The use of Artificial Intelligence (AI) in medical care and pharmaceutical production is no new concept – think mass production, assembly lines, etc. - but in today's technologically-driven world, it is a nearly impossible task to keep up with the ever-evolving use of AI in healthcare, not to mention the regulation thereof. The use of AI in drug discovery (i.e., the process by which new candidate medications are discovered), diagnostic or predictive technology, identifying high-risk individuals, and data gathering are just a few on a seemingly endless list of possibilities and advancements.

A LOOK BACK
While use of the term “Artificial Intelligence” typically conjures images of robots, self-driving cars, and in short, the future, the excitement surrounding AI has been present since the reigning times of icons such as Elvis Presley and Marilyn Monroe. In fact, the birth of the field of AI occurred at a conference at Dartmouth College in 1956. In the early 1970s, AI crossed over into the medical field, when several biomedical systems, such as Internist-1, CASNET, and MYCIN, were developed. Unfortunately, the hype around these systems exceeded their actual use by healthcare practitioners, and in the mid-1970s, AI lost its momentum as well as government and public interest. Even with the development of problem-solving programs or “expert systems,” such as XCON, the late ’70s and ’80s saw something of a rocky history for AI and progress slowed.

AI did not fully begin to flourish until the ’80s and ’90s, a time when certain technological advancements came to be and the world witnessed the rise of computational power, the internet, cloud technologies, and big data. In 1997, IBM’s supercomputer Deep Blue defeated Garry Kasparov in chess, marking a milestone in the history of AI, and cognitive computers have since been rapidly developing for use in the health and pharmaceutical industries. Today, we are in a world looking at the use of AI in healthcare in ways the general public can better grasp, through products such as IBM’s Watson Oncology, Microsoft’s Hanover project, and Google’s DeepMind platform, to name a few.

AI IN TODAY’S MEDICAL PRACTICE
How many have typed their flu-like symptoms into WebMD only to walk away grappling with how to break the news of their impending death to others? While the use of AI in diagnostic technology is no new concept, the evolution of its use in the exam room has made vast strides in recent years and is changing the practice of medicine daily.

We cannot discuss the diagnostic capabilities of AI without first looking at AI’s role in data management. The advancements in AI have enabled the collection of big data, and with big data comes an endless list of possibilities of what to do with that data. Data mining of a patient’s history alongside a global database of comparable cases provides a platform for physicians to make faster diagnoses and analyze an array of treatment options, presumably eliminating human biases and reducing human error. The use of AI in interpreting personal health records in patient care spans from diagnostic assistance to risk monitoring to genome sequencing – not to mention cost reduction.

THE EVOLUTION OF THE USE AND REGULATION OF ARTIFICIAL INTELLIGENCE IN MEDICAL PRACTICE AND DRUG DEVELOPMENT

The use of AI in drug discovery (i.e., the process by which new candidate medications are discovered) has been a topic of interest in recent years. AI can help in the identification of drug targets, prediction of drug efficacy, and optimization of drug compounds. For example, AI can be used to analyze large datasets of chemical structures and biological activities to identify potential drug targets.

Moreover, AI can be used in the development of personalized medicine, where a patient’s genetic makeup is analyzed to determine the best treatment options. AI can help in predicting how a patient will respond to a particular drug based on their genetic profile.

Regulation of AI in drug discovery is an important aspect to consider. While AI can help in the development of new medications, it is crucial to ensure that the use of AI is ethical and transparent. The regulatory landscape for AI in drug discovery is evolving, and it is important to stay updated on the latest regulations.

In conclusion, AI has the potential to revolutionize the drug discovery process by improving efficiency, reducing costs, and personalizing treatment options. However, it is essential to address ethical and regulatory concerns to ensure that the benefits of AI are realized safely and responsibly.
Currently, Memorial Sloan Kettering Cancer Center is teaching IBM’s Watson Oncology how to interpret cancer patients’ clinical information and identify individualized, evidence-based treatment options. It is currently used in more than 50 hospitals in 13 countries. IBM’s website describes the program as able to “derive hundreds of attributes from a patient’s electronic health record, including doctors’ notes and lab reports, and analyzes them using Natural Language Processing (NLP) technology. Then, it provides clinicians with confidence-ranked treatment options and supporting evidence to help them make treatment decisions for their patients.”

Another example is seen in Google’s AI program DeepMind. In July 2016, Google and Moorfields Eye Hospital announced a collaboration in which DeepMind would be applied to analyze eye scans, searching for serious conditions and early signs of diseases associated with blindness.

**AI IN DRUG AND DEVICE DISCOVERY**

On the pharmaceutical side of the spectrum, we are seeing how AI enables pharmaceutical companies to quickly review masses of scientific data in drug discovery and drug development and furthermore, reduce the time to market. It also assists in regulatory compliance, clinical trials, manufacturing, and supply chain. AI can be used to predict how molecules will react in a given biological system, thereby reducing costs spent on drug testing. On the clinical trial side, the industry is seeing the use of AI to predict the benefits of using one individual in a clinical trial over another individual, as well as detecting adverse events and reporting to the FDA.

Just last year, the program Atomwise launched a virtual search for existing medicines that could be restructured to treat the Ebola virus. Atomwise uses supercomputers to scan databases of molecular structures and pulls out therapies therefrom. Within one day, the program found two drugs predicted for use in treating Ebola, an analysis that typically would have taken months or even years. Data mining is similarly used in the pharmaceutical industry to analyze drug impacts and predict future uses. “Real World Evidence” is collected outside of clinical trials and is used to determine patient use of a device for other indications outside the device’s intended use. The evidence is then used to gain FDA permission for such use.

Clinical trials for medical devices are also impacted significantly by AI. The ability to gather so much data can result in better implemented design adaptation in later stages of medical device approval. Adaptive clinical study design accounts for planned modifications based on the accumulation of study data without undermining the study’s integrity. Changing the course of a study’s design can pose risks to patients as well as to the integrity of the study; however, “if well executed, adaptive design can reduce the time and cost of clinical research.” With faster and more thorough collection of data via AI, risks are fewer and new devices can get to patients faster.

**NAVIGATING GOVERNMENT REGULATION OF AI**

The regulation of AI, like AI itself, is, well, complicated. Beyond the obvious patient information protection laws, such as HIPAA, the regulation of AI is a moving target. Although the 21st Century Cures Act, which was passed and...
CAROLINE L. ELEY

signed into law at the end of 2016, clarified the FDA’s regulation of medical software, and although there are numerous statutes and mandates designating councils and programs to oversee research and development of AI, the regulation of AI (beyond guidelines and the overlap of laws governing healthcare and pharmaceuticals generally) can be difficult to navigate for providers and drug and device manufacturers.

To address the regulatory challenges the FDA has faced as a result of the constant evolution of AI in healthcare – mobile medical apps, tracking devices that report to databases afar, the use AI for diagnostics or treatment advice, cyber security issues, etc. – the FDA has created a digital health unit within its Center for Devices and Radiological Health. The unit will be comprised of software engineers and digital health experts with a goal of assisting the development of reliable predictors of quality, test data collection and analysis models and ultimately streamlining the software review process.

What will come of the government’s efforts to regulate AI’s undeniable presence in healthcare? The future will tell. The FDA is currently developing draft guidance for public comment to help the administration fully contemplate how the 21st Century Cures Act affects FDA’s oversight of medical device software. Other issues that will likely arise from the use of AI in the medical exam room are licensing questions and new twists to medical malpractice lawsuits. In the data-driven and predictive world that AI’s use in healthcare has presented, it appears the regulation of such is not so predictable after all.