field, not reading your journals once a week or once a month.

It is very important to recognize the fluidity and the rapid progress, and to develop evergreen approaches to monitoring this emerging——

Senator MARSHALL. I hear you say this would be really hard to put—it is going to be hard to put guardrails around it because it is changing so fast.

Dr. MANDL. It will be a challenge.

Senator MARSHALL. Yes. Dr. Inglesby.

Dr. INGLESBY. Yes, that is—I think it is a really important question. I think what I would say is Congress should not take their eye off some of the most serious risks, because if those risks become a major problem, either in bias or in what I am worried about, particularly around life science, pandemic risks, or others, I think those kinds of developments could derail or really distract the AI companies, could distract the Government for a long time—if major problems emerge.

What you—back to what you said early in this hearing was, I do think that the AI companies have extraordinary expertise, and it is going to be very important for the Government to stay close with them and not be at a distance and not kind of disengage. I think it is going to be require a very close partnership because a lot of the expertise.

The great majority of expertise right now is in the industry and not within the Government. I do think the Government has to build its workforce of very smart AI talented people to be able to keep up.

I think you are right, working with industry closely is going to be very important in order to both reap the many benefits, but also to develop systems that are reasonable and scaled to deal with the risks.

Senator MARSHALL. Okay. Ms. Huberty, within your association, when you go for continuing education, when people in your profession talk about AI, what concerns have we not talked about today that you have, or any of your solutions? Go ahead.

Ms. HUBERTY. Right. I would like to actually speak to the question that you asked the doctors, because we have been sitting here talking about what if, what if, what if. I am sitting here telling you that we have seen the negative consequences. We have seen the devastating effects of AI for years.

I was here in May testifying before the Medicare Advantage Plan hearing. And so, I am sitting here saying, well, here is harm, here is proven harm from AI, so what are we going to do about it? My fear is that we are doing nothing.

We aren't doing anything. So that is my contribution to that, is that we need to be doing something.

Senator MARSHALL. Okay. Dr. Inglesby let's talk about viral gain of function just for a second—viral gain of function research. And certainly, AI could be used with this area, and it probably has been, whether you are trying to find and develop a protein spike that fits on a SARS virus.

Maybe insert an HIV code from the HIV virus in to decrease people's level of immune reaction or put it a Furin cleavage site as well. One thing that scares me, though, is if Congress puts too many guardrails on it is we let our enemies do research and develop things that we won't be able to counter.

It would be counterterrorism, if you would speak. Any just vague general thoughts on that? It is kind of a wild, outside the box question, sorry.

Dr. INGLESBY. I think it is very, very, very important. I think this last year and a half, there has been a lot of work between the Government and the scientific community around trying to develop the right policy that focuses only on the very highest risks around potential pandemic pathogen research.

I do think that if the U.S. gets its house in order, it can then argue for kind of the similar standards around the world. In this case, I don't think other countries want to be creating new viruses. I don't think Governments are going to want to create viruses with pandemic risks that they are not aware of.

They are going to want to have the same kind of understanding of what their science communities are doing. I think ultimately we should—all governments, in theory, should be moving toward the same kind of arrangements, which is not slowing science down, but being aware of that little area, that small area of science, which could pose extraordinary risks and just doing the right thing, working with industry.

Senator MARSHALL. Doing the right thing is so important, right. We have all seen in health care, innovation, so many technologies come by our desk. There was a time when people thought, oh, my gosh, we shouldn't do MRI's because it could lead to overdiagnosis.

Certainly, you don't want an obstetrician reading an MRI, but it didn't stop us from developing the MRI technology. As I think about these algorithms, at the end of the day, I think it comes down to people doing the right thing and that is teaching our medical students the right thing, that this is one more tool.

It is no more important than a CBC or an X-ray, and it is no more important than a stethoscope. Do you remember that fourth year of medical school when you suddenly realized the most important tool you had in the toolbox was listening to a patient? If you can only have one thing, it would be listening to the patient. I just would implore you all that—to keep the patient first.

As we teach our medical students that this is a tool. I tell people, I have seen one pregnant person with a virus. You have seen one pregnant person with this virus. The next pregnant patient may not obey the algorithm. There are more than two standard deviations outside the box.

That is all algorithms are for the most part. Here is two standard deviations. Most people should be in the hospital 2.3 days after being admitted with pneumonia unless they develop a blood clot.

We still—it is going to come up to the person, people doing the right thing in our professions to protect. I would love to come back to doctor—what are your professions doing to protect the integrity of health care. But I do appreciate you all coming in. It has been great insight. Thank you.

Senator MARKEY. I am going to ask a few more questions, if that is all right, Senator Marshall. Thank you. Back in the 90's, when there would be a big headline, like once a week, insurance compa-

nies records hacked. We had public or hospital records hacked, made public, or you name it. Hacked, made public.

I asked Joe Tucci, who was the CEO of EMC, of the Massachusetts, which was the leading data storage company in the world—Dell has now purchased it. I said, what is going on?

He says, oh, we could have protected all those companies. We try to sell them our highest end security product, but they just don't want to buy it because it cost them too much money, so they would rather run the risk of having the data breach.

I said, so the technology is there, the counter algorithm is there to fight against what becomes the state-of-the-art in terms of the criminals trying to break in? Oh, yes, yes, it is there but many companies or the executives just don't want to spend that extra money.

They are hoping they retire before their company gets hacked, so they don't have to explain to the board of directors why they had to spend all that extra money. So, it was a big insight to me that, oh, yes, there is a battle that is going on, good versus evil, but good is in the battle too. It is just, are we going to have it deployed?

Are we going to ask that be just maybe a little extra cost that has to get built into the system to protect against the deleterious aspects of any new technology? And it is that challenge, right, because profits would say, no. No, look at how much we max out if we just deployed this new technology without additional safeguards which could be built in.

I introduced which Senator Budd, Republican on this Committee, the Artificial Intelligence and Biosecurity Risk Assessment Act, and the Strategy for Public Health Preparedness and Response to Artificial Intelligence Threats Act to direct the U.S. Department of Health and Human Services to prepare for AI biosecurity threats.

In your testimony, you noted that President Biden's Executive Order is an essential step forward for AI oversight, but that there is more to be done. Dr. Inglesby, could you just tell us how important it is for Congress to play a role in regulating AI now?

Dr. INGLESBY. Yes. I am happy to do that. I think your Act really spoke to the importance of that. I think the Executive Order goes a long way in assigning responsibilities to this, Department of Energy, Commerce, HHS, but it doesn't require much yet of the companies. I think they are trying to understand the nature of the problem.

But I think what your Act proposed and what I would also recommend is that, that you get an assessment from HHS. I think is the most logical place. HHS, ASPR I think would have the right expertise to give you a stronger sense of what are the risks of the creation of—AI helping to simplify or accelerate the creation of new, very serious biological risks, and what could be done.

What authorities, if any, are needed to be able to deal with that. I think some are in sight now, which are I think Congress should be giving audit authority to an agency, whether it is Commerce or Energy or HHS, around AI risks.

But I think such a risk assessment that is done rapidly aimed at Congressional leadership, which is a little bit different from

what is now in the Executive Order, I think would be very valuable for leadership here to decide what they might want to do.

Senator MARKEY. Yes. And again, that is the goal that Senator Budd and I have, just kind of moving this ball further down the line. And we see it in all kinds of areas with—in the automotive sector, the automotive industry, they want to sell you a new car, but they didn't want to have a mandatory seatbelt that was built in.

That will be an extra cost. Not every consumer wants seatbelts. I know my father was a truck driver. He really didn't like seat belts. So, they were saying consumer choice. And then airbags. Well not every consumer wants an airbag, but it is a safety feature. Yes, but we will leave it up to the consumers to do it.

The industry is trying to downsize their safety cost requirements until the consumers get a little bit of a taste of an airbag and a seatbelt, and then they are saying, I am not going to buy a car that doesn't have safety built in, right, from the get-go.

We continue to have this conversation that coexist with the technological advance, but then as people catch up, they go, well, could we have a little more—could we have a child safety cap on top of that medicines? Is that too much of a cost to please ask you to build that in and so there is going to be some resistance.

But you are just trying to balance it. You don't want to take away the good part of it, but you know that there is a sinister side to cyberspace. So, can I just come back to you, Dr. Sale, and I just heard that conversation that Senator Marshall was having about fourth year of medical school, which I will never know.

My wife knows it as a physician and she keeps her maiden name because she says, I don't remember a Dr. Markey graduating from my medical school class. So, she keeps her own maiden name as Dr. Blumenthal. But in your testimony, you spoke about how AI allows you to spend more time with patients by greatly reducing the administrative burden of charting.

However, some of the health care organizations may look at AI as a means to just cut costs by cutting their workforce. Dr. Sale, can you speak to how the success of artificial intelligence depends on actual health care providers being involved, as you were saying in your conversation with Dr. Marshall?

Dr. SALE. Absolutely. Thank you for that. I would echo Senator Marshall's comment earlier how this is a tool, right.

Much in line with the EMR, this is a chance for us to optimize our workflows, improve our efficiencies, add information and perform tasks that historically take away from our time with our patients, and add value back to our encounters so we can work with our patients more closely, listen to our patients, and really develop a more beneficial relationship with our patients so we can get when we are typing an information into an EMR.

I think there is tremendous opportunity, I think, to continue to use this as a tool. I think it is important to remind our clinicians that is what it is and that you still have to play a role in this, because, right, what I fear sometimes is complacency or reliance, overreliance on this tool, right.

You think about instances where in an EMR we have copy forwarded an error, right. And so, how do we avoid that with this kind of a tool? Because I think AI has the potential to propagate errors.

Senator MARKEY. So can I—excuse me. So how should a nurse view this, as a threat to her employment or as an augmentation of her ability to help with her patient care?

Dr. SALE. It is a great question. I would say if you were to ask my nurse, she would love to spend less time on the phone doing work that is beneath her level of licensure and doing menial tasks and chart review and chart things that could be done by AI and rather spend time with the patient doing education and training.

I think most of our nursing staff and our clinicians would relish the opportunity to remove themselves from some of those administrative and documentation tasks that we have become overwhelmed with in our EMR world, and instead focus our time and efforts with our patients.

Senator MARKEY. You don't—you don't view it as a threat?

Dr. SALE. I don't really think it is going to replace clinician judgment or patient engagement. I think if anything, we have a nursing shortage, a physician shortage, an over a health care worker shortage that has been existing even pre-pandemic and was exacerbated by the pandemic. I think that this is—and if anything helps us close some of the gaps that exist in our ability to take care of patients.

Senator MARKEY. Okay, great. Thank you. Any other questions? Beautiful. So here is what I am going to do, finish up 1 minute apiece for each one of you in reverse order of the original testimony.

The 1 minute you want the Subcommittee to remember as we are moving forward on legislation to deal with AI as it interacts with the health care system. Begin with you, Ms. Huberty. You have 1 minute.

Ms. HUBERTY. Thank you so much. I think it is important to know that I have been here today to describe the actual patient harm that is in place due to this AI and sound the alarms for the points where the doctors cannot override the AI and it causes that harm, that patient harm.

It has a ripple effects through the economy, not only for that person's medical bills, but also the facilities that can't keep up and that can't accept patients anymore either. I think I am here to say this is exactly what is happening, and this is—we can use this as a model, what can we do with this information now so that it doesn't happen with other AI technology in the future.

Senator MARKEY. Great. Dr. Mandl.

Dr. MANDL. I would like to reemphasize the importance of measurement, the importance of making data available so that we have AI trained on the full diversity of the American population, and so that we can monitor AI and its impacts, along with boosting tremendously the way we monitor drugs, devices, procedures.

That we actually create a more efficient health care system as a byproduct. That is a—that is one important focus within this domain.

Senator MARKEY. Okay. Great. And Dr. Inglesby.

Dr. INGLESBY. Yes. Thank you, Senator. I think I would just like to close by re-emphasizing the enormous potential benefit of AI in health care.

But to get the full benefit of AI in health care and in public health, we need to now, at the start of this huge change, to address the risks not only of privacy, bias, data integrity, and beyond, but also focus on the very high end risks around AI and the biological sciences.

I think a number of ideas and steps are already on the table, but Congress can go further with some immediate steps and with more information from the agencies. Thanks very much.

Senator MARKEY. Dr. Sale, you have the final word.

Dr. SALE. Thank you very much. First of all, it has been an honor and a pleasure to be here. I would say, while I acknowledge the large scale and big picture concerns around AI, I feel like there may be some small window opportunities for us to utilize this technology in ways that really help improve patient care, physician and practice—practitioner well-being, and can really actually improve our outcomes in health care, with mitigating that risk.

I think that requires close collaboration with our physicians and our clinical workforce as we develop these tools and define their uses of application within health care. I think it encompasses mitigating risk with privacy and security of data.

I think ultimately, with the goal in mind of improve patient care and avoiding physician and clinician replacement, but rather enhancement of the practice of medicine.

Senator MARKEY. Beautiful. Thank you so much. And like Dr. Naismith, you have served the State of Kansas very well, so we thank you for your testimony. Although the best basketball player in the world right now plays for the Denver Nuggets, for Senator Hickenlooper's home team.

[Laughter.]

Senator MARKEY. And——

Senator MARSHALL. Potentially, potentially.

Senator MARKEY. I think it is an evidence based determination I am making on that——

[Laughter.]

Senator HICKENLOOPER. Until that young man from—Wembanyama down in San Antonio, he might quickly change the algorithm.

[Laughter.]

Senator MARKEY. We thank everyone who participated today, especially our witnesses who traveled here from Massachusetts, Kansas, Wisconsin, and Maryland.

Your perspectives are essential for ensuring that we guard against the harms of artificial intelligence. We need to put people

over profit, prioritize worker voices, and keep focused on how to best treat patients.

I ask unanimous consent to enter into the record a statement from stakeholders outlining priorities for addressing AI in health care. Without objection.

[The following information can be found on page 66 in Additional Material.]

Senator MARKEY. For any Senators who wish to ask additional questions of our witnesses for the record, they will be due in 10 days, November 22, 2023, at 5.00 p.m. And we thank everyone. And with that, this hearing is adjourned. Thank you.

ADDITIONAL MATERIAL

EXPLORING CONGRESS' FRAMEWORK FOR THE FUTURE OF AI

Introduction

Artificial intelligence (AI) is a transformational tool, carrying enormous power and potential to improve life for every American. As a foundational enabling technology, AI can be adapted for nearly any use to solve a myriad of problems. Health care is a prime example of a field where AI can do enormous good, with the potential to help create new cures, improve care, and reduce administrative burdens and overall health care spending. AI is also increasingly being adopted by businesses, consequently reshaping work, the workplace, and the labor market. But greater use of AI also carries significant risks. Experts exploring how the technology may affect the education field, for example, raise well-founded concerns about how AI might be used as a low-quality shortcut by both students and teachers, even as the technology might provide more personalized learning for students and reduce teacher workload. Our challenge as policymakers is to weigh the tradeoffs inherent with any powerful technology and modify or create the legal frameworks needed to maximize technologies' benefits while minimizing risks.

To assess and balance the benefits and risks that AI creates, we must first define the term. Defining AI is challenging since AI experts have not arrived at a static definition of the rapidly developing general-purpose technology. "Artificial intelligence" was coined in 1955 when the primitive computers of that time were often referred to as "thinking machines." This definition bears little resemblance to today's cutting-edge technology.[1] The working definition of AI for this paper, synthesized from others' definitions, is computers, or computer-powered machines, exhibiting human-like intelligent capabilities.[2] It is an umbrella term that encapsulates multiple distinct technologies and approaches. AI multiplies the availability of human-level intelligence that can be applied to solve problems. But like any technology, how it works, and the risks it creates, depends on how it is used.

As the U.S. Senate begins to consider legislation to address AI, we must account for the specific context in which AI's capabilities are applied. A sweeping, one-size-fits-all approach for regulating AI will not work and will stifle, not foster, innovation.[3] To use an analogous example, there is no Federal department of software, nor should there be: software is regulated based on how it is used, whether in power plants, airplanes, or X-ray machines. Likewise, we must adapt our current frameworks to leverage the benefits and mitigate the risks of how AI is applied to achieve certain goals. And only if our current frameworks are unable to accommodate con-

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[1] Stanford University. (n.d). Defining AI. *https://ai100.stanford.edu/2016-report/section-i-what-artificial-intelligence/defining-ai*

[2] The definitions from which this one is synthesized include the following: Oxford Languages: "The theory and development of computer systems able to perform tasks that normally require human intelligence, such as visual perception, speech recognition, decisionmaking, and translation between languages." Oxford English Dictionary: "The capacity of computers or other machines to exhibit or simulate intelligent behavior; the field of study concerned with this." *https://www.oed.com/view/* Technologist Marc Andreessen: "The application of mathematics and software code to teach computers how to understand, synthesize, and generate knowledge in ways similar to how people do it." *https://a16z.com/2023/06/06/ai-will-save-the-world/*.

[3] Adam Thierer. (June 21, 2023). The Most Important Principle for AI Regulation. R Street. *https://www.rstreet.org/commentary/the-most-important-principle-for-ai-regulation/*.

tinually changing AI, should Congress look to create new ones or modernize existing ones.

Congress' proactive consideration of AI's implications is encouraging—we need to pay attention to this fast-changing field to protect consumers and ensure that the U.S. maintains global technological leadership. However, Congress must be just as mindful of the risks of changes to the AI regulatory environment as we are to the risks from AI itself. Top-down, all-encompassing frameworks risk entrenching incumbent companies as the perpetual leaders in AI, imposing an artificial lid on the types of problems that dynamic innovators of the future could use AI to solve. Instead, we need robust, flexible frameworks that protect against mission-critical risks and create pathways for new innovation to reach consumers. As Ranking Member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, I'm focused on making sure that we strike the right balance for Americans from the earliest stages of developing new products through deployment of an AI system or solution solving complex problems.

Researching and Developing New Medicines

AI holds enormous potential to improve the speed and success of creating new medicines. For decades, drug development has begun with a laborious "discovery" process—researchers running painstaking experiments to assess one-by-one whether individual molecules have potential to treat disease. This process typically takes up to 26 months before clinical trials can begin.[4] AI can help bring engineering principles to this guesswork-filled process, empowering researchers to predict which molecules make the best drug candidates, and increasingly design drugs to address specific targets, rather than discover them through slower, manual laboratory methods.[5] It's been reported that the first drug designed entirely with AI has moved into clinical trials in China.[6] Investors have estimated that even modest improvements reaped through AI could create an additional 50 novel therapies over a decade.[7] Not only can AI help create new therapies for patients, it could also help lower the costs of the time-consuming, expensive drug development process. Some estimates have found that leveraging AI could reduce development costs for manufacturers by up to $54 billion annually.[8]

Our framework for preclinical and clinical investigation of new drugs, implemented by the Food and Drug Administration (FDA), is generally well-suited to adapt to the use of AI to research and develop new drugs. Indeed, FDA has done an admirable job facilitating the use of AI in early stage drug development: in 2021, over 100 drug applications submitted to the FDA included AI components.[9] In May 2023, FDA published two discussion papers on the use of AI in drug development and manufacturing, respectively.[10] The agency is spearheading initiatives for industry, academia, patients, and global regulatory authorities to engage on how best to facilitate AI in this field. Congress should support continued growth in the use of AI for research and development, and encourage FDA to continue to spur the use of innovative approaches while ensuring that new technologies are properly validated and monitored. As AI leads drug development to become both more productive and more complex, FDA needs world-leading expertise to keep up. As drug developers use AI to design new medicines, FDA's need to leverage experts in critical fields like computer science, biostatistics, biomedical engineering, and others will only grow. Congress needs to work with FDA on implementing last year's user fee agreements, which included significant funding increases for new review staff. Congress should also explore how to help FDA address perennial challenges recruiting

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[4] Garurav Agrawal et al. (February 10, 2023) Fast to first-in-human: Getting new medicines to patients more quickly. McKinsey & Company. *https://www.mckinsey.com/industries/life-sciences/our-insights/fast-to-first-in-human-getting-new-medicines-to-patients—more-quickly.*

[5] Vijay Pande. (Nov. 12, 2018) How to Engineer Biology. *https://a16z.com/2018/11/12/how-to-engineer-biology/.*

[6] Jamie Smyth. (June 26, 2023) Financial Times, Biotech begins human trials of drug designed by artificial intelligence. *https://www.ft.com/*

[7] Morgan Stanley. (Sept. 9, 2022). Why Artificial Intelligence Could Speed Drug Discovery. *https://www.morganstanley.com/ideas/ai-drug-discovery.*

[8] Kevin Gawora. (December 7, 2020). Fact of the Week: Artificial Intelligence Can Save Pharmaceutical Companies Almost $54 Billion in R&D Costs Each Year. Information Technology & Innovation Foundation. *https://itif.org/publications/2020/12/07/fact-week-artificial-intelligence-can-save-pharmaceutical-companies-almost/.*

[9] Patrizia Cavazzoni, M.D. (May 10, 2023). FDA Releases Two Discussion Papers to Spur Conversation about Artificial Intelligence and Machine Learning in Drug Development and Manufacturing. Food and Drug Administration. *https://www.fda.gov/news-events/fda-voices/fda-releases-two-discussion-papers-spur-conversation-about-artificial-intelligence-and-machine.*

[10] Id.

and retaining qualified staff, including through finding ways to use external sources to tap needed expertise and manage limited resources.

This can be assisted by FDA using AI to increase the speed and efficiency of the agency's review process. FDA (and other agencies, like the National Institutes of Health [NIH]) can play an important role as early adopters and customers for new AI-powered research and development tools. Such tools could unlock enormous benefits, freeing FDA experts to focus on the tasks most critical to public health.

Diagnosing and Treating Diseases

Diagnostic and treatment applications of artificial intelligence are proliferating each year.[11] They hold the potential to expand health care access, improve outcomes, and increase efficiency. However, FDA's framework for regulating medical devices was not designed for devices that incorporate evolving AI—Congress may need to consider targeted updates to provide predictability and flexibility for AI-powered devices while ensuring that such devices are safe and effective for patients. Moreover, foundational questions about AI applications remain regarding the transparency of algorithm development, ongoing effectiveness of such applications, and who carries the liability if something goes wrong.

Using AI-Enabled Tools to Detect, Diagnose, and Treat Disease

Consumers, patients, and health care providers use AI-enabled products throughout the patient lifecycle. AI is used to detect the earliest signs of medical conditions in otherwise healthy people, accurately diagnose patients when they get sick, and treat deadly diseases. In 2022 alone, FDA authorized 91 AI-enabled medical devices, after authorizing a record 115 devices in 2021.[12] Many of these devices leverage advances in sensor technology and imaging and data analytics to examine symptoms of a particular condition and use extensive datasets to inform diagnosis or treatment.[13] These devices range from Apple's atrial fibrillation sensor built into its watch and image reconstruction algorithms used in radiology and cardiology to detect cancers and lesions to clinical decision support software to predict a patient's risk of developing sepsis.

AI-enabled diagnostic tools synthesize large amounts of data and perform pattern analysis to help detect a diagnosable condition, like a tumor.[14] Diagnostic AI tools are used across a variety of fields where the pattern-matching capabilities of AI can compare images from X-rays, CT scans, and other devices against massive data bases of similar images to identify outliers that may indicate a disease or condition. These tools have shown the capability to increase the accuracy and efficiency of diagnosing patients. One application that has demonstrated incredible effectiveness is the use of AI for early screening for signs of diabetic retinopathy.[15] There are very few trained eye technicians who are able to expertly diagnose the condition compared to the vast number of diabetic patients who need screening. Automated analysis software that uses AI helps increase the accuracy of diagnosis and expand the number of clinicians who can do this important screening. More diagnoses are made earlier, helping more patients avoid blindness.

The utility of AI-enabled devices depends on clinician adoption—no patients are better off if these tools sit on a shelf. To a greater degree than traditional devices, AI-enabled products raise novel questions about supplementing, or even supplanting the clinician's role: the same tool that could reduce error could also miss outlier symptoms. In order to best leverage the utility of AI-enabled devices, clinicians need to be effectively trained, including in how to reduce the risk of misdiagnosis and mistreatment. In order to have a robust and effective framework, standards to demonstrate clinical validity will need to be developed and testing to proper safety standards will need to be implemented.[16]

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[11] Ben Leonard et al. (June 29, 2023). Big bets on health care AI. Politico. *https://www.politico.com/newsletters/future-pulse/2023/06/29/big-bets-on-health-care-ai*

[12] Elise Reuter. (November 7, 2022). 5 takeaways from the FDA's list of AI-enabled medical devices. MedTechDive. *https://www.medtechdive.com/news/FDA-AI-ML-medical-devices—5-takeaways/635908/*.

[13] Id.

[14] U.S. Government Accountability Office. (September 29, 2022). Artificial Intelligence in Health Care: Benefits and Challenges of Machine Learning Technologies for Medical Diagnostics. *https://www.gao.gov/assets/gao—22—104629.pdf*.

[15] SK Padhy et al. (July 2019). Artificial intelligence in diabetic retinopathy: A natural step to the future. Indian Journal of Ophthalmology. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6611318/pdf/IJO—67—1004.pdf*.

[16] See, Artificial Intelligence in Health Care.

Adapting the FDA Framework for AI

AI poses two foundational challenges to FDA's current regulatory framework for medical devices. First, products that incorporate AI-enabled software face varying degrees of premarket regulatory scrutiny, based on whether they meet the statutory definition of medical device or are subject to either a statutory carve-out or FDA's policy of enforcement discretion for certain products. Second, FDA's review of the safety and effectiveness of devices inherently applies to a specific product at a specific moment in time, meaning that FDA's review, and the statutory requirements it implements, was not designed for products that incorporate AI to improve over time.

In light of these challenges, FDA is still figuring out how best to assess medical devices that use AI. It has attempted a pre-certification pilot for software treated as medical devices that would certify software developers as opposed to the products themselves. FDA also published an attempt at an AI framework through guidance in 2019 and subsequent action plans.[17] Pursuant to policies enacted by Congress in December 2022, FDA has begun accepting predetermined change protocol plans in premarket product submissions where developers can outline anticipated modifications to avoid subsequent review and approval. Yet these efforts have presented more questions about how FDA will actually treat medical devices that integrate AI, and FDA (and others) acknowledge that Congress may need to consider updating the decades-old medical device framework.[18]

Considerations for Transparency, Effectiveness, and Liability

Ensuring that AI tools are trusted by all stakeholders is essential to support greater AI adoption and enable patients to receive maximum benefits. First, AI tools should be developed in a transparent way, so patients and providers can understand how they are meant to be applied to ensure appropriate use. One of the barriers to adoption of AI tools is a lack of understanding about how any given algorithm was designed. Improving transparency about how an AI product works will build stakeholder trust in such products.

Second, any framework must build in a clear method to measure effectiveness so AI products can be further improved. AI algorithms are trained on data sets which may only represent a specific population. Algorithms may not be appropriate for different populations from ones they were trained on, which can create bias and decrease effectiveness. Effective algorithms must also leverage accurate data sets to ensure that the information being used to make determinations is properly collected and inputted. Congress may need to consider how to best ensure that AI-enabled products do not give undue weight to potential biases.

Third, stakeholders need a clear understanding of potential liability around the use of AI. Like any medical device, failure of a product that incorporates AI could harm patients, such as through incorrect diagnoses (both false positives and false negatives). These risks are magnified with AI devices that are trained by additive data sets and evolve over time, and where later results may differ from earlier iterations. A predictable framework is needed to facilitate adoption of these tools, which requires determining where liability lies—the original developer, most recent developer, clinician, or other party.

Supporting Patients and Providers

A burgeoning application of AI is in the development of clinical decision support algorithms, which use data sets of patient data and an individual patient's own medical record to alert a clinician through their electronic health record software of a diagnosis, treatment, or predicted likelihood of developing a condition that they may want to consider. Hospital systems across the country use internally developed clinical decision support algorithms based off of their own patient population and patient data.

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[17] Food and Drug Administration. (January 7, 2019). Developing a Software Precertification Program: A Working Model. *https://www.fda.gov/media/119722/download*. (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan, Food and Drug Administration (January 12, 2021), *https://www.fda.gov/media/161815/download*.

[18] The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings, Food and Drug Administration (September 27, 2022), *https://www.fda.gov/media/161815/download*; See also, Scott Gottlieb and Lauren Silvis, Regulators Face Novel Challenges as Artificial Intelligence Tools Enter Medical Practice, JAMA Forum (June 8, 2023), *https://jama—network.com/journals/jama-health-forum/fullarticle/2806091*.

One leading electronic health record (EHR) vendor that developed an algorithm intended to predict whether a patient would develop sepsis came under scrutiny when the Journal of the American Medical Association found that it only accurately predicted the occurrence of sepsis 7 percent of the time.[19] This highlighted the risk involved if clinicians rely too heavily on algorithms. In response, FDA proposed a guidance for industry in September 2022 asserting authority over these algorithms and requiring them to go through FDA review as medical devices.[20]

AI interfaces that engage directly with patients are also promising enhanced care and improving outcomes by predicting and catching conditions early.[21] For example, patient-facing chatbots have reduced emergency department visits at one health system by 5 percent, saving $1 million.[22] Yet incorporating AI in patient care warrants caution. A recent study found that 60 percent of patients would be uncomfortable with a provider relying on AI when receiving care.[23] Patients are understandably concerned about how AI could result in a less robust patient-provider relationship. As we move forward, integrating AI into patient care will require both effective products, as well as the much harder task of building trust with patients.

Address Health Care Administration and Coverage

Administrative activities are a significant component of the health care system. These activities are responsible for executing the operations of health care, including practice management, payment processing, engagement with regulators, and integrating new tools to improve health outcomes. Approximately 15–30 percent of all health care spending is spent on administrative activities.[24] However, as health care has become more complex, administrative tasks take up an increasing part of providers' time, taking them away from patient care. Studies have found that physicians spend approximately 8.7 hours a week on administrative activities and must devote approximately 28 percent of a patient visit to administrative tasks, such as data entry into EHR systems, filling out health insurance claims forms and prior authorization requests, and scheduling appointments.[25] As administrative tasks have become more time intensive, physicians have reported higher levels of burnout.

Administrative functions related to EHR use are a leading cause of burnout, leading to workforce shortages and a lower quality of care for patients.[26]

AI has the potential to not only streamline health care administration by leveraging automation and analytical tools to reduce provider time on spent on administrative tasks, but also reduce potential mistakes, streamline management decisions, and improve claims management. One hospital system used AI to improve surgical scheduling and saw a 10 percent reduction in physician overtime and improved utilization of surgical suites by 19 percent.[27] EHR systems are also

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[19] Anand Habib et al. (June 21, 2021) The Epic Sepsis Model Falls Short-The Importance of External Validation. JAMA Internal Medicine. *https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2781313.*

[20] U.S. Food and Drug Administration. (September 28, 2022) Clinical Decision Support Software; Guidance for Industry and Food and Drug Administration Staff. *https://www.fda.gov/media/109618/download.*

[21] Bill Siwicki. (June 22, 2023). Where AI is making a difference in healthcare now. Healthcare IT News. *https://www.healthca-reitnews.com/news/where-ai-making-difference-healthcare-now*

[22] Id.

[23] Alec Tyson et al. (February 22, 2023). 60 percent of Americans Would Be Uncomfortable With Provider Relying on AI in Their Own Health Care. Pew Research Center. *https://www.pewresearch.org/science/2023/02/22/60-of-americans-would-be-uncomfortable-with—provider-relying-on-ai-in-their-own-health-care/.*

[24] Health Affairs. (October 6, 2022) The Role Of Administrative Waste In Excess U.S. Health Spending. *https://www.healthaffairs.org/.*

[25] Steffie Woolhandler and David Himmelstein. (2014) Administrative work consumes one-sixth of U.S. physicians' working hours and lowers their career satisfaction, International Journal of Health Services. *https://pubmed.ncbi.nlm.nih.gov/.* Fabrizio Toscano et al., How Physicians Spend Their Work Time: an Ecological Momentary Assessment, Journal of General Internal Medicine (August 17, 2019), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7661623/pdf/* Rebecca Pifer, Hurtling into the future: The potential and thorny ethics of generative AI in healthcare, Healthcare Dive (April 21, 2023).

[26] Steffie Woolhandler and David Himmelstein. (2014) Administrative work consumes one-sixth of U.S. physicians' working hours and lowers their career satisfaction. International Journal of Health Services. *https://pubmed.ncbi.nlm.nih.gov/.* Scott Yates. (September 11, 2019). Physician Stress and Burnout, The American Journal of Medicine *https://www.amjmed.com/action/*

[27] Thomas Davenport and Randy Bean. (April 11, 2022). Clinical AI Gets the Headlines, but Administrative AI May Be a Better Bet, MIT Sloan Management Review. *https://*

leveraging AI tools to reply to patient messages and eventually summarize patient medical history and translate between languages and reading levels for patient materials.[28] AI has also been used to improve claims management, by improving the speed by which claims can be reviewed and prepared. Some vendors have used AI to enable instant claims approval, reducing uncertainty and paperwork for patients.[29]

Health insurers can also leverage AI to great benefit, reducing the time, energy, and expenses dedicated to determining and managing health risks. AI can more accurately predict and measure an individual's risk and the specific type of care they need, reducing administrative burdens and saving time and money.[30] AI can also drive health care savings by reducing long-term costs and unnecessary paperwork. Some estimates have found that greater uptake of AI could reduce national health care spending by of five to 10 percent.[31]

However, we must also ensure that using AI for coverage decisions does not reduce needed care. One report found that a health insurer used an algorithm to batch claims that were denied by the thousands with a single click.[32] Stakeholders later emphasized the need for greater regulatory oversight of using AI to review prior authorization requests.[33] Steps should also be taken to ensure that AI is not overriding clinical judgment. Some patients have been unable to receive a provider opinion due to algorithms automatically deciding a treatment plan.[34]

While AI has the potential to streamline health care administration and address spending by optimizing provider resources and improving patient care, there are still questions about how patient information will be used to advance care and whether this may weaken patient privacy protections. Leveraging individual health data is essential to deliver specific care outcomes to a patient, but Congress must ensure that AI tools are not used to deny patients access to care or use patient information for purposes that a patient has not given consent for.

Safeguarding Patient Privacy Throughout the Health Care Lifecycle

The foundational requirement for developing an AI tool is a large data set upon which to train an algorithm to analyze information and make determinations and predict outcomes. The dataset can take many forms, including thousands of medical images accompanied by indications of whether and where cancerous tumors are present. After learning from enough images, the algorithm should be able to process a new image and alert a clinician as to whether cancer is indicated in the scan. To obtain such vast datasets, algorithm developers may affiliate with an institution that already has internal datasets, such as a hospital system or EHR vendor. These institutions are typically regulated as covered entities or business associates under the Health Insurance Portability and Accountability Act (HIPAA). Developers may also use health data collected via third-party applications. This information is not always protected by the HIPAA framework and raises questions about what protections the information may be entitled to. In many instances, patients and consumers have expectations for how their health information should be handled that may differ from existing requirements on those who collect health data. AI can be leveraged

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sloanreview.mit.edu/article/clinical-ai-gets-the-headlines-but-administrative-ai-may-be-a-better-bet/.

[28] Rebecca Pifer. (April 21, 2023). Hurtling into the future: The potential and thorny ethics of generative AI in healthcare. HealthcareDive. *https://www.healthcaredive.com/trendline/tech/*

[29] PR Newswire (April 13, 2023). Google Cloud Unveils New AI-enabled Claims Acceleration Suite to Streamline Health Insurance Prior Authorization and Claims Processing, Helping Experts Make Faster, More Informed Decisions. *https://www.prnewswire.com/*

[30] Albert Pomales. (January 10, 2023). Using AI And Machine Learning To Improve The Health Insurance Process. *https://www.forbes.com/sites/forbesbusinesscouncil/2022/01/10/using-ai-and-machine-learning-to-improve-the-health-insurance-process/*

[31] Nikhil Sahni, George Stein, Rodney Zemmel, and David M. Cutler. (January 2023). The Potential Impact of Artificial Intelligence on Healthcare Spending, National Bureau of Economic Research. *https://www.nber.org/papers/w30857*.

[32] Patrick Rucker, Maya Miller, and David Armstrong. (March 25, 2023). How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them. ProPublica. *https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims*.

[33] American Medical Association (June 14, 2023). AMA adopts policy calling for more oversight of AI in prior authorization. *https://www.ama-assn.org/press-center/press-releases/ama-adopts-policy-calling-more-oversight-ai-prior-authorization*.

[34] Casey Ross and Bob Herman. (July 11, 2023). How UnitedHealth's acquisition of a popular Medicare Advantage algorithm sparked internal dissent over denied care. *https://www.statnews.com/2023/07/11/Medicare-advantage-algorithm-navihealth-united—health-insurance-coverage/*

to enhance privacy protections by aggregating disparate data to anonymize personally identifiable information, though it can also be used to re-identify previously de-identified health information.[35] Congress needs to consider if changes are needed in how health information is protected when it falls outside the scope of HIPAA.

Improving Student Learning and Transforming Education

Educators, school officials, and researchers are debating the merits and shortcomings of utilizing this new technology in classrooms. Proponents posit that AI can revolutionize education by providing more personalized learning for students while reducing the workload for teachers. This technology might prove especially helpful in light of the COVID–19 pandemic, which resulted in years of lost learning and the largest decline in test scores seen on national assessments in decades.[36] However, there are well-founded concerns around how AI might be used as a low-quality shortcut by both students and teachers, how to account for errors in AI's output, and how the underlying models and algorithms might not be setup to adequately serve all students.

School districts across the country have used Federal funds to provide tutoring to address student learning loss. Now, researchers are exploring whether AI can serve as a supplemental tutor during class time or at home to provide homework help. The rise of platforms such as Khan Academy's Khanmingo shows that the technology can provide customized responses to students' questions, guiding them through their thinking process to help them come up with an accurate answer.[37] AI can help educators with routine tasks, like grading assessments and identifying trends in student outcomes, to reduce the ever-growing burdens on teacher time. For example, teachers are starting to use AI to assist in lesson planning, by aligning standards to activities, identifying strategies to engage all learners, and developing assessments.[38] This can free up teachers' time to focus on activities that make a greater impact on learning outcomes, such as providing individualized instruction or whole-group remediation.

AI can even be used to help support other school personnel, like security guards. School districts are starting to purchase and use AI-powered robots that can surveil school grounds and notify security staff about intruders.[39] While reliant on guidance from humans, these robots are equipped to video record interactions with intruders, transmit communications from safety staff, and even use flashing lights and lasers to disarm an individual.[40] While these robots are a new, and expensive, development, it is a promising innovation that can improve school safety.

Use of AI in post-secondary education, from workforce development to higher education, involves similar opportunities and potential concerns. A famous example of AI success in higher education is on student completion and success at Georgia State University. The institutional graduation rate stood at 32 percent and Pell students, those from low-income backgrounds, were graduating at a rates 10 percentage points lower than non-Pell students.[41] According to their report, in 2003, Georgia State University was the "embodiment of these national failings."[42] Now, the graduation rate is up and the racial, ethnic, and economic disparities are no longer predictors of success at Georgia State. The university successfully demonstrated the impact of analytics-based proactive advisement, using AI, from identifying students at-risk of not graduating to chatbots to provide customized communications in real-time.[43]

While these advances may be a bright spot for the future of education, results from a recent survey of teachers and administrators by the digital learning plat-

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[35] Katharine Miller, De-Identifying Medical Patient Data Doesn't Protect Our Privacy, Stanford University Human-Centered Artificial Intelligence, July 19, 2021, *https://hai.stanford.edu/news/de-identifying-medical-patient-data-doesnt-protect-our-privacy/*.

[36] The National Assessment of Educational Progress. (June 2023). Reading and Mathematics Scores Decline during COVID–19 Pandemic. *https://www.nationsreportcard.gov/highlights/ltt/2022/*.

[37] Khanmigo. (n.d.) Khan Academy. *https://www.khanacademy.org/khan-labs—khanmigo*.

[38] Jorge Valenzuela. (March 15, 2023). Using AI to Help Organize Lesson Plans. Edutopia. *https://www.edutopia.org/article/ai-lesson—plans/*.

[39] Megan Tagami. (July 7, 2023) Your School's Next Security Guard May Be an AI-Enabled Robot. Wall Street Journal. *https://www.wsj.com/articles/this-schools-new-security-aide-has-360-degree-vision-its-a-robot-a4f983b5*.

[40] Ibid.

[41] Ibid.

[42] Georgia State University. (September 2020) Complete College Georgia. Carnegie Foundation. *https://www.carnegiefoundation.org/*

[43] Ibid.

form, Clever, show that there are more obstacles to overcome. Nearly half of survey respondents believed that "AI will make their jobs more challenging within 3 years" and these challenges may stem from the lack of professional development preparing teachers to use these new technologies in the classroom.[44] However, as with any new technology, like introduction of the internet or tablets in the classroom, there will be growing pains as teachers begin to grapple with and use AI in their classrooms. School leaders will need to take the lead in ensuring that their staff is appropriately trained, and best practices for use are developed and widely disseminated.

As localities consider if and how they will use AI in their classrooms, the country's largest school district, New York City Public Schools, has taken a decisive step by banning ChatGPT on all district devices and networks.[45] One of the chief concerns shared by district leaders and teachers is how AI can enable students to cheat on assessments.[46] In fact, the Department of Education recently released a report that raised both this concern and a more widespread issue—how AI can provide information that appears to be accurate but perpetuates misunderstandings.[47]

While students are now able to use the internet and other technologies to help answer basic homework questions, recent advancements will enable students to use AI as a substitute for their own thinking for assignments aimed at building or testing their critical thinking skills. AI can be used to write essays, prepare an argument for debate, or construct proofs for complex math problems. If both AI's content and students' use of the technology is left unchecked, students may never fully develop the critical thinking skills needed to succeed in the workforce. Students must be taught to use AI to strengthen, rather than replace their critical thinking skills. For instance, students could be asked to critique the reasoning of an essay prepared by AI or submit their argument to AI and ask for probing questions to work through that might strengthen their logic. AI will either be a shortcut for students' critical thinking or an incredible sparring partner to strengthen them—what actions can we take to ensure it is the latter?

Responsible Use of AI Can Improve the Workplace

Human resources (HR) technology spending on AI tripled in 2021 as companies adjusted to remote work and staffing challenges.[48] This year, H.R. technology ranks as the top spending priority for H.R. leaders, higher than staffing, total rewards, or learning and development.[49] Employers are using AI to create efficiencies across the employee lifecycle, from recruiting, to interviewing, hiring, onboarding, upskilling, managing, promoting, and downsizing. Proponents argue AI can help firms make better employment-related decisions and enhance work for employees. To fill employment gaps, AI is facilitating connections between job seekers and potential employers, and helping employers attract, hire, and retain high-value employees, including those with untraditional backgrounds. When designed or used inappropriately, AI can lead to violations of Federal law or alter how work is done to the detriment of workers.

For example, the use of AI to monitor and manage employees has often been cited as a cause of deteriorating workplace conditions. In certain cases, employees have expressed concerns that AI was inappropriately used to determine who is laid off.[50] In addition, the digitalization of H.R. departments has often meant information on employee productivity, employee potential, and other metrics derived using AI

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[44] PR Newswire. (June 21 2023). Half of Teachers Surveyed Believe AI Will Make Their Jobs More Challenging. *https://www.prnewswire.com/*

[45] Maya Yang. (January 6, 2023). New York City Schools Ban AI Chatbot That Writes Essays and Answers Prompts. The Guardian. *https://www.theguardian.com/us-news/2023/jan/06/new-york-city-schools-ban-ai-chatbot-chatgpt*.

[46] Ibid.

[47] Office of Educational Technology. (May 2023). Artificial Intelligence and the Future of Teaching and Learning. U.S. Department of Education. *https://www..ed.gov/documents/ai-report/ai-report.pdf*.

[48] Dondo, Jean. (2021, December 21). H.R. technology budget triples in 2021. HRD America. *https://www.hcamag.com/us/specialization/hr-technology/hr-technology-budget-triples-in-2021/320668*.

[49] Feffer, Mark. (2023, March 16). H.R. Sees Technology as One Solution to Rising Costs. HCM Technology Report. *https://www.hcmtechnologyreport.com/hr-sees-technology-as-one-solution-to-rising-costs/*.

[50] Nurski, L. and Hoffman, M. (2022, July 27). The impact of artificial intelligence on the nature and quality of jobs, Working Paper, Bruegel. *https://www.bruegel.org/sites/default/files/2022–07/WP percent2014 percent202022.pdf*.

played a role in adverse H.R. decisions.[51] Meanwhile, some companies are deploying employee monitoring methods such as keystroke and eye tracking software, video monitoring or automated job interviews, and wearable tracking devices, which can raise concerns over employee privacy and dignity.[52] The shift to remote work that occurred during the pandemic spurred adoption of these technologies, intensifying concerns. Companies are also using AI to ensure the safety and protection of their workers. For example, AI models are being developed for fire detection, limiting unauthorized access, and collision warnings for moving vehicles.[53]

Another area of potential harm that has garnered ample attention by policymakers and regulators is discrimination. At the Federal level, Congress, the Department of Labor (DOL), the Equal Employment Opportunity Commission (EEOC), the National Labor Relations Board (NLRB), and the White House have each opined on the potential risk of AI to produce discriminatory employment decisions.[54],[55],[56],[57],[58] Debates are just beginning about whether adequate protections are provided by technology-neutral Federal anti-discrimination statutes, such as Title VII of the Civil Rights Act of 1964, the Americans with Disabilities Act of 1990, and the Age Discrimination in Employment Act of 1967.[59],[60],[61]

Three AI challenges facing policymakers are working conditions, discrimination, and job displacement. AI is disrupting the labor market by automating some jobs and threatening to displace more.[62] In one estimate, about two-thirds of jobs globally are exposed to partial AI automation, and about one-fourth of jobs could be replaced.[63] Early estimates focus on potential job loss among low-skilled, low-income jobs. White-collar jobs are increasingly considered at risk, particularly with the

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[51] Verma, Pranshu. (2023, February 20). AI is starting to pick who gets laid off. The Washington Post. *https://www.washingtonpost.com/technology/2023/02/20/layoff-algorithms/*.

[52] Lazar, Wendi, & Yorke, Cody. (2023, April 25). Watched while working: Use of monitoring and AI in the workplace increases. Reuters. *https://www.reuters.com/legal/legalindustry/watched-while-working-use-monitoring-ai-workplace-increases*.

[53] Boesch, G. (2023, January 5). Top 18 applications of Computer Vision in security and surveillance. viso.ai. *https://viso.ai/applications/computer-vision-applications-in-surveillance-and-security/*.

[54] Senate Judiciary Subcommittee on Privacy, Technology, and the Law. (2023, July 25). Senate hearing on Regulating Artificial Intelligence Technology. CSPAN. *https://www.c-span.org/video/*

[55] Goldman, T. (2022, October 4). What the blueprint for an AI bill of rights means for workers. DOL Blog. *https://blog.dol.gov/2022/10/04/what-the-blueprint-for-an-ai-bill-of-rights-means-for-workers*.

[56] U.S. Equal Employment Opportunity Commission. (2022, May 12). [Technical Guidance] The ADA and AI: Applicants and Employees. U.S. Equal Employment Opportunity Commission. *https://www.eeoc.gov/laws/guidance/americans-disabilities-act-and-use-software-algorithms-and-artificial-intelligence*.

[59] Abruzzo, J. A. (2022, October 31). Electronic Monitoring and Algorithmic Management of Employees Interfering with the Exercise of Section 7 Rights. National Labor Relations Board. *https://www.nlrb.gov/news-outreach/news-story/nlrb-general-counsel-issues-memo-on-unlawful-electronic-surveillance-and*.

[58] The U.S. Government. (2023, March 16). Blueprint for an AI bill of rights. The White House. *https://www.whitehouse.gov/ostp/ai-bill-of-rights/*.

[59] Equal Employment Opportunity Commission . (1964). Title VII of the Civil Rights Act of 1964. U.S. EEOC. *https://www.eeoc.gov/statutes/title-vii-civil-rights-act—1964*.

[60] Equal Employment Opportunity Commission . (1990). Americans with Disabilities Act of 1990. U.S. EEOC. *https://www.eeoc.gov/publications/ada-your-responsibilities-employer*.

[61] Equal Employment Opportunity Commission . (1967). Age Discrimination in Employment Act of 1967. U.S. EEOC. *https://www.eeoc.gov/statutes/age-discrimination-employment-act—1967*.

[62] Challenger, Gray & Christmas, Inc. (2023, June 1). Layoffs Jump in May on tech, retail, auto; TYD hiring lowest since 2016. Challenger Report May 2023. *https://omscgcinc.wpenginepowered.com/wp-content/uploads/2023/06/The-Challenger-Report-May23.pdf*.

[63] Briggs, Joseph, Hatzius, Jan, Kodnani, Devesh, & Pierdomenico, Giovanni. (2023, March 26). The Potentially Large Effects of Artificial Intelligence on Economic Growth (Briggs/Kodnani). Goldman Sachs Economic Research. *https://www.key4biz.it/*

[64] Ibid.

[65] Brown, Sara. (2021, April 21). Machine learning, explained. MIT Sloan. *https://mitsloan.mit.edu/ideas-made-to-matter/machine-learning-explained*.

[66] Liddy, Elizabeth D. (2001). Natural Language Processing. SURFACE at Syracuse University. *https://surface.syr.edu/cgi/viewcontent.cgi*

[67] Perara, Angela. (2022, October 8). Artificial Intelligence in HR: Using AI for identifying and hiring suitable candidates. Business-Tech Weekly. *https://www.businesstechweekly.com/hr-and-recruitment/artificial-intelligence-ai-for-hiring/*.

rapid development of generative AI (i.e., AI systems using existing patterns within data sets to create new content, such as ChatGPT).

As EEOC Commissioner Keith Sonderling notes, machine learning and natural language processing are the most pertinent iterations of AI in the employment context.[64] Machine learning is a subfield of AI that allows computing systems to process large amounts of data to change the original programming, i.e. "learn," without explicitly being programmed. At any point in the process, programmers may alter the model to push it to more accurate results or assess the system with evaluation data.[65] Natural language processing is a set of computational techniques to analyze and produce written or oral language in a way that appears to be human.[66] Chatbots are a common example.

AI's impact on work is far from understood, as the workplace, workers' preferences and expectations, and the technology itself is rapidly developing. AI's potential positive impact on work is less discussed, but may prove more significant. AI systems have been used to help workers look for a job, or upskill to a new one. AI education tools can be seamlessly integrated into an employee's workflow, and adjusted in real time as the economy changes.[67] AI can increase workplace access for disabled employees. Examples include lip-reading recognition tools, image and facial expression recognition, and wearable technologies, such as robotic arms. AI tools can create more flexible scheduling, matching labor demands with worker availability, qualifications, and preferences. Flexible scheduling is particularly important for family caregivers.[68] Research has indicated that AI often results in more diverse hires and less biased promotion decisions.[69] Perhaps counterintuitively, the use of AI in the workplace has been correlated with greater employee satisfaction, giving actionable information on workplace stressors in real time and facilitating interactions with management.[70], [71]

The U.S. Government has not adopted a centralized regulatory approach to AI in the employment context. Several states and localities—Maryland, Illinois, and New York City, for example—have enacted AI laws, and more local and state regulation is pending.[72] Executive branch policy is beginning to address AI, to include technical assistance from the EEOC and a memo by NLRB General Counsel, but is still in its infant stages. Federal lawmakers have shown interest in regulating AI, but significant problems, including the novelty of the technology and the still undecided nature of its impact, remain.

AI and Job Displacement

Technological unemployment has been a recurring fear since the manufacturing era, and is once again with the advent of AI. According to a Goldman Sachs study, globally 300 million full-time jobs could be at risk of automation.[73] The World Economic Forum estimates that 85 million jobs could be displaced by 2025 but 97 mil-

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[63] Briggs, Joseph, Hatzius, Jan, Kodnani, Devesh, & Pierdomenico, Giovanni. (2023, March 26). The Potentially Large Effects of Artificial Intelligence on Economic Growth (Briggs/Kodnani). Goldman Sachs Economic Research. *https://www.key4biz.it/*

[64] Ibid.

[65] Brown, Sara. (2021, April 21). Machine learning, explained. MIT Sloan. *https://mitsloan.mit.edu/ideas-made-to-matter/machine-learning-explained*.

[66] Liddy, Elizabeth D. (2001). Natural Language Processing. SURFACE at Syracuse University. *https://surface.syr.edu/cgi/viewcontent.cgi*

[67] Perara, Angela. (2022, October 8). Artificial Intelligence in HR: Using AI for identifying and hiring suitable candidates. Business-Tech Weekly. *https://www.businesstechweekly.com/hr-and-recruitment/artificial-intelligence-ai-for-hiring/*.

[68] Siddiqui, A. R. (2023, June 7). How ai is helping society break free from the 9-to–5 mold. Entrepreneur. *https://www.entrepreneur.com/leadership/how-ai-is-breaking-the-9-to-5-mold/*

[69] Houser, Kimberly. (2020, July 12). Can AI Solve the Diversity Problem in the Tech Industry? Mitigating Noise and Bias in Employment Decision-Making. SSRN. *https://papers.ssrn.com/sol3/papers.cfm*

[70] Candelon, Francois, Khodabandeh, Shervin, & Lanne, Remi. (2022, November 4). A.I. empowers employees, not just companies. Here's how leaders can spread that message. FORTUNE. *https://fortune.com/2022/11/04/artificial-intelligence-ai-employee-empowerment/*.

[71] Houser, Kimberly. (2020, July 12). Can AI Solve the Diversity Problem in the Tech Industry? Mitigating Noise and Bias in Employment Decision-Making. SSRN. *https://papers.ssrn.com/sol3/papers*.

[72] Zhu, K. (2023, August 3). The State of State AI laws: 2023. EPIC. *https://epic.org/the-state-of-state-ai-laws-2023/*.

lion new jobs may be generated by technology.[74] Many economists argue robots are not replacing workers, but instead workplaces are integrating them into their ecosystem.[75] Despite these fears, as adoption of AI increases across the private sector, the major workforce challenge most companies face is filling job vacancies.

The potential automation of truck driving has often been predicted to threaten millions of U.S. jobs. According to the American Trucking Association, in 2022, 8.4 million Americans were employed in jobs that relate to trucking activity.[76] Hearings on autonomous vehicles and trucking have focused on this risk. The Senate Commerce Committee reported the AV STARTAct (S. 1885) in 2017, but exempted vehicles weighing more than 10,000 pounds after pressure from the Teamsters Union.[77] In 2021, the Departments of Transportation and Labor published a congressionally directed study on the impacts of automated trucking on the workforce, which acknowledged the potential for job displacement in the trucking industry but noted the lack of data would require further studies to generate a stronger prediction.[78] A 2019 Government Accountability Office (GAO) report noted widespread deployment of automated trucks could be years or decades away.

Studies have suggested that the impact of automation on jobs may be less abrupt than is envisioned.[79] A significant portion of job losses, for example, will take place through attrition, including retirement. In addition, studies comparing predictions of job loss and job creation due to technology fail to predict even the most common job titles over the coming decades.[80] Sixty percent of today's workforce occupy jobs that did not exist in the 1940's.[81] Increased demand for AI is predicted to generate job opportunities in engineering, software design, and programing. Industries such as finance and health care will experience job creation for high skilled roles including biologists, financial technology specialists, and geneticists.[82] The Massachusetts Institute of Technology (MIT) Work of the Future report noted, "[W]e anticipate that in the next two decades, industrialized countries will have more job openings than workers to fill them, and that robotics and automation will play an increasingly crucial role in closing these gaps."[83]

Labor unions have expressed concern over various implications of AI, including recently at a White House listening session, where union leaders flagged safety, privacy, civil rights, and job loss as key risk areas.[84] Concurrently, AI has become a central issue in current contract negotiations between the respective actors' and writers' labor unions and studios.[85] The Screen Actors Guild has articulated the principal concern from the actors regarding AI is the risk of actors losing control over their likeness, specifically if their image or voice is used without their consent

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[74] Schwab, Klaus, & Zahidi, Saadia. (2020, October 20). The Future of Jobs Report 2020. WeForum. *https://www.weforum.org/reports/the-future-of-jobs-report-2020/*

[75] Dahlin, Eric. (2022, October 17). Are Robots Really Stealing Our Jobs? Perception versus Experience. Socius, 8. *https://doi.org/*.

[76] American Trucking Association. (n.d.). Economics and industry data. American Trucking Associations. *https://trucking.org/economics-and-industry-data*.

[77] DC Velocity Staff. (2017, October 4). Senate Committee caps weight limit on vehicles to be subject to AV laws. DCVelocity. *https://www.dcvelocity.com/articles/29203-senate-committee-caps-weight-limit-on-vehicles-to-be-subject-to-av-laws*.

[78] U.S. GAO. (2019, March). Automated Trucking Federal Agencies Should Take Additional Steps to Prepare for Potential Workforce Effects. U.S. Government Accountability Office (U.S. GAO). *https://www.gao.gov/assets/gao-19-161.pdf*.

[79] Gmyrek, P., Berg, J., & Bescond, D. (2023, August). Generative AI and jobs: A global analysis of potential effects on job quantity and quality. ILO Working Paper 96. *https://www.ilo.org/wcmsp5/groups/public/—dgreports/—inst/documents/publication/wcms—890761.pdf*.

[80] Thierer, Adam. (2023 March). Can We Predict the Jobs & Skills Needed for the AI Era?. R Street. *https://www.rstreet.org/wp-content/uploads/2023/03/r-street-policy-study-no-278.pdf*.

[81] The Economist. (2023, May 7). Your job is (probably) safe from artificial intelligence. *https://www.economist.com/finance-and-economics/2023/05/07/your-job-is-probably-safe-from-artificial-intelligence*.

[82] Schwab, Klaus, & Zahidi, Saadia. (2020, October 20). The Future of Jobs Report 2020. WeForum. *https://www.weforum.org/reports/the-future-of-jobs-report-2020/*

[83] Autor, David, Mindell, David, & Reynolds, Elisabeth. (2020). The Work of the Future: Building Better Jobs in an Age of Intelligent Machines. MIT Work of the Future. *https://workofthefuture.mit.edu/wp-content/uploads/2021/01/2020-Final-Report4.pdf*.

[84] The U.S. Government. (2023, July 3). Readout of white house listening session with union leaders on Advancing Responsible Artificial Intelligence Innovation. The White House. *https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/03/readout-of-white-house-listening-session-with-union-leaders-on-advancing-responsible-artificial-intelligence-innovation/*.

[85] Patten, Dominic. (2023, July 10). SAG-AFTRA Strike Could Hinge On AI; Deep Divisions Remain Between Actors & Studios In Final Hours Of Talks. Deadline. *https://deadline.com/2023/07/actors-strike-ai-kim-kardashian-fran-drescher-contract-deadline-1235432142/*.

or without pay.[86] Likewise, the Writers Guild of America is concerned with the greater utilization of AI-generated storylines or dialog, especially when it relates to credits that are linked to recognition pay.[87] Automation was also a major concern of dockworkers during the West Coast labor negotiations, particularly the potential of job loss presented by container-handling and transporting equipment.[88] This aspect was one of the last areas of agreement reached before the negotiations concluded. Other unions are positioning themselves to provide training and resources for workers entering new roles, or learning to work with technology in their current roles. AFL–CIO President Liz Shuler claimed AI will be "the next frontier for the labor movement," anticipating growing productivity will allow the union organization to be "the center of gravity for working people as they transition to new and better jobs."[89]

Upskilling or educating workers to understand new technological advancements works to mitigate the negative impacts of new technology. For example, Senator Richard Durbin's (D-IL) Investing in Tomorrow's Workforce Act of 2021 would provide grants toward upskilling workers displaced due to automation.[90] Senators Gary Peters (D-MI) and Mike Braun's (R-IN) AI Leadership Training Act would train Federal employees on AI. Tim Kaine (D-VA) and Senator Braun's JOBS Act, which would extend short term Pell Grants to workforce education programs, has been put forward as a response to automation caused by AI.[91]

AI itself may also be an answer to training workers for new tasks and jobs ahead. A Price Waterhouse Coopers (PwC) study found, "AI allows those in training to go through naturalistic simulations in a way that simple computer-driven algorithms cannot. The advent of natural speech and the ability of an AI computer to draw instantly on a large data base of scenarios, means the response to questions, decisions or advice from a trainee can challenge in a way that a human cannot."[92] Several companies are currently leveraging AI to identify learning opportunities for their workers and facilitate personalized and flexible upskilling. Through machine learning, AI can recommend and facilitate employee role pathways and learning sequences. AI-facilitated upskilling can be seamlessly integrated into an employee's workflow.[93]

AI and Working Conditions

AI presents the opportunity for firms to derive meaningful data from workers and the workplace in ways not previously possible. This may translate to productivity gains and improved worker conditions. However, if not designed and implemented properly, AI may play a role in worsening workplace conditions by dehumanizing workers through inhospitable AI-driven management techniques, intruding on worker privacy, or increasing discrimination.

The COVID–19 pandemic shifted many in-person roles to remote, some temporarily and some permanently. Remote work centered the discussion of employee monitoring as employers attempted to find ways to hold remote workers accountable. Data collected from such monitoring may contribute to employment decisions such as promotions, raises, demotion, or termination. However, there is concern these tools are simply an invasion of workers' privacy. Federal law is largely silent

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[86] Webster, Andrew. (2023, July 13). Actors say Hollywood studios want their AI replicas—for free, forever. The Verge. *https://www.theverge.com/2023/7/13/23794224/sag-aftra-actors-strike-ai-image-rights*.

[87] Dalton, Andrew. (2023, July 13). AI is the wild card in Hollywood's strikes. Here's an explanation of its unsettling role. AP News. *https://apnews.com/article/artificial-intelligence-hollywood-strikes-explained-writers-actors-e872bd63ab52c3ea9f7d6e825240a202*.

[88] Berger, Paul. (2023, April 20). West Coast Dockworkers Reach Tentative Deal on Port Automation. The Wall Street Journal. *https://www.wsj.com/articles/west-coast-dockworkers-reach-tentative-deal-on-port-automation-b4b828fe*.

[89] Kullgren, I. (2023, August 29). Unions must be at forefront of AI battle, AFL–CIO president says. Bloomberg Law. *https://news.bloomberglaw.com/us-law-week/unions-must-be-at-forefront-of-ai-battle-afl-cio-president-says*.

[90] S. 1212—117th Congress (2021–2022) Investing in Tomorrow's Workforce Act of 2021. (2021, April 19) *https://www.Congress.gov/*

[91] Munhoz, Diego Areas. (2023, May 22). Congress Moves to Engage Workforce with AI, Not Fight Against It. Bloomberg Law. *https://news.bloomberglaw.com/daily*

[92] PricewaterhouseCoopers International Limited. (n.d.) No longer science fiction, AI and robotics are transforming healthcare. PWC. *https://www.pwc.com/gx/en/industries/healthcare/publications/ai-robotics-new-health/transforming-healthcare.html*.

[93] H.R. Policy. (2023, January 31). HRPA Statement to EEOC: "Growing Opportunity for the U.S. Workforce in the Age of AI". HR-policy. *https://www.hrpolicy.org/insight-and-research/resources/2023/hr-workforce/public/02/hrpa-statement-to-eeoc-growing-opportunity-for-the/*.

on the issue of worker surveillance in the workplace.[94] Several states have passed laws limiting employer surveillance, particularly in rest and changing rooms, including in California, New York, and West Virginia.[95] Nevertheless, U.S. employers have great discretion to monitor the workplace. Courts have upheld that employee monitoring is permitted if there is a valid business purpose. In Smyth v. Pillsbury Co., an employee claimed to be wrongfully terminated after sending inappropriate emails through the employer's email system. The court decided the plaintiff was not wrongfully terminated because there was not a reasonable expectation of privacy.[96]

Employer use of AI to streamline worker management has also come under scrutiny. Safety and health issues have been implicated by aggressive requirements imposed by AI systems on workers' movements, breaks, and other behaviors within the workplace. The labor movement has taken keen interest in the intersection of working conditions and technology.

For example, testing of tracking technology on UPS delivery trucks drew strong push back from the Teamsters Union in 2020.[97] UPS Teamsters United claimed UPS used worker surveillance systems to "harass and discipline [its] drivers."[98] Advocates for such technologies claim they improve worker safety. For example, Amazon partnered with Netradyn to develop a driver information camera system that utilized telematics to ensure the safety of the driver and vehicle.[99] However, the announcement received push back from the American Civil Liberties Union due to concerns of bias.[100]

Many use cases of AI have contributed to improved working conditions and worker well-being. AI has the ability to reduce human error, as such creating a safer workplace. Marks & Spencer, a UK-based multinational retailer, reported a reduction of workplace incidents by 80 percent when they introduced a computer vision technology at a distribution center because the technology identified and rectified unsafe behaviors.[101] Integration of AI and other innovative technologies may ultimately improve workplace conditions, worker safety, and worker mobility.[102] App-based food delivery companies use AI to organize and design the system of pick-ups, deliveries, and food recommendations.[103] Through this system, drivers are able to maximize efficiency and profits. A study on the use of generative AI in the workplace found that workers who used the technology increased their productivity by 14 percent on average. It also found attrition rates plunged by 8.6 percent, suggesting lower stress levels among employees.[104]

AI and Discrimination

The use of AI in employment decisions has become mainstream. Nearly 80 percent of employers use some sort of AI or automation in the recruitment and hiring process.[105] AI is often used to reach a specific candidate audience via targeted ads, to screen and rank applicants, and to analyze candidates' facial expressions or eye con-

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[94] American Bar Association. (2018, January). How much employee monitoring is too much?. Americanbar. *https://www.americanbar.org/news/abanews/publications/youraba/2018/January*

[95] Id.

[96] Smyth v. Pillsbury Co., 914 F. Supp.97 (E.D. Pa. 1996).

[97] Scarpati, Jessica. (2023, March). Telematics. Techtarget. *https://www.techtarget.com/searchnetworking/definition/telematics*

[98] UPS Teamsters United. (n.d.). Protect Drivers From Cameras In UPS Trucks. UPS Teamsters for a democratic union. *https://ups-teamstersforademocraticunion.nationbuilder.com/sign—the—petition—against—ups—cameras—in—trucks—today*.

[99] Amazon. (n.d.). Amazon Netradyn Driver Information. Vimeo. *https://vimeo.com/*.

[100] Stanely, Jay. (2021, March 23). Amazon Drivers Placed Under Robot Surveillance Microscope. ACLU. *https://www.aclu.org/news/privacy-technology/amazon-drivers-placed-under-robot-surveillance-microscope*.

[101] Healy, Charlotte. (2023, June 2). UK: AI's Impact on Workplace Safety. SHRM. *https://www.shrm.org/resourcesandtools/hr-topics/global-hr/pages/uk-ai-safety.aspx*.

[102] Altman, Elizabeth J., Kiron, David, & Riedl, Christoph. (2023, April 13). Workforce ecosystems and AI. Brookings. *https://www.brookings.edu/articles/workforce-ecosystems-and-ai/*.

[103] Ramesh, Raghav. (2018, May 2). How DoorDash leverages AI in its world-class on-demand logistics engine. Artificial Intelligence Conference. *https://conferences.oreilly.com/artificial-intelligence/ai-ny-2018/public/schedule/detail/65038.html*.

[104] Brynjolfsson, Erik, Li, Danielle, & Raymond, Lindsey R. (2023, April). Generative AI at Work. NBER. *https://www.nber.org/system/files/working—papers/w31161/w31161.pdf*.

[105] Brin, Dinah Wisenberg. (2019, March 22). Employers Embrace Artificial Intelligence for HR. SHRM. *https://www.shrm.org/resourcesandtools/hr-topics/global-hr/pages/employers-embrace-artificial-intelligence-for-hr.aspx*.

tact during a video interview.[106] AI is also being used to track performance of employees by following log in times, computer usage, and online activity.[107] Evidence suggests AI may have the potential to exacerbate biases in hiring.[108] Data being inputted may reflect existing workplace biases and it is difficult to discern how an AI system's inputs translate into its outputs.[109]

Title VII of the Civil Rights Act (Title VII) prohibits discrimination on the basis of race, color, religion, national origin, or sex in the employment context. According to the EEOC, which enforces Title VII, a business may be found to have violated Title VII for either disparate treatment or, more relevant to AI operators, disparate impact. Disparate treatment occurs "when an employer or other person subject to the [Civil Rights] Act intentionally excludes individuals from an employment opportunity on the basis of race, color, religion, sex, or national origin" (emphasis added). However, intent is not necessary to establish a claim of disparate impact, where the only concern is whether a facially neutral policy disproportionally excludes individuals within a protected class.[110] Disparate impact is typically the focus of discrimination concerns regarding AI.[111]

Employers are also prohibited from unlawfully discriminating based on age or disability under the Age Discrimination in Employment Act (ADEA). The ADEA prohibits employers and employment agencies from discriminating against workers 40 or older in job advertising, recruiting, hiring, and other job opportunities.[112] In December 2022, in one of the first AI-related charges filed with the EEOC, Real Women in Trucking filed a discrimination charge against Meta Platforms Inc. The group alleged Meta Platforms steered employment ads away from women and people over 55 years. After an investigation of a complaint by a man who could not complete an online application due to age restrictions, the Illinois Attorney General investigated several automated hiring platforms for discouraging older workers from applying.[113]

The Americans with Disabilities Act (ADA) expressly bans pre-employment assessments that tend to screen out individuals with a disability unless the test can be shown to be job-related and consistent with a business necessity. For example, an AI-powered personality test may ask or intuit an applicant's sense of optimism, and disqualify them based on their living with Major Depressive Disorder.[114] Job applicants diagnosed with autism may be screened out from job opportunities based on video interviews assessed by AI trained to detect certain patterns, such as eye contact and pauses in speech.[115] In addition, the ADA prohibits employers from inquiring into an applicant's disability during the application and interview processes. AI systems that determine a potential employee's disability status may violate the ADA. Advocates in favor of using of AI in the workplace, however, argue that with

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[106] Casimir, Lance, Kelley, Bradford J., & Sonderling, Keith E. (2022, August 11). The Promise and The Peril: Artificial Intelligence and Employment Discrimination. University of Miami Law Review. *https://repository.law.miami.edu/cgi/viewcontent.cgi*

[107] Ibid.

[108] The U.S. Government. (2016, May). Big Data: A Report on Algorithmic Systems, Opportunity, and Civil Rights. Executive Office of the President. *https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/2016—0504—data—discrimination.pdf*.

[109] Rawashdeh, Samir. (2023, March 6). Artificial intelligence can do amazing things that humans can't, but in many cases, we have no idea how AI systems make their decisions. UM-Dearborn Associate Professor Samir Rawashdeh explains why that's a big deal. UM Dearborn. *https://umdearborn.edu/news/ais-mysterious-black-box-problem-explained*.

[110] U.S. Equal Employment Opportunity Commission. (1988, August 1). [Guidance] CM–604 theories of discrimination. U.S. Equal Employment Opportunity Commission. *https://www.eeoc.gov/laws/guidance/cm-604-theories-discrimination*.

[111] New EEOC guidance on when the use of artificial intelligence in selection procedures may be discriminatory. FordHarrison. (2023, June 13). *https://www.fordharrison.com/eeocs-guidance-on-artificial-intelligence-hiring-and-employment-related-actions-taken-using-artificial-intelligence-may-be-investigated-for-employment-discrimination-violations*.

[112] Department of Labor. (n.d.). Age discrimination. U.S. Department of Labor. *https://www.dol.gov/general/topic/discrimination/*

[113] Ajunwa, Ifeoma. (2020, May 1). Protecting Workers' Civil Rights in the Digital Age. UNC School of Law. *https://scholarship.law.unc.edu/cgi/viewcontent.cgi*

[114] U.S. Equal Employment Opportunity Commission. (2022, May 12). [Technical Guidance] The ADA and AI: Applicants and Employees. U.S. Equal Employment Opportunity Commission. *https://www.eeoc.gov/laws/guidance/americans-disabilities-act-and-use-software-algorithms-and-artificial-intelligence*.

[115] Landon, Oliver. (2022, April). AI video assessment. Employment autism. *https://www.employmentautism.org.uk/blog/ai-video-assessments*.

certain safeguards, the technology can speed up the hiring process while limiting discrimination and bias. [116]

Conclusion

As the U.S. Senate assesses the readiness of American regulatory frameworks for AI, as Ranking Member of the HELP Committee, I'm focused on ensuring that we are prepared for the continued deployment of AI. The insights of stakeholders that can describe the advantages and drawbacks of AI in our health care system, in the classroom, and in the workplace are critical as policymakers grapple with this topic. Please submit feedback and comments for ways to improve the framework in which these technologies are developed, reviewed, and used to HELPGOP—AIComments@help.senate.gov by Friday, September 22.

[116] Sonderling, Keith E. (n.d.). How People Analytics Can Prevent Algorithmic Bias. IHRIM. *https://www.ihrim.org*

Questions for Consideration

Health Care

Supporting Medical Innovation:

- How can FDA support the use of AI to design and develop new drugs and biologics?
- What updates to the regulatory frameworks for drugs and biologics should Congress consider to facilitate innovation in AI applications?
- How can FDA improve the use of AI in medical devices?
- What updates to the regulatory frameworks for medical devices should Congress consider to facilitate innovation in AI applications while also ensuring that products are safe and effective for patients?
- How can Congress help FDA ensure that it has access to the expertise required to review products that are developed using AI or that incorporate AI?
- How can FDA better leverage AI to review product submissions?
- How can FDA harness external expertise to support review of products that are developed using AI or that incorporate AI?
- What are the potential consequences of regulating AI in the United States if it remains unregulated in other countries?

Medical Ethics and Protecting Patients:

- What existing standards are in place to demonstrate clinical validity when leveraging AI? What gaps exist in those standards?
- What practices are in place to mitigate bias in AI decisionmaking?
- What should be the Federal role, if any, in addressing social and/or political bias?
- How can AI be best adopted to not inappropriately deny patients care?
- Is the current HIPAA framework equipped to safeguard patient privacy with regards to AI in clinical settings? If not, how not or how to better equip the framework?
- What standards are in place to ensure that AI maintains respect and dignity for human life from conception to natural death?
- Who should be responsible for determining safe and appropriate applications of AI algorithms?
- Who should be liable for unsafe or inappropriate applications of AI algorithms? The developer? A regulating body? A third party or private entity?

Education

General Policy:

- What should the Federal role be in supporting AI in education?
- What should the state role be in supporting AI in education?
- What should be the local role in supporting AI in education?
- Do these roles vary by the educational setting?
- What should be the Federal role in supporting and ensuring safe and responsible use of AI with respect to the workforce and the workplace?
- What should the state role be in supporting and ensuring safe and responsible use of AI with respect to the workforce and the workplace?
- What are the best practices currently being used to ensure that AI systems are designed, developed, and deployed in a manner that protects people's rights and safety?

Practical Uses for AI in Education Settings:

- How is AI already being used in the classroom? Are there any innovative models emerging?
- How is AI being used throughout school buildings or on post-secondary campuses? What areas are advocates hopeful AI can help in besides the classroom?
- How can AI be used to promote school safety? Are there pilots in this area?

- How do we ensure kids can use AI without relying on it? How can it be used to promote critical thinking, rather than replace it? What part of the workflow can AI take over for teachers? What part of the workflow should not be replaced by AI?
- How can we ensure that AI is used effectively and meaningfully in the classroom to support teachers and improve learning, rather than becoming another burdensome new tech for teachers to navigate?

Fostering Students' Understanding of AI:

- How does AI impact what students need to be taught?
- What are the skills students need to use AI responsibly and effectively?
- How does AI impact how student learning is assessed?
- What are the components of next-generation digital literacy related to AI (e.g., algorithmic bias, ethics and academic integrity, asking critical questions/spotting deep fakes, etc.)?

Preparing for AI in the Classroom:

- What do teachers/professors/instructors need to understand about AI before using it?
- How can we incentivize and fund high quality professional development for teachers and administrators in AI and computer science?
- How could AI impact teacher preparation programs?
- What does refusal look like in a classroom? When can and should teachers decline advice/recommendations from an AI system?
- How should errors in AI's output be handled? How should teachers be trained to spot and correct these? Students?
- Right now, schools are putting many of their AI courses into their Career and Technical Education (CTE) programs, but AI lacks industry-recognized credentials. How can industry create meaningful credential development, recognizing also that the curricula and assessments may need to be updated frequently to reflect the changing technology?

Design for AI Use in Schools and with Kids and Young Adults:

- What are the demonstrable steps taken during the design process that give districts/teachers/parents confidence that the AI is fit for use?
- How do foundational models that were not designed with children or the classroom in mind come into play here?
- How is data that is collected during the use of these programs in schools used by the AI?
- How is personally identifiable information managed, stored, and used in accordance with FERPA?
- What protections are in place to keep AI from "learning" the wrong things?
- How can policymakers and technologists work together to build trust in responsibly developed AI? What does responsible development look like?

Higher Education Admissions:

- What is the current and future use of AI in college admissions?
- What protections are put into place to ensure admissions is not biased in decisionmaking?
- How will AI affect the admissions timelines, and would it increase the response time from schools on their admissions decisions?

Degree or Credential Completion and Success:

- Are there lessons that can be learned from other policy areas or program spaces about how to leverage AI to improve the student experience and improve outcomes?
- How do we protect students from being just another number and instead use AI to build social connections that lead to student success?

Labor

Practical Uses for AI in the Workplace:

- What role does AI play in the workplace? Where is AI most often deployed in the context of the workplace?
- What are the key areas companies anticipate making investments in AI in the workplace context?
- What are the chief reasons employers deploy AI in the workplace?
- What considerations do companies purchasing AI software make to ensure it is safe and does not infringe on human rights prior to implementing it in their systems?
- What do workers need to understand about AI in the workplace?
- What do AI developers need to understand about AI in the workplace?
- What steps do companies take when they become aware of a safety or humans rights issue caused by the use of AI with respect to workers?
- How are companies integrating AI into their remote workforce?

AI Standards

- What role will AI standards, such as the National Institute of Standards and Technology AI Risk Management Framework, play in regulatory and self-regulatory efforts?
- What do policymakers need to know about the development of AI standards?
- What do employers need to know about the development of AI standards?
- How can policymakers work with AI developers and users to update and improve such standards as the technology develops?

AI and the Job Market

- What role will AI play in creating new jobs?
- What jobs are most at risk of experiencing displacement due to AI?
- What is the rate of job displacement due to AI?
- What skillsets will become more important as AI is adopted in the workplace
- How is AI being used to fill gaps in the labor market?
- Should Congress be involved to mitigate job displacement from AI? How will the market adapt if Congress does not step in?

AI and Working Conditions

- What are high-risk use cases of AI with respect to working conditions?
- What are low-risk use cases of AI with respect to working conditions?
- The General Counsel of the NLRB has taken a particular interest in the use of AI in employee monitoring. How are employers viewing this issue? How are they preparing in the case they are brought before the Board for review?
- How is AI being used to promote safety in the workplace?
- How is AI being used to promote accessibility in the workplace?
- How is AI being used to increase flexibility in the workplace, including for remote workers?
- What are the concerns regarding the use of AI and worker privacy and dignity, including for remote workers?
- What is the impact of AI on worker productivity?
- What is the impact of AI on worker retention?

AI and Workplace Bias

- What are high-risk use cases of AI with respect to discrimination?
- What are low-risk use cases of AI with respect to discrimination?
- Are the current technology-neutral Federal anti-discrimination laws sufficient to prevent discrimination in the workplace?

STATEMENT OF THE AMERICAN COLLEGE OF SURGEONS

On behalf of the more than 88,000 members of the American College of Surgeons (ACS), we thank you for convening the hearing entitled "Avoiding a Cautionary Tale: Policy Considerations for Artificial Intelligence in Health Care." The ACS is dedicated to improving the care of the surgical patient and to safeguarding standards of care in an optimal and ethical practice environment. As such, we understand the critical role that technology plays in achieving this mission, as well as the need for thoughtful policymaking to ensure that tools such as artificial intelligence (AI) are used with the utmost regard for patients' rights and safety. As we discuss below, it is essential that AI tools are trained and maintained with high quality, diverse, valid, and representative data; are regularly assessed for continued accuracy and reliability; that regulators engage clinical experts in the assessment of AI health tools; and that physicians' clinical judgment remains paramount.

The ACS appreciates the Senate Health, Education, Labor, and Pensions (HELP) Primary Health and Retirement Security Subcommittee's attention to this critical issue and welcomes the opportunity to share some legislative and regulatory considerations for the use of AI in health care.

Ensuring Reliability Over Time

AI can be a powerful tool for medical innovation, but it is critical to ensure that these tools remain accurate and reliable as they develop. The ACS supports efforts to expand the use of real-world evidence (RWE) in the development and maintenance of medical technology. RWE is clinical evidence regarding the use and the potential benefits or risks of a medical product derived from analysis of real-world data (RWD), data related to a patient's health status or delivery of care that can be collected from a variety of sources such as mobile devices, wearables, and sensors; patient generated data used in home-use settings; product and disease registries; claims and billing activities; electronic health records, and more. Such data can complement data that are collected through traditional means and enhance clinical decisionmaking.

For the Food and Drug Administration (FDA) and other regulators, RWE is necessary for monitoring the safety of drugs, devices, and emerging technologies such as AI. As devices that use AI evolve, RWD will be reported back to the FDA regarding the product's safety, effectiveness, and potential risks. The true power of AI-based software lies in its ability to improve over time instead of remaining static. But this is problematic for regulation because the device that was approved or cleared may no longer be operating in a similar fashion as it learns. RWD is necessary to show that the AI-based device still functions appropriately and in the way that it was intended. RWD is also important for accurately training AI algorithms. These data should be high quality, diverse, valid, and representative of the uses for which it will be applied. Any regulatory framework should require that AI applications are assessed, maintained, and updated over their lifetime to ensure continued clinical safety and effectiveness, but also technological integrity. AI tools must be reviewed to make sure they are still valid, reliable, and accurate as they learn.

AI health tools must be both (1) clinically and (2) technologically sound. Validity, reliability, and accuracy are required on both levels. The ACS believes that clinical experts, such as physician informaticists, are best positioned to determine whether data used in AI applications are the best quality and the most appropriate from a clinical perspective, and to monitor the technology for clinical validity as it evolves over time. The FDA should engage advisory groups for clinical and technical excellence that are conditionally or programmatically defined with cross specialty expertise, in order to ensure an AI tool is reliable and valid on multiple levels.

In addition, physicians and specialty societies are well-equipped to assist the FDA as they consider what tools and/or information would be most useful in driving improvements and advancements in clinical care and the format in which the information should be expressed. Understanding where physicians see the benefits of AI in their practices is crucial to help build trust in the capabilities of the technology, leading to broader utilization. Likewise, understanding why physicians decide not to use or do not trust certain health technologies in their clinical practices would also be useful as regulators certify products for real-time use.

Validation of AI Health Tools

Validation of digital health tools, including AI applications, is truly essential to physician trust, improving care delivery, and avoiding patient harm. There are many aspects to validation. Validation is necessary in terms of the technology/algo-

rithm used, the patient population on which the device is trained, whether the outcomes are accurate and unbiased, and whether the tool is appropriate for the specific setting in which it is used. While the FDA is responsible for regulating many digital health tools, the FDA should work in collaboration with an appropriate specialty society, clinical expert, or physician informaticist to reinforce physician trust in the tool. Use and validation of digital health tools are two of the most critical areas for physicians to successfully realize the potential of these technologies. In the case of AI tools, it is especially important to emphasize that the data used to train algorithms is critical to their validity and reliability. The data should be high quality, diverse, valid, and representative of the uses for which it will be applied. While the data used to train the AI-based tool is important, it is equally important that up-to-date data are used to retrain such tools so that the algorithms themselves remain current, reliable, and valid. Additionally, Congress could take steps to create a government-sponsored relationship with a synthetic patient environment, a free, open-source test bed that could be used to test the clinical and technical aspects of any AI application.

At the facility level, institutions should have their own governance and structure for AI-based tools, including pathways for user feedback and timely responses to feedback as physicians have concerns or encounter issues. Liability risks and uncertainty about who is responsible for issues with certain algorithms, outputs, or user errors can hinder implementation of these tools. Before leveraging AI technology, institutions should be confident in the quality of the tool and its capabilities.

Ultimately, digital health tools should reduce, not add to, a physician's cognitive burden. AI technology can enhance a physician's ability to gather, process, and exchange knowledge and ultimately improve patient care when the tool is developed using semantic data exchange standards in alignment with validated clinical workflows. This enables these tools to provide the right information at the right time and seamless incorporation into the clinical workflow.

Mitigating Bias

It is critical to consider bias when designing, training, and using AI health tools. Various forms of bias based on race, ethnicity, gender, sexual orientation, socioeconomic status, and more can be perpetuated through the use of certain advanced digital health tools, especially those using AI. Bias can manifest in digital tools in various ways. For instance, if an AI algorithm is trained with data that fails to include all patient populations for which the tool is used, this would introduce inherent bias. Bias could also be unintentionally written into algorithms, leading to outputs that could have a biased impact on certain populations. The context in which the tool is used should also be considered when trying to avoid bias. If the tool were trained on a certain population for a specific purpose and is applied in a different setting with a different patient population with varying risk factors, this could also result in bias.

While we will be unable to eliminate bias completely, steps can be taken to validate the quality of the data and reduce bias in AI algorithms. As discussed above, the need for trusted and complete data sources for AI tools is critically important, and ensuring the algorithms and data are properly validated is crucial. If the tool is not developed and trained with data that are representative of the patient population the physicians serve, the data outputs could be inaccurate or biased. To lower the risk of bias, the use of trusted and complete data sources in development and testing stages is extremely important. The data sources, methods of data collection, data quality, data completeness, whether the data are fit for purpose, and how the data are analyzed, must all be considered.

In addition, building a framework through collaboration with stakeholders possessing clinical and technical expertise that guides the development and validation of algorithms can assist in reducing bias if done with a high level of rigor. The framework could include a checklist with certain steps that developers would have to complete to ensure algorithms have gone through rigorous testing and validation. By following the processes and validation criteria set forth by the framework, developers can ensure that the algorithms are free of significant bias and will output accurate predictions. This type of framework coupled with external validation that utilizes data across various practice settings and demographics, can also be applied periodically following the implementation of the tool, to ensure that as the algorithms take in real-time data, they are still achieving a high-level of accuracy.

Safe and Appropriate Use

The FDA holds an important role in ensuring the safe and appropriate application of AI technology. Physicians can place greater trust in devices using digital technology if these devices have received FDA clearance or approval. FDA approval is also important for patient trust. Patients should know when they are receiving AI-informed care, and that it comes from validated instruments.

However, the ACS believes strongly that AI tools should never replace a physician's clinical judgment; rather, the goal of these and other digital health tools is to enhance physicians' knowledge and augment their cognitive efforts. Medical care relies not only on science, but on the capabilities of the care team, the local resources, and the goals of the patient. Care is highly personalized and requires a physician-patient interface where the medical knowledge is contextualized and personalized in a trusted manner for each patient and physicians are empowered to make clinical decisions. As we assess AI applications, part of the assessment must evaluate the insertion of AI knowledge artifacts into a human workflow. It is the AI application's utility in the workflow that makes a difference in the informed nature of care, in the diagnosis, and in the treatment.

Concluding Remarks

The ACS thanks the HELP Primary Health and Retirement Security Subcommittee for convening this important hearing on considerations for the use of AI in health care. In order to best serve patients and the physicians who care for them, it is essential that AI tools are trained and maintained with high quality, diverse, valid, and representative data; are regularly assessed for continued accuracy and reliability; that regulators engage clinical experts in the assessment of AI health tools; and that physicians' clinical judgment remains paramount. The ACS looks forward to continuing to work with lawmakers on these important issues. For questions or additional information, please contact Carrie Zlatos with the ACS Division of Advocacy and Health Policy at *czlatos@facs.org*.

NATIONAL NURSES UNITED, WRITTEN STATEMENT FOR AI INSIGHT FORUM: WORKFORCE

Thank you, Majority Leader Schumer and Senators Heinrich, Rounds, and Young, for inviting me to participate in this important conversation about the impact of artificial intelligence (AI) on the workforce. My name is Bonnie Castillo, I'm a registered nurse and the Executive Director of National Nurses United, the nation's largest union and professional association of registered nurses, representing nearly 225,000 nurses across the country.

Our members primarily work in acute care hospitals, where they are already experiencing the impacts of artificial intelligence and other data-driven technologies. The decisions to implement these technologies are made without the knowledge of either nurses or patients and are putting patients and the nurses who care for them at risk. AI technology is being used to replace educated registered nurses exercising independent judgment with lower cost staff following algorithmic instructions. However, patients are unique and health care is made up of non-routine situations that require human touch, care, and input. In my comments, I will demonstrate the risks that AI poses to patient care and to nursing practice and propose key legislative and regulatory steps that must be taken to utilize the precautionary principle—an idea at the center of public health analysis—in order to protect patients from harm.

AI and data-driven technologies have already been implemented at acute-care hospitals around the country.

The health care industry has been implementing various forms of artificial intelligence and other data driven technologies for a number of years. The nursing workforce is therefore uniquely situated to provide feedback and analysis on the impacts that these technologies have had on workers and on patients.

Technologies that have already been implemented include the clinical decision support systems embedded in electronic health records (EHRs), acute-care hospital-at-home and remote patient monitoring schemes, virtual acute-care nursing, automated worker surveillance and management (AWSM) and staffing platforms that support gig nursing, and increasingly, emerging technologies like generative AI systems.

Through our experiences working with and around these systems, it is clear to registered nurses that hospital employers have used these technologies in attempts

to outsource, devalue, deskill, and automate our work. Doing so increases their profit margins at the expense of patient care and safety.

Many of these technologies are ostensibly designed to improve patient care, but in fact they track the activities of health care workers and are designed to increase billing of patients and insurers. Automated monitoring technology feeds into algorithmic management systems that make unreasonable and inaccurate decisions about patient acuity, staffing, and care with the goal of lowering labor costs. As a result, nurses and other health care professionals are expected to work faster, accept more patients per nurse than is safe, and reduce nurses' use of independent professional skill and judgment. Tracking nurses is designed to facilitate routinization—breaking the holistic process of nursing into discrete tasks—with the goal of replacing educated registered nurses exercising independent judgment with lower-cost staff following algorithmic instructions.

Employers generally assert that these powerful technologies are just updates of older technology that has long been in the workplace, such as treating computer-vision aided cameras the same as traditional security cameras, or EHRs as electronic versions of old paper medical records. However, these technologies are much more than modern iterations of well understood tools and are being introduced widely despite lack of robust research showing safety, reliability, effectiveness, and equity. Rather, AWSM technologies pull vast and diverse data from an entire ecosystem of monitoring equipment and process this information through opaque algorithms that then make clinical and employment decisions. There is no current method for evaluating AI and no requirement for external validation; it is clear to nurses that AI technologies are being designed to be a replacement for skilled clinicians as opposed to a tool that many clinicians would find helpful.

A "nursing shortage" is often the justification for the deployment of this technology. However, the United States is not experiencing a nursing shortage, only a shortage of nurses willing to risk their licenses and the safety of their patients by working under the unsafe conditions the hospital industry has created. By deliberately refusing to staff our Nation's hospital units with enough nurses to safely and optimally care for patients, the hospital industry has driven nurses away from direct patient care. When we add the complete failure by the hospital industry to protect the health and safety of nurses and patients during the COVID pandemic, many nurses have made the difficult decision to stop providing hands-on nursing care to protect themselves, their nursing licenses, their families, and their patients.

Except for a small handful of states, there are sufficient numbers of registered nurses to meet the needs of the country's patients, according to a 2017 U.S. Department of Health and Human Services report on the supply and demand of the nursing workforce from 2014 to 2030.[1] Some states will even have surpluses. The report identifies an inequitable distribution of nurses across the country, rather than a nationwide shortage. In fact, there are 1.2 million RNs with active licenses that are not working as RNs across the United States, and the exodus of RNs from the hospital bedside is ongoing.[2]

AI and data-driven technologies are negatively impacting nursing practice and limiting the use of nurses' professional judgment. This is putting patients and nurses at risk.

Registered nurses have extensive education and clinical experience that enables us to provide safe, effective, and equitable patient care. These standards of nursing care can only be accomplished through continuous in-person assessments of a patient by a qualified licensed registered nurse. Every time an RN interacts with a patient, we perform skilled assessments and evaluations of the patient's overall condition. These assessments are fundamental to ensuring that the patient receives op-

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[1] Health Resources and Services Administration. 2017. "National and Regional Supply and Demand Projections of the Nursing Workforce: 2014–2030." U.S. Department of Health and Human Services. *https://bhw.hrsa.gov/sites/default/files/ bureau-health-workforce/data-research/ nchwa-hrsa-nursing-report.pdf.*

[2] NNU has several recent reports on the industry-created staffing crisis and the failure to provide a safe and health work environment. See Protecting Our Front Line: Ending the Shortage of Good Nursing Jobs and the Industry-created Unsafe Staffing Crisis available at: *https://www.nationalnursesunited.org/protecting-our-front-line-report*; Workplace Violence and COVID–19 in Health Care: How the Hospital Industry Created an Occupational Syndemic available at: *https://www.nationalnursesunited.org/sites/default/files/nnu/documents/1121—WPV—HS—Survey—Report—FINAL.pdf*; and Deadly Shame: Redressing the Devaluation of Registered Nurse Labor Through Pandemic Equity available at: *https://www.nationalnursesunited.org/campaign/deadlyshame-report.*

timal care. Health care is not one-size-fits-all. Nurses must be able to alter expected treatment plans based on the unique circumstances of the patient and the patient's wishes and values and to use their experience and nursing judgment to provide the best course of care. Indeed, we are ethically and legally required to do so. We should not be pressured by management to conform to decisions made by algorithms that are prone to racial and ethnic bias as well as other errors that arise when one applies information that may apply to a population but not to individual patients.

We are already experiencing the degradation and devaluation of our nursing practice through the use of technologies that have been implemented in recent years. For example, health care employers are using EHRs to replace RN judgment by automating the creation of nursing care plans and assigning patient acuity levels. RNs develop the nursing skill and judgment necessary to accurately evaluate a patient and create an effective care plan through education and experience in the clinical setting. That human skill and judgment cannot be replaced by an algorithm without serious consequences for safe patient care.

The highly skilled work of a registered nurse, by its very definition, cannot be automated. When hospital employers use technology to override and limit the professional judgment of nurses and other health care workers, patients are put at risk. In fact, patients have already been harmed by AWSM systems, including at least four deaths in the VA health care system linked to errors made by Cerner's electronic health records. [3]

One example that illustrates this risk can be found in efforts to decrease the incidence of sepsis, a complication from infection that carries a high degree of mortality. [4] One AI Early Warning System (EWS) analyzed patient data with the goal of identifying patients with a substantial risk of developing sepsis. The EWS was widely implemented at hundreds of hospitals throughout the country. [5] However, when this sepsis EWS underwent external validation, researchers found that the program missed over 67 percent of sepsis cases. [6] The authors of this study concluded of the EWS that "it appears to predict sepsis long after the clinician has recognized possible sepsis and acted on that suspicion."

Employers are also using AI to side-step vital RN-to-RN communication during patient hand-off and transfer of duty and to automate patient assignments. Patient transfers are one of the most dangerous points in a patient's care. Disruptions in communication can lead to life-threatening errors and omissions. Our nurses report that AI-generated communication leaves out important information while overburdening nurses with information that is not essential, forcing nurses to waste precious time searching medical records for information that could have been completely and accurately communicated during a brief person-to-person interaction. The use of AI to automate patient transfers has resulted in patients being sent to the wrong level of care because an RN was not involved in comparing the patients' needs with the resources available on the unit. This automation has also resulted in situations where patients were transferred to a room, and the RN did not know that they were there.

This removal of human communication puts both nurses and patients at risk. At one member's hospital in Michigan, the AI system's failure to relay basic information, such as the patient being positive for COVID or the patient having low white blood cell counts, have resulted in nurses needlessly exposing themselves to the virus or immunocompromised patients being placed on COVID or flu units.

We have grave concerns about the fundamental limits on the ability of algorithms to meet the needs of individual patients, especially when those patients are part of

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[3] Rodriguez, S. (2023, March 21) VA Admits Oracle Cerner EHRM Issues Contributed to 4 Veteran Deaths. EHR Intelligence, Adoption and Implementation News. *https://ehrintelligence.com/news/va-admits-oracle-cerner-ehrm-issues-contributed-to–4-veteran-deaths.* Accessed October 28, 2023.

[4] Leng, Y., Gao, C., Li, F., Li, E., & Zhang, F. (2022). The Supportive Role of International Government Funds on the Progress of Sepsis Research During the Past Decade (2010–2019): A Narrative Review. Inquiry : a journal of medical care organization, provision and financing, 59, 469580221078513. *https://doi.org/10.1177/00469580221078513.*

[5] Wong, A., Otles, E., Donnelly, J. P., Krumm, A., McCullough, J., DeTroyer-Cooley, O., Pestrue, J., Phillips, M., Konye, J., Penoza, C., Ghous, M., & Singh, K. (2021). External Validation of a Widely Implemented Proprietary Sepsis Prediction Model in Hospitalized Patients. JAMA Internal Medicine, 181(8), 1065–1070. *https://doi.org/10.1001/jamainternmed.2021.2626.*

[6] Schertz, A. R., Lenoir, K. M., Bertoni, A. G., Levine, B. J., Mongraw-Chaffin, M., & Thomas, K. W. (2023). Sepsis Prediction Model for Determining Sepsis vs SIRS, qSOFA, and SOFA. JAMA Network Open, 6(8), e2329729-e2329729. *https://doi.org/10.1001/jamanetworkopen.2023.29729.*

racial or ethnic groups that are less well represented in the data. Nurses know that clinical algorithms can interfere with safe, therapeutic health care that meets the needs of each individual patient. While clinical algorithms may purport to be an objective analysis of the scientific evidence, in fact their development involves significant use of judgment by their creators and creates the opportunity for creator bias—from conflicts of interest, limited perspective on the lives of racial minorities, or implicit racial bias—to be introduced into the algorithm.

Even under optimal conditions, clinical algorithms are based on population-level data and are not appropriate for every patient. In addition, the way clinical algorithms are implemented, regardless of how they are created, often inappropriately constrains the use of health care professionals' judgment, which can worsen the impact of a biased algorithm. It is essential that the use of race or ethnicity in clinical algorithms is scrutinized, including whether race or ethnicity are serving as proxies for other factors that should be identified explicitly. However, it will not be possible to eliminate the use of judgment or the need for individual assessment in care decisions. These judgments should be made at the bedside between the patient and their health care provider, not by a committee based on population-level data.

The deployment of artificial intelligence should be subjected to the Precautionary Principle test.

Nurses believe that we must approach any change in health care using the precautionary principle; the proposition that, as Harvard University Professor A. Wallace Hayes explains, "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically."

The deployment of artificial intelligence should be subjected to this precautionary principle test, especially when it comes to patient care. Policymakers must ensure that the burden of proof rests on healthcare employers to demonstrate that these technologies are safe, effective, and equitable under specific conditions and for the specific populations in which they are used, before they are tested on human beings. It is imperative that the usage and process of deployment be as transparent as possible, and that issues of liability are discussed early and often. As nurses, we believe it is unacceptable to sacrifice any human life in the name of technological innovation. Our first duty is to protect our patients from harm, and we vehemently oppose any risk to patient health or safety and quality of care inflicted by unproved, untested technology.

Nothing about artificial intelligence is inevitable. How AI is developed and deployed is the result of human decisions, and the impacts of AI—whether it helps or harms health care workers and the patients we serve—depends on who is making those decisions. To safeguard the rights, safety, and well-being of our patients, the healthcare workforce and our society, workers and unions must be involved at every step of the development of data-driven technologies and be empowered through strengthened organizing and bargaining rights to decide whether and how AI is deployed in the workplace.

NNU urges the Federal Government to pursue a regulatory framework that safeguards the clinical judgment of nurses and other health care workers from being undermined by AI and other data-driven technologies.

NNU recommends that Congress take the following actions:

1. **All statutes and regulations must be grounded in the precautionary principle.** NNU urges Congress to develop regulations that require technology developers and health care providers to prove that AI and other data-driven digital technologies are safe, effective, and therapeutic for both a specific patient population and the health care workforce engaging with these technologies before they are deployed in real-world care settings. This goes beyond racial, gender, and age-based bias. As each patient has unique traits, needs, and values, no AI can be sufficiently fine-tuned to predict the appropriate diagnostic, treatment, and prognostic for an individual patient. Liability for any patient harm associated with failures or inaccuracies of automated systems must be placed on both AI developers and health care employers and other end users. Patients must provide informed consent for the use of AI in their treatment, including notification of any clinical decision support software being used.

2. **Privacy is paramount in health care—Congress must prohibit the collection and use of patient data without informed consent, even in so-called deidentified form.** There are often sufficient data

points to reidentify so-called de-identified patient information. Currently, health care AI corporations institute gag clauses on users' public discussions of any issues or problems with their products or cloak the workings of their products in claims of proprietary information. Such gag clauses must be prohibited by law. Additionally, health care AI corporations and the health care employers that use their products regularly claim that clinicians' right to override software recommendations makes them liable for any patient harm while limiting their ability to fully understand and determine how they are used. Thus, clinicians must have the legal right to override AI. For nurses, this means the right to determine nurse staffing and patient care based on our professional judgment.

3. Patients' informed consent and the right to clinician override are not sufficient protections, however. **Nurses must have the legal right to bargain over the employer's decision to implement AI and over the deployment and effects of implementation of AI in our workplace.** In addition to statutes and regulations codifying nurses' and patients' rights directly, Congress needs to strengthen workers' rights to organize, collectively bargain, and engage in collective action overall. Health care workers should not be displaced or deskilled as this will inevitably come at the expense of both patients and workers. At the regulatory level, the Centers for Medicare and Medicaid Services must require health care employers to bargain over any implementation of AI with labor unions representing workers as a condition of participation.

4. **Congress must protect workers from AI surveillance and data mining.** Congress must prohibit monitoring or data mining of worker-owned devices. Constant surveillance can violate an employee's personal privacy and personal time. It can also allow management to monitor union activity, such as conversations with union representatives or organizing discussions, which chills union activity and the ability of workers to push back against dangerous management practices. The Federal Government must require that employers make clear the capabilities of this technology and provide an explanation of how it can be used to track and monitor nurses. Additionally, Congress must prohibit the monitoring of worker location, data, or activities during off time in devices used or provided by the employer. Employers should be restricted from collecting biometric data or data related to workers' mental or emotional states. Finally, employers should be prohibited from disciplining an employee based on data gathered through AI surveillance or data mining, and AI developers and employers should also be prohibited from selling worker data to third parties.

Thank you again for inviting me to participate in this discussion. These comments are by no means an exhaustive list of concerns. National Nurses United looks forward to future conversations on this topic, and to working with Congress to ensure that the Federal Government develops effective regulations that will protect nurses and patients from the harm that can be caused by artificial intelligence and data-driven technologies in health care.

NATIONAL NURSES UNITED,
WASHINGTON, DC,
November 8, 2023.

Hon. ED MARKEY, Chairman,
Hon. ROGER MARSHALL, Ranking Member,
U.S. Senate Committee on Health, Education, Labor, and Pensions,
428 Senate Dirksen Office Building,
Washington, DC 20510.

DEAR CHAIRMAN MARKEY, RANKING MEMBER MARSHALL, AND MEMBERS OF THE COMMITTEE:

In light of the Committee's hearing today on "Avoiding a Cautionary Tale: Policy Considerations for Artificial Intelligence in Health Care," I write to you on behalf of National Nurses United, the nation's largest union and professional association of registered nurses (RNs) to discuss the ways that our nearly 225,000 members are already experiencing the impacts of artificial intelligence (AI) and data-driven technologies at the hospital bedside.

The decisions to implement these technologies are often made without the knowledge of either nurses or patients, and are putting patients and the nurses who care for them at risk. AI technology is being used to replace educated registered nurses exercising independent judgment with lower-cost staff following algorithmic instructions. However, patients are unique and health care is made up of non-routine situations that require human touch, care, and input. AI poses significant risks to patient care and to nursing practice, and all legislative and regulatory steps taken must utilize the precautionary principle—an idea at the center of public health analysis—in order to protect patients from harm.

NNU urges the Federal Government to pursue a regulatory framework that safeguards the clinical judgment of nurses and other health care workers from being undermined by AI and other data-driven technologies. NNU recommends that Congress take the following actions:

- All statutes and regulations must be grounded in the precautionary principle. NNU urges Congress to develop regulations that require technology developers and health care providers to prove that AI and other data-driven digital technologies are safe, effective, and therapeutic for both a specific patient population and the health care workforce engaging with these technologies before they are deployed in real-world care settings.
- Privacy is paramount in health care—Congress must prohibit the collection and use of patient data without informed consent, even in so-called deidentified form, as there are often sufficient data points to reidentify so-called de-identified patient information.
- Nurses must have the legal right to bargain over the employer's decision to implement AI and over the deployment and effects of implementation of AI in our workplace. In addition to statutes and regulations codifying nurses' and patients' rights directly, Congress needs to strengthen workers' rights to organize, collectively bargain, and engage in collective action overall.
- Congress must protect workers from AI surveillance and data mining. Congress must prohibit monitoring or data mining of worker-owned devices. Constant surveillance can violate an employee's personal privacy and personal time. It can also allow management to monitor union activity, such as conversations with union representatives or organizing discussions, which chills union activity and the ability of workers to push back against dangerous management practices.
- Congress must prohibit the monitoring of worker location, data, or activities during off time in devices used or provided by the employer. Employers should be restricted from collecting biometric data or data related to workers' mental or emotional states.

These comments are by no means an exhaustive list of concerns, and I am attaching to this letter recent testimony that was given by our Executive Director, Bonnie Castillo, RN, at Majority Leader Schumer's most recent AI Insight Forum. National Nurses United looks forward to future conversations on this topic, and to working with Congress to ensure that the Federal Government develops effective regulations that will protect nurses and patients from the harm that can be caused by artificial intelligence and data-driven technologies in health care.

Sincerely,

AMIRAH SEQUEIRA,
National Government Relations Director,
National Nurses United.

PREMIER INC, WRITTEN STATEMENT FOR THE RECORD

On behalf of Premier Inc. and the providers we serve, we thank the leadership of the Committee on Health, Education, Labor, and Pensions for their commitment to examining the ways in which technology can be leveraged in healthcare to reduce costs, improve quality and access, alleviate workforce shortages and advance health equity. Premier appreciates the opportunity to share our recommendations and insights related to the role of Artificial Intelligence (AI) in healthcare and looks forward to working with Congress on these issues.

I. Background on Premier Inc.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,350 U.S. hospitals and approximately 300,000 continuum of care providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, NC, Premier is passionate about transforming American healthcare.

Premier is already leveraging AI to move the needle on cost and quality in healthcare, including:

- Stanson Health, a subsidiary of Premier, designs technology to reduce low-value and unnecessary care. Stanson leverages real-time alerts and relevant analytics to guide and influence physician's decisions through clinical decision support technology, providing higher-quality, lower-cost healthcare. Stanson's mission is to measurably improve the quality and safety of patient care while reducing the cost of care by enabling context-specific information integrated into the provider workflow.
- Premier's PINC AI Applied Sciences (PAS) is a trusted leader in accelerating healthcare improvement through services, data, and scalable solutions, spanning the continuum of care and enabling sustainable innovation and rigorous research. These services and real-world data are valuable resources for the pharmaceutical, device and diagnostic industries, academia, Federal and national healthcare agencies, as well as hospitals and health systems. Since 2000, PAS researchers have produced more than 1,000 publications which appear in 264 scholarly, peer-reviewed journals, covering a wide variety of topics such as population-based analyses of drugs, devices, treatments, disease states, epidemiology, resource utilization, healthcare economics and clinical outcomes.
- Conductiv, a Premier purchased services subsidiary, harnesses AI to help hospitals and health systems streamline contract negotiations, benchmark service providers and manage spend based on historical supply chain data. Conductiv also works to enable a healthy, competitive services market by creating new opportunities for smaller, diverse suppliers and helping hospitals invest locally across many different categories of their business.

Premier has thought critically about the potential legislative and regulatory framework for AI in healthcare and recently published an Advocacy Roadmap for AI in Healthcare.[1] While Premier believes that AI can and should play a critical role in advancing healthcare and spurring innovation, Premier also believes that AI cannot and should not replace the practice of medicine

Additional detailed comments and recommendations, based on our depth of experience in using AI in healthcare, are included below.

II. Protecting Patient Rights, Safety and National Security

Premier supports the responsible development and implementation of AI tools across all segments of American industry—particularly in the healthcare industry—where numerous applications of this technology are already improving patient outcomes and provider efficiency. Premier sees a defined role for Congress in advancing clear statutory guidelines that will allow providers and payers to deploy AI technology to its full potential, while still protecting individual rights and safety.

Premier strongly supports AI policy guardrails that include standards around transparency and trust, bias and discrimination, risk and safety, and data use and privacy.

Promoting Transparency

Trust—among patients, providers, payers and suppliers—is critical to the development and deployment of AI tools in healthcare settings. To earn trust, AI tools must have an established standard of transparency. Recent policy proposals, including *those proffered by the Office of the National Coordinator for Health Information*

[1] See Appendix A.

Technology (ONC), suggest transparency can be achieved through a "nutrition label" model. This approach seeks to demystify the black box of an AI algorithm by listing the sources and classes of data used to train the algorithm. Unfortunately, some versions of the "nutrition label" approach to AI transparency fail to acknowledge that when an AI tool is trained on a large, complex dataset, and is by design intended to evolve and learn, the initial static inputs captured by a label do not provide accurate insights into an ever-changing AI tool. Further, overly intrusive disclosure requirements around data inputs or algorithmic processes could force AI developers to publicly disclose intellectual property or proprietary technology, which would stifle innovation.

Premier recommends that AI technology in healthcare should be held to a standardized, outcomes-focused set of metrics, such as accuracy, bias, false positives, inference risks, recommended use and other similarly well-defined values. Outcomes, rather than inputs, are where AI technologies hold potential to drive health or harm. Thus, Premier believes it is essential to focus transparency efforts on the accuracy, reliability and overall appropriateness of AI technology outputs in healthcare to ensure that the evolving tool does not produce harm.

Mitigating Risks

It is important to acknowledge potential concerns around biased or discriminatory outcomes resulting from the use of AI tools in healthcare, as well as potential concerns around patient safety. Fortunately, there are several best practices that Premier and others at the forefront of technology are already following to mitigate these risks. First, we reiterate Premier's recommendation for standardized, outcomes-based assessments of AI technologies' performance, which would **hold AI developers and vendors responsible for monitoring for any biased outcomes.** Performance reporting could incorporate results from disparity testing before and after technology deployment to ensure that bias stays out of the AI "machinery."

Premier also supports the development of a standardized risk assessment, drawing on the extensive groundwork already laid by the National Institute of Standards and Technology (NIST) in the AI Risk Management Framework. An AI risk assessment should identify potential risks that the AI tool could introduce, potential mitigation strategies, detailed explanations of recommended uses for the tool and risks that could arise should the tool be used inappropriately. Premier urges Congress to consider a nuanced approach to risk level classification for the use of AI tools in healthcare. While there are some clinical applications of AI technology that could be considered high risk, it is certainly true that not all healthcare use cases carry the same level of risk. For example, the use of AI technology to reduce administrative burden or improve workflow in a hospital carries a much different level of risk and very different safety considerations than the use of AI technology to treat patients. Premier also supports the development of standardized intended use certifications or reporting requirements for AI technologies, which would prevent new systems from producing harmful outcomes due to use outside of the technology's design.

Finally, Premier understands the importance of data standards, responsible data use and data privacy in the development and deployment of AI technology. Data standards should specifically focus on objective assessment of potential sources of bias or inaccuracy introduced through poor dataset construction, cleaning or use. These may include, but are not limited to, appropriately representative datasets, bias in data collection (e.g., subjectivity in clinical reports) or introduced by instrument performance or sensitivity (e.g., pulse oximetry devices producing inaccurate measurements of blood oxygen levels in patients with darker skin), bias introduced during curation (e.g., datasets with systemically introduced nulls and their correlation, such as failure to pursue treatment due to lack of ability to pay), and training and test data that is appropriately applicable to various patient subpopulations (e.g., data that sufficiently represents symptoms or characteristics of a condition for each age/gender/race of patient that the tool will be used to treat). Premier also supports the establishment of guidelines for proper data collection, storage and use that protect patient rights and safety. This is particularly important given the sensitivity of health data.

III. Drug Research, Development and Manufacturing

One critical area where we would highlight the transformative potential of AI is drug research, development and production. Congress and the Administration must work collaboratively to pre-empt uncertainty and responsibly govern the deployment of emerging technologies in these areas in a patient-centered manner. Premier spe-

cifically recommends timely legislative and/or regulatory guidance for the use of AI in clinical trials and drug manufacturing.

Opportunities for AI in Clinical Trials

Premier sees particular promise for the use of AI in streamlining processes and expanding patient access in clinical trials.

Identifying trial participants: One of the biggest challenges facing health systems that seek to participate in or enroll patients in clinical trials is identifying and enrolling patients in a timely manner. Delays in meeting trial enrollment targets and timelines can increase the cost of the trial. AI tools have the ability to analyze the extensive universe of data available to healthcare systems in order to identify patients that may be a match for clinical trials that are currently recruiting. This application of natural language processing systems can make developing new drugs less expensive and more efficient, while also improving patient and geographical diversity in trials to address health equity.

Generating synthetic data: AI, once trained on real-world data (RWD), has the capability to generate *synthetic data* and patient profiles that share characteristics with the target patient population for a clinical trial. This synthetic data can be used to simulate clinical trials to optimize trial designs, model the possible effects or range of results of a novel intervention, and predict the statistical significance and magnitude of effects or biases. Ultimately, synthetic patient data can help optimize trial design, improve safety and reduce cost for decentralized clinical trials. Further, synthetic control arms in clinical trials can help increase trial enrollment by easing patient fears that they will receive a placebo. To encourage continued innovation, clear guidance is needed from Congress and/or the Food and Drug Administration (FDA) on the process for properly obtaining consent from patients for the use of their RWD to produce AI-generated synthetic control arms in clinical trials.

Opportunities for AI in Drug Manufacturing

Premier sees potential for AI to transform at least three key segments of the drug manufacturing process: component supply chain, advanced process control, and quality monitoring.

Supply chain visibility: Premier believes the application of AI can advance national security by helping build a more efficient and resilient healthcare supply chain. Specifically, AI can enable better demand forecasting for products and services, such as drug components, through analysis of historical and emerging clinical and patient data. As the COVID–19 pandemic demonstrated, the ability to understand and react to shortages poses a critical challenge to healthcare providers; AI enables better planning and response time to national or regional emergencies. AI can drive better inventory management by automating the monitoring and replenishment of inventory levels. Healthcare providers can leverage AI to better manage suppliers through faster more efficient contracting processes and by monitoring of supplier key performance metrics. As Premier works to combat drug shortages, the most effective remedies begin with supply chain visibility and reliable predictions that allow manufacturers to plan for and respond to shortages or disruptions—this crucial element of the drug manufacturing process presents a key value-add opportunity for AI technology.

Advanced process control: Another significant value-add for AI in the drug manufacturing process is in the development and optimization of advanced process control systems (APCs). Process controls typically regulate conditions during the manufacturing process, such as temperature, pressure, feedback and speed. However, a recent report found that industrial process controls are overwhelmingly still manually regulated, and less than 10 percent of automated APCs are active, optimized and achieving the desired objective. These technologies are now ready to transform drug manufacturing on a commercial scale; however, challenges still remain to widespread adoption. Premier strongly believes that the FDA should issue clear guidance that supports the industry-wide transition to AI-powered APCs. Such technologies offer drug manufacturers the opportunity to assess the entire set of input variables and the effect of each on system performance and product quality, automating plant-wide optimization. This application of AI technology can transform the physical manufacturing of drugs and pharmaceuticals, leading to cost-savings and increased resiliency, transparency and safety in the drug supply chain.

Quality monitoring: AI can also provide value-add to drug manufacturing in the field of quality monitoring and reporting. Current manufacturing processes provide an immense volume of data from imagers and sensors that, if processed and ana-

lyzed more quickly and efficiently, could transform approaches to safety and quality control. AI models trained on this data can be used to predict malfunctions or adverse events. AI can also perform advanced quality control and inspection tasks, using data feeds to quickly identify and correct product defects or catch quality issues with products on the manufacturing line. Taken together, these capabilities can improve both the accuracy and speed of inspections and quality control, helping companies to reliably meet regulatory requirements and avoid costly delays that disrupt the drug supply chain.

IV. Training the Healthcare Workforce of the Future

Premier believes technology can and should work alongside and learn from healthcare professionals, **but current technology will not and should not replace the healthcare workforce.**

To ensure clinical validity and protect patients, Premier reiterates the importance of comprehensive risk assessments, recommended use, and trainings that combat automation bias and incorporate human decisionmaking into the use of AI technology in healthcare. The risks and safety concerns around AI technology are unique to each use case, and Premier supports the requirement of a risk assessment and mitigation plan specific to the level of risk associated with the use case. Premier also supports the development of standardized intended use certifications or reporting requirements for AI technologies, which would prevent new systems from producing harmful outcomes due to use outside of the technology's design.

Premier acknowledges the risks of automation bias and fully automated decisionmaking processes. To reduce these risks, promote trust in AI technologies used in healthcare and achieve the goal of supporting the healthcare workforce through AI, **Premier recommends that healthcare workforce training programs provide comprehensive AI literacy training**. Healthcare workers deal with high volumes of incredibly nuanced data, research and instructions—a growing percentage of which may be supplied by AI. This is particularly true for applications of AI in drug development, where manufacturers and quality control specialists may be reviewing high volumes of AI-powered recommendations or insights and making rapid decisions that affect the safety of patients. By ensuring our healthcare workers understand how to evaluate the most appropriate AI use cases and appropriate procedures for evaluating the accuracy or validity of AI recommendations, we can maximize the advisory benefit of AI while mitigating the risk to patients and provider liability. Additionally, clear, risk-based guidance on which uses of AI technology in healthcare require human review and decisionmaking is essential.

Additionally, watermarking or provenance data/systems for AI-generated content were a component of the voluntary commitments *recently announced* by the Administration. Premier generally supports the development of similar metrics for scientific research or clinical decision support recommendations produced by AI technology. It is important that patients, scientists, drug manufacturers and medical professionals understand when decisions or recommendations are made by AI so they can consciously respond and evaluate the new information accordingly.

Specifically, watermarking is one potential strategy to combat automation bias, a risk especially pertinent to the use of AI technology in healthcare. Automation bias refers to human overreliance on suggestions made by automated technology, such as an AI device. This tendency is often amplified in high-pressure settings that require a rapid decision. The issue of automation bias in a healthcare setting is discussed at length by the FDA in *guidance* on determining if a clinical decision support tool should be considered a medical device. Premier suggests that future guidance or standards for the use of AI should consider automation bias in risk assessments and implementation practices, such as workforce education and institutional controls, to minimize the potential harm that automation bias could have on patients and vulnerable populations, including to mitigate any potential risk of AI used in unintended settings or built on biased datasets. In the drug manufacturing process, it is important that workers evaluating a supply chain disruption prediction, optimization recommendation, or quality control report know that the data or recommendation is AI-generated and evaluate it effectively.

V. Conclusion

In closing, Premier appreciates the opportunity to share comments on the topic of AI and its role in healthcare. If you have any questions regarding our comments, or if Premier can serve as a resource on these issues to the Committee in its policy development, please contact Mason Ingram, Director of Payer Policy, at *Mason—Ingram@premierinc.com* or 334–318–5016.

Skilled Nursing Facility

nH Predict | Outcome

DOB: Gender:
Admit Date: 06/05/2023

This report applies analytics modeling methods. You should always consider patient needs and conditions when using this report.

Likelihood of Hospital Admission from SNF in less than 30 days: 35% (High)

Patient Evaluation	Basic Mobility	Daily Activity	Applied Cognition	Total Average Score
Impairment Group: Pulmonary Diagnostic Group: COPD Primary Dx: J44.1-CHRONIC OBSTRUCTIVE PULMONARY DISEASE WITH (ACUTE) EXACERBATION Usual Living Setting: Home with Family/Friend Functional Comorbidity Index: 3 - Active, system disease limiting function Medical Adjuster(s): None	E.g. Transfers, ambulation, stairs, wheelchair skills	E.g. Bathing, toileting, dressing, eating (ADL/IADL)	E.g. Memory, communication, problem solving	Average of Basic Mobility, Daily Activity, and Applied Cognition scores
Admission Function	32 0 ... 100 Max A to Mod A	33 0 ... 100 Mod A to Min A	63 0 ... 100 Close/Frequent Supervision	43 0 ... 100 Mod A to Min A
SNF Outcomes Prediction (Average)	40 Mod A to Min A	45 SU/Supervision/SBA to Mod I	65 Close/Frequent Supervision	50 Min A to SU/Supervision/SBA
Projected non-skilled caregiver needs post SNF	3.25 Hours/Day	1.25 Hours/Day	Frequent	4.5 Hours/Day

Actual Discharge Setting After SNF of Similar Patients

Home Alone	5%
Home with Care	49%
Assisted Living	13%
Long Term Care	33%

Anticipated Length of Stay in Days*: 14.2 — 16.0 Avg. — 17.8

Projected SNF Discharge: 6/21/2023

Therapy:
Cycle: 14.3 Days on Average
487 Minutes per Week
5x/week: 97 minutes/day
6x/week: 81 minutes/day
7x/week: 70 minutes/day

Clinical Considerations: High (>25%) readmission alert.

naviHealth

DOB: Gender:
Admit Date: 06/05/2023

nH Predict | Outcome

The Report

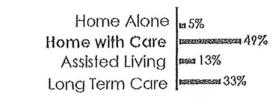
Your goal is our goal -- to return to the community as quickly and safely as possible. We have gathered your information and compared that against thousands of patients, similar to you, to understand what outcomes you may achieve with therapy. This report will give you an idea of what you may be able to do after therapy and how much assistance you may need.

Your Care Coordinator is: _____

Your Journey

Following therapy, patients like you have experienced the following:

Actual Discharge Setting After Skilled Nursing Facility of Similar Patients



Basic Mobility

You may need a lot (more than 50%) of physical assistance with such activities as walking, climbing and transfers inside your home.

Caregiver Assistance Needs after Skilled Nursing Facility:
3.25 Hours/Day

Daily Activity

You may need a little (less than 25%) physical assistance with such activities as grooming, dressing or bathing.

Caregiver Assistance after Skilled Nursing Facility:
1.25 Hours/Day

Applied Cognition

You may have difficulties with conversations or reading and doing such complicated activities as medication management, using a map or preparing a meal. You may require frequent supervision.

Caregiver Assistance Needs after Skilled Nursing Facility:
Frequent

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naviHealth

nH Predict | Outcome

DOB: Gender:
Admit Date: 06/05/2023

Your Care Skilled Nursing Facility

Your care will be based on your individual needs. Similar patients have experienced the following:

Target Discharge Date:	6/21/2023	Anticipated length of stay:	14 - 18 Days
Therapy:	8.0 Hours/Week	**High likelihood of hospital admission from the Skilled Nursing Facility within 30 days**	

Our Expertise

naviHealth works with your care team to help coordinate care and support clinical decision making. We draw upon the knowledge of experienced licensed clinicians. Using data from a patient database of over 3 million records, we help set realistic goals with you based upon what other patients like you have been able to achieve.

www.navihealth.com

Notes/Barriers to Discharge:

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naviHealth

PREMIER

PREMIER'S ADVOCACY ROADMAP FOR THE 118TH CONGRESS: ARTIFICIAL INTELLIGENCE IN HEALTHCARE

Premier supports the responsible development and implementation of artificial intelligence (AI) tools across the healthcare industry, where AI is already demonstrating its ability to help improve patient outcomes and provider efficiency. AI holds great potential for empowering the healthcare workforce, mitigating supply chain shortages, advancing health equity and driving higher-quality care. While Premier embraces AI's potential, we also acknowledge that trust – among patients, providers, payers, policymakers and suppliers – is critical for the responsible adoption of AI tools in healthcare settings. To earn trust, AI tools must be subject to clear statutory, regulatory and subregulatory guidelines that ensure transparency and protect individual rights and safety.

While Premier believes that AI can and should play a critical role in advancing healthcare and spurring innovation, Premier also believes that AI cannot and should not replace the practice of medicine.

OPTIMIZING THE VALUE OF HEALTHCARE

Providers, both acute and non-acute, continue to experience significant fiscal challenges stemming from a combination of increased labor costs, record inflation and lagging reimbursement rates that do not account for these unprecedented financial challenges.

Promote the use of AI in value-based care to amplify delivery system transformation. AI tools hold immense potential for identifying the highest-risk patient populations, as well as the best ways to deploy clinical resources to serve them. Innovative payment models allow resource flexibility to invest in technology such as AI to shift the paradigm of population health management.

Advance the use of AI in healthcare quality programs and measurement. Providers, payers and the federal government can all benefit from technology resources that look deeper than descriptive data. Premier will continue to work with our federal partners to demonstrate transformative use cases for AI in Medicare and other quality programs.

Create opportunities for AI to support the overburdened healthcare workforce. Premier will advocate for federal healthcare workforce programs that leverage AI to identify root causes of healthcare workforce shortage and train the clinical workforce on how to best leverage AI technology to optimize workflows and patient care.

BUILDING RESILIENT HEALTHCARE SUPPLY CHAINS

Premier advocates for policies that create visibility and transparency into the healthcare supply chain. Premier's goal is to ensure that every provider in the country has access to the right product, at the right time, at the right quality and at the right price for patient care.

Advance the use of AI to provide visibility into drug and medical supply chains. Premier will advocate for federal programs and financial incentives to increase the use of AI for medical supply chain insights, including the source of raw materials, to enhance national security and preparedness.

Provide AI-driven insights to build resilient supply chains. Premier will operationalize AI insights to inform federal policymaking and preparedness while bolstering supply chain resiliency, including strengthening supply chain integrity.
Leverage AI-driven tools to predict drug and device shortages. Premier will operationalize AI insights to inform federal policymaking related to drug and device shortages, including opportunities for the Food and Drug Administration (FDA) to leverage private sector AI algorithms to proactively predict shortages.

Incorporate AI into advanced manufacturing techniques. Premier will advocate for policies that support the incorporation of AI into advanced manufacturing techniques to support diversification of supply chains and manufacturing resiliency.

TECH-ENABLING HEALTHCARE

Premier advocates for policies to advance technology that will enhance patient safety and quality improvement, facilitate secure and timely communication and data exchange among healthcare stakeholders, and produce actionable and reportable data.

Improve trust and transparency for healthcare AI solutions. Premier will pursue trustworthy AI standards, including transparency in algorithmic decision-making, focusing accountability on the outputs and outcomes of AI technology.

Encourage AI innovation and competition. Premier will work with government partners to encourage policies that promote innovation in AI and the ability of U.S. companies to compete with international counterparts.

Support the use of clinical decision support technology. Premier will advocate for federal policies that advance the adoption of clinical decision support technologies, including continued support for accelerated approvals for physician-developed tools.

ELIMINATING GAPS IN HEALTHCARE

Premier advocates for policies that address the disparities in access to and quality of healthcare experienced by vulnerable communities and populations.

Support innovation in clinical trial recruitment and operations, ensuring all populations have access to breakthrough medical technology. Premier will work with the FDA to ensure clear and consistent guidance allowing for innovative uses of AI to identify and recruit patients for trials, construct control arms using real-world data, and develop synthetic data to improve trial design and safety.

Support the incorporation of novel digital endpoints into clinical trials. Premier will work with the FDA and industry partners to find ways to harness the analytical power of AI to incorporate novel digital endpoints and previously unavailable inferences into clinical trials, strengthening evidence available about new drugs and devices.

Prevent bias from hindering AI's effectiveness. Premier will work across government and industry to incorporate standards and regulations designed to detect and prevent bias in AI systems, including data standards, ongoing disparity testing, quality controls and outcome monitoring, and a risk-based framework for AI deployment in healthcare.

Click here to download Premier's Advocacy Roadmap.

For more information on Premier's advocacy agenda, please contact:
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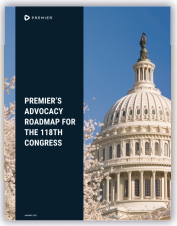

[Whereupon, at 4:17 p.m., the meeting was adjourned.]

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