When the Planet of the Apes Becomes the Planet of A.I.

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Man vs. Robot—no, it is not the latest and greatest food challenge show but a common theme in human innovation. Fascination with technology, in particular "intelligent" technology, has motivated, challenged, and sometimes terrified humans for decades. The quirky, yet loveable Rosie the Robot, maid to the futuristic Jetsons family, captured Americans' fascination as far back as the 1960s, representing the convenience (and hilarity) artificial intelligence could bring to the home. Although less endearing, today's homes are now filled with robot vacuums and so many "smart" appliances it can make the end user feel dumb trying to figure them all out. In the mid-1980s, KITT from *Knight Rider* showed us the crime fighting potential of intelligent machinery. Today, voice-controls, GPS, and perhaps most impressive, self-driving technology have turned the average car into a personal chauffeur. As long as someone can dream it, someone will (try to) build it.

The health care industry is not immune to this innovation addiction. Artificial intelligence presents valuable opportunities for efficiencies. In many ways, necessity has bred invention: as much as 30% of the world's stored data is generated in the health care industry, and a single patient generates close to 80 megabytes each year in imaging and electronic medical record data.[1] Human constraints on time and speed make it impossible for sophisticated processes to be carried out without machines. Accordingly, creative minds race to find "smart" solutions to both simple and complex problems facing providers today.

However, this is the real world, not a fantasyland; the props are living people and there is no script. Looking specifically at the use of artificial intelligence in pharmaceutical supply chain management and physician prescribing, this article discusses some of the potential applications of intelligent technology in the provider setting. Finally, the article analyzes some of the key legal and regulatory constraints (or lack thereof) in this burgeoning industry.

Defining Artificial Intelligence

"Artificial intelligence" is broadly applied to describe the use of algorithms in software to analyze complex data in a way that approximates human cognition. At its core, artificial intelligence represents the ability (or potential) for machines to replicate human thought processes through "machine learning." More specifically, a system executes a heuristic process to "learn" from experience by creating layers of knowledge without prescriptive or explicit instructions. Further, more sophisticated systems can employ "deep learning," which occurs when the system operates from the recognition of raw data rather than relying directly on task-specific algorithms. Regardless of the complexity of the system's learning capabilities, the "intelligence" of the machine is enhanced by virtue of combining the outputs from prior layers to make decisions with a higher degree of accuracy, similar to the development of neural networks in the human brain.[2]

Use of Artificial Intelligence in the Health Care Industry

Global spending on artificial intelligence software and systems is expected to jump from $12 billion to $57 billion by 2021,[3] and the health care industry appears to already account for the

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largest portion of the market.[4] Specifically, the health care artificial intelligence market alone is expected to reach $34 billion by 2025[5] and the use of artificial intelligence is anticipated to generate $52 billion in savings worldwide.[6] Artificial intelligence has the potential to move the cost needle in the health care industry; however, the downstream effects of implementation of intelligent designs remain to be seen. Tasking machines with roles traditionally performed by humans enters uncharted regulatory waters—laws are designed to regulate humans, not machines. To date, only one piece of national legislation has been introduced, but not enacted, in the United States that provides for exploratory measures to study, analyze, and report to the Department of Commerce certain administrative and legislative recommendations.[7] Without significant and meaningful development in this area, there is a risk that the technology might significantly outpace the regulatory framework necessary to protect relevant stakeholders. One such significant area of risk is pharmaceutical supply chain management and the need to better monitor prescribing errors.

Applications to Drug Supply Chain Management and Physician Prescribing Errors

Drug Supply Chain Management

Hospitals require accurate and efficient supply chain and procurement systems, particularly in pharmaceutical purchasing, as drugs account for a large portion of spending. In one survey, 81% of hospital staff reported spending about one-third of their overall operating expenses on supply chain[8] that largely consisted of manual inventory management (i.e., counting by hand).[9] Most experts agree that effective supply chain operations require efficient inventory management, waste reduction, leakage prevention, and cost control. To manage these various competing interests, real-time data about pharmacy inventory, patient needs, provider prescribing patterns, supply availability, and anticipated disruptions needs to be aggregated and analyzed, and it must be done promptly for such data to be meaningful. This presents a massive undertaking if relying upon human efforts alone.

Enter artificial intelligence. As applied, an intelligent system could create "end-to-end visibility" by identifying prescribing patterns and account for forecasted weather data to determine which drugs are required or anticipated to be required at any given point in time. The role of human staff shifts from execution to oversight with controls to further calibrate the system. From an internal perspective, utilizing intelligent systems can streamline functionalities to further improve efficiencies and reduce costs.[10] From an external perspective, a robust supply chain management system can better position hospitals to negotiate contracts by reducing the variability of operational costs (or at least a portion thereof), resulting in a more reliable price formula to stabilize margins over an extended contract period.

Physician Prescribing Errors

A desired benefit in improving efficiency is a reduction in error. Medical errors in general are the third-leading cause of death in the United States.[11] With increasing demands and workloads placed on physicians, artificial intelligence could potentially offer solutions to reduce prescribing errors. At the current level of technology available, artificial intelligence can, among other clinical applications, (1) prevent medical errors and readmission rates by retrospectively analyzing patient data from medication errors, and (2) prospectively identifying high-risk patients by analyzing readmission root causes to guide medication decisions.[12] In a study of sepsis patients in the United States, use of artificial intelligence to identify patterns predicted, with 78% accuracy, that the patient would die after 30 days of discharge from the ICU. In a separate study on child mortality in Peru, artificial intelligence predictions were closer to the observed outcomes than any other existing standard prediction score.[13] These results suggest that artificial intelligence may be useful when insufficient or disaggregated data exists to make an informed decision.

Closer to home, the opioid epidemic may be the best platform to see if artificial intelligence can provide immediate benefits. With approximately 115 deaths a day in the United States, the opioid crisis has an estimated total economic burden of $78.5 billion.[14] Taking a prophylactic approach, artificial intelligence may be able to gather information from available sources, such as state prescription drug monitoring programs, to identify high-risk patients and promote early intervention.[15]

Legal and Regulatory Considerations

Federal Regulatory Guidance

Currently, drug supply chain management is largely unregulated. Additionally, technologies lack interoperability. By way of comparison, the Food and Drug Administration (FDA) created the "unique device identification" system to track medical devices through distribution and use.[16] This system lays a universal framework whereby manufacturers, health care providers, regulators, and consumers can manage and monitor medical devices on the market.

In November 2013, The Drug Supply Chain Security Act (DSCSA)[17] outlined steps to build an electronic, interoperable system to identify and trace certain prescription drugs upon distribution. A chief goal of the DSCSA is to track counterfeit, stolen, or contaminated drugs. However, the DSCSA also directs the FDA to establish a national licensure standard for wholesale distributors and third-party logistics providers.

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Further, the DSCSA presents an opportunity for software developers to create synergies to expand interoperability through the use of the universal licensure and tracking standard. The FDA has dedicated resources on its website related to supply chain integrity, including a toolkit for medical products to help protect consumers.[18]

Currently, the FDA is running a DSCSA Pilot Project Program in which voluntary participants across the drug supply chain will test new technologies and come up with additional tracking solutions.[19] The goal of the Pilot Project Program is to establish an interoperable electronic system by 2023.[20] Participants are asked to examine certain focus areas including the creation of product identifiers, barcodes, interoperability, database system issues, aggregation and disaggregation of data, and errors.[21]

As the FDA grapples to regulate the supply chain process globally (or at least begins to do so), questions remain as to its regulation of various points. What role, if any, should the FDA play in regulating artificial intelligence itself? As the federal consumer watchdog in health care, it remains to be seen how the FDA can regulate this industry. Just as device and pharmaceutical manufacturers must demonstrate the clinical efficacy of their products, how will artificial intelligence designers verify the accuracy of their system outputs, particularly where humans will rely on such outputs for clinical decision-making purposes, or scarier yet, where the machine will make a clinical decision and execute it? The question of where human responsibility ends and the machine begins (and how a machine can be held accountable) is not just a matter of consumer safety, but also currently a legal ambiguity.

Medical and Products Liability

While an intelligent system may not be able to "clone" judgment and other subtleties hardwired in a human brain that is also emotional and ethical, the best outcomes are achieved when physicians and artificial intelligence work in tandem.[22] In fact, artificial intelligence systems are specifically designed to take different approaches than human thinking to achieve faster, better, and cheaper outcomes.[23] Physicians still must independently weigh system outputs, just like they do with other diagnostic tools, and draw upon their own knowledge and experience to reach an informed course of action. If artificial intelligence is meant to only be an aid in assisting physicians, then the ultimate responsibility for poor outcomes may still rest with the physician as she incorporates artificial intelligence outputs into her workflow.

That said, when issues of liability arise, we want to know, who is responsible? Is it the physician, the software developer, or whoever inputted the initial algorithm into the system? Courts are reluctant to apply products liability theories to software developers, even more so in the health care context because the technology has been characterized as a tool where ultimate decision making remains with the human clinician.[24] If the product itself is truly "at fault" there would have to be something inherently defective in the technology that caused the malfunction, even with reasonable care and exercise of judgment on the user's part. Patients generally can recover under a strict liability theory for injuries from products that are defective due to manufacturing, design, or failure to warn defects, but providers and health care institutions generally are not held strictly liable for defects in the products that they implement in the course of providing care.[25] Under a negligence theory of liability, for a physician or hospital to meet the applicable standard of care in using a certain technology, the minimum level of due diligence required is to ensure that the system software is up-to-date and free from other security vulnerabilities within the provider's control to identify.[26]

As between health care institutions and developers of these technologies, one method of allocating risk is through specific contractual terms. There are varying levels of artificial intelligence technologies of different levels of complexity. Some technologies are meant to diagnose certain conditions; others aggregate disparate data and provide a meaningful synopsis. The risk profile of the product itself will likely drive the particulars of contractual responsibility between the developer and the end user. As with other forms of technology, it is to be expected that developers will provide the technology on an "as is" basis, disclaim warranties of merchantability or fitness for a particular purpose, draft robust indemnification language, and cap limits on liability. In assessing contractual language, hospitals and practitioners should consider the sophistication of the technology itself, along with the intended benefits of its use to the institution. In today's environment, the value calculation for institutions is whether use of the technology, given contractual limitations risk, can proportionately reduce risk for physicians and their patients as an added benefit of its use, or if there are acceptable or unacceptable gaps. This value proposition is likely to be different for each institution given its unique risk profile and user sophistication with the technology.

Looking to the Future

Perhaps not imminently, but the technological landscape may surely develop in the future as more practitioners and health systems integrate intelligent systems into clinical decision making. As a result, the laws and regulatory framework will catch up, through either proactive legislation or reactive regulation by courts. It remains to be seen whether the use of artificial intelligence systems eventually will create a new "standard of care" such that physicians will be required to use some level of technological assistance in treating patients, or whether physicians will be penalized for failing to do the same where such technology is available. Will artificial intelligence be the proverbial "carrot" or the "stick"?

As the regulatory framework develops and becomes more commonplace, physician-certifying bodies may update standards for particular clinical specialties to include a certain level of understanding of artificial intelligence. In tandem, medical education will need to adapt quickly enough to prepare new physicians for practice to use (and, in some respects, depend upon) artificial intelligence.

Although questions remain, innovation continues, and forward progress is made every day. As we have just explored, the tools available for addressing the challenges of artificial intelligence applications may still be in their infancy, but the opportunities for efficiencies and better outcomes for hospitals, physicians, and patients through the use of artificial intelligence remain limitless. C

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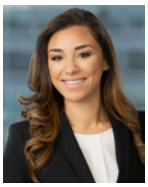

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