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Z. Opening the Pod Bay Doors: The Impact of Artificial Intelligence on Program Integrity

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"Sir, in this audience, let my disclaiming from a purpos'd evil free me so far in your most generous thoughts that I have shot my arrow o'er the house and hurt my brother."
- *Hamlet, Act 5, Scene 2*

Disclaimer: *The views and opinions expressed in this presentation are my own and do not necessarily reflect the official policy or position of the American Medical Association.*

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The Slide that Tells You About All the Other Slides

- What?
- How?
  - Natural Language Processing
  - Machine Learning
- Challenges

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DANGER, DANGER ATTENDEES!

- I'm speaking in generalities for purposes of this 30 minute presentation.
- Many, many ways to splice, dice, and define artificial intelligence, its methods, and the related processes/algorithms.
- Thank you for your understanding!

What?

- Artificial Intelligence
- Augmented Intelligence
- Machine Intelligence
- Computational Intelligence
- General/Specific AI
- Strong/Weak AI
- Data Science/informatics
- Turing Test?
- Ability of a computer to complete tasks in a manner typically associated with a rational human being
- Iterative processing
- Helps automate processes

How?

- Many methods of AI
- Processes made up of algorithms
  - A series of actions, instructions, or steps taken in order to achieve a particular end
  - Iterative, potentially iterative, rules-based

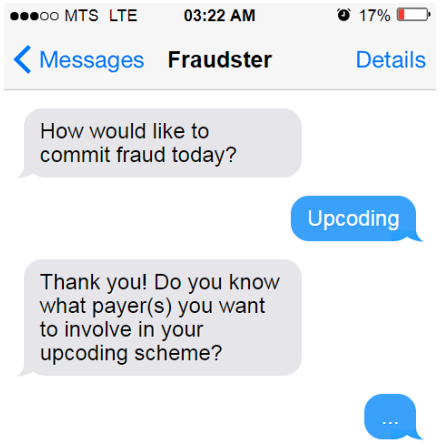
How?

Impact:

- *Adapts to changing behaviors in a population through automated model building (compare: rules-based approach can be reversed-engineered)*
- *Uncover unknown fraud schemes*
- *Discover new fraud trends*
- *Ability to predict future data*

Natural Language Processing

- Interaction between computer and natural (human) languages
- Filing the gap between human communication and computer understanding
- How to process and analyze large amounts of natural language data



Natural Language Processing

Impact:

- *Capacity to process and understand more natural language than humans. Automate data collection and integration.*
- *Ability to take vast amounts of unstructured health care data (EHRs) and provide consistent meaning (semantics).*
- *Comparing patient data with claims data or clinical standards to provide analytics into patient care (or false billing)*

Caveat: Not there yet!

- *High error rate of speech recognition in the medical field.*

Natural Language Processing

Examples:

- *Program Gatekeeping*
- *Sound Payment*
- *Compliance*
- *Monitoring*

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Machine Learning

- Giving computers the ability to learn without being explicitly program (to learn on its own)
- Algorithms use computational methods to "learn" information directly from data without relying on a predetermined equation as a model
- The algorithms adaptively improve their performance as the number of samples available for learning increases

3 – 9

4 – 16

8 – 64

9 – ?

- Find patterns in data
- Get insights
- Predict the unknown for better decisions

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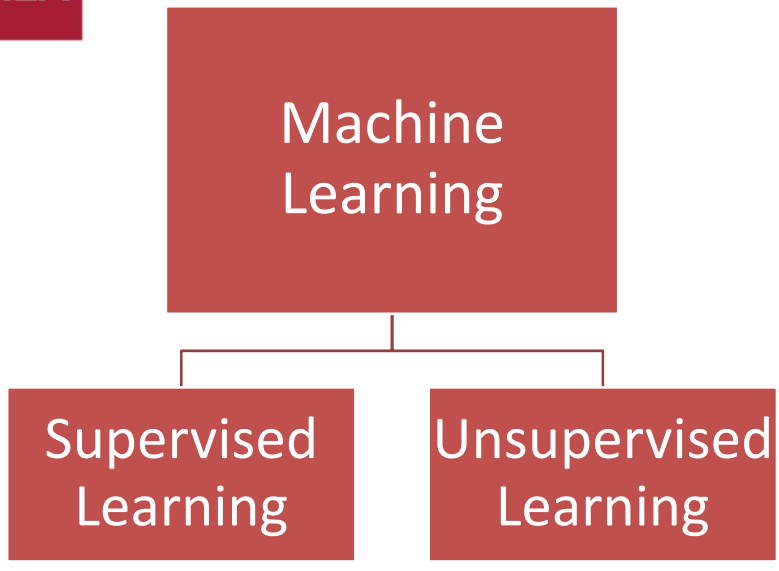

ML's Impact

Impact:

- *Automate workflow by prioritizing cases, recommending investigative steps, and expediting straightforward cases.*
- *Ability to encode large numbers of conditions, variables, and events into models and detect things that rules and human analysts would miss.*

Machine Learning

Examples:

- *Program Gatekeeping*
- *Sound Payment*
- *Compliance*
- *Monitoring*

Challenges: Data and Patient Safety

- Only as good as the data
- Humans
- Perpetuate bias that impacts care
- Cybersecurity

Data

Impact:

- *Data = $$$$ and humans like $$$$*
- *Focus not only on the accuracy, validity, and reliability of data but also the impact of the data on individual patient care*
- *What is not included in the data and how it affects decisions and recommendations*
- *Ability to re-identify de-identified data*

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POP QUIZ: Train or not?

Fresh Media News

Daily updates of the hidden things

THE WORLD TODAY | POLITICS | VIDEOS | SPORT

'The Largest Bust in U.S. History' 412 Muslims Arrested from Michigan!

The state of Michigan is quickly turning into a Sharia swamp, thanks to the reckless immigration policies of Obama over the past 8 years. Not only are portions of Michigan being transformed into a "mini Baghdad," but the state is also being overrun with rampant illegal activity, where the Muslim populace is constantly being busted in welfare fraud and disgusting mutilation practices on little girls.

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Challenges: Black Box

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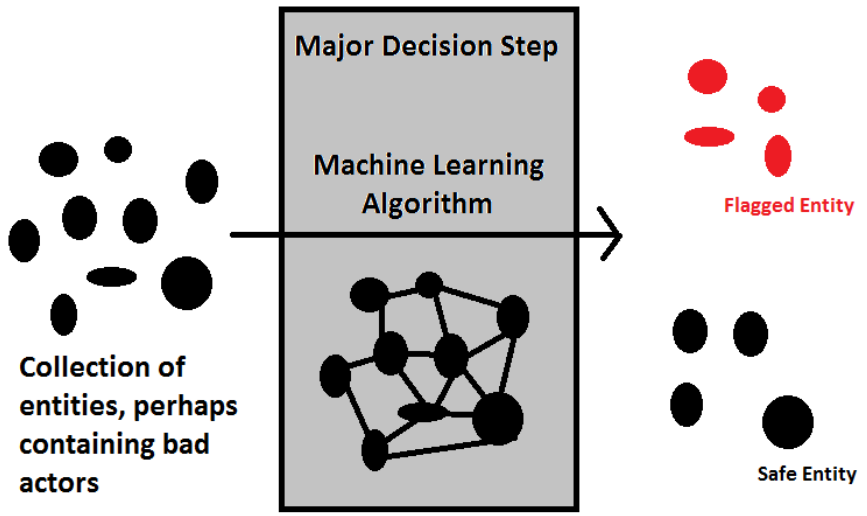
ML as a Decision-Maker



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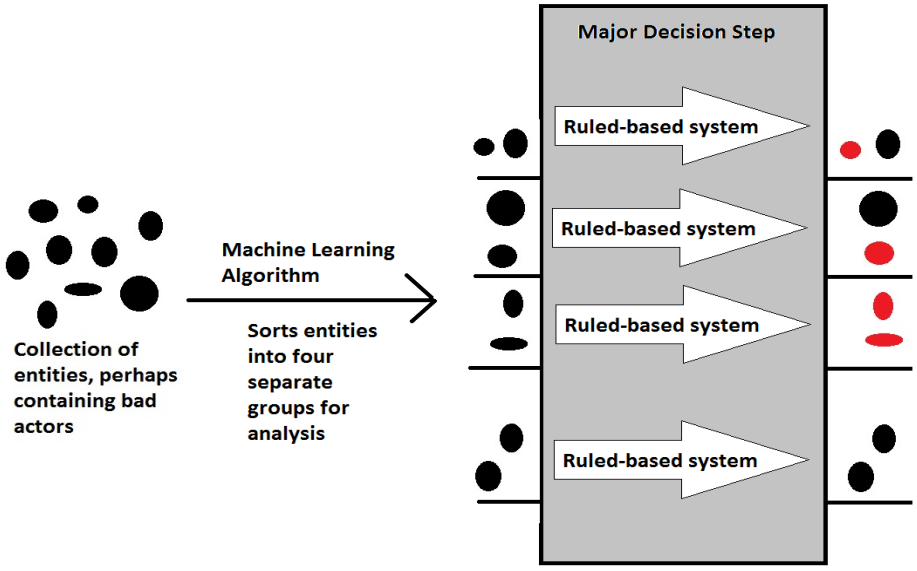
ML as the Sorting Hat



Explain it

Impact:

- *In assessing the use of AI need to understand*
  - *Types of algorithms being used*
  - *Development process of the AI and what input was received by subject matter experts*
- *Demystify with a white box?*
- *Blockchain to the rescue?*

Chinese hospital introduces facial recognition for bill pay

Xinhua | Updated: 2018-09-21 16:49

Jiangxi Provincial People's Hospital, China's first hospital to offer facial recognition services to patients for medical bill

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What do we do?

- Nefarious
  - Injecting false information into a medical record
- Unintended
  - Promoting care coordination
- AI as remuneration
- Who's liable?
  - Countless interactions among many people
  - Distributed agency?
- Reimbursement?
- Exclude an AI?
- How do you regulate something that's constantly changing?

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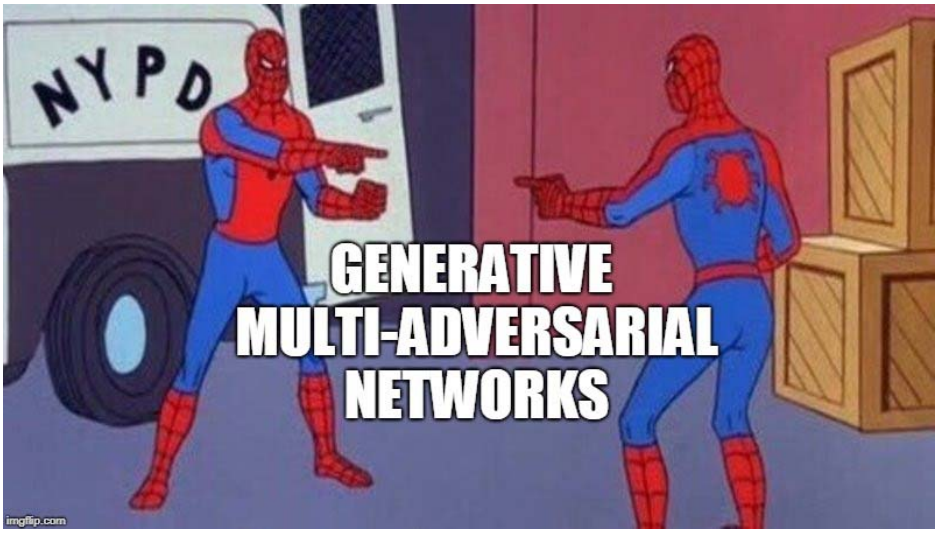
In the future....



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Takeaways

- No intimidation
- Iterative and automatic
- Risk tolerance is low
- Risks of data and explanation
- Different regulatory framework?

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Questions?

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Opening the Pod Bay Doors: The Impact of Artificial Intelligence on Program Integrity

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1. **Artificial Intelligence** (AI) is a world of marketing hyperbole, confusing vocabulary, and technical terminology with as-yet-undeliverable promises of truly automated insights. Even after decades of study, AI is still an elusive subject because of its size and nebulous nature. Moreover, most advances in AI are not recognized or realized to most people. Instead of Rosie the Robot or R.U.D.I from *The Jetsons*, AI has shown advances in search algorithms, machine learning, and incorporating statistical analysis into comprehending the world through subtle approaches like forecasting, determining market sentiment, and examining search and purchase histories.

    a. Background and History

        i. While the intellectual roots of AI may be found in Greek mythology, the technical and practical aspects start in the 1950s.

            1. Turing and his test

                a. In 1950, Alan Turing authored his classic essay *Computing Machinery and Intelligence*.[1] The essay envisions the possibility of computers created for simulating human intelligence and introduces many concepts that are now associated with AI like potential ways to test intelligence and to learn automatically.

                b. The paper also presents the concept of the "Imitation Game." The game, now known as the Turing test, involves three participants: the interrogator, a human (confederate), and a machine. The goal of the interrogator, through type responses, is to identify which entity is human and which is machine. If the interrogator could not tell the difference between the two, Turing hypothesized that this would demonstrate that machines can think.

[1] Turing, Alan *Computing Machinery and Intelligence*", *Mind*, (October 1950), 10.1093/mind/LIX.236.433.

c. While no AI has passed a true Turing test, Turing's vision of what AI could accomplish helped define the field of AI.

2. Dartmouth Conference and the first AI Summer

a. In 1956, the historic Dartmouth Summer Research Project on Artificial Intelligence conference was held and is considered the birth of AI. For example, the term "artificial intelligence" was first coined at the conference; the first AI program, "Logic Theorist", was presented; and, overall, the field gained its mission to investigate ways in which machines could simulate aspects of human intelligence.[2]

b. From 1956-1974, AI research exploded into an era of discovery. Basic algorithms using heuristics solved complex problems in algebra and geometry. Early work in computer vision laid the basis for today's facial recognition. This time also sees the first forays into natural language processing including machine translation and the first chatterbot ELIZA.[3] During this time, the predecessor to DARPA invested tens of millions of dollars in research to MIT, CMU, and Stanford with few requirements.[4]

i. First AI Winter

1. In the 1970s, governments decided to pull back on AI research because the AI hype far exceeded its accomplishments. Specifically, the Automatic Language Processing Advisory Committee (ALPAC) report by the U.S. Government and the Lighthill report from the British government. ALPAC, which focused on machine translation from Russian to English, found little yield from the government's investment.[5] The Lighthill report states that "in no part of the field have discoveries made so far

[2] Crevier, Daniel, *AI: The Tumultuous Search for Artificial Intelligence*, New York, NY: BasicBooks (1993); McCorduck, Pamela, *Machines Who Think* (2nd ed.), Natick, MA: A. K. Peters, Ltd. (2004).

[3] McCorduck 2004, pp. 291–296, Crevier 1993, pp. 134–139.

[4] *See generally* Crevier 64-94.

[5] Automatic Language Processing Advisory Committee, *Language and Machines — Computers in Translation and Linguistics*, Washington, DC, (1966).

produced the major impact that was then promised."[6] In response, the British government limited AI research to only a few projects at a few universities.

ii. Second AI Summer of Expert Systems

1. Expert System is a program that answers questions or solves problems in a specific knowledge area. An expert system generally has three components: (1) database of facts and rules representing human knowledge; (2) an inference engine that applies the facts and rules to deduce inferences or new facts; and (3) interface for human interaction (input/output). While developed and used during the 1950s and 1960s, expert systems were used a competitive tool in corporations in the 1980s and were in-house spending over a billion dollars on expert systems.[7]

2. In the 1980s, Japan invested over a billion dollars in attempts to form the Fifth Generation Computer System (FGCS) with machines being building multi-processor machines specializing in logic programming.[8] Other countries followed suite by funding AI and information technology projects.[9]

iii. Second AI Winter

1. The late 1980s and early 1990s saw a second AI winter because the AI hardware to maintain expert systems was too costly given the advent of desktop computers. It was also too expensive to maintain the successful expert systems and only useful in special contexts. Furthermore, Japan's FGCS failed to realize intelligent software partly due to hardware capacity and software limitations. Countries also cut funding.

iv. Let's Not Call it AI

1. Although quietly, in the late 1990s and early 2000s, AI starts achieving some of the goals set out in the 1950s especially in data mining and industrial robotics. These achievements are partially due to exponential increase in computer power so that hardware is no longer a limiting

[6] Sir Lighthill, James. *Artificial Intelligence: A General Survey*, Artificial Intelligence: A paper symposium, Science Research Council, (1973).

[7] McCorduck, pp. 434–435, Crevier, pp. 161–162,197–203.

[8] McCorduck 2004, pp. 436–441, Crevier 1993, p. 211.

[9] McCorduck 2004, pp. 426–432.

factor (i.e., Moore's Law). Thus, AI was now capable of evaluating a huge amount of data from sensors and then making probabilistic decisions. To avoid references to past AI winters, many researchers used different terms to reference AI. "Computer scientists and software engineers avoided the term artificial intelligence for fear of being viewed as wild-eyed dreamers."[10]

2. Milestones

    a. 1997: Deep Blue defeats reigning world chess champion, Garry Kasparov.

    b. 2005: DARPA's Grand Challenge, an autonomous vehicles prize competition, is one for the first time by a team from Stanford for driving autonomously for 131 miles along an unrehearsed desert trail.

    c. 2007: DARPA's Urban Challenge is won by CMU by navigating 55 miles in an urban environment while adhering to traffic hazards and all traffic laws.

    d. 2011: IBM's Watson wins *Jeopardy* soundly beating Brad Rutter and Ken Jennings.

v. A Third Summer of Big Data and Neural Networks?

1. From 2011 to present, AI has seen a resurgence in funding and anticipation with emphasis on managing big data and advance in deep learning involving image and video processing, object detection, text analysis, and speech recognition.[11] Also, large technology companies are acquiring other companies to gain access and control over troves of health care data and proprietary analytics systems to mine the data for insights (e.g., IBM acquiring Phytel, Explorys, and Truven).

2. Data on AI

    a. Spending on cognitive and AI systems will reach $19.1 billion in 2018, an increase of 54.2% over the amount spent in 2017.[12]

[10] John Markoff, *AI Reemerges from a Funding Desert*, N.Y. Times, (Oct 13, 2005).

[11] LeCun, Yann; Bengio, Yoshua; Hinton, Geoffrey, *Deep Learning*, *Nature*.436–444, *available at* 10.1038/nature14539

[12] International Data Corporation, *Worldwide Spending on Cognitive and AI Systems Will Grow to $19.1 Billion in 2018* (Mar. 22, 2018).

b. Four industries accounting for 50% of AI spending (Retail: $3.4B, Banking: $3.3B; Manufacturing: $2B; and Healthcare: $1.7B).[13]

c. According to Accenture analysis, when combined, key clinical health AI applications can potentially create $150 billion in annual savings for the United States healthcare economy by 2026. This includes an estimated $17 billion in fraud detection.[14]

d. AI products and services are on track to save hospitals $52 billion worldwide by 2021 ($21 billion in U.S.).[15]

b. Common Terminology

i. **Algorithms** are "a sequence of instructions used to solve a problem. Developed by programmers to instruct computers in new tasks, algorithms are the building blocks of the advanced digital world. Computer algorithms organize enormous amounts of data into information and services, based on certain instructions and rules."[16]

ii. **Artificial Intelligence** is "the ability of a computer to complete tasks in a manner typically associated with a rational human being—a quality that enables an entity to function appropriately and with foresight in its environment. True AI is widely regarded as a program or algorithm that can beat the Turing Test, which states that an artificial intelligence must be able to exhibit intelligent behavior that is indistinguishable from that of a human."[17]

iii. **Augmented Intelligence** is "an alternative conceptualization that focuses on AI's assistive role, emphasizing the fact that its design enhances human intelligence rather than replaces it."[18]

iv. **Machine Learning** is a part of the discipline of artificial intelligence and refers to constructing algorithms that can make

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[13] *Id*.

[14] Accenture, Artificial Intelligence: Healthcare's New Nervous System (2017), *available at* https://www.accenture.com/t20171215T032059Z__w__/us-en/_acnmedia/PDF-49/Accenture-Health-Artificial-Intelligence.pdf.

[15] ABIresearch, *AI to Save Healthcare Sector US$52 Billion in 2021*, (June 4, 2018), *available at* https://www.abiresearch.com/press/ai-save-healthcare-sector-us52-billion-2021/

[16] American Medical Association, *Primer on Artificial and Augmented Intelligence*, Report of the Council on Long Range Planning and Development (June 2018).

[17] *Id*.

[18] *Id*.

accurate predictions about future outcomes. Machine learning can be supervised or unsupervised.

1. Types or Learning Modes

    a. In supervised learning, algorithms are presented with "training data" that contain examples with their desired conclusions, such as pathology slides that contain cancerous cells as well as slides that do not. Every input has its corresponding label/target.

    b. Unsupervised learning does not typically leverage labeled training data. Instead, algorithms are tasked with identifying patterns in data sets on their own by defining signals and potential abnormalities based on the frequency or clustering of certain data.[19]

    c. Reinforced learning is designed to achieve an overall goal and receives incremental positive or negative feedback as it progresses towards that goal (e.g., video game AI).

v. **Deep Learning** is "a subset of machine learning that employs artificial neural networks (ANNs) and algorithms structured to mimic biological brains with neurons and synapses. ANNs are often constructed in layers, each of which performs a slightly different function that contributes to the result. Deep learning is the study of how these layers interact and the practice of applying these principles to data."[20]

vi. **Cognitive Computing** is often used interchangeably with machine learning and artificial intelligence. However, cognitive computing systems "do not necessarily aspire to imitate intelligent human behavior, but instead to supplement human decision-making power by identifying potentially useful insights with a high degree of certainty. Clinical decision support and augmented intelligence come to mind when considering this definition."[21]

vii. **Natural Language Processing** (NLP) forms the "foundation for many cognitive computing exercises. The ingestion of source materials, such as medical literature, clinical notes, or audio dictation records requires a computer to understand what is written, spoken or otherwise being communicated. One commonly used

[19] *Id.*
[20] *Id.*
[21] *Id.*

application of NLP is optical character recognition (OCR) technology that can turn static text, such as a PDF of a lab report or a scan of a handwritten clinical note, into machine readable data. Once the data are in a workable format, the algorithm parses the meaning of each element to complete a task such as translating into a different language, querying a database, summarizing information or supplying a response to a conversation partner. In the health care field, where acronyms and abbreviations are common, accurately parsing through this "incomplete" data can be challenging."[22]

2. Government Activity involving AI

    a. United States

        i. While no introduced legislation on AI is specifically directed at health care, this legislation has been introduced regarding AI including defining AI, which may be used by future legislation. Recent laws that impact the health care industry implicate AI. For example, 21st Century CURES Act included provisions changing the U.S. Food and Drug Administration's oversight over software as a medical device.

        ii. Pending Legislation

            1. **H.R. 4625/S. 2217**, Fundamentally Understanding The Usability and Realistic Evolution of Artificial Intelligence Act of 2017 or the FUTURE of Artificial Intelligence Act of 2017, directs the Department of Commerce to establish the Federal Advisory Committee on the Development and Implementation of Artificial Intelligence to advise Commerce on matters relating to the development of artificial intelligence U.S. competitiveness, U.S. workforce, education, open sharing of data and research on AI, and international cooperation and competitiveness.[23] Notably, the Department of Health and Human Services is not one of enumerated federal agency members of this commission.

            2. **H.R. 3388** Safely Ensuring Lives Future Deployment and Research In Vehicle Evolution Act or the SELF DRIVE Act preempts state regulations that limit manufacturers' ability to put self-driving cars on the road, allows for hundreds of thousands of automated vehicles on the roads, and requires manufacturers to institutes cybersecurity and

[22] *Id.*

[23] Fundamentally Understanding The Usability and Realistic Evolution of Artificial Intelligence Act of 2017, H.R. 4625/S. 2217, 115th Cong. (2018).

privacy protection.[24] Interesting, as it relates to state laws, the Act upholds state authority regarding registration, licensing, driving education and training, insurance, law enforcement, crash investigations, safety and emissions inspections, congestion management of vehicles on their streets, and traffic laws and regulations. Thus, a similar approach could be pursued in relation to healthcare AI to leave states with certain Tenth Amendment powers to protect the welfare, safety, and health of its citizens. On September 6, 2017, H.R. 3388 passed the House of Representatives. It has been referred to the Committee on Commerce, Science, and Transportation in the Senate.[25]

3. **H.R. 5356** National Security Commission Artificial Intelligence Act of 2018 establishes an independent National Security Commission on AI to advance the development of artificial intelligence, machine learning, and associated technologies by the United States to comprehensively address the national security needs of the Nation, including economic risk, and any other needs of the Department of Defense or the common defense of the Nation.[26]

iii. White House

1. May-June 2016: The White House had a series of public-outreach activities by the White House Office of Science and Technology Policy (OSTP) and sent out a request for information to solicit feedback on overarching questions in AI, including AI research and the tools, technologies, and training that are needed to answer these questions.[27]

2. October 2016: OSTP issued a report on preparing the future of AI that surveys the current state of AI, its existing and potential applications, and the questions that progress in AI raise for society and public policy.[28]

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[24] Safely Ensuring Lives Future Deployment and Research In Vehicle Evolution Act, H.R. 3388, 115th Cong. (2017).

[25] 163 Cong. Rec. H6677 (daily ed. Sept. 6, 2017); 163 Cong. Rec. S5052 (daily ed. Sept. 7, 2017).

[26] National Security Commission Artificial Intelligence Act of 2018, H.R. 5356, 115th Cong. (2018).

[27] 81 Fed. Reg. 41610 (June 27, 2016).

[28] Executive Office of the President, *Preparing for the Future of Artificial Intelligence* (Oct. 2016), *available at* https://obamawhitehouse.archives.gov/sites/default/files/whitehouse_files/microsites/ostp/NSTC/preparing_for_the_future_of_ai.pdf.

3. December 2016: OSTP issued a report on AI, automation, and the economy that examines the expected impact of AI-driven automation on the economy, and describes broad strategies that could increase the benefits of AI and mitigate its costs.[29]

4. May 2018: OSTP issues a fact sheet about prioritizing funding for AI research and development and removing barriers to AI innovation.[30] In addition, the President's FY 2019 Budget Request specifically calls out harnessing AI and high-performance community as a priority in research and development federal government funding.[31]

iv. Food and Drug Administration (FDA)

1. In a blog post, the FDA defines AI to be a device or product that can imitate intelligent behavior or mimics human learning and reasoning. Artificial intelligence includes machine learning, neural networks, and natural language processing. Some terms used to describe artificial intelligence include: computer-aided detection/diagnosis, statistical learning, deep learning, or smart algorithms.[32]

2. At Datapalooza 2018, Commissioner Gottlieb announced the FDA is placing focus on AI within the Digital Health Software Precertification Pilot Program. The Pre-Cert pilot is exploring guidelines to help manufacturers demonstrate a robust culture of quality—including the safety and effectiveness of its processes and software developers—which would enable the FDA to streamline approvals.[33]

3. In April 2018, FDA permitted marketing of a medical device to use AI to detect diabetic retinopathy. "The device, called IDx-DR, is a software program that uses an artificial intelligence algorithm to analyze images of the eye taken with a retinal camera called the Topcon NW400.

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[29] Executive Office of the President, *Artificial Intelligence, Automation, and the Economy*, (Dec. 2016), *available at* https://www.whitehouse.gov/sites/whitehouse.gov/files/images/EMBARGOED%20AI%20Economy%20Report.pdf.

[30] OSTP, Artificial Intelligence for the American People, (May 10, 2018), *available at* https://www.whitehouse.gov/briefings-statements/artificial-intelligence-american-people/.

[31] Office of Management and Budget, FY 2019 Budget (2018), *available at* https://www.whitehouse.gov/wp-content/uploads/2018/02/ap_18_research-fy2019.pdf.

[32] FDA, *Digital Health Criteria*, (Sept. 2017), *available at* https://www.fda.gov/medicaldevices/digitalhealth/ucm575766.htm.

[33] Remarks by Scott Gottlieb, M.D., *Transforming FDA's Approach to Digital Health*, (Apr. 26, 2018), *available at* https://www.fda.gov/NewsEvents/Speeches/ucm605697.htm.

A doctor uploads the digital images of the patient's retinas to a cloud server on which IDx-DR software is installed. If the images are of sufficient quality, the software provides the doctor with one of two results: (1) more than mild diabetic retinopathy detected: refer to an eye care professional or (2) negative for more than mild diabetic retinopathy; rescreen in 12 months. If a positive result is detected, patients should see an eye care provider for further diagnostic evaluation and possible treatment as soon as possible." IDx-DR could correctly identify the presence of mild diabetic retinopathy 87.4% of the time and able to identify individuals who did not have mild diabetic retinopathy 89.5% of the time. [34]

v. JASON Report on Artificial Intelligence for health and Health Care[35]

1. Agency for Healthcare Research and Quality, the Office of the National Coordinator for Health IT, and the Robert Wood Johnson Foundation asked JASON[36] to consider how AI could shape the future of the public health, community health, and health care delivery from a personal to a system level.

2. This report may end up being one of seminal reports on Healthcare AI focusing on health diagnostics, proliferations of devices and apps for data collection and analysis, advancing AI algorithm development, large scale health data like the National Institutes of Health's *All of Us* research, issues for success, and findings and recommendations.

b. European Union

i. In January 2017, European Union Parliament issued a report on AI including general principles, liability, research and innovation, ethical principles, intellectual property rights, and more. Specific

[34] FDA, *FDA Permits Marketing of Artificial Intelligence-Based Device to Detect Certain Diabetes-Related Eye Problems*, (Apr. 11, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm604357.htm.

[35] JASON, *Artificial Intelligence for Health and Health Care*, JSR-17-Task-002, (Dec. 2017), *available at* https://www.healthit.gov/sites/default/files/jsr-17-task-002_aiforhealthandhealthcare12122017.pdf.

[36] JASON is an independent group of elite scientists which advises the United States government on matters of science and technology.

sections related to health included care robots, medical robots, and human repair and enhancement.[37]

ii. On April 10, 2018, European countries signed a Declaration of Cooperation on Artificial Intelligence (AI). The countries agreed to cooperate on boosting Europe's technology and industrial capacity in AI; addressing socio-economic challenges (e.g., education, training, upskilling, reskilling); and ensuring an adequate legal and ethical framework (e.g., privacy, transparency, accountability, safety and vigilance in design).[38] The European Commission has also appointed experts to support the implementation of the European strategy on AI.[39]

c. United Kingdom

i. In September 2016, the House of Commons Science and Technology Committee published a report on "Robotics and Artificial Intelligence" that examined economic and social implications (e.g., employment, job augmentation, education); ethic and legal issues (e.g., transparency bias, privacy, accountability, and liability); and further research, funding, and innovation.[40]

ii. In January 2017, an All Party Parliamentary Group on Artificial Intelligence was established to address ethical issues, social impact, industry norms, and regulatory options for AI in Parliament. Notably, they recommended the appointment of a Minister for AI in the Cabinet Office.[41]

iii. In June 2017, the Parliament established the Select Committee on AI. In April 2018, the Committee published an in-depth report and proposed an AI Code with five principles:[42]

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[37] European Parliament, Report (with recommendations to the Commission on Civil Law Rules on Robotics, A8-0005/2017 (Jan. 27, 2017), *available at* http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+REPORT+A8-2017-0005+0+DOC+XML+V0//EN.

[38] European Commission, EU Member States Sign Up to Cooperate on Artificial Intelligence (Apr. 10, 2018), *available at* https://ec.europa.eu/digital-single-market/en/news/eu-member-states-sign-cooperate-artificial-intelligence

[39] European Commission, *High-Level Expert Group on Artificial Intelligence*, (June 2018), *available at* https://ec.europa.eu/digital-single-market/en/high-level-expert-group-artificial-intelligence.

[40] United Kingdom, House of Commons, Science and Technology Committee, Robotics and Artificial Intelligence, 5th Report of Sess. 2016-2017 (published Oct. 12, 2016), *available at* https://publications.parliament.uk/pa/cm201617/cmselect/cmsctech/145/145.pdf.

[41] All-Party Parliamentary Group on Artificial Intelligence, *Findings 2017* (2017), *available at* http://www.appg-ai.org/wp-content/uploads/2017/12/appgai_2017_findings.pdf.

[42] House of Lords, Select Committee on Artificial intelligence. *AI in the UK: ready, willing and able?*, Report of Sess. 2017-19 (published April 16, 2018).

1. Artificial intelligence should be developed for the common good and benefit of humanity.

2. Artificial intelligence should operate on principles of intelligibility and fairness.

3. Artificial intelligence should not be used to diminish the data rights or privacy of individuals, families or communities.

4. All citizens have the right to be educated to enable them to flourish mentally, emotionally and economically alongside artificial intelligence.

5. The autonomous power to hurt, destroy or deceive human beings should never be vested in artificial intelligence.[43]

In June 2018, the United Kingdom government responded to the report's recommendation and highlights the intentions and recommendation of the United Kingdom for managing the development of AI moving forward.[44]

d. New York City

i. Local Law 49 of 2018 was passed by New York City Council that requires the creation of a task force that provides recommendations on how information on agency automated decisions systems may be shared with the public and how agencies may address instances where people are harmed by agency automated decision systems.[45] Mayor de Blasio established the Automated Decisions Systems Task Force on May 16, 2018.

3. Program Integrity

a. Background

i. Program Integrity is defined in many ways:

[43] *Id.*at 125.

[44] Secretary of State for Business, Energy and Industrial Strategy by Command of Her Majesty, Government response to House of Lords Artificial Intelligence Select Committee's Report on AI in the UK: Ready, Willing and Able?, (June 2018), *available at* https://www.parliament.uk/documents/lords-committees/Artificial-Intelligence/AI-Government-Response.pdf.

[45] Local Laws of the City of New York for the Year 2018, No. 49 (enacted Jan. 11, 2018), *available at* http://legistar.council.nyc.gov/LegislationDetail.aspx?ID=3137815&GUID=437A6A6D-62E1-47E2-9C42-461253F9C6D0.

1. Practical concept that programs should be organizationally and structurally sound[46]

2. Commitment to combating Medicaid provider fraud, waste, and abuse which diverts dollars that could otherwise be spent to safeguard the health and welfare of Medicaid enrollees.[47]

3. Rooting out fraud, waste, and abuse by promoting the economy, efficiency, and effectiveness of the programs and the individuals it serves[48]

4. Reduce improper payments by intensifying efforts to eliminate payment error, waste, fraud, and abuse in the major programs administered by the HHS, while continuing to ensure that HHS programs serve and provide access to their intended beneficiaries.[49]

ii. Goals of Program Integrity

1. Eligibility decisions are made correctly

2. Prospective and enrolled providers meet federal and state participation requirements

3. Services provided to patients are medically necessary and appropriate

4. Provider payments are made in the correct amount and for appropriate services

iii. Reasons for the Goals of Program Integrity

1. Desire to protect patients from harm (e.g., provider screening, receiving only necessary and appropriate care, protecting identity from being stolen)

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[46] *See* Michael W. Duttweiler and Sara F. Dayton, *Program Integrity: A Powerful Organizing Construct or Just More Jargaon*, J. Extension (2009).

[47] See, e.g., Medicaid and CHIP Payment and Access Commission, Program Integrity, (2017), available at https://www.macpac.gov/subtopic/program-integrity/; Daniel R. Levinson, A New Era of Medicare Oversight,

15 J. Health Care L. & Pol'y 249 (2012), available at http://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1195&context=jhclp.

[48] Council of the Inspectors General on Integrity and Efficiency, *The Inspectors General*, (July 14, 2014), https://www.ignet.gov/sites/default/files/files/IG_Authorities_Paper_-_Final_6-11-14.pdf.

[49] *See e.g.*, Health Resource and Services Administration, *Grants: Program Integrity*, (2017), https://www.hrsa.gov/grants/manage/program-integrity/index.html.

2. Desire to protect honest providers from harm (e.g., making sure you are working with other good actors, protecting identity from being stolen)

3. Desire for financial integrity (e.g., is money being spent properly, making sure that clinical judgment isn't compromised by improper incentives)

b. AI Interaction: AI, like program integrity, has implications across the healthcare delivery system. AI can help mitigate or exacerbate program integrity concerns. Properly deployed AI can promote proper gatekeeping, sound payment, effective compliance, and continuous monitoring to help prevent fraud, waste, and abuse. Improperly deployed AI can promote the opposite through nefarious and intentional measures of bad actors or because the AI was developed on misguided rules or used inappropriate or insufficient data when trained. This improper deployment increases the risk of improper payments and may cause patient harm through improper diagnosis or recommending inappropriate procedures.

i. Program Gatekeeping

1. Goal: Keeping dishonest individuals and entities out of the healthcare system by controlling entry into the system. While most of the attention is paid on weeding out bad providers, other individuals and entities may also play a role in defrauding the healthcare system. This includes beneficiaries, employees, contractors, and suppliers/vendors.

2. AI interacts: AI can improve program gatekeeping through its ability to synthesize and deduce many data sources and apply them to applicable rules and policies.

a. Through machine learning and/or an expert system, AI can be trained to generate hypothesis based off available data, regulatory rules, and the entity's policies; provide a decision(s); and show data support the decision (e.g., relationship between the individual and vendors; ability of individual to steer business to certain vendors). From this step, human analysis can make the final determination, which can be fed back into the algorithm so the AI "learns" from success and mistakes. This approach is like an investigator using the Fraud Theory Approach of analyzing available data, creating a

hypothesis, testing it, and then refining and amending accordingly.[50]

b. In the move to value-based care, more non-traditional providers will be interacting with patients. Existing data sources may not be useful in determining previous program integrity history (e.g., no Masterfile demonstrating licensure and education for home health aides exists). Thus, examining individuals and their relationships with others through link analysis may build a better profile in determining whether to work with or hire a specific individual.

ii. Sound Payment

1. Goal: Payment models being designed to achieve intended outcomes, payment rates and amounts being established correctly, and examination of actual payment to ensure proper payment.

2. AI interacts:

a. A common type of healthcare fraud is billing for an items, service, treatment, or procedure that was never rendered. Generally, no supporting documentation is found in the patient's medical record. Investigations usually involve identifying reported dates of services on claim forms and comparing any evidence of the patient being present at the facility. Thus, to ensure appropriate payment, AI can examine and compare the date of service on the claim form with the existence of any medical record in the EHR system prior to submitting the claim for payment. In the digital health world (e.g., telemedicine), AI can compare the date of service to any digital interaction between computers (e.g., header data).

b. In receiving payments for services rendered from patients or other entities, AI can analyze the likelihood of a chargeback or fraudulent action by examining data like time and date, merchant category codes, IP address, or past transaction

[50] Association of Certified Fraud Examiners, *Introduction of the Certified Fraud Examination for 2013* (2013), http://www.acfe.com/uploadedFiles/Shared_Content/Products/Books_and_Manuals/Intro_2013_Final.pdf.

history. By training AI on this data, the system can learn and improve to better predict risk of future improper payments.

c. In the value-based world, quality and performance data add new variables in structuring payments. Natural Language Processing algorithms can read medical records to decipher certain quality outcomes (e.g., identifying hospital-acquired conditions). This type of AI-assisted automation of a time-consuming process may provide a more accurate view of patient care and cost, so that models are appropriately designed. AI is also being used to manage and improve patient population outcomes.

iii. Compliance

1. Goal: Engagement in meaningful self-policing to improve business operations and better manage business and legal risks. Healthcare compliance is the process of following rules, regulations, laws, ethical and professional standards, and company policies and procedures that relate to providing healthcare.

2. AI interacts: AI can help create, update, and measure effectiveness of an entity's compliance program.

a. In creating a compliance program, AI, through a rules compression algorithm, could be trained on Office of Inspector General (OIG) Corporate Integrity Agreements to create a specific compliance program. It could also identify trends and differences on how OIG's thoughts have evolved on CIAs.

b. In updating a compliance program, the system may pull in information from OIG's semiannual reports and work plan activities, government settlement agreements, and Depart of Justice press releases.

c. In measuring effectiveness, AI can help manage the meticulous documentation needed to demonstrate that the seven elements of a compliance program are met or where deficiencies exist that need to be addressed. For example, AI can manage compliance trainings and communication initiatives or ensure

proper follow-up on hotline information and other tips. For example, in verifying maintenance of policies on waivers of co-payments and deductibles, AI can ensure that the entity's financial records show appropriate payments—or not—of co-payments and deductibles.

iv. Monitoring

1. Goal: Minimize fraud and abuse by detecting potential and improper payment, evaluating of potential risks, and consistent retooling and evaluating of monitoring and compliance activities.

2. AI interacts: Monitoring involves all the above methods to help prevent and detect fraud, waste, and abuse. AI can use pattern recognition strategies to flag abnormalities; peer comparison claims history and link it to other aberrant behaviors; can constantly monitor various data sources like exclusion lists, suspicious activity reports, and media reports. Social media can also be used to identify patterns and abnormalities like inappropriate displays of wealth or when a provider or patient is on vacation.

c. Cybersecurity

i. The healthcare industry is shifting into a progressively digital world. This adoption offers improved patient care and convenience but also greater opportunity for attack. Cybersecurity remains a priority for protecting patient medical records and financial records. The global healthcare cybersecurity market will reach $10.85 billion by 2022 with an estimated annual economic impact of cyber attacks at $6 billion annually for hospitals and health systems.[51]

1. AI interacts: AI can be trained on large data sets including categories of end users, network traffic, and devices connected to a health system's network. Based on this information and with machine learning, AI may gain an understanding of a normal environment and monitor fluctuations and potential threats.

2. An expert system with automation and machine learning can create actionable intelligence to detect and withstand

[51] Grand View Research, *Healthcare Cyber Security Market Worth $10.85 Billion by 2022*, (Apr. 2016), *available at* https://www.grandviewresearch.com/press-release/global-healthcare-cyber-security-market.

severe and continued attacks. Automation can dynamically segment traffic by isolating sensitive patient data behind firewalls (This can stop a compromised device from spreading laterally throughout an IT system). Automation can also track and patch devices and configure security and network devices. "Security needs to be able to operate at digital speeds, which means automating security responses and comprehensively applying intelligence combined with self-learning technologies so that networks can make effective and autonomous decisions."[52]

d. Blockchain

i. The challenges identified regarding data and an inability to explain decisions can be mitigated by blockchain.

ii. "Blockchain technology organizes data so transactions can be verified and recorded through the consensus of all parties involved. For healthcare, this means that any data entered into a computer system or EHR/EMR can have each transaction or entry validated. This could include anything from a financial transfer to an update to an individual's personal health record. Each new action is verified against an authoritative ledger of previous events. With blockchain, each member who can enter information has his or her own copy of the ledger instead of the data being held in one location. However, no new transaction can be approved unless a majority agrees that the requested action is indeed accurate."[53]

iii. Blockchain, with its inherently secure technology, may be suited to building a foundation of trust that could connect different organizations and create a mutual health information exchange for developing and training AI.[54]

iv. Machine Learning changes and adapts over time, so using an "immutable tool like blockchain to monitor those changes can create an audit trail that allows developers to track that evolution and make adjustments accordingly."[55] Metadata stored on the blockchain allows developers to trace the origin of data that goes

[52] Derek Manky, *How Automation and AI Can Improve Healthcare Cybersecurity*, (Jan. 26, 2018), *available at* https://www.healthcarebusinesstoday.com/how-automation-and-ai-improve-healthcare-cybersecurity/.

[53] Elizabeth Snell, *Why Blockchain Technology Matters for Healthcare Security*, HealthITSecurity, (2018), *available at* https://healthitsecurity.com/features/why-blockchain-technology-matters-for-healthcare-security.

[54] Jennifer Bresnick, *How AI, Blockchain Combine to Fuel Healthcare Big Data Analytics*, HealthITAnalytics, (2018), *available at* https://healthitanalytics.com/features/how-ai-blockchain-combine-to-fuel-healthcare-big-data-analytics.

[55] *Id.*

into the training data sets of an AI algorithm. If bias is present, the blockchain can allow for identification of what data caused said bias.

4. Challenges with AI's Impact on Program Integrity

    a. Data and Patient Safety

        i. Overall

            1. "The promise of AI is tightly coupled to the availability of relevant data. In the health domains, there is an abundance of data. However, the quality of, and accessibility to, these resources remain a significant challenge in the United States. On one hand, health data has privacy issues associated with it, making the collection and sharing of health data particularly cumbersome compared to other types of data. In addition, health data are quite expensive to collect, for instance in the case of longitudinal studies and clinical trials, so it tends to be tightly guarded once it is collected. Further, the lack of interoperability of electronic health record systems impedes even the simplest of computational methods and the inability to capture relevant social and environmental information in existing systems leaves a key set of variables out of data streams for individual health."[56]

            2. An AI derived algorithm "is only as good as the data it works with".[57] The training data sets on which AI algorithms are trained on are created by human agents who are imperfect and economically motivated. Training data sets on research, patient care, or insurance records is variable and may exclude certain characteristics (e.g., excluding pregnant women from research) or factors (e.g., medical records generally do not have data on social determinants of health or environmental factors).[58]

            3. Based on data, AI systems may, invisibly and unintentionally, "reproduce and normalize" the biases of their training data sets, which can "reflect the conditions

[56] JASON, *Artificial Intelligence for Health and Health Care*, JSR-17-Task-002, p. 11, (Dec. 2017), *available at* https://www.healthit.gov/sites/default/files/jsr-17-task-002_aiforhealthandhealthcare12122017.pdf.

[57] Barocas S, Selbst AD, *Big Data's Disparate Impact*, California Law Review 2016;104:671–732; Osoba O, Welser IV, W. *An Intelligence in Our Image: The Risks of Bias and Errors in Artificial Intelligence* (2017), at https://www.rand.org/pubs/research_reports/RR1744.html

[58] *See generally* American Medical Association, *Augmented Intelligence in Health Care*, Board of Trustees Report 41-A-18 (June 2018).

only of the fortunate" and yield "an aggregate understanding of health and illness that fundamentally excludes the marginalized" in a way that risks exacerbating existing health disparities.[59]

ii. Impact on Patient Safety and Program Integrity

1. Patient safety is a program integrity concern because it is tied to quality of care received. AI may have profound positive impact on patient safety by ensuring the right patients gets to the right physician at the right time. It can help reduce medical errors, limit in-hospital mortality, prevent unplanned transfers, and improve medical diagnosis. However, given the variability and potential bias in data training sets, AI also could harm patients by making inappropriate recommendations and further perpetuate bias. Patients are unique and AI may be basing its analysis on inaccurate data or general population data and comparison to the nearest neighbor may not be effective.

iii. Accuracy of Natural Language Processing

1. Accurate clinical documentation is key to health care quality and safety and for communicating a patient's diagnosis and treatment across the care continuum. Failed communication can lead to communication errors. Health care providers have widely adopted dictation services supported by speech recognition and medical transcriptionists. Speech recognition is the automatic translation of voice into text and could help ensure that "medical documents be accurate, complete, legible, and readily accessible for the purposes of patient safety, health care delivery, billing, audit, and possible litigation proceedings."[60]

2. Studies, however, have observed that the error rate of speech recognition generated documents to be higher compared to those created with a keyboard. Emergency department clinicians use of speech recognition had 4.3

[59] *Id. (quoting* AI Now Institute. *The Social and Economic Implications of Artificial Intelligence Technologies in the Near-Term* (2016)).

[60] Zhou L. et al., *Analysis of Errors in Dictated Clinical Documents Assisted by Speech Recognition Software and Professional Transcriptionists*, JAMA Open Network (July 6, 2018), *available at* https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2687052.

times as many errors as keyboard-created documents.[61] In addition, speech recognition in discharge summaries and operative notes had an average of 7.4 errors per 100 words while earlier studies demonstrated .45 errors per 100 words for keyboard documentation.[62] However, through machine learning and provider training and education, speech recognition technology is continually improving, while keyboard documentation may not be improving at a similar rate.

b. Black Box

i. As AI evolves and becomes still more complex and autonomous, it also becomes harder for humans to understand its decisions. This is true for both the general public and the individuals who created or designed the AI. For example, deep learning/neural networks essentially program itself and often learn mysterious rules that no human can fully understand. From a compliance perspective, individuals and entities need an explanation as to why someone was selected for further investigation because of the resources involved in investigating and the ability to explain decisions to oversight entities when there are potential fraud and abuse implications.

ii. Deep Patient, a neural network AI, was created by a research group at Mount Sinai Hospital and trained on using data from about 700,000 individuals with hundreds of variables. Without any expert instructions, Deep Patient discovered hidden patterns and could indicate when people were going to develop certain diseases. However, Deep Patient cannot explain why it can anticipate schizophrenia, which is difficult for physicians to predict.[63] More broadly, AI is being used to diagnosis patients, make treatment recommendations, and generally act as a clinical decision support tool. Thus, explanation is key because it provides confidence in the decision and justification for the use of AI to regulatory oversight bodies.

iii. Recent research has started to demystify the black box through multimodal explanations for real-world tasks to point to evidence in an image and to provide a natural sentence justification for its

[61] *Id.* (*citing* Hodgson T., Magrabi F., Coiera E., *Efficiency and Safety of Speech Recognition for Documentation in the Electronic Health Record*, J Am Med Inform Assoc. (2017)).

[62] *Id.*

[63] Will Knight, *The Dark Secret at the Heart of AI*, MIT Technology Review, (Apr. 11, 2017), *available at* https://www.technologyreview.com/s/604087/the-dark-secret-at-the-heart-of-ai/

decision.[64] In addition, "white-box" companion AI can also help explain the decision-making process (e.g., a scorecard, a set of visuals).

c. Unknown Government Oversight Landscape

i. Current regulations lack of standards to assess the safety and efficacy of AI systems. Oversight needs to focus on the prevention of patient harm from ever occurring rather than a regulation-by-litigation regime. Litigation and the courts tend to focus on the risks of technology which could stifle innovation and adoption of digital technologies. Courts are good on a case-by-case basis focused on specific past harms but not good at making general determinations associated with emerging technologies. Furthermore, applying the current liability system may inappropriately shift risk onto providers and patients. Incentives should be aligned so those best positioned to have knowledge of risks and best positioned to minimize harm through design, development, validation, or implementation of AI.

[64] DH Park et al., arVix, *Multimodal Explanations: Justifying Decisions and Pointing to the Evidence*, (Feb. 15, 2018), *available at* https://arxiv.org/abs/1802.08129.