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Paging Dr. Robot: Applying an Outdated, Regulated Scheme to Robotic Medicine

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PAGING DR. ROBOT: APPLYING AN OUTDATED, REGULATED SCHEME TO ROBOTIC MEDICINE

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I. INTRODUCTION

On April 22, 2018, eighteen-year-old Deanna Recktenwald stared death square in the face and did not even know it, at least not until her robotic sidekick—her Apple Watch—notified her to seek immediate medical attention.[1] As Deanna quietly and calmly sat in church, her smart watch pinged her out of nowhere, alerting her that her resting heart rate had skyrocketed from a normal rate of sixty to one hundred beats per minute to a rate of one hundred ninety beats per minute.[2] Her watch immediately instructed her to reach the nearest hospital and, upon arrival, emergency room physicians performed a series of tests confirming that Deanna's smart watch was correct—her heart rate was abnormally high.[3] Within hours, medical professionals told Deanna that her Apple Watch "helped catch a serious condition from which she was unaware she was suffering," a genetic condition known as Alport system.[4] The condition was causing Deanna's kidneys to function at twenty percent and fail.[5] Doctors warned her that she was lucky to be alive and told her that if the smart watch had not alerted her to the symptoms, she would have required an emergency kidney transplant.[6]

Deanna's story is not unique, but is one of the many stories considered at the start of a technological revolution in the healthcare world—an Artificial Intelligence ("AI") revolution.[7] The words AI and revolution in one sentence may evoke futuristic images of robotic machines who become more innovative and advanced than their creators, ultimately deciding to annihilate civilization.[8] But, in reality, imagining a *dystopian future* with an

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1. *Teen's Life Saved by Apple Watch That Alerted Her Heart Condition*, INSIDE EDITION: NEWS (May 4, 2018, 8:23 AM), http://www.insideedition.com/teens-life-saved-apple-watch-alerted-her-heart-condition-43024.

2. *Id.*

3. *Id.*

4. *Id.*

5. Christina Capatides, *Teen's Apple Watch May Have Saved Her Life*, CBS NEWS (May 2, 2018, 6:18 PM), http://www.cbsnews.com/news/teens-apple-watch-may-have-saved-her-life/.

6. *Id.*

7. *See id.*; Carrie Marshall, *The Doctor on Your Wrist: How Wearables Are Revolutionizing Healthcare*, TECHRADAR: NEWS (July 7, 2018), http://www.techradar.com/news/the-doctor-on-your-wrist-how-wearables-are-revolutionizing-healthcare; Michael Reilly, *With a Little AI, Apple Watch May Be Able to Spot a Heart Problem*, MIT TECH. REV.: CONNECTIVITY (May 12, 2017), http://www.technologyreview.com/s/607867/with-a-little-ai-apple-watch-may-be-able-to-a-spot-heart-problem/. In fact, the Apple Watch is credited with saving over three lives by alerting its wearers to *seek immediate medical help*. Marshall, *supra*.

8. Scott Bennett & Leeann Habte, *Artificial Intelligence in Health Care: Welcome to the Machine*, AHLA CONNECTIONS, June 2018, at 16, 17.

impending doom is not necessary to see just how AI can change the way we live our lives.[9] Wearables such as the Apple Watch or Fitbit are no longer engineered to just monitor how many steps a user takes in one day or a user's resting heart rate; they employ a form of AI technology that mimics the human brain to detect irregular heartbeats and spot health issues such as high blood pressure, sleeping issues, and even atrial fibrillation.[10] AI has turned these flashy devices from fashion into robotic doctors on your wrist and that is only a sliver of how healthcare is beginning to incorporate data-driven intelligence to save lives.[11]

The very first glimpse of AI occurred in the late 1950s.[12] One of the brightest minds of Dartmouth, professor John McCarthy, brought together a group of computer scientists in a workshop, known today as the Dartmouth Workshop, to create his vision of getting computers to learn language just as humans do.[13] McCarthy's ideas on computer learning led the creation of the field of AI.[14] From the 1950s on, the field developed and never stopped.[15] From computers that played checkers to the first computer world chess champion, milestone after milestone was reached as computers completed tasks, just like humans.[16]

AI has come a long way since, but as innovation continues to move at the speed of light, complex issues begin to present themselves.[17] While AI is taking humankind into the future—left, right, and center—AI is being applied to various industries, but laws and regulations are struggling to keep

9. *Id.*

10. Megan Molteni, *With AI, Your Apple Watch Could Flag Signs of Diabetes*, WIRED: SCI. (Feb. 7, 2018, 10:00 AM), http://www.wired.com/story/with-ai-your-apple-watch-could-flag-signs-of-diabetes/; *see also This Artificial Intelligence Model Mimics Human Brain*, ECON. TIMES (July 24, 2018, 12:22 PM), http://www.economictimes.indiatimes.com/news/science/this-artificial-intelligence-model-mimics-human-brain/articleshow/65115249.cms.

11. *See* Jane R. Bambauer, *Dr. Robot*, 51 U.C. DAVIS L. REV. 383, 388 (2017); Marshall, *supra* note 7.

12. Tom Simonite, *The Wired Guide to Artificial Intelligence*, WIRED: BUS. (Feb. 1, 2018, 9:22 AM), http://www.wired.com/story/guide-artificial-intelligence/.

13. *Id.*

14. *Id.*

15. *See id.*

16. *Id.*; *see also* Pavel Hamet & Johanne Tremblay, *Artificial Intelligence in Medicine*, 69 METABOLISM CLINICAL & EXPERIMENTAL, S36, S37 (2017).

17. *See* Michael Guihot et al., *Nudging Robots: Innovative Solutions to Regulate Artificial Intelligence*, 20 VAND. J. ENT. & TECH. L. 385, 394 (2017); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753, 1753–54 (1996).

tempo with the growth and change of such technological advancement.[18] One of the biggest and most worrisome issues facing regulatory agencies is AI as applied to the healthcare world, its medical devices, and its drugs.[19] The daunting task of determining what is the best route to regulate AI medicine so it is safe and effective falls to the purview of the United States Food and Drug Administration ("FDA").[20] While the FDA's traditional reaction to change in the healthcare world is to wait out innovation until a public health crisis forces regulatory amendment, history will not repeat itself this time.[21] The FDA has issued guidance and attempted to get ahead of innovation, promoting AI in healthcare—but that begs the question, is caution warranted?[22]

This Comment will first provide an introduction to AI, going in-depth on its history and how it has rapidly developed in the medical culture.[23] More specifically, the Comment will discuss the types of AI, breaking down the difference between machine-learning ("ML") and deep-learning ("DL") intelligence.[24] Part III of this Comment will then discuss the FDA in great detail, providing a historical overview of how the FDA has developed since its establishment and how it has reacted to previous healthcare advancements.[25] Additionally, it will discuss how the FDA currently regulates medical devices and drug discoveries.[26] Part IV of this Comment will explain the FDA's newest proposed regulatory guidelines for how to regulate AI's incorporation into healthcare devices and the risks of regulating AI so quickly.[27] Finally, Part V will offer a conclusion.[28]

II. AN INTRODUCTION TO AI

"The development of full [AI] could spell the end of the human race . . . . [AI] would take off on its own, and re-design itself at an ever-increasing

18. Asokan Ashok, *The Impact of Artificial Intelligence in Healthcare*, MEDIUM (Aug. 24, 2017), http://www.medium.com/@Unfoldlabs/the-impact-of-artificial-intelligence-in-healthcare-4bc657f129f5.

19. *Id.*

20. *See* Bambauer, *supra* note 11, at 385; Ashok, *supra* note 18.

21. *See* Merrill, *supra* note 17, at 1761–62; Ashok, *supra* note 18.

22. *See* Ashok, *supra* note 18; Aaron Gin & Bryan Helwig, *FDA Signals Fast-Track Approval for AI-Based Medical Devices*, BLOOMBERG L. (May 9, 2018, 2:26 PM), http://news.bloomberglaw.com/tech-and-telecom-law/fda-signals-fast-track-approval-for-ai-based-medical-devices-1/.

23. *See infra* Section II.A.

24. *See infra* Section II.A.2–3.

25. *See infra* Section III.A.

26. *See infra* Section III.B.

27. *See infra* Part IV.

28. *See infra* Part V.

rate. Humans, who are limited by slow biological evolution, [could not] compete, and would be superseded."[29]

A. *History of AI*

Modern society is no stranger to the term AI.[30] The reality is that AI is not a novel concept; since the 1950s, AI has been embedded in our culture as an idea of science fiction, with everything from onscreen entertainment to education.[31] The common perception of AI is derived from box-office hits such as *Star Wars*, *I, Robot*, *Blade Runner*, and *Interstellar*, where "AI beings who . . . challenge[] what it means to be human" have been brought to the screen of modern society.[32] But what is AI?[33] Where did this unorthodox and critically important scientific idea that is going to affect so many industries come from?[34] Before embarking on AI's origin story—and how it became a field in need of its own regulation—it is important to define what intelligence is first.[35] In terms of mankind, intelligence has been defined as characteristics comprised of "consciousness, self-awareness, language use, the ability to learn, the ability to abstract, the ability to adapt, and the ability to reason."[36] Calculations or approximations of such characteristics shape the *benchmark of attempts* to recreate or mimic such intelligence, also known as AI.[37] Understanding what the threshold criteria should be for a simulation possessing such intellectual qualities to be deemed an AI is precisely what Dartmouth professor, John McCarthy, attempted to define in 1956 when he coined the term AI.[38]

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29. Bernard Marr, *28 Best Quotes About Artificial Intelligence*, FORBES (July 25, 2017, 12:28 AM), http://www.forbes.com/sites/bernardmarr/2017/07/25/28-best-quotes-about-artificial-intelligence/#50783d374a6f.

30. *See* Michael Hogan & Greg Whitmore, *The Top 20 Artificial Intelligence Films — in Pictures*, GUARDIAN (Jan. 8, 2015, 7:29 PM), http://www.theguardian.com/culture/gallery/2015/jan/08/the-top-20-artificial-intelligence-films-in-pictures; Simonite, *supra* note 12.

31. *See* Ashok, *supra* note 18; Hogan & Whitmore, *supra* note 30; Simonite, *supra* note 12.

32. Hogan & Whitmore, *supra* note 30.

33. *See* Guihot et al., *supra* note 17, at 393–96; Simonite, *supra* note 12.

34. *See* Simonite, *supra* note 12.

35. Guihot et al., *supra* note 17, at 393.

36. *Id.*

37. *Id.* at 393–94.

38. *Id.*; Simonite, *supra* note 12. The pioneers of AI date back to names such as Alan Turing and John von Neumann who focused on strong AI. M. Tim Jones, *A Beginner's Guide to Artificial Intelligence, Machine Learning, and Cognitive Computing*, IBM DEVELOPER (June 1, 2017), http://developer.ibm.com/articles/cc-beginner-guide-machine-learning-ai-cognitive/.

McCarthy "defined AI as 'the science and engineering of making intelligent machines, especially intelligent computer programs.'"[39] He was careful not to confine intelligence in AI to an exact *replication of human intelligence*; instead, McCarthy contended that machines had the ability to exhibit other intelligences that required "much more computing than people can do."[40] McCarthy created and coined the field of AI by approaching a small group of colleagues and asking them to study the possible idea of making "machines do things [such as] use language."[41] The study has been referred to as the Dartmouth Workshop, recognized for "[giving] birth to what developed into a new interdisciplinary research area."[42] The work accomplished at the Dartmouth Workshop "focused on solving fairly abstract problems in math and logic" that resulted in the algorithms that we know and see in AI today.[43]

Early AI research, such as the Dartmouth Workshop, created a hype in the development of the AI field that resulted in computers starting "to solve . . . complex mathematical problems."[44] Computer scientists began to develop "[i]nstruments with increasing computational power.[45] These discoveries paved the way for technological achievements such as IBM's Deep Blue winning the title of World Chess Champion in 1997, when it defeated its human opponent, Gary Kasparov.[46] Today, AI is treated as a subset of the engineering field that implements innovative concepts and "solutions to []solve complex challenges."[47]

1. What is AI?

In today's day and age, AI plays a role by "powering . . . technology that impacts people's daily lives."[48] AI is the substructure of nearly every

39. Guihot et al., *supra* note 17, at 394 (quoting John McCarthy, *What Is Artificial Intelligence?*, STAN. U. 2 (Nov. 12, 2007, 2:05 AM), http://jmc.stanford.edu/articles/whatisai/whatisai.pdf).

40. *Id.*; McCarthy, *supra* note 39, at 3.

41. Simonite, *supra* note 12.

42. Hamet & Tremblay, *supra* note 16, at S37; Simonite, *supra* note 12.

43. Simonite, *supra* note 12. An algorithm is a program that evaluates data and executes given instructions. *See* Jeff Goodell, *Inside the Artificial Intelligence Revolution: A Special Report, Pt. 1*, ROLLING STONE: CULTURE (Feb. 29, 2016, 2:05 PM), http://www.rollingstone.com/culture/culture-news/inside-the-artificial-intelligence-revolution-a-special-report-pt-1-118333/.

44. Hamet & Tremblay, *supra* note 16, at S37.

45. *Id.*

46. Simonite, *supra* note 12.

47. Hamet & Tremblay, *supra* note 16, at S37.

48. *Understanding the* Black Box *of Artificial Intelligence*, SENTIENT: BLOG (Jan. 9, 2018), http://www.sentient.ai/blog/understanding-black-box-artificial-intelligence/.

website, cellphone, and tool that we use today—without it, iPhones would not ring, iPads would not turn on, and Twitter would not tweet.[49] So what exactly is AI?[50] Well, simply put, it is a complex "mathematical equation that [instructs] a computer [on] what [task] to perform."[51] The guide to breaking down AI algorithms can be complex and dense because these mathematical equations have many different parts to them.[52] In its earliest stages, the main focus on the development of AI was to get a machine to "perform any intellectual task that a human could [do]."[53] This developmental focus became known as *strong AI* or Artificial General Intelligence ("AGI"), which does not exist yet in today's society.[54] AGI is defined or referred to as *machine sentience* or the "possess[ion] [of] a reasonable degree of self-understanding, . . . the ability to solve a variety of complex problems in a variety of contexts, and [the ability to] learn to solve new problems that [it] didn't know about at the time of [its] creations."[55] Due to a lack of progress in the field of AI for many years, an area in the field of AI was created on its own—one which is prevalent in our everyday lives—known as *weak* or *narrow* AI.[56] This type of AI is exactly what it sounds like: AI that is not real and "focused on [carrying out] a single task."[57] Narrow AI is what "is used to recommend what films you watch on Netflix or what songs you listen to on Spotify," or even to recommend a course of medical treatment; it essentially powers unexceptional machinery with exceptional algorithms.[58]

2. ML

However, achieving such technological advancement in making machines smart did not occur without digression from the original goal of

49. *See id.*; Goodell, *supra* note 43.

50. Jason Chung & Amanda Zink, *Hey Watson — Can I Sue You for Malpractice? Examining the Liability of Artificial Intelligence in Medicine*, ASIA PAC. J. HEALTH L. & ETHICS, Mar. 2018, at 51, 53.

51. Goodell, *supra* note 43.

52. *See* Jones, *supra* note 38. The definitions, or lack thereof, is a discussion beyond the scope of this Comment.*

53. *Id.*

54. Guihot et al., *supra* note 17, at 396.

55. ARTIFICIAL GENERAL INTELLIGENCE vi (Ben Goertzel & Cassio Pennachin eds., 2007); Chung & Zink, *supra* note 50, at 53.

56. Chung & Zink, *supra* note 50, at 53; Jones, *supra* note 38.

57. Chung & Zink, *supra* note 50, at 53.

58. *Understanding the* Black Box *of Artificial Intelligence*, *supra* note 48; Chung & Zink, *supra* note 50, at 54.

AI.[59] During the early years of AI development and research, scientists and engineers found themselves torn between AI and AGI, ultimately stumbling upon a new type of algorithm known as ML.[60] ML, originally developed in the 1980s, quickly became a leading subset of AI research.[61] The goal behind ML is to give machines, especially computers, "the ability to learn and build models so . . . they [are able to] perform activities [such as] prediction within specific domains."[62] But, what is ML?[63] Is it a technology or a separate type of intelligence?[64] Google defines ML as:

> A program or system that builds—[or] trains—a predictive model from input data. The system uses the learned model to make useful predictions from new—[or] never-before-seen—data drawn from the same distribution as the one used to train the model. [ML] also refers to the field of study concerned with these programs or systems.[65]

ML can be thought of as types of AI math equations that tell a computer what to do.[66] These math equations are based off of algorithms that "have been around for thousands of years and [used for basic] modern computer[s]."[67] Put simply, these equations put data in the computer and the "algorithm spits out a result."[68] What is different about ML algorithms is that the computers *write their own algorithms*.[69] How does this work?[70] If you wanted to teach a computer how to perform an MRI of a brain, first you would write an algorithm that teaches the computer the controls of the MRI machine and input the data.[71] Next, you would tell the computer how and what parts of the brain you want scanned—known as the result.[72] Finally, the computer will give its own algorithm that tells the MRI machine how to

59. *See* Hamet & Tremblay, *supra* note 16, at S37; Goodell, *supra* note 43; Jones, *supra* note 38.
60. *See* Jones, *supra* note 38.
61. *Id.*
62. *Id.*
63. *See id.*; Goodell, *supra* note 43.
64. *See* Jones, *supra* note 38.
65. *Machine Learning Glossary*, GOOGLE DEVELOPER, http://developers.google.com/machine-learning/glossary/?utm_source=google-ai&utm_medium=card-image&utm_campaign=training-hub&utm_content=ml-glossary#m (last visited May 1, 2019).
66. Goodell, *supra* note 43.
67. *Id.*
68. *Id.*
69. *Id.*
70. *See id.*
71. *See* Goodell, *supra* note 43.
72. *See id.*

perform a scan of a brain.[73] This ML approach is called supervised ML, which allows computer software to learn by example, either by a photograph or specific data.[74] This type of learning means the data is classified.[75]

On the other hand, an unsupervised ML approach is defined as "[l]earning without annotated examples, just from experience of data or the world—trivial for humans but not generally practical for machines."[76] Unsupervised learning means there are no classified data sets.[77] Using the example above, in an unsupervised learning approach the algorithm would not tell the computer how to use MRI controls or even what result it wanted.[78] Instead, the computer itself would realize there are different machine controls to be used and different ways to perform an MRI scan and would try to perform the task on its own.[79] In modern society, the application of ML is around us every day.[80] The phone app Google Maps uses supervised ML algorithms to find the *quickest route* and "calculate traffic delays based on real-time data."[81]

3. DL

ML has a lot of mathematical and statistical areas to it.[82] One of those areas is called DL.[83] DL is defined as a "[ML] technique in which data is filtered through self-adjusting networks of math loosely inspired by neurons in the brain."[84] Those *self-adjusting networks* are known as Artificial Neural Networks ("ANNs") and were originally discovered in 1958 but lost their popularity quickly due to a lack of belief that they would be very powerful.[85] In 2012, scientists proved that ANNs would be extremely effective and would fuel large piles of data, thereby giving computers the ability to perceive new intelligence capabilities.[86] Today, DL is able to revolutionize the way AI is used by employing neural networks.[87] With the

73. *See id.*
74. *See id.*; Simonite, *supra* note 12.
75. *See* Goodell, *supra* note 43; Jones, *supra* note 38.
76. Simonite, *supra* note 12.
77. *See id.*; Jones, *supra* note 38.
78. *See* Goodell, *supra* note 43; Simonite, *supra* note 12.
79. *See* Goodell, *supra* note 43; Simonite, *supra* note 12.
80. Goodell, *supra* note 43.
81. *Id.*
82. *See* Simonite, *supra* note 12.
83. *Id.*
84. *Id.*
85. *Id.*
86. *Id.*
87. Ariel Bleicher, *Demystifying the Black Box That Is AI*, SCI. AM. (Aug. 9, 2017), http://www.scientificamerican.com/article/demystifying-the-black-box-that-is-ai/.

use of ANNs, DL is able to put "large data sets through networks set up to mimic the human brain's neural network in order to teach computers to solve specific problems on their own, such as recognizing patterns or identifying . . . object[s] in a photo[]."[88] The process begins by a neural network first receiving an input of data—so, for example, pixels of a photograph of a dog—and scoring this data "according to simple mathematical rules, and then pass[ing] the [results] to the next layer of [neurons]."[89] A DL network has "anywhere from three to hundreds of layers."[90] The last layer in a DL network outputs a singular prediction—so, for example, it would predict: This is a photo of a dog.[91] If the last layer makes the incorrect prediction—for example, this is a photo of a bear—then the algorithm will correct itself because the neural net has "create[d] a structured set of relationships [during the process] . . . that can classify new images or perform actions under conditions it has never encountered before."[92] The neural networks make it possible for AI systems to adapt to—and learn with accuracy—patterns that are too complex and that would take too long for humans to be able to accomplish on their own.[93] Additionally, these networks reflect the trial and error process of the human brain, and they do so at a speed that is not humanly possible.[94]

So, what is the difference between regular ML, which involves supervised and unsupervised learning, and DL?[95] ML forces computers to perform tasks through the use of *repeated drills* written in the algorithm; the computer is constantly being corrected and given instruction by the programmer—the process is similar to the way a child learns a new word: A teacher will have the child repeat the word again and again, or perhaps give a spelling test until that child has learned that new skill.[96] During the process of ML, the computer does not learn from its mistakes until the programmer points them out and, until the computer reaches a *certain level of accuracy*,

88. Larry Greenemeier, *AI Is Not Out to Get Us*, SCI. AM. (Oct. 24, 2016), http://www.scientificamerican.com/article/ai-is-not-out-to-get-us/.

89. Bleicher, *supra* note 87.

90. *Id.*

91. *Id.*

92. *Id.*

93. *See id.*

94. *Understanding the* Black Box *of Artificial Intelligence*, *supra* note 48.

95. Bernard Marr, *What Is the Difference Between Deep Learning, Machine Learning and AI?*, FORBES (Dec. 8, 2016, 2:14 AM), http://www.forbes.com/sites/bernardmarr/2016/12/08/what-is-the-difference-between-deep-learning-machine-learning-and-ai/#6f4e537226cf.

96. Abhi Arunachalam, *How Deep Is Your Learning?*, FORBES (Mar. 29, 2016, 1:13 PM), http://www.forbes.com/sites/valleyvoices/2016/03/29/how-deep-is-your-learning/.

the process continues.[97] On the other hand, DL eliminates the need for a programmer—or teacher—and instead the computer can "self-improve [via] the [analysis of] large data sets."[98] With DL, the algorithm is basically teaching the computer to learn like a human all on its own.[99] Various companies have already applied the technologies of DL algorithms to their products.[100] Products that serve as digital assistants, such as Apple's Siri or Amazon's Alexa, are able to recognize speech and translate perfectly because of neural networks.[101] Machines and computers are able to recognize images, predict disease, and beat humans at video games because of deep neural networks.[102] Now, the application of DL to the healthcare world is making its debut.[103]

B. *AI in Medicine*

AI is constantly being applied to countless industries—from finance to transportation—and these algorithms are changing the way we live life.[104] One of the most exciting and hopeful applications of AI to modern industries is in the context of healthcare.[105] For years, specialists in the field of healthcare have struggled with balancing the exorbitant amount of patient information with diagnosing disease accurately, and with an overall shortage of clinical support.[106] According to the World Health Organization, there is no indication that there will be a decline in disease, death, or medicine in general in the future:

> [B]y 2020, the prevalence of chronic disease is expected to rise [fifty-seven percent]. However, advancements in detecting and diagnosing diseases will help to minimize the cost of treating chronic diseases. Some of these new technologies include genomics, proteomics, cell biology, stem cell and organ therapy, and minimally invasive and robotic surgery.[107]

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97. *Id.*
98. *Id.*
99. *Id.*
100. *Id.*; Goodell, *supra* note 43.
101. Bleicher, *supra* note 87.
102. *Id.*
103. *See id.*
104. Ashok, *supra* note 18.
105. *See id.*
106. *See id.*; Jennifer Bresnick, *Can Healthcare Avoid* Black Box *Artificial Intelligence Tools?*, HEALTHITANALYTICS.COM: TOOLS & STRATEGIES (Feb. 2, 2018), http://healthitanalytics.com/news/can-healthcare-avoid-black-box-artificial-intelligence-tools.
107. Ashok, *supra* note 18.

Thankfully, with the implementation of AI in the medical industry, the way physicians and healthcare professionals handle diagnosing and treating disease will be approached from an entirely new platform.[108] In modern society, AI technologies in healthcare are already present in various medical products such as: Virtual medical devices that can readily diagnose and track a patient's health without a doctor present, DL algorithms that can accelerate and assist in drug development, and the use of robots in biologicals, genomics, and surgical care.[109] The exponential and doubling growth of these technologies is why regulatory bodies need to keep a watchful eye on their outdated polices and the shifting change of how the medical world is incorporating these devices.[110] Many of the medical products and devices using AI algorithms today, such as Mobile Health ("mHealth") or Deep Patient, are breaching the topic of black-box medicine—the concern about transparency behind a machine's thoughts, such as how and why a machine generates the prediction or diagnosis that it does.[111]

C. *Black-Box Medicine*

To put it simply, "black-box medicine [is] the use of opaque computational models to make decisions related to health care."[112] The user or programmer understands what goes in to the computer and the result that comes out of the computer, but what about the process in between that the computer performs?[113] That remains a mystery.[114] One of the biggest issues in applying AI to medicine is trying to figure out why a neural network makes the decision it does—trying to get to the core behind what happens between DL layer one and three hundred.[115] The concept of black-box medicine is not new—for years users have been trusting the results of technology, apps, and computers without knowing how *A* gets translated into

108. *Id.* Early studies conducted found that nearly $630 million was spent in the healthcare industry in 2014 on AI technology. Bennett & Habte, *supra* note 8, at 17. That number is expected to grow more than nine-fold by the year 2021. *Id.*

109. *Id.*

110. *See id.* at 17–18.

111. W. Nicholson Price II, *Regulating Black-Box Medicine*, 116 MICH. L. REV. 421, 429–31 (2017); Bleicher, *supra* note 87.

112. W. Nicholson Price II, *Black-Box Medicine*, 28 HARV. J.L. & TECH. 419, 421 (2015).

113. *Understanding the* Black Box *of Artificial Intelligence*, *supra* note 48.

114. *See id.*

115. *Id.*; Bleicher, *supra* note 87.

B.[116] The prevalence of black-box medicine is most often seen in clinical decision making, whether diagnostic or therapeutic, because the computer or system is most likely providing a particular recommendation to a patient and will need to be trustworthy—an issue if the software is unable to give its reasoning as to how it arrived at its recommendation.[117]

1. The Diagnosing Devices of AI

In 2010, IBM built one of the most influential machines in AI history: Watson.[118] The company's AI masterpiece shocked the country with its television debut on *Jeopardy!*, taking home the grand prize and defeating two all-time champions.[119] Watson's "ability to synthesize [large] quantities of data and produce evidence-based hypotheses" was a unique characteristic that had never been seen before.[120] By 2012, Watson was using its data processing abilities to help medical students diagnose and treat patients.[121] By 2014, Watson had been developed to be used by doctors "to connect genomic and medical data to help drive more personalized treatments."[122] Today, Watson has worked with over twenty cancer institutes, the Department of Veteran Affairs ("VA"), and is now the frontrunner to work with the country's top oncologists to analyze samples of tumors "look[ing] for mutations in the cancer's genome."[123]

Watson has worked with over twenty-seven hundred veterans and will continue to do so through 2019.[124] But how exactly does Watson work?[125] "Watson [is] powered by DeepQA software," meaning it is using

116. Bresnick, *supra* note 106. The foundation of why a ML or DL computer does what it does is usually not necessary for the average consumer. *See id.* This issue and transparency of black-box medicine is beyond the scope of this Comment.*

117. *Id.*

118. Chung & Zink, *supra* note 50, at 54. Watson "can read [eight hundred] million pages a second and can digest the entire corpus of Wikipedia, [and can even read] decades of law and medical journals." Goodell, *supra* note 43.

119. Chung & Zink, *supra* note 50, at 54.

120. *See id.* at 54–55.

121. *Id.* at 54.

122. *Id.*

123. Sarah Wells, *IBM Watson Health and the VA Extends Partnership in Cancer Research*, TECHCRUNCH (July 19, 2018), http://www.techcrunch.com/2018/07/19/ibm-watson-health-and-the-va-extends-partnership-in-cancer-research/.

124. *Id.* "[T]he National Cancer Institute . . . estimate[s] [that about] 1,735,350 new cases of cancer will be diagnosed in 2018" and "that the veteran population [is] 3.5 [percent] of the nation's cancer patients." *Id.*

125. Alison E. Berman, *A Look at IBM's Watson 5 Years After Its Breathtaking Jeopardy Debut*, SINGULARITY HUB (Aug. 10, 2016),

an AI software used to analyze, reason, and answer content that is *fed into* it.[126] Oncologists use Watson by "[u]pload[ing] the DNA fingerprint of a patient's tumor, which indicates which genes are mutated . . . and Watson . . . sift[s] through thousands of mutations [to] try to identify which [one] is driving the tumor and therefore what a drug must target."[127] Unfortunately, researchers still have kinks to figure out as the United States health system and its flaws create flaws in the way Watson's algorithm functions and processes data—the medical records and information Watson sorts through is not error free and was "initially digitized for . . . hospital administrators, not for . . . disease treatment."[128]

But IBM and Watson are not the only dynamic duo making waves in the world of medical AI; in 2018, Google released a new type of algorithm that could help predict a patient's risk of death.[129] In May, "[a] woman with late-stage breast cancer came to a city hospital, fluids already flooding her lungs. She saw two doctors and [received] a radiology scan. The hospital's computers read her vital signs and estimated a 9.3 percent chance she would die during her stay."[130] Google applied its new algorithm to Jane Doe to asses her death risk, something unheard of in healthcare.[131] The result?[132] A 19.9 percent chance, and within just a matter of days, Jane Doe had passed.[133] Google used Jane Doe's data to publish research regarding the use of ANNs and DLs to create a system that would be able to "forecast . . . patient outcomes, including how long people may stay in hospitals, their odds of re-admission and chances they will soon die."[134] The AI system used everything from a random scribbled nurse's note hidden deep in Jane's file to large CT scans to make its prognosis—and it did so in twice the speed of a doctor, with almost none of the mistakes.[135] The system amazed researchers and physicians as it "gobbled up all [the] unruly information

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http://www.singularityhub.com/2016/08/10/a-look-at-ibms-watson-5-years-after-its-breathtaking-jeopardy-debut/.

126. *Id.*

127. *Id.*

128. *Id.*

129. Mark Bergen, *Google Is Training Machines to Predict When a Patient Will Die*, BLOOMBERG (June 18, 2018, 5:00 AM), http://www.bloomberg.com/news/articles/2018-06-18/google-is-training-machines-to-predict-when-a-patient-will-die.

130. *Id.*

131. *See id.*

132. *See id.*

133. *Id.*

134. Bergen, *supra* note 129.

135. *Id.*

[and] then spat out predictions . . . even show[ing] which records led it to [what] conclusions."[136]

Innovation does not stop there; in 2018, more than three new medical devices that focused on different types of diagnoses received attention from the FDA.[137] First, Viz.ai engineered a *large vessel occlusion* ("LVO") *Proactive Stroke Pathway* ("PSP").[138] Using DL technology, the software helps automatically detect and alert on-call physicians that a patient is having signs of a stroke.[139] Additionally, IDx LLC released its new device IDx-DR which is engineered to detect a condition known as diabetic retinopathy, exclusively found in adults with diabetes.[140] Moreover, AI developers have started to utilize algorithms similar to Watson's, that allow software to make a diagnosis by reviewing images stored in a database.[141]

The impact of software such as IBM's Watson, and Google's Medical Brain on regulatory bodies are countless.[142] Such black-box applications of ML and DL algorithms to provide for "medication assistance . . . and communicat[ion] with doctors" create access to data and the ability

136. *Id.*

137. Rabiya S. Tuma, *Caution Needed with Artificial Intelligence in Medicine, Experts Warn*, MEDSCAPE (May 29, 2018), http://www.medscape.com/viewarticle/897350#vp_1; *see also* Gin & Helwig, *supra* note 22. In 2016, an "experimental neural net . . . called Deep Patient" was created to review over "[twelve] years' worth of electronic health records—including [everything from] test results [to] hospital visits—from 700,000 patients." Bleicher, *supra* note 87. The system was successful and able to predict accurate diagnosis on its own without the help or input from a doctor. *Id.* This system is a traditional black-box medical AI, as researchers know what goes in and understand the result that comes out, but do not receive an analysis or reasoning behind the diagnosis given. *Id.*

138. Gin & Helwig, *supra* note 22; Tuma, *supra* note 137; *Viz.ai*, VIZ. AI, http://www.viz.ai[http://www.web.archive.org/web/20181109145100/https://www.viz.ai/] (last visited May 1, 2019).

139. Gin & Helwig, *supra* note 22; *Viz. ai*, *supra* note 138.

140. Gin & Helwig, *supra* note 22; *see also* Tuma, *supra* note 137.

141. *See* Kif Leswing, *Apple CEO Tim Cook Gave a Shout-Out to a $100-Per-Year App for Doctors — Here's What It Does*, BUS. INSIDER (Nov. 19, 2017, 8:30 AM), http://www.businessinsider.com/visualdx-machine-learning-app-for-skin-diagnosis-ceo-interview-2017-11.

142. *See* Drew Simshaw et al., *Regulating Healthcare Robots: Maximizing Opportunities While Minimizing Risks*, 22 RICH. J.L. & TECH., no. 2, 2016, at 1, 15. Predicting medical events before they occur is also a very big benefit of AI's application to health. *See* Abby Norman, *Your Future Doctor May Not Be Human. This Is the Rise of AI in Medicine.*, FUTURISM: SCI-FI VISIONS (Jan. 31, 2018), http://futurism.com/ai-medicine-doctor/. Recent studies indicate that with "data from 378,256 patients, a self-taught AI [was able to predict] 7.6 percent more cardiovascular events in patients than the [previous] standard of care." *Id.* To put it in layman's terms, the AI "had 1.6 percent [less] . . . cases in which [a] risk was overestimated, possibly leading to patients having unnecessary, [risky] procedures or treatments [done]." *Id.*

to share such data on a global scale.[143] These applications and data collections are very distinguishable from what is already being utilized in the healthcare world, such as websites like WebMD and the like, creating a regulatory loophole in classification categories that fall under the jurisdiction of regulatory bodies such as the FDA.[144]

2. Surgical Robots

For nearly a decade, the idea of going *[u]nder the [r]obotic [k]nife* has been making headlines.[145] Infamous AI robot systems, like the daVinci Surgical System, provide doctors with a robotic arm of a sort, turning surgery into a robotic video game.[146] The daVinci system allows surgeons to change how operations are performed by allowing them to make a few small incisions.[147] While surgical robots "present a number of . . . legal issues [such as] . . . product and practice liability," they also apply ML and DL AI in *traditional medical devices* providing for unique regulation challenges.[148] The daVinci is not the only robodoc; in 2010, Canadian surgeons used daVinci in-tandem with the world's first *robot anesthesiologist*, McSleepy, to perform surgery successfully.[149] The evolution of robotic surgeons does not necessarily mean a green light for the AI application to the medical device world; the FDA needs to be on the look-out.[150] A study conducted in 2015 by MIT staff using FDA data of robotic surgery statistics discovered that "144 patient[s] [had died] and 1,391 patient injuries [had been] reported [due to] technical difficulties or device malfunctions."[151] The study showed that the more complex the surgery, the higher the number of events occurred.[152] The question to consider becomes: As AI begins to be applied to accountable areas of life such as medicine and surgery, who begins to regulate it and how?[153]

143. *See* Simshaw et al., *supra* note 142, at 11.
144. *See id.* at 15, 17–20.
145. Norman, *supra* note 142.
146. *See id.*; Simshaw et al., *supra* note 142, at 9.
147. Hamet & Tremblay, *supra* note 16, at S37; Anthea Gerrie, *The da Vinci Code: Why a Robotic System Replaces* Chopstick *Surgery*, MEDTECH ENGINE: INNOVATION & ENTREPRENEURSHIP (Oct. 14, 2016), http://www.medtechengine.com/article/da-vinci-surgical-system/.
148. Simshaw et al., *supra* note 142, at 9.
149. Norman, *supra* note 142.
150. *See id.*
151. *Id.*
152. *Id.*
153. *See* Simshaw et al., *supra* note 142, at 7, 15, 17–20.

3. Precision Medicine and Drug Discovery

As the role of AI continues to be applied to various areas of the medical world, one of the biggest applications is in the *one-size-fits-all* treatment mentality that has plagued the healthcare industry.[154] Thanks to these technologies, we are now aware that everyone has a different genetic code and when it comes to disease treatment and prevention, may react differently to medications.[155] Precision medicine is the emerging approach for drug treatment, taking into account the varying genetic codes and disregarding the *one-size-fits-all* approach.[156] The National Institute of Health defines precision medicine as "an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment, and lifestyle."[157] This type of treatment would break the barriers of illness, allowing people to recover faster and stay healthy longer.[158] How do we accomplish the wonders of precision medicine?[159] Well, due to the length of time it takes to develop a drug and the extremely high cost, not to mention the amount of data, AI, ML, and DL algorithms can help to resolve many of the issues that are present when it comes to treating diseases such as Ebola and cancer.[160] In 2015, a company called Atomwise released its software—a database that runs off of DL and AI—to help re-engineer existing medications that could help treat the Ebola virus.[161] The DL black-box system was successful in identifying two medications that would help reduce the pain and suffering that people with the virus experience—a process that usually takes ten months to ten years to uncover.[162] But the drug innovation does not stop there; in May of 2018, researchers at the University of Washington School of Medicine developed a

154. Hema Chamraj, *Powering Precision Medicine With Artificial Intelligence*, INTEL AI (Mar. 6, 2018), http://ai.intel.com/powering-precision-medicine-artificial-intelligence/; *see also There Is No Precision Medicine Without Artificial Intelligence*, MED. FUTURIST (Oct. 19, 2017), http://medicalfuturist.com/no-precision-medicine-without-artificial-intelligence/.

155. *See* Chamraj, *supra* note 154; *There Is No Precision Medicine Without Artificial Intelligence*, *supra* note 154.

156. Chamraj, *supra* note 154.

157. *Id.*

158. *Id.*

159. *See id.*; *There Is No Precision Medicine Without Artificial Intelligence*, *supra* note 154.

160. *See* Ashok, *supra* note 18; Chamraj, *supra* note 154; *There Is No Precision Medicine Without Artificial Intelligence*, *supra* note 154.

161. *There Is No Precision Medicine Without Artificial Intelligence*, *supra* note 154; *see also* Marr, *supra* note 95.

162. *There Is No Precision Medicine Without Artificial Intelligence*, *supra* note 154.

way to use mini robots to fight kidney disease.[163] Through the use of *liquid-handling robots* researchers have changed the growth of stem cells to produce *more complex three-dimensional structures* that are able to mimic "mutations that cause polycystic kidney disease."[164] Researchers and innovators in the drug development world call this and other applications of AI a "*secret weapon* in our fight against disease."[165]

4. mHealth

mHealth is commonly known as a type of AI medicine that uses "mobile communications devices [such as] smartphones [or tablets] for health or medical purposes, usually for diagnosis, treatment, or . . . well-being and maintenance."[166] When it comes to mHealth apps that provide maintenance or guidance on how to stay healthy, think of the FitBit, the Apple Watch, and other devices that track steps and monitor heart rates.[167] Such devices have already been given regulatory review by the FDA and, as such, this Comment is focused on mHealth apps that are focused on predicting diagnosis and providing diagnosis, treatment, or other important information that would usually be administered by a physician.[168] An example of such an app is VisualDx.[169] A mobile app "targeted at trained and credentialed doctors who . . . use it to help diagnose skin conditions and disorders."[170] Dr. James Shoemaker, a doctor with Elkhart Emergency Physicians in Elkhart, Indiana, is an avid user of VisualDx and often uses it with his patients.[171] Shoemaker was able to even diagnose a young child with a very rare disorder called Stevens-Johnson syndrome, remarking that he "had an idea it [was] that" and that "[t]he program reinforced [his] diagnosis and helped [him] figure out the next step."[172] The app uses an AI program called CoreML, which allows it to use an ML algorithm on a phone and—this is the exciting part—instead of having to process photos on a

163. *Robots Grow Mini-Organs from Human Stem Cells*, SCIENCEDAILY (May 17, 2018), http://www.sciencedaily.com/releases/2018/05/180517123300.htm.

164. *Id.*

165. *Id.*

166. Price II, *supra* note 111, at 428 (quoting Nathan Cortez, *The Mobile Health Revolution?*, 47 U.C. DAVIS L. REV. 1173, 1176 (2014)).

167. *See id.* at 428–29.

168. *Id.*; *see also infra* Part I–V.

169. Leswing, *supra* note 141.

170. *Id.*

171. Arlene Weintraub, *Hospitals Utilize Artificial Intelligence to Treat Patients*, U.S. NEWS & WORLD REP.: CIVIC (Oct. 31, 2017, 11:00 AM), http://www.usnews.com/news/healthcare-of-tomorrow/articles/2017-10-31/hospitals-utilize-artificial-intelligence-to-treat-patients.

172. *Id.*

server, the algorithm can readily process it on a handheld device.[173] What exactly does this mean?[174] It means that VisualDx allows physicians to scan a portion of a patient's body, rather than taking a photo that is saved and uploaded, and the neural network is trained by a "library of professional medical images" to provide doctors with a search of "symptoms, signs, and other patient factors" and then "confirm and validate [a] diagnos[i]s."[175]

III. THE FDA: AN OVERVIEW

"[T]he upheavals [of AI] can escalate quickly and become scarier and even cataclysmic. Imagine how a medical robot, originally programmed to rid cancer, could conclude that the best way to obliterate cancer is to exterminate humans who are genetically prone to the disease."[176]

Established in 1906, the FDA is the regulatory authority over the majority of food, drugs, and medical products that the public consumes on a daily basis.[177] As such, the FDA is charged with the responsibility of regulating all drugs and medical devices that implement AI technologies.[178] Since its establishment, the FDA has had to respond to numerous changes in the field of healthcare and it is vital to briefly review such changes within the FDA's regulatory framework before discussing the FDA's current AI framework.[179]

A. *Historical Overview of the FDA's Regulatory Framework*

In 1906, the Federal Food and Drugs Act was signed into law, creating what is known today as the FDA.[180] Upon the initial passage of the Act, the FDA's regulatory powers were limited to regulating drugs that were *unsanitary or unsafe*.[181] The FDA's effectiveness in regulating therapeutic drugs before they hit the mass markets was a problem for Congress, as well

173. Leswing, *supra* note 141.

174. *See id.*

175. *Id.*

176. Nick Bilton, *Artificial Intelligence as a Threat*, N.Y. TIMES, Nov. 6, 2014, at E2.

177. RONALD HAMOWY, MEDICAL DISASTERS AND THE GROWTH OF THE FDA 3 (2010), http://www.independent.org/pdf/policy_reports/2010-02-10-fda.pdf; Merrill, *supra* note 17, at 1758.

178. Merrill, *supra* note 17, at 1753, 1753.

179. *See* HAMOWY, *supra* note 177, at 5.

180. Merrill, *supra* note 17, at 1758; *see also* Act of June 30, 1906, ch. 3915, 34 Stat. 768. Before 1927, the FDA was known as the Division of Chemistry and did not get the name FDA until June 1940. John P. Swann, *FDA's Origin*, FDA (Feb. 1, 2018), http://www.fda.gov/AboutFDA/History/FOrgsHistory/EvolvingPowers/ucm124403.htm.

181. Merrill, *supra* note 17, at 1802.

as the consumer, because the FDA did not have the regulatory scope to premarket review every drug or medical device.[182] Instead, the regulatory process that the FDA did have placed all the standards of review on the product, food, or device instead of on the manufacturers themselves; this created large loopholes for the FDA.[183]

In 1937, the FDA's lack of regulatory authority became a public health crisis after an administration of elixir sulfanilamide led to the death of over one hundred people, many of them children.[184] The public health crisis prompted Congress to pass the Federal Food, Drug, and Cosmetic Act ("FDCA"), enabling the requirement of *premarket approval*.[185] The process for a manufacturer to market a drug changed drastically with the FDCA as it required manufacturers to contact the FDA within a span of one hundred eighty days before placing a drug out on the market; if no challenge or question was raised with regard to safety concerns by the FDA, then the manufacturer would be allowed to sell its drug to the public.[186] When drafting the FDCA, Congress made sure to consider all "exotic mechanical and electrical devices" that would fall under the scope of the definition of *drug*.[187] Such considerations took evidence when Congress "expanded the definition of *drug* to include *devices*," making an effort to expand the FDA's regulatory scope to *device-like* products—subjecting them to premarket approval—without having to create a secondary regulatory category.[188] At the time, standard devices such as wheelchairs, leg braces, and surgical nails posed no danger to patients.[189] However, it was shortly after the passing of the FDCA that a new wave of technologies, with much more sophisticated designs, began to advance the medical world.[190]

The new wave of technological innovation following the FDCA created a severe lack of regulatory authority for the FDA.[191] The FDA was unable to premarket approve medical devices that were not considered nor provided for under the FDCA's original or expanded definition of a *drug*.[192]

182. *Id.* at 1761, 1802.

183. *Id.* at 1761–62.

184. *Id.* at 1761; HAMOWY, *supra* note 177, at 6.

185. Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717 § 505, 52 Stat. 1040, 1052 (1938) (codified at 21 U.S.C. § 301 (2012)); Merrill, *supra* note 17, at 1764–65.

186. Drug Amendments of 1962, Pub. L. 87–781, § 104, 76 Stat. 780 (codified as amended at 21 U.S.C. § 301 (2012)); Merrill, *supra* note 17, at 1764–65.

187. Merrill, *supra* note 17, at 1765, 1801–02; HAMOWY, *supra* note 177, at 9; *see also* Federal Food, Drug, and Cosmetic Act, § 201(g), at 1041.

188. Merrill, *supra* note 17, at 1802.

189. *Id.* at 1803.

190. *Id.*; *see also* Federal Food, Drug, and Cosmetic Act, § 1, at 1040.

191. Merrill, *supra* note 17, at 1803–04; *see also* Federal Food, Drug, and Cosmetic Act, § 1, at 1040.

192. *See* Merrill, *supra* note 17, at 1804.

Over time, larger and larger loopholes formed in the FDA's regulatory process, as medical devices and drugs that the FDA attempted to declare *new drugs*, fell out of regulatory reach and hit the market before the FDA approved them as safe and effective.[193]

In 1960, Congress was faced with another mass health crisis when numerous infants were born with *severe birth defects* due to the ingestion of thalidomide, a drug given to pregnant woman for nausea.[194] Congress and the FDA realized it was time to amend the FDCA when costly and disruptive recalls of medical devices, such as intrauterine devices ("IUDs") and antibiotics, plagued the country due to an outdated regulatory scheme being applied to the growing technological advances in the medical field.[195] The Medical Device Amendments ("the Amendments") of 1976 expanded the scope of the FDA and transformed the regulatory scheme of the FDA's authority into one of the most complicated and conservative drug regulation systems in the world.[196] The FDA had now been given the ability to issue guidance on manufacturing standards for medical devices, to ban dangerous products that had already been on the market, and to require premarket notification of such defective products.[197] The Amendments also established the fundamental frameworks of the regulatory process that the FDA uses today: Classification, levels of control, and premarket notification.[198] While the FDCA gave the FDA the authority to regulate medical devices for the first time, the Amendments established the FDA's authority to require manufacturers of any medical device to prove its safety and effectiveness before selling it to the public.[199]

B. *Regulating Drugs and Devices*

The FDA is arranged into multiple centers that focus on regulating specific areas of products: the Center for Food Safety and Applied Nutrition ("CFSAN"); the Center for Drug Evaluation and Research ("CDER"); the Center for Biologics Evaluation and Research ("CBER"); and the Center for

193. *See id.* at 1805–06.

194. HAMOWY, *supra* note 177, at 11; Merrill, *supra* note 17, at 1764 & n.35.

195. *See* Merrill, *supra* note 17, at 1805–06.

196. *See id.* at 1808; Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539.

197. Merrill, *supra* note 17, at 1808.

198. *Id.* at 1809–10; Medical Device Amendments of 1976, §§ 85 1-2.

199. *See* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052 (1938) (codified at 21 U.S.C. §§ 301 (2012)); Merrill, *supra* note 17, at 1765, 1776, 1800.

Devices and Radiological Health ("CDRH").[200] The centers primarily responsible for regulating drugs, medical devices and biopharma are CDER, CBER, and CDRH.[201]

1. CDER

CDER is charged with regulating "over-the-counter and prescription drugs, including biological therapeutics and generic drugs."[202] If a pharmaceutical company or drug manufacturer wants to market a new drug, it must abide by the regulations set out by CDER.[203] The multi-step process for manufacturing and selling a new drug is exhaustive and costly.[204] First, the manufacturer has to file an Investigational New Drug ("IND") application—which is based on test results from initial experiments conducted on animals—to get approval for research to experiment the drug on human subjects.[205] If the applicant is approved, then he or she can begin human clinical trials and attempt to test the safety and efficacy of the drug.[206] The purpose of this step is to gather evidence that the new drug meets the FDA's requirements for marketing approval.[207] The process of clinical human trials is lengthy, consisting of three phases.[208] Phase I studies focus on gathering test data regarding the safety of the drug and typically involve twenty to eighty human subjects; Phase II focuses on the effectiveness of the drug and involves several dozen to three hundred people; and Phase III

200. John Miller, *Beyond Biotechnology: FDA Regulation of Nanomedicine*, COLUM. SCI. & TECH. L. REV., 2003, at 1, 13; *see also About CBER*, FDA, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123340.htm (last updated Feb. 6, 2018); *How Drugs Are Developed and Approved*, FDA, http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/default.htm (last visited May 1, 2019); *Overview of CDRH Transparency*, FDA, http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm199624.htm (last updated Sept. 14, 2018).

201. Miller, *supra* note 200, at 13; *see also About CBER*, *supra* note 200; *How Drugs Are Developed and Approved*, *supra* note 200; *Overview of CDRH Transparency*, *supra* note 200.

202. *About the Center for Drug Evaluation and Research*, FDA, http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ (last updated Feb. 27, 2019).

203. *See How Drugs Are Developed and Approved*, *supra* note 200.

204. *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, FDA, http://www.fda.gov/drugs/resourcesforyou/consumers/ucm143534.htm (last updated Nov. 24, 2017).

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

focuses on specific treatment variables and involves anywhere from a few hundred to three thousand people.[209]

"The goal [of these phases] is to determine what the drug's most frequent side effects are and, often, how the drug is metabolized and excreted."[210] The length of each phase can vary greatly; for example, Phase II trials can vary anywhere from "[s]everal months to [two] years."[211] At this stage, "[a]pproximately [thirty-three percent] of drugs [are approved to] move to the next phase."[212] If there is evidence of effectiveness, Phase III studies begin with the purpose of "demonstrat[ing] whether or not a product offers a treatment benefit to a specific population . . . [and] these studies involve [three hundred] to [three thousand] participants."[213] The length of Phase III trials can vary anywhere from one to four years.[214] According to the FDA: "Phase [III] studies provide most of the safety data. In [Phase I and II] studies, it is possible that less common side effects might have gone undetected. Because [the Phase III] studies are larger and longer in duration, the results are more likely to show long-term or rare side effects."[215]

Once the IND clinical trials are completed, CDER requires that post-market studies be completed; these are at times referred to as Phase IV trials.[216] Phase IV trials involve several thousand volunteers and involve the gathering of data on the drug "after the FDA has approved [the] product for marketing."[217] After the IND phase is complete, the drug manufacturer applies for a New Drug Application ("NDA") and submits along with it all the animal and human experimental data, proposed labeling, and chemical makeup of the drug.[218] At this stage, CDER reviews all the data and, after evaluating the data from the clinical trials, weighs whether the product's benefits outweigh its risks to decipher whether to approve or deny the drug.[219] CDER's surveillance is never quite finished when it comes to a

209. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 204.

210. *Id.*

211. *Step 3: Clinical Research*, FDA, http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405622.htm (last updated Jan. 4, 2018).

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.*

216. *Step 3: Clinical Research*, *supra* note 211.

217. *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 204; *Step 3: Clinical Research*, *supra* note 211.

218. *How Drugs Are Developed and Approved*, *supra* note 200; *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 204.

219. *See How Drugs Are Developed and Approved*, *supra* note 200.

drug's development of efficacy and safety.[220] "[I]t is impossible to have [all the] information about the safety of a drug at the time of approval."[221] Thus, CDER and the FDA are constantly reviewing drugs post-market for safety.[222]

2. CDRH

The FDA center responsible for regulating medical devices is the CDRH.[223] The process for classifying a medical device is significantly easier and less restrictive than the drug approval process.[224] A medical device is defined as:

> [A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including [any] component part, or accessory which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals.[225]

Medical devices are regulated using a *risk-based classification* system.[226] Using this approach, all devices could fall under FDA regulation, which would entail "registration, listing, and . . . reporting requirements."[227] The higher the risk, the higher the class: Class I—simple low-risk devices;

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220. *See id.*; *About the Center for Drug Evaluation and Research*, *supra* note 202; *Step 5: FDA Post-Market Drug Safety Monitoring*, FDA, http://www.fda.gov/ForPatients/Approvals/Drugs/ucm405579.htm (last updated Jan. 4, 2018).

221. *Step 5: FDA Post-Market Drug Safety Monitoring*, *supra* note 220.

222. *See The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 204. With regard to right-to-try laws, this falls beyond the scope of this Comment and will not be discussed. *See* Jacqueline Howard, *What You Need to Know About Right-to-Try Legislation*, CNN: HEALTH (May 29, 2018, 1:50 PM), http://www.cnn.com/2018/03/22/health/federal-right-to-try-explainer/index.html.

223. *Overview of Device Regulation*, FDA, http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/default.htm (last updated Aug. 31, 2018).

224. *See Is the Product a Medical Device?*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYour Device/ucm051512.htm (last updated Mar. 22, 2018); *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective*, *supra* note 204.

225. 21 U.S.C. § 321(h) (2012); *Is the Product a Medical Device?*, *supra* note 224.

226. Price II, *supra* note 111, at 438.

227. *Id.*

Class II—medium risk devices; or Class III—high risk devices.[228] These categories are determined based upon the risks such devices may pose and the regulatory controls that will need to be provided to assure safety and effectiveness.[229] "Class I devices . . . pose the lowest risk to [a] patient . . . Class III devices pose the highest risk."[230] The controls that a class is subject to is based upon the regulatory measures necessary to ensure safety and efficacy.[231] In addition to a *three-tiered classification* system, the CDRH employs varying levels of review that must be met before allowing a device to enter the market.[232] A new device may be subject to either a total exemption or a 510(k) premarket notification process if the device is subject to a Class I or II classification or, if the device falls under Class III, a premarket approval process ("PMA").[233] Generally, the largest area of regulation for medical devices rests with the category of Class III medical devices.[234] Any device manufactured after 1976 is defaulted into Class III

228. *Id.*

229. *See* 21 U.S.C. § 360c(a)(1) (2012).

230. *Overview of Medical Device Classification and Reclassification*, FDA, http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cdrh/cdrhtransparency/ucm378714.htm (last visited May 1, 2019). Class I devices are subject to general controls, Class II are subject to special controls, and only Class III devices are subject to complete review for safety and effectiveness. 21 U.S.C. § 360c(a)(1); *Premarket Approval (PMA)*, FDA, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/default.htm (last visited May 1, 2019); *see also Regulatory Controls*, FDA, http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/generalandspecialcontrols/default.htm (last updated Mar. 27, 2018).

231. *See* 21 U.S.C. § 360c(a). An example of a Class I product is an elastic bandage. *What's My FDA Medical Device Classification*, CORTEX DESIGN INC.: IDEAS (June 25, 2018), http://www.cortex-design.com/blog/whats-my-fda-medical-device-classification/. An example of a Class II product is an infusion pump. *Id.* An example of a Class III product is a cochlear implant. *Id.*

232. Spenser F. Powell, *Changing Our Minds: Reforming the FDA Medical Device Reclassification Process*, 73 FOOD & DRUG L.J. 177, 184 (2018).

233. *Id.* at 184–85; *Premarket Approval (PMA)*, *supra* note 230.

234. *See Premarket Approval (PMA)*, *supra* note 230. In 1997, the FDA Modernization Act was passed and it allowed for the exemption of the majority of Class I devices from 510(k) premarket notification on the condition that "the device is not 'intended for a use which is of substantial importance in preventing impairment of human health' and does not 'present[] a potential unreasonable risk of illness or injury.'" Powell, *supra* note 232, at 185 (quoting Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, § 206(a), 111 Stat. 2296, 2339 (codified as amended at 21 U.S.C. § 301 (2012))). In 2012, the FDA Safety and Innovation Act further expedited the process of medical device approval, giving the FDA "the authority to alter device classification [via] administrative order rather than regulation." Powell, *supra* note 232, at 185 (quoting Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 FOOD & DRUG L.J. 365, 367 n.3677 (2014)); *see also* Food and Drug Administration Safety

and subject to a PMA, unless the CDRH finds that, either there is a substantially equivalent device on the market classified as I or II and grants 510(k) approval—this acts as a loophole to having a Class III device being regulated as such—or that based upon a de novo determination by the FDA the statutory definition of Class I or II is met.[235]

3. CBER

CBER regulates a broad area of concern in public health.[236] This is the regulation of biological related products called biologics, including anything from blood, vaccines, tissues, and gene therapies—many of which are created using biotechnology.[237] The FDA opines that "[t]hese products often represent cutting-edge biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have few or no other treatment options."[238] The process for a manufacturer to obtain approval for either clinical testing or license to market a new biological product is similar to the process under CDER's purview.[239] CBER is responsible for determining that a product is "safe, pure, potent, and manufactured accordingly."[240]

C. *The 21st Century Cures Act*

In 2016, the 21st Century Cures Act ("the Cures Act") was enacted by Congress.[241] The Cures Act was enacted with various purposes in mind, but one of the key factors was the clarification of "the FDA's regulatory authority over digital health and medical devices."[242] More specifically, one aspect of the Act titled *Clarifying Medical Software Regulation* clarified what medical software does and does not fall under the purview of the

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and Innovation Act, Pub. L. No. 112-144, § 101, 126 Stat. 993, 996 (2012) (codified as amended at 21 U.S.C. § 301 (2012)).

235. *See* 21 U.S.C. § 360c(f)(2)-(3); *Premarket Approval (PMA)*, *supra* note 230.

236. *See About CBER*, *supra* note 200.

237. *Id.*

238. *Id.*

239. Miller, *supra* note 200, at 15.

240. *Id.* (quoting 1 JAMES T. O'REILLY, HISTORY LEADING TO THE BIOLOGICS PRICE COMPETITION AND INNOVATION ACT OF 2009 § 13:156, Westlaw (database updated June 2018).

241. Bennett & Habte, *supra* note 8, at 18; *see also* 21st Century Cures Act, Pub. L. No 114-255, § 1, 130 Stat. 1033, 1033 (2016).

242. Bennett & Habte, *supra* note 8, at 18; *see also* 21st Century Cures Act, § 1, 130 Stat. at 1033.

FDA.[243] Pursuant to the Act, digital health—under purview of the FDA and subject to regulatory authority—includes machines or devices that use AI algorithms such as ML or DL "to provide diagnostic information for patients."[244] The Cures Act completely changed the way the FDA regulated medical devices, including the way mobile devices are incorporated into the definition of both digital devices and medical devices.[245] Most importantly, the Cures Act allowed for the provision that Class III devices be regulated or excluded from regulation as Class I or Class II devices, given they are low-risk medical software that "serve as electronic patient records, assist in displaying or storing data, or provide limited clinical decision support."[246] To put it simply, if the algorithm does not provide a diagnosis or predict a course of treatment, then the FDA does not regulate it.[247] Until modern society began utilizing Fitbits, Apple Watches, and other mobile devices to track steps taken, monitor their hearts, and for other health reasons, a medical device was traditionally thought of and used only to provide measurements or give treatments.[248] Given the increasing amount of entities using and implementing the amount of AI software or support, and the imperfect fit between AI and healthcare, the FDA provided a pilot program to *pre-certify* eligible digital health developers who could market their devices without additional FDA review.[249]

IV. REGULATING DR. ROBOT

> The pace of progress in [AI]—I'm not referring to narrow AI—is incredibly fast. Unless you have direct exposure to groups like Deepmind, you have no idea how fast—it is growing at a pace

243. Price II, *supra* note 111, at 439–40 (citing to 21st Century Cures Act § 3060, 130 Stat. at 1130).

244. Bennett & Habte, *supra* note 8, at 18; *see also* 21st Century Cures Act, § 3051, 130 Stat. at 1121.

245. *See* Price II, *supra* note 111, at 439–40; *see also* 21st Century Cures Act, § 515c, 130 Stat. at 1121. The Cures Act attempts to streamline and address some of the issues the FDA has already faced in seeking to clarify software device and non-software device involved in diagnosing and treating diseases. Price II, *supra* note 111, at 439–40. However, the Cures Act does not specifically address all AI technology. *See* 21st Century Cures Act, § 515c, 130 Stat. at 1121–24.

246. Bennett & Habte, *supra* note 8, at 18; *see also* Price II, *supra* note 111, at 438.

247. Bennett & Habte, *supra* note 8, at 18; *see also* 21st Century Cures Act, § 515c, 130 Stat. at 1121–24.

248. *See* Bambauer, *supra* note 11, at 386.

249. Bennett & Habte, *supra* note 8, at 18.

> close to exponential. The risk of something seriously dangerous happening is in the five-year time frame. [Ten] years at most.[250]

A. *The FDA's Digital Health Innovation Action Plan*

In 2018, the FDA released a potential remedy to the AI loophole in its regulatory policies.[251] The Digital Health Software Precertification Program ("Pre-Cert") was created by the FDA to potentially regulate certain software that abides by FDA medical device standards to "qualify for either an exemption from premarket review for lower risk . . . products, or [for] a faster review of higher risk products."[252] The main difference between Pre-Cert and the Cures Act?[253] "Pre-Cert focuse[s] on free-standing software . . . apps designed to diagnose or treat disease."[254] The program is designed to speed up regulatory review for companies that have exhibited quality medical devices and drugs, as well as in software development.[255] Pre-Cert works by using five working models based on principles that will be used to evaluate devices that manufacturers submit for Pre-Cert.[256] The principles are: "(i) product quality, (ii) patient safety, (iii) clinical responsibility, (iv) cybersecurity protection, and (v) proactive culture."[257] The FDA uses these principles to evaluate and monitor the AI algorithm which a medical device uses.[258] The main goal of this program is to look at the developer of the software instead of targeting the product itself, as the FDA has done in years prior.[259] It is important to note that the Pre-Cert program is not law, and FDA guidance still creates a loophole for manufacturers that are creating

250. Marr, *supra* note 29.

251. *FDA Releases Software Precertification Working Model*, JONES DAY (May 30, 2018), http://www.jdsupra.com/legalnews/fda-releases-software-precertification-65942/.

252. *Id.*; *see also* Theodore T. Lee & Aaron S. Kesselheim, *U.S. Food and Drug Administration Precertification Pilot Program for Digital Health Software: Weighing the Benefits and Risks*, 168 ANNALS INTERNAL MED. 730, 730–31 (2018).

253. *Compare* Lee & Kesselheim, *supra* note 252, at 731, *with* 21st Century Cures Act, Pub. L. No. 114-255, § 1, 130 Stat. 1033, 1033 (2016).

254. *Experts Express Concerns About FDA Precertification Program for Health Apps*, HEALIO (Apr. 10, 2018), http://www.healio.com/internal-medicine/practice-management/news/online/%7B30f0ee35-f2e2-408f-a35a-723df18a9217%7D/experts-express-concerns-about-fda-precertification-program-for-health-apps.

255. Lee & Kesselheim, *supra* note 253, at 730; *FDA Releases Software Precertification Working Model*, *supra* note 251.

256. *FDA Releases Software Precertification Working Model*, *supra* note 251.

257. *Id.*

258. *See id.*; Gin & Helwig, *supra* note 22.

259. *See FDA Releases Software Precertification Working Model*, *supra* note 251.

helpful medical devices and drugs for the time being.[260] For now, until such guidance is adopted as law by Congress, developers can still seek classification of their medical device through the FDA's 510(k) process or wait it out if their device is a Class III device.[261]

Nine companies were selected by the FDA to participate in a pilot program of the Pre-Cert process.[262] The companies—Apple, Samsung, Verily, Johnson & Johnson, Roche, and Fitbit, among them—were all named companies selected to participate and, as such, are now required to share information such as quality management and post-market data, and to allow FDA visitation to corporate sites.[263] The Pre-Cert program may be "an encouraging move on the FDA's part, [but there are] some . . . raising concerns that it will pose more risks to consumers by allowing them to purchase products before there are evidence-based results"—one of the few risks of regulating Dr. Robot.[264]

B. *The Risks of Regulating Dr. Robot*

Apple Watches are telling us our heart rates, Fitbits are telling us how many steps we walk, and mobile apps are telling us to drink more water.[265] All of these technologies are possible because of AI algorithms—algorithms that are even making medication smarter.[266] But "innovation moves fast—much faster than" regulation—and patients look to regulators to protect them from the dangers that devices and drugs can potentially pose.[267] The biggest risk of regulating robots in health comes with the speed in which

260. *See* Gin & Helwig, *supra* note 22; Lee & Kesselheim, *supra* note 253, at 731.

261. *See* Gin & Helwig, *supra* note 22; Lee & Kesselheim, *supra* note 253, at 731.

262. *FDA Selects Participants for New Digital Health Software Precertification Pilot Program*, FDA: NEWS RELEASE (Sept. 26, 2017) http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm577480.htm.

263. *Id.*

264. Shireen Yates, *A Digital Health Revolution Is Happening Now, but the FDA Can't Keep Up*, OBSERVER (Mar. 8, 2018, 9:19 AM), http://www.observer.com/2018/03/digital-health-revolution-happening-now-fda-cant-keep-up/.

265. Marshall, *supra* note 7; Molteni, *supra* note 10; Hint Water, *10 of the Best Water Apps to Use for Free*, QUENCH (June 21, 2016), http://www.thequench.com/water/8-of-the-best-water-apps-to-use-for-free/.

266. Chamraj, *supra* note 154; *see also* Bambauer, *supra* note 11, at 391–92.

267. Yates, *supra* note 264; *see also* Tuma, *supra* note 137.

the FDA either wants to or cannot regulate these devices and drugs such as, for example, the home genomics kit 23andMe.[268]

Initially, the home genomics kit, utilizing AI, escaped regulation because it was not considered a medical device by definition.[269] The FDA began to give attention to the kit when it "began to provide customized health reports" to its users.[270] What was concerning about this was the risk to users regarding the AI learning and *knowledge component*.[271] 23andMe is a prime example of why AI in healthcare offers a scare to regulatory authority; all the knowledge provided by AI is based on models and algorithms—models that are based on code.[272]

Another risk that comes with the regulation of AI in healthcare "is that the[se] models are based on such . . . large volume[s] of data and are so complex that no one really knows what is driving [the] outcomes, why one patient falls into one group or another according to the model."[273] The algorithms that drive ML and DL are written by humans and, while the systems learn on their own from there, if a bad code is written—or bad data is fed into the system—we have yet to learn how long it will take before that self-learning system will harm itself or the patients that are using it.[274] Consistency and accuracy is a key function in not only technology, but also in medication treatment and diagnosis.[275] If data sets are trained or coded to encounter a limited number of or certain types of illnesses in the medical world, it is very likely that in a clinical setting they will come across scenarios they have never learned or been coded for.[276] The FDA will have to reach out to other regulatory bodies to help it understand and consider all the aspects of AI technologies, including everything from "ethics [and] computing [to] clinical care."[277]

V. CONCLUSION

"With such a controversial technology such as [AI], it is imperative that policymakers make decisions while the technology is still young, before

268. Bambauer, *supra* note 11, at 388; Lee & Kesselheim, *supra* note 253, at 730; Yates, *supra* note 264.

269. Bambauer, *supra* note 11, at 388.

270. *Id.*

271. *Id.*

272. *See id.*; Jones, *supra* note 38; Tuma, *supra* note 137.

273. Tuma, *supra* note 137.

274. *See id.*; Jones, *supra* note 38.

275. Sobia Hamid, *The Opportunities and Risks of Artificial Intelligence in Medicine and Healthcare*, CAMBRIDGE U. SCI. & POL'Y EXCHANGE, Summer 2016, at 1, 2.

276. *Id.*

277. Tuma, *supra* note 137.

they are forced to make policy reactively."[278] The application of AI technologies such as ML and DL to healthcare devices and drugs has been rampant in the last ten years—ranging from telemedicine to cancer detection to algorithms to help neurovascular brain deterioration.[279] With over $1.7 billion spent in 2016 alone on AI technologies in the healthcare industry, it is no longer just a choice for the FDA to start developing a framework on how to regulate ML and DL products in the context of medicine.[280] However, the FDA should not approach these regulations alone, as the speed at which AI continues to grow proves to be too fast for one regulatory body to handle.[281] Instead, multiple regulatory bodies should review the potential harms of regulatory flexibility pertaining to AI technologies being applied to medical devices and drugs and err on the side of caution.[282]

Looking back at the history of the FDA, it is easy to identify a pattern of how the agency approaches the regulation of new technologies and drug developments.[283] Instead of having foresight and getting ahead of innovation, the FDA allows itself to fall behind—warranting catastrophe to stockpile up into public health events—ultimately triggering *overly tight regulations*.[284] But this time, there is a technological revolution in front of its eyes—the FDA's way of handling changes in how drugs and medical devices are regulated will not be able to keep up if the agency continues to let itself fall behind.[285] The age of AI has arrived.[286]

278. Hamid, *supra* note 275, at 4.

279. *See* Ashok, *supra* note 18; Mary Bates, *Deep Learning Algorithms Can Detect Subtle Brain Lesions*, BIOENGINEERING TODAY: BRAIN (Mar. 9, 2018), http://www.bioengineeringtoday.org/brain/deep-learning-algorithms-can-detect-subtle-brain-lesions.

280. Ashok, *supra* note 18; Tuma, *supra* note 137; *Worldwide Spending on Cognitive and Artificial Intelligence Systems Will Grow to $19.1 Billion in 2018, According to New IDC Spending Guide*, BUS. WIRE (Mar. 22, 2018, 11:15 AM), http://www.businesswire.com/news/home/20180322005847/en/Worldwide-Spending-Cognitive-Artificial-Intelligence-Systems-Grow.

281. Tuma, *supra* note 137.

282. *Id.*

283. *Id.*

284. *Id.*

285. *Id.*; Yates, *supra* note 264.

286. *See* Ashok, *supra* note 18; Tuma, *supra* note 137.