AI RENAISSANCE: PHARMACEUTICALS AND DIAGNOSTIC MEDICINE

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ABSTRACT

The explosive growth of Artificial Intelligence ("AI") has led to significant advancements in medicine. In drug discovery, AI technology is used to classify proteins as drug targets or non-targets for specific diseases, to more accurately interpret and quantitatively describe pharmacology, and to predict protein structures based on only a protein sequence for input. AI methods are used in drug development to generate predictive models for drug screening purposes, refine and modify candidate structures of drugs to optimize compounds, and predict a drug's physiochemical properties, bioactivity, and toxicity. In the medical diagnostics space, the advancement of AI technology in colonoscopy, percutaneous coronary intervention, acute stroke and intracranial hemorrhage, vascular surgery, and ophthalmology may all offer increased efficacy as compared to traditional patient-care techniques. As the United States develops comprehensive legislation and regulations for AI, President Joseph R. Biden's Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence offers a strong starting point, though it was recently revoked by President Donald Trump's latest executive order "Removing Barriers to American Leadership in Artificial Intelligence." Given the substantial advances in the use of AI in medicine, Congress should delegate authority to the National Institute of Standards and Technology ("NIST") to regulate AI technology, developers, and sellers. As long as NIST engages meaningfully with the Department of Health and Human Services and the Food and Drug Administration, it can impose meaningful guardrails on the use of AI while protecting the gains made in the biotechnology sector.

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I. INTRODUCTION

The public perception of artificial intelligence ("AI") has been heavily influenced by popular media since its introduction to the American silver screen in the 1952 film *The Day the Earth Stood Still*.[1] The fervor surrounding AI gained major traction in the 1970s, 1980s, and 1990s with the debut of films such as *Star Wars*, *The Terminator*, and *The Matrix*.[2] These films took turns painting AI in different lights: *Star Wars* and *The Day the Earth Stood Still* portrayed AI in a positive light, while *The Terminator* and *The Matrix* depicted the technology as a dystopian, cataclysmic event.

As AI technology evolves from theory to the fledgling stages of practicality, the attention of the public is also shifting. A survey from Forbes Advisor found that only 54% of reporting consumers felt they would be able to discern between human-made content and AI-generated content.[3] In the same survey, 76% reported concern about being misled by AI-generated content and 77% expressed fear surrounding the potential for AI to replace human workers in certain jobs.[4] The public focus on these issues isn't wholly unwarranted: human-created scams have become increasingly complex over the last couple of decades, and innovative technologies have historically led to some level of workforce reduction as the new technology renders some positions less efficient and effective.[5] The more concerning effects of the growth of AI are not likely to pervade society any time soon, however, and are even less likely to affect the average consumer if proper regulations are enacted regarding AI.

This article begins by exploring innovative and emerging uses of AI in drug discovery, drug development, and diagnostic medical devices. The article then turns to recent efforts to regulate AI, including U.S. President Joseph R. Biden's October 2023 "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence." Various proposals for regulating AI in the United States are discussed. We argue that the best way to regulate the less desirable aspects of AI while preserving the substantial gains in medicine is for the National Institute of Standards and Technology ("NIST") to be the ultimate regulatory decisionmaker on

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[1] Zachary Tomlinson, *Artificial Entertainment: A Century of AI in Film*, INTERESTING ENG'G (Nov. 3, 2018), https://interestingengineering.com/culture/artificial-entertainment-a-century-of-ai-in-film [https://perma.cc/39UN-52D2] (indicating that first depiction of AI in cinema came in the 1927 film Metropolis, where the titular city was beset by a sentient robot bent on causing mayhem and securing control).

[2] *See id.* This era in American filmography introduced a popularization in the belief that AI could be beneficial to society, reflecting a growing optimism in the technology.

[3] Kathy Haan, *Over 75% Of Consumers Are Concerned About Misinformation from Artificial Intelligence*, FORBES ADVISOR (July 20, 2023), https://www.forbes.com/advisor/business/artificial-intelligence-consumer-sentiment/ [https://perma.cc/US2K-ANSQ] (describing that a survey, which commissioned responses from 2,000 employed Americans, revealed a trend of concern regarding the technology; further indicating that survey respondents reported a growing interest in using AI for common search functions (65%), and an inclination to still trust companies that use AI technology (65%)).

[4] *See id.* ("According to the survey data, a combined 76% of respondents express concern about AI causing misinformation on a business's website, with 43% being very concerned and 33% somewhat concerned. Most survey respondents (77%) are concerned AI will cause job loss within the next 12 months. Based on the survey, strategies such as re-skilling programs, job transition support and educational initiatives could play a role in addressing these concerns and help workers adapt to the changing job landscape.").

[5] *See* Isobel O'Sullivan, *The Companies that Have Already Replaced Workers with AI in 2024*, TECH.CO (Nov. 13, 2024) https://tech.co/news/companies-replace-workers-with-ai [https://perma.cc/8JVY-366D] (indicating that companies such as MSN, Google, Ikea, and Duolingo have already replaced workers with AI, or likely will in the near future).

AI policy, with input from key stakeholders like the Department of Health and Human Services ("HHS") and the Food and Drug Administration ("FDA").

II. ARTIFICIAL INTELLIGENCE IN THE MODERN ERA

The common media perception of AI, as depicted in movies like *The Matrix* and *The Terminator*, is not likely to make the jump from theory to practice any time soon. Some levels of AI capability are in practice today, but others are still purely theoretical. IBM has split the capability levels of AI into three categories: Artificial Narrow Intelligence, Artificial General Intelligence, and Artificial Superintelligence.[6] Artificial General Intelligence and Artificial Superintelligence remain purely hypothetical at this point: the first would have the capability to learn from prior tasks and make informed decisions without continued human training or input, and the latter is a form of AI that can learn, make judgments, and perform complex tasks without human input.[7]

Artificial Narrow Intelligence is the only category of capability that is in practice at this time, and is further split into two sub-categories: Reactive Machine Artificial Intelligence and Limited Memory Artificial Intelligence.[8] Reactive Machine Artificial Intelligences are simple in comparison to the other capability levels: these are machines that are developed to respond to a single stimulus and perform a simple task.[9] For example, IBM developed IBM Deep Blue in the late 1990s, an AI that was taught to play chess and defeated chess grandmaster Garry Kasparov.[10]

Limited Memory Artificial Intelligence, on the other hand, is what encompasses the current craze in AI: AI systems with this level of capability are able to use limited stores of information and current inputs in order to make informed decisions, boost task efficiency, and produce more effective work product than even humans can manage.[11] Limited Memory AI has become increasingly prevalent in the last year, giving rise to the popularity of consumer-facing products such as ChatGPT and Google's Gemini, as well as more corporate-focused AI systems.[12] The

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[6] *Understanding the Different Types of Artificial Intelligence*, IBM (Oct. 12, 2023), https://www.ibm.com/think/topics/artificial-intelligence-types [https://perma.cc/LT3B-D9D7] (explaining that capability in this context refers to the processing and computing powers of an AI, its ability to store information, and its ability to perform increasingly complex tasks).

[7] *Id.* ("Artificial Narrow Intelligence, also known as Weak AI, what we refer to as Narrow AI is the only type of AI that exists today. Any other form of AI is theoretical. It can be trained to perform a single or narrow task, often far faster and better than a human mind can. However, it can't perform outside of its defined task. Instead, it targets a single subset of cognitive abilities and advances in that spectrum.").

[8] *Id.* (discussing only the two functional levels of AI that are currently in use: Reactive Machine AI and Limited Memory AI; the two other functionality levels, Theory of Mind AI and Self-Aware AI, are purely hypothetical).

[9] Neil Sahota, *7 Types of Artificial Intelligence (With Examples)*, NEIL SAHOTA (Sept. 27, 2022), https://www.neilsahota.com/7-types-of-artificial-intelligence-with-examples/ [https://perma.cc/KPY3-DLZC] ("Reactive machines are the basic type of AI systems that operate on immediate reactivity—they cannot store memories and past experiences to use in future decisions.").

[10] *Id.* Another example of Reactive Machine AI is the Netflix Recommendation Engine. The decisions made by these AI systems are not based on any historical data, only the current information presented to them.

[11] Bernard Marr, *What are the Four Types of AI?*, BERNARD MARR & CO. (Sept. 7, 2024), https://bernardmarr.com/what-are-the-four-types-of-ai/ [https://perma.cc/QN8U-7H7W] ("Limited memory AI can complete complex classification tasks and uses historical data to make predictions. Self-driving cars use limited memory AI because the algorithms that power these vehicles use data they were trained and programmed on to understand how to operate but can also interpret data it observes to read its environment and adjust when necessary.").

[12] *Understanding the Different Types of Artificial Intelligence*, IBM (Oct. 12, 2023), https://www.ibm.com/blog/understanding-the-

development of business-focused AI has also enabled companies such as Amazon Web Services (AWS) to work more closely with certain industries to develop specialized AI solutions, such as in pharmaceutical drug discovery.[13]

III. AI IN THE PHARMACEUTICAL SECTOR

AI has already begun transforming the pharmaceutical industry in important ways, changing some long-held beliefs about inefficiencies in drug development and rewards needed to incentivize manufacturers to pursue the research and development of treatments and cures. To some degree, this digital disruption in drug development has been anticipated for some time.[14] Yet only recently have early stages of drug discovery and development been aided by the recent emergence of AI techniques that promise to revolutionize the field. The FDA, recognizing the importance of these developments, released two discussion drafts in 2023 and a Draft Guidance in January 2025 to address various aspects of the use of AI in drug discovery, development, and manufacture.[15]

A. Pharmaceutical Discovery

The FDA develops regulations concerning pharmaceuticals, monitors developers of pharmaceuticals, and enforces its regulations. Discovery is the first step in the drug development process and is the point at which identification and selection of potential drug candidates occurs, typically in a laboratory setting.[16] During this historically costly and time-consuming phase of the drug development process, researchers will discover new drug candidates that may have therapeutic potential for a particular disease or condition.

Identification of new therapeutic targets will often generate new research into potential classes of new treatments, large-scale testing of molecular compounds to identify potential beneficial effects, research into existing drugs to identify secondary effects, and use of new and

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different-types-of-artificial-intelligence/ [https://perma.cc/LH6N-8ZPH] (indicating that the Limited Memory AI level of functionality also sees use in virtual assistants and chatbots, such as Siri, Alexa, and Google Assistant, and in Self-Driving Cars).

[13] Lisa McFerrin & Ujjwal Ratan, *Highlights from the AWS Life Sciences Executive Symposium 2023: Accelerating Pharma Drug Discovery with ML and Generative AI*, AWS BLOG (May 31, 2023), https://aws.amazon.com/blogs/industries/highlights-from-the-aws-life-sciences-executive-symposium-2023-accelerating-pharma-drug-discovery-with-machine-learning/ [https://perma.cc/DD6A-DY4Z] ("The opening sessions of the symposium showcased how AWS is enabling life sciences organizations leverage generative AI, FMs (Foundation Models), and LLMs (Large Language Models) for drug discovery, across use cases like identifying potential adverse drug reaction, and searching clinical trial datasets.").

[14] Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era*, 2001 ILL. L. REV. 173, 174–75 (2001) ("[T]he science of genomics . . . will usher in a new era of pharmaceutical innovation . . . researchers should be able to develop drugs in a faster, more streamlined fashion, through computerized analysis of the genes proteins, and biochemical pathways that cause particular diseases.").

[15] U.S. FOOD & DRUG ADMIN., USING ARTIFICIAL INTELLIGENCE & MACHINE LEARNING IN THE DEVELOPMENT OF DRUG & BIOLOGICAL PRODUCTS: DISCUSSION PAPER AND REQUEST FOR FEEDBACK 4 (2023) [hereinafter DISCUSSION DRAFT 1]; U.S. FOOD & DRUG ADMIN., ARTIFICIAL INTELLIGENCE IN DRUG MANUFACTURING: DISCUSSION DRAFT 1 (2023) [hereinafter DISCUSSION DRAFT 2]; U.S. FOOD & DRUG ADMIN., CONSIDERATIONS FOR THE USE OF ARTIFICIAL INTELLIGENCE TO SUPPORT REGULATORY DECISION-MAKING FOR DRUG AND BIOLOGICAL PRODUCTS – GUIDANCE FOR INDUSTRY AND OTHER INTERESTED PARTIES (JANUARY 2025) [hereinafter GUIDANCE].

[16] U.S. Food & Drug Admin., *The Drug Development Process* (Jan. 4, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process [https://perma.cc/S4NR-8LLC] (showing that the discovery phase of the FDA's drug development process is the first step in the research cycle, beginning with target identification and screening).

innovative technology that may increase researchers' capabilities in the laboratory.[17] Researchers at this stage may identify thousands of potential new target compounds, but that list often shrinks considerably after initial testing and selection.[18] This process is often described as "hit-to-lead" or "lead optimization."[19]

The decrease in viable options to treat certain conditions is the first indicator of what is commonly referred to as the "valley of death": the historical funneling of potential targets identified in the drug discovery phase down to drugs that are sufficiently safe and effective to merit FDA approval.[20] The drug discovery process is challenging, time-consuming, and expensive,[21] yielding only a small fraction of viable drugs in comparison to the potential targets identified.[22] The use of AI in the drug discovery process, however, promises to make this process more cost-effective, time-efficient, and user-friendly for greater numbers of researchers.

B. Current Use of AI in Pharmaceutical Discovery

AI is already being harnessed to make the discovery phase of drug development more efficient and effective, particularly in the areas of target identification, pharmacometrics, and protein synthesis.[23] Target identification relies on manipulating molecules in order to determine whether they would be effective in treating a selected disease.[24] AI can be used in target identification to compare existing data models to current data in order to identify the likelihood that a particular molecule will interact favorably with a selected disease.[25] AI technology has also been used to determine the efficacy of potential molecules for target identification by analyzing historical data on how genetic information is converted into potential functions, whether or not mutations have appeared in different interactions, and how proteins interact with other proteins.[26]

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[17] U.S. Food & Drug Admin., *Step 1: Discovery and Development* (Jan. 4, 2018), https://www.fda.gov/patients/drug-development-process/step-1-discovery-and-development [https://perma.cc/WWE8-UMP3] ("Typically, researchers discover new drugs through (1) new insights into a disease process that allow researchers to design a product to stop or reverse the effects of the disease, (2) many tests of molecular compounds to find possible beneficial effects against any of a large number of diseases, (3) existing treatments that have unanticipated effects, and (4) new technologies, such as those that provide new ways to target medical products to specific sites within the body or to manipulate genetic material.").

[18] *Id.* ("At this stage in the process, thousands of compounds may be potential candidates for development as a medical treatment. After early testing, however, only a small number of compounds look promising and call for further study.").

[19] J.P. Hughes et al., *Principles of Early Drug Discovery*, 162 BRIT. J. PHARMACOLOGY 1239, 1246 (2011).

[20] Barry S. Coller & Robert M. Califf, *Traversing the Valley of Death: A Guide to Assessing Prospects for Translational Success*, 1 SCIENCE TRANSLATIONAL MED. 1, 1 ("Special attention has been paid to the difficulty of crossing the proverbial 'valley of death': the gulf between finding a promising new agent and demonstrating its safety and efficacy in humans. Venturing into these badlands can be challenging for academic investigators who lack experience in drug development and regulatory processes.").

[21] Hughes et al., *supra* note 19, at 1239.

[22] *Id.* at 1248.

[23] *See* Alex Zhavoronkov et al., *Will Artificial Intelligence for Drug Discovery Impact Clinical Pharmacology?*, 107 CLINICAL PHARMACOLOGY & THERAPEUTICS 780, 780 (2020); Debleena Paul et al., *Artificial Intelligence in Drug Discovery and Development*, 26 DRUG DISCOVERY TODAY 80, 83 (2021); *see also* Lalitkumar K. Vora et al., *Artificial Intelligence in Pharmaceutical Technology and Drug Delivery Design*, 15 PHARMACEUTICS 1916 (2023).

[24] Rizwan Quershi et al., *AI in Drug Discovery and its Clinical Relevance*, 9 HELIYON 1, 3 (2023) ("Target identification during drug discovery aims to identify molecules, usually proteins, that could alter a disease state if their activity was modulated.").

[25] *Id.* at 3–4 ("Machine learning algorithms can analyze various types of data, including gene expression profiles, protein-protein interaction networks, and genomic and proteomic data, to identify potential targets that are likely to be involved in disease pathways."); *see also* Yujie You et al., *Artificial Intelligence in Cancer Target Identification and Drug Discovery*, 7 SIGNAL TRANSDUCTION & TARGETED THERAPY 156 (2022).

[26] *See* Jouhyun Jeon et al., *A Systematic Approach to Identify Novel Cancer Drug Targets Using Machine Learning, Inhibitor Design and*

To begin the target identification process, a causal relationship must be identified that will indicate the molecule's efficacy in interacting with the selected disease.[27] Researchers have identified the potential for an AI system to make progressive yes-or-no decisions to classify drugs as potential treatments or not, based on data regarding interactions between proteins and genetic outputs, to determine whether a specific gene is associated with disease.[28] AI systems in target identification rely on historical data in order to make informed decisions, therefore techniques such as text mining and deep-learning systems are invaluable for the proper utilization and growth of AI in this field.[29] AI systems have allowed researchers to determine molecule interaction within a cell without having to also determine how the molecule will interact with other potential targets that have generated the historical data.[30]

Pharmacometrics, another field where AI is gaining traction, aims to use quantitative data to accurately describe how a potential therapy will interact with the human body.[31] Model selection in pharmacometrics utilizes a process known as "local search algorithms" that begins with identifying foundational features, which are then evaluated against random and tangential effects.[32] AI is being used in pharmacometrics model selection to create an alternative to local search algorithms: a global search method dubbed "Genetic Algorithm."[33] The Genetic Algorithm search method creates a queue of identified hypothetical feature combinations, organizes an optimal layout of those combinations, and then sorts through the queue to create an optimal hypothesis based on the most frequently selected features.[34] A Genetic Algorithm model has been created to determine appropriate parameters for data selection; the testing of an AI model that uses reinforcement learning has shown that AI models can outperform human researchers in this area.[35]

High-Throughput Screening, 6 GENOME MED. 57, 67 (2014).

[27] *See* Bo-Min Lv et al., *Causal Inference in Microbiome Medicine: Principles and Applications*, 29 TRENDS IN MICROBIOLOGY 736, 738 (2021).

[28] *See* Pedro R. Costa et al., *A Machine Learning Approach for Genome-Wide Prediction of Morbid and Druggable Human Genes Based on Systems-Level Data*, 11 BMC GENOMICS S9 (2010).

[29] *See* Junaed Younus Khan et al., *Toward Preparing a Knowledge Base to Explore Potential Drugs and Biomedical Entities Related to Covid-19: Automated Computational Approach*, 8 JMIR MED. INFORMATICS e21648 (2020).

[30] Quershi et al., *supra* note 24, at 3 ("Drug–target interactions may also be inferred, based on descriptor similarity to reference ligands, in the same cell without explicitly addressing the target identity of those reference ligands. A software tool (SPiDER) discretizes the input feature similarity vector onto a so-called feature map using a neural network-inspired approach."); *see also* Josh Abramson, et al., *Accurate Structure Prediction of Biomolecular Interactions with AlphaFold 3*, 630 NATURE 493, 493 (2024).

[31] Ene I. Ette & Paul J. Williams, Book Review, 71 AM. J. PHARM. EDUC. 3, 3 (2007) (reviewing X.H. HUANG & J. LI, PHARMACOMETRICS: THE SCIENCE OF QUANTITATIVE PHARMACOLOGY (2007) ("Pharmacometrics is the science of interpreting and describing pharmacology in a quantitative fashion. It lives at the intersection of pharmacokinetic models, pharmacodynamic models, pharmacodynamic-biomarker-outcomes link models, statistics, stochastic simulation, data visualization, and computer programming.").

[32] Ayyappa Chaturvedula, *Artificial Intelligence and Pharmacometrics: Time to Embrace, Capitalize, and Advance?*, 8 CPT PHARMACOMETRICS SYS. PHARMACOLOGY 440, 440 (2019) ("Model selection in pharmacometrics is often described as a linear process, starting with 'structural' features and followed by random effects and covariate effects, each tested one at a time.").

[33] *Id.* ("A global search method called Genetic Algorithm (GA) can be proposed as a better alternative.").

[34] *Id.* ("GA creates a user-defined 'search space' of candidate models representing all hypotheses to be tested (e.g., number of compartments, covariates, random effects). This set of possible hypotheses are then coded into a 'genome' consisting of a string of 0s and 1s, with genes representing each hypothesis. GA then searches this space for the optimal combination of 'features.' GA uses the mathematics of 'survival of the fittest' with mutation and cross-over for the optimal combination of 'features' (e.g., compartment, random effect, covariate effects, initial parameter estimates) based on a user-provided function that describes the quality of the model, typically based on log-likelihood and a parsimony penalty.").

[35] Robert R. Bies et al., *A Genetic Algorithm-Based, Hybrid Machine Learning Approach to Model Selection*, 33 J. PHARMACOKINETICS PHARMACODYNAMICS 195, 198–202 (2006); Eric J. Topol, *High-Performance Medicine: The Convergence of Human and Artificial Intelligence*, 25 NATURE MED. 44, 48 (2019).

Research indicates that the further use of this approach would provide a more effective means for the development of succinct models in pharmacometrics.[36]

Major challenges have been identified in the realm of protein structure prediction, and little progress has been made to advance technology designed to address those challenges.[37] A recent breakthrough in AI technology that relies solely on the protein sequence for protein structure identification received some speculation as to its efficacy; by its nature, it was biased toward the prescribed data set, so researchers evaluated the model by utilizing it to determine protein structure stability.[38] The AI system was able to accurately predict key structural features, and it has been posited that further refinement from increased use could enable researchers to identify and analyze unknown protein functions.[39] Results show that the AI system could further develop the availability to generate structural information in bioinformatics and see further use alongside traditional analytical methods in similar experiments.[40]

These innovations in the drug discovery process have generated an accelerated interest in the use of AI in drug discovery, which will only increase in popularity in the coming years.

C. Pharmaceutical Development

The second step in the FDA drug development process is the development phase, where drug developers will take the identified viable treatment options from the drug discovery phase and invest additional time and resources in developing a potential treatment.[41] The major goals of drug developers at this point are to determine how the drug interacts with the human body, how the drug functions and its potential uses, the most effective dose for effective treatment, what methods of delivery would be best for human use, the potential toxicity of the drug, how the drug might interact with humans based on a myriad of characteristics, the drug's compatibility with existing treatments, and whether the drug outperforms existing drugs for different purposes.[42]

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[36] *See* Eric J. Topol, *High-Performance Medicine: The Convergence of Human and Artificial Intelligence*, 25 NATURE MED. 44, 44 (2019).

[37] Priscila S.F. Gomes et al., *Protein Structure Prediction in the Era of AI: Challenges and Limitations when Applying to In Silico Force Spectroscopy*, 2 FRONTIERS IN BIOINFORMATICS 1, 5 (2022) ("Protein structure prediction has been one of the grand challenges in Biology since the 1950's. Several methods have been developed over the past 40 years that span from comparative modeling with the increase of experimentally determined protein structures by X-ray crystallography, nuclear magnetic resonance spectroscopy (NMR) and cryo-electron microscopy (cryo-EM), but little progress was seen on *ab-initio* methodologies that rely solely on the protein sequence.").

[38] *Id.* at 5–6 ("However, as nearly any other AI-based tool, AlphaFold is biased towards its training set, meaning that the search for unusual folds is unlikely to provide an accurate result. Despite the software's success on the folded part of most proteins, AlphaFold lacks accuracy for regions where fewer sequences are available for alignment and intrinsically disordered regions, the latter are about one third of the human proteome, present in all proteomes of all kingdoms of life, and of all viral proteomes analyzed so far. . . . In order to show how revolutionary AlphaFold is for the single-molecule biophysics community, here we put AlphaFold to the test by using it to model full length *Staphylococcus* adhesins and estimate how stable are the protein structures.").

[39] *Id.* at 6 ("Ignoring the disordered regions, AlphaFold was able to model the Ig-like domains of MSCRAMMs adhesins as well as other key structural features of these proteins, such as the homologous B domains, for all the tested sequences. With a little refinement from *in-equilibrium* MD simulations, the generated structures could help to investigate the properties of many of the domains that still have an unknown function.").

[40] Ewen Callaway, *What's Next for AlphaFold and the AI Protein-Folding Revolution*, 604 NATURE 234, 235–236 (2022).

[41] U.S. Food & Drug Admin., *supra* note 16 (indicating that Drug Development is the second phase of the FDA's Drug Development cycle, where a significant amount of testing occurs in order to test the viability of a potential new drug).

[42] *Id.* ("Once researchers identify a promising compound for development, they conduct experiments to gather information on [1] [h]ow it is absorbed, distributed, metabolized, and excreted[;] [2] [i]ts potential benefits and mechanisms of action[;] [3] [t]he best dosage[;] [4] [t]he best way to give the drug (such as by mouth or injection)[;] [5] [s]ide effects or adverse events that can often be referred to as toxicity[;] [6] [h]ow it affects different groups of people (such as by gender, race, or ethnicity) differently[;] [7] [h]ow it interacts with

By the end of the drug development phase, a new drug candidate will typically have been in laboratory development for approximately four-and-a-half years, and the potential candidates will have been narrowed down from thousands to a couple hundred.[43] AI has proven useful in the drug development stage by considerably reducing the human work needed to screen potential treatments, the need for human-led testing through the utilization of simulations, and the time and money required to perform tasks during this phase.[44]

D. Current Use of AI in Pharmaceutical Development

The use of AI in drug development has also markedly increased in recent years, as seen in its increased use in the realms of virtual screening, compound optimization, and the prediction of drug properties.[45] AI has become a crucial contributor to the screening process of the development phase due to its ability to develop predictive models, which provide insight as to whether a proposed drug will interact favorably with a target protein.[46]

Target identification traditionally references historical data to determine whether a molecule will interact with a specific target.[47] AI models have been used to quickly navigate chemical spaces by using new and innovative methods that sort through potential hypotheses to create an optimal set of features or use a high frequency of tests to determine the most efficient route.[48] Other innovative AI models have been used to create compounds and chemical structures with specific characteristics by analyzing historical data.[49] In order to predict the positive and negative effects of comingling the drug with targeted molecules, the AI models can rely on diverse data sets, develop efficient routes for the creation of compounds, and help researchers determine how drugs will react in certain conditions.[50]

AI is also being used in compound optimization to identify more specific and refined chemical structures.[51] In order to effectively optimize small molecules, researchers must design

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other drugs and treatments[; and] [8] [i]ts effectiveness as compared with similar drugs.").

[43] Duxin Sun et al., *Why 90% of Clinical Drug Development Fails and How to Improve It?*, 12 ACTA PHARMACEUTICA SINICA B 3049, 3050 (2022) ("Analyses of clinical trial data from 2010 to 2017 show four possible reasons attributed to the 90% clinical failures of drug development: lack of clinical efficacy (40%–50%), unmanageable toxicity (30%), poor drug-like properties (10%–15%), and lack of commercial needs and poor strategic planning (10%).").

[44] U.S. FOOD & DRUG ADMIN., *supra* note 15.

[45] *See* Quershi et al., *supra* note 24, at 2.

[46] *See id.* at 4–6 ("AI can be used to virtually screen and optimize compounds, estimate their bio-activities, and predict protein-drug interactions. One way AI can help in virtual screening is through the development of predictive models, that can identify compounds with a high probability of binding to a target protein.").

[47] *Id.* at 2 ("A drug discovery pipeline will usually consist of several stages. . . . In target-based discovery, the first step is to identify novel targets, with evidence of association to disease, from a large space of proteins (an organism's proteome). Potentially interacting molecules are identified by high throughput screening of compound libraries against these targets.").

[48] *See* Sara Romeo Atance et. al., *De Novo Drug Design Using Reinforcement Learning with Graph-Based Deep Generative Models*, 62 J. CHEM. INFO. MODELING 4863, 4863 (2022).

[49] *See* Quershi et al., *supra* note 24, at 9 ("Generative Adversarial Networks (GAN) can generate synthetic compounds, or molecules, with a desired property and learn the probability distribution of the training data and generate new chemical structures by sampling from the learned probability distribution. Chemical fingerprints, SMILES, molecular graphs, three-dimensional structures, and other molecular representations can be used in generative models.").

[50] *See* Óscar Álvarez-Machancoses & Juan Luis Fernández-Martínez, *Using Artificial Intelligence Methods to Speed Up Drug Discovery*, 14 EXPERT OPIN. DRUG DISCOVERY 769, 769–770 (2019).

[51] *See* Quershi et al., *supra* note 24, at 9–10 ("The generation of new chemical structures with desired properties can be realized by searching the continuous latent space by any optimization method. The property value is applied to VAE's latent space, which can be used to sample

"chemical spaces" to more accurately analyze variations in the structure of those molecules.[52] Researchers are developing virtual chemical spaces using historical molecular data to generate holistic analyses, expedite the identification and abandonment of undesirable structures, and optimize resource management.[53] These virtual spaces can be used to model various characteristics of the compounds, such as orientation and stability.[54]

Uncertainty surrounds the use of deep learning models for drug development due to their "black box" nature, as they generate predictions without the researchers knowing the AI's scientific justifications for making those predictions.[55] Despite the uncertainty of the deep learning models' processes, related optimization models have addressed drug discovery problems by determining the parameters of a model and selecting molecules to address specific characteristics.[56]

The prediction of drug properties has been heavily bolstered by the introduction of AI-driven methods, such as in the prediction of nonclinical physiochemical properties, bioactivity, and toxicity.[57] In predicting physiochemical properties, AI can use large amounts of data to predict the amount of energy a molecule will have, how many electrons will surround the molecule, and the location of the molecule's atoms to create optimal molecular structures with desirable characteristics.[58] Deep learning methods and neural networks have also been used to predict the ability of a molecule to mix with water or oily substances for various compounds.[59] Further, AI can be used to predict bioactivity by measuring how strongly a drug will interact with its target by considering the drug's features and chemical characteristics in comparison to a target.[60] The viability of a drug is based in part on how well it binds to its target; if a drug has poor binding performance when interacting with its target, the therapy will be ineffective and may lead to toxicity.[61] Machine learning methods can determine how similar a drug is to a target protein by taking into account the drug's features and similarities to the protein to predict how well it will

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molecules in the direction of the desired property value.").

[52] *See id.* at 15.

[53] Christos Nicolaou & Nathan Brown, *Multi-Objective Optimization Methods in Drug Design*, 10 DRUG DISCOVERY TODAY: TECHS. e427–e435, e432 (Sept. 2013).

[54] *See* Quershi et al., *supra* note 24, at 4 ("MD simulation and docking methods can be used to model the orientation, stability, and dynamics of the compounds.").

[55] *Id.* at 15 ("Another challenge is the black-box nature of deep learning models. We can not [sic] fully trust the predictions, without knowing the underlying biological and chemical reasons.").

[56] *See* E.O. Pyzer-Knapp, *Bayesian Optimization for Accelerated Drug Discovery*, 62 IBM J. RES. DEV. 2:1 (Nov. 2018).

[57] *See* U.S. FOOD & DRUG ADMIN., DISCUSSION DRAFT 1, *supra* note 15, at 5.

[58] Paul et al., *supra* note 23, at 83 ("Different AI-based tools can be used to predict physicochemical properties. For example, ML uses large data sets produced during compound optimization done previously to train the program. Algorithms for drug design include molecular descriptors, such as SMILES strings, potential energy measurements, electron density around the molecule, and coordinates of atoms in 3D, to generate feasible molecules via DNN and thereby predict its properties.").

[59] *Id.* ("Neural networks based on the ADMET predictor and ALGOPS program have been used to predict the lipophilicity and solubility of various compounds. DL methods, such as undirected graph recursive neural networks and graph-based convolutional neural networks (CVNN), have been used to predict the solubility of molecules.").

[60] *Id.* ("In some instances, it might also be possible that developed drug molecules interact with unintended proteins or receptors, leading to toxicity. Hence, drug target binding affinity (DTBA) is vital to predict drug-target interactions. AI-based methods can measure the binding affinity of a drug by considering either the features or similarities of the drug and its target.").

[61] *See* Hakime Öztürk et al., *DeepDTA: deep drug–target binding affinity prediction*, *in* 34 BIOINFORMATICS i821 (2018).

bind to the target protein.[62]

Other deep learning methods operate without the availability of structural information, showing increased performance in the prediction of bioactivity compared with other machine learning methods.[63] A more user-friendly deep learning model has been developed to predict bioactivity using traditionally effective formatting techniques to evaluate compounds and protein identity for the appearance of favorable structural characteristics.[64] AI systems have also shown aptitude in predicting the toxicity of a drug by comparing the characteristics of the drug to historical data or by creating a projection of toxicity upon identification and examination of certain features.[65] The detection or projection of toxicity is a historically resource-intensive challenge, but is necessary in order to detect potentially dangerous effects of a drug on the human body.[66]

The National Institutes of Health, Environmental Protection Agency, and the FDA issued the Tox21 Data Challenge to evaluate multiple techniques for their efficacy in predicting toxicity across a large sample of target compounds—a machine learning system proved the most effective technique due to its ability to analyze thousands of features in a minuscule amount of time.[67] Other machine learning approaches have proven to estimate toxicity of molecules with high accuracy by developing large-scale data on proteins and classifying multiple types of properties at the same time.[68] As the drug development phase typically sees a large attrition rate from potential treatments to viable drugs, the use of AI to reduce the time and cost of research in this phase will continue to grow to mitigate these historical costs.

IV. AI AND MEDICAL DIAGNOSTICS

AI has also begun transforming medical diagnostics in ways that stand to improve care delivery and outcomes for patients.[69] In some cases, clinical outcomes are improved when clinicians use AI to diagnose and treat disease, and promising uses for AI continue to emerge in this sector. Despite these promising developments, some express caution regarding the ways the technology should be used in patient care.[70]

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[62] Eugen Lounkine et al., *Large-Scale Prediction and Testing of Drug Activity on Side-Effect Targets*, 486 NATURE 361, 361 (2012); *see also* Paul et al., *supra* note 23, at 83 ("AI-based methods can measure the binding affinity of a drug by considering either the features or similarities of the drug and its target.").

[63] *See* Lounkine, *supra* note 62.

[64] *See* Mostafa Karimi et al., *DeepAffinity: Interpretable Deep Learning of Compound–Protein Affinity Through Unified Recurrent and Convolutional Neural Networks*, 35 BIOINFORMATICS 3329, 3329 (2019).

[65] Paul et al., *supra* note 23, at 84 ("Advanced AI-based approaches look for similarities among compounds or project the toxicity of the compound based on input features.").

[66] *See* Xin Yang et al., *Concepts of Artificial Intelligence for Computer-Assisted Drug Discovery*, 119 CHEM. REV. 10520, 10521 (2019).

[67] *See id.* at 10563.

[68] *See* Limeng Pu et al., *eToxPred: A Machine Learning-Based Approach to Estimate the Toxicity of Drug Candidates*, 20 BMC PHARMACOLOGY TOXICOLOGY 2 (2019).

[69] *See* Sara Gerke, *Health AI for Good Rather Than Evil? The Need for a New Regulatory Framework for AI-Based Medical Devices*, 20 YALE J. HEALTH POL'Y L. & ETHICS 433, 444 (2021) ("Medical imaging and diagnostics, alongside robotics and augmented reality, are just the beginning of many more potential clinical AI applications that may significantly change the way health care providers practice medicine.").

[70] Carey Beth Goldberg et al., *To Do No Harm — and the Most Good — with AI in Health Care*, 30 NATURE MED. 623, 623 (2024) ("[I]f AI's potential for improving health turns out to be as great as it now seems, then arguably all health care leaders bear the responsibility to support ways to help patients and staff take advantage of it."); *see also* Charlotte Tschider, *Deus ex Machina: Regulating Cybersecurity*

A. Current Use of AI in Diagnostic Medicine

As AI continues to evolve, its role in clinical medicine will only continue to grow. AI use has become commonplace in many areas of diagnostic medicine—medical devices enable and advance diagnostic and therapeutic procedures with the assistance of AI.[71] Advancements in the areas of colonoscopy, percutaneous coronary intervention ("PCI"), acute stroke and intracranial hemorrhage ("ICH"), vascular surgery, and ophthalmology indicate potential areas of further growth for AI technology in medical research and patient care.

1. Colonoscopy

Colonoscopy is the most effective method of diagnosing colorectal cancer; data indicate a substantial reduction in mortality for patients who undergo the procedure.[72] In order for colonoscopy to be effective, the procedure relies on the detection and removal of adenomas and precancerous lesions that may progress to cancer if ignored.[73] The procedure is more effective when performed and analyzed by multiple clinicians.

AI systems have been identified as a potentially effective "second reader" given their ability to detect polyps at, or exceeding, the level of performance of a human clinician, and they can conduct the analysis without tiring.[74] A group of randomized trials examined the ability of AI systems to detect polyps using a deep learning method, finding that this method outperformed the control group in detecting smaller adenomas.[75] The detection of smaller adenomas has clinical importance because studies have shown that such polyps can still be precancerous and would otherwise be left behind to grow if not discovered by a human clinician.[76] AI methods are also better at detecting polyps that appear in the colonoscope's frame of view for a significantly smaller amount of time, outperforming human clinicians' ability to detect those polyps by a wide margin and indicating a substantial area for improvement in polyp detection.[77]

In a tandem study, patients were randomly assigned to initial colonoscopies with or without

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and Artificial Intelligence for Patients of the Future, 5 SAVANNAH L. REV. 177, 179 (2018) ("Although AI has the potential to improve overall health outcomes, it may also introduce additional threat vectors that could compromise patient safety without appropriate cybersecurity measures.").

[71] *See* NAT'L ACAD. OF MED., DISCUSSION PAPER, MEETING THE MOMENT: ADDRESSING BARRIERS AND FACILITATING CLINICAL ADOPTION OF ARTIFICIAL INTELLIGENCE IN MEDICAL DIAGNOSIS 1, 21 (2022), https://doi.org/10.31478/202209c [https://perma.cc/VX6R-TTFV] ("Across medical specialties, these tools demonstrate potential to make the clinical diagnostic process more efficient and accurate, ultimately improving patient outcomes.").

[72] James Weiquan Li et al., *Artificial Intelligence-Assisted Colonoscopy: A Narrative Review of Current Data and Clinical Applications*, 63 SINGAPORE MED J. 118, 118 (2022) ("Colonoscopy is the reference standard procedure for the prevention and diagnosis of CRC and has been shown to reduce CRC-related mortality.").

[73] *Id.* ("The role of colonoscopy in the prevention of CRC lies in the accurate detection and adequate resection of colorectal adenomas that are considered premalignant and may progress to CRC. A 1% increase in adenoma detection rate (ADR) has been shown to reduce interval CRC by 3%.").

[74] *See id.* at 119 ("Computer-aided detection (CADe) functions as an automated second reader, but without the inherent problems of distraction and fatigue that may affect the performance of the endoscopist and the human second reader.").

[75] *See* Cesare Hassan et al., *Performance of Artificial Intelligence in Colonoscopy for Adenoma and Polyp Detection: A Systematic Review and Meta-Analysis,* GASTROINTESTINAL ENDOSCOPY 93, 77–85 (2021).

[76] Kevin O. Turner et al., *Lesions of All Types Exist in Colon Polyps of All Sizes*, 113 AM. J. GASTROENTEROLOGY 304, 306 (2018).

[77] Dan M. Livovsky et al., *Detection of Elusive Polyps Using a Large-Scale Artificial Intelligence System (with Videos)*, 94 GASTROINTESTINAL ENDOSCOPY 1099, 1102–1108 (2021).

the assistance of AI, which all were then followed up by a secondary colonoscopy; the AI groups showed significant increases in the total detection rate of polyps compared to the traditional method.[78] An AI model was used to diagnose and to display predicted information to clinicians performing colonoscopies in real-time, allowing the clinicians to then use that information to make more informed and accurate decisions regarding further patient treatment.[79]

Predicted information from AI allows the clinician to assess multiple treatment options and decide on the best path to optimal care while also informing existing strategies which can lead to more efficient resource management in colonoscopy and subsequent polyp removal.[80] A set of studies compared the efficacy of an AI system in polyp characterization to the performance of non-expert clinicians in the field, which resulted in the comparatively superior performance of the AI system and indicated the potential for AI to further develop as a key tool for the field.[81] AI models have also shown aptitude in polyp classification based on certain characteristics that indicate to the clinician whether a polyp is likely to develop into different types of cancers.[82] AI monitoring methods also could assist with the implementation of quality standards in colonoscopy that may otherwise be ignored or rushed due to time constraints, inadequate training of clinicians, or lack of actual enforcement of policies.[83]

AI was used to automatically monitor colonoscopy quality measures in a randomized trial; data was relayed to the clinician in real-time and enabled the clinician to know how quickly the procedure needed to occur, enhancing the clinician's ability to detect polyps as compared to a control group.[84] Another study used a deep learning method to determine how effective the preparation of the patient's bowel was before surgery.[85] The results indicated that the better prepared a bowel was before colonoscopy, the higher the detection rate of polyps.[86] Moreover, the results affirmed that there is further potential for AI systems to operate alongside traditional colonoscopy methods to provide more detailed, real-time quality assurance information to

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[78] Pu Wang et al., *Lower Adenoma Miss Rate of Computer-Aided Detection-Assisted Colonoscopy vs Routine White Light Colonoscopy in a Prospective Tandem Study*, 159 GASTROENTEROLOGY 1252, 1254–60 (2020).

[79] Eladio Rodriguez-Diaz et al., *Real-Time Artificial Intelligence-Based Histologic Classification of Colorectal Polyps with Augmented Visualization*, 93 GASTROINTESTINAL ENDOSCOPY 662, 667–69 (2021).

[80] James Weiquan Li et al., *Artificial Intelligence-Assisted Colonoscopy: A Narrative Review of Current Data and Clinical Applications*, 63 SINGAPORE MED. J. 118, 120 (2022) ("The predicted histology of colorectal polyps aids the endoscopist in selecting the optimal method of resection. The optical prediction of polyp histology is also a crucial element of the 'resect and discard' and 'detect and leave' strategies, which can make endoscopic examinations and treatment of diminutive colorectal polyps more cost-effective, provided these satisfy the criteria of the American Society for Gastrointestinal Endoscopy (ASGE) Preservation and Incorporation of Valuable endoscopic Innovations (PIVI) recommendations.").

[81] Thomas Lui et al., *Accuracy of Artificial Intelligence on Histology Prediction and Detection of Colorectal Polyps: A Systematic Review and Meta-Analysis*, 92 GASTROINTESTINAL ENDOSCOPY 11, 20–21 (2020).

[82] Eun Mi Song et al., *Endoscopic Diagnosis and Treatment Planning for Colorectal Polyps Using a Deep-Learning Model*, 10 SCI. REPS. 1 (2020).

[83] *See generally* Susan G. Coe et al., *Quality in Colonoscopy Reporting: An Assessment of Compliance and Performance Improvement*, 44 DIGESTIVE & LIVER DISEASE 660, 660–64 (2012).

[84] *See* Dexin Gong et al., *Detection of Colorectal Adenomas with a Real-Time Computer-Aided System (ENDOANGEL): A Randomised Controlled Study*, 5 LANCET GASTROENTEROL HEPATOLOGY 352 (2020).

[85] *See* Wei Zhou et al., *Multi-Step Validation of a Deep Learning-based System for the Quantification of Bowel Preparation: A Prospective, Observational Study*, 3 LANCET DIGIT. HEALTH e697–e706, e701–03 (2021).

[86] *Id.*

operating clinicians.[87] Should the technology be developed further, AI could be used to assist in other areas of traditional colonoscopy maintenance and care that are typically slow and resource-heavy processes, such as post-colonoscopy surveillance.[88]

2. Percutaneous coronary intervention ("PCI")

The treatment of coronary heart disease relies greatly upon the development of accurate prognoses. To obtain greater control over cardiovascular disease and other risk factors, clinicians must be able to choose the optimal method for treating coronary heart disease in a patient.[89]

One study evaluated multiple machine learning models to compare how adept each model would be at assessing the risk of various methods of treatment for patients with coronary artery disease and who had previously undergone PCI.[90] The models were extensively validated and compared in order to determine which model performed the best at predicting rates of mortality between treatment methods.[91] One AI method, the Random Forest-PCI model, performed significantly better than the rest, predicting mortality rates at high levels of accuracy and indicating the potential for such a model in the field of PCI prognostication.[92]

The overall results of the study showed that machine learning programs on average generate accurate predictions for the risk of different treatments in patients who have undergone PCI.[93] The ease at which the programs can be used in clinical practice and the programs' ability to become more efficient and effective through exposure to larger data sets indicates substantial promise for the further use of AI-based systems in this field.[94] The authors conclude by noting, "[t]he completeness of disease-related information of PCI patients [in electronic medical records makes] the practical application of ML … highly feasible."[95]

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[87] *Id.*

[88] Emma Peterson et al., *Automated Identification and Assignment of Colonoscopy Surveillance Recommendations for Individuals with Colorectal Polyps*, 94 GASTROINTESTINAL ENDOSCOPY 978, 978 (2021).

[89] Shangyu Liu et al., *Machine Learning-Based Long-Term Outcome Prediction in Patients Undergoing Percutaneous Coronary Intervention*, 11 CARDIOVASCULAR DIAGNOSIS THERAPY 736, 740 (2021) ("Prognosis assessment is the key to coronary heart disease diagnosis and treatment. It can assist clinicians in choosing the best intervention methods according to the different risk stratification. Furthermore, it is crucial to conduct a risk assessment for patients after PCI treatment as it will help provide more targeted control and management of cardiovascular disease and other accompanying risk factors, thereby improving the long-term prognosis of patients.").

[90] *Id.* at 737–738 ("We compared the performance of six ML models (support vector machine, decision tree, random forest, gradient boosting decision tree, neural network, and logistic regression) in predicting all-cause death in coronary heart disease patients who underwent PCI.").

[91] *Id.* at 739 ("Cross-validation: we used 10-fold cross-validation to evaluate the performance of all six models. The entire dataset was divided into ten mutually exclusive subsets, nine of which were used for training and one for evaluation. This process was repeated 10 times using 10 different but overlapping training sets and 10 unique testing sets. Model performance was assessed according to the area under the receiver operating characteristic curve (AUC).").

[92] *Id.* at 740 ("In the present study, among the evaluated ML classifiers, the RF model demonstrated the best performance. With an average AUC of over 0.71, the RF-PCI score can be used to predict the long-term prognosis of PCI patients.").

[93] *Id.* at 741.

[94] *Id.* ("[T]he results shows that ML-based predictive scores provide good practical prediction of the long-term prognostic risk stratification of patients after PCI and are easy to apply in clinical practice. This feature of ML methods is particularly important, given the ease with which the machine can seamlessly incorporate new data to continually update and optimize its algorithm and thus continually improve its predictive performance over time.").

[95] *Id.*

3. Stroke

As stroke is one of the primary causes of death worldwide, identifying stroke as early as possible is crucial for clinicians to be able to effectively treat affected patients and improve patients' quality and length of life.[96] AI has been identified as a potential substantial contributor to the field of neuroimaging, which is used to accurately detect signs of stroke in a patient and determine optimal paths for treatment for acute ischemic stroke (due to clots) and intracranial hemorrhages ("ICH", due to bleeding).[97]

Public datasets have been made available for the use of machine learning in the detection of stroke; the datasets are being used for the development and testing of AI systems and further tailoring of the technology for diagnostic purposes.[98] AI-based methods have been used in the detection of stroke symptoms and characteristics, with results showing the feasibility of using these methods for detection.[99] AI methods have been able to determine the severity of strokes by identifying the extent and parameters of lesions in the brain, a process essential to the effective triage of stroke patients.[100] For a disease where "time is brain," accelerated timelines for accurate diagnosis and treatment have historically been limited.[101]

Studies point to AI's ability to successfully identify lesions of different sizes and determine if lesions are actually indicative of stroke.[102] One study used an "artificial neural network" that was able to classify areas of interest as acute stroke or mimics within a comparatively small amount of time and with substantial accuracy.[103] Machine learning techniques were shown to be more effective than existing pre-treatment methods in determining the outcome of stroke-related procedures when the patient had specific characteristics that might complicate the procedure.[104]

Deep learning models were evaluated in their efficacy in detecting ICH, with results indicating that such models are adept at identifying and classifying multiple types of

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[96] J.E. Soun et al., *Artificial Intelligence and Acute Stroke Imaging*, 42 AM. J. NEURORADIOLOGY 2, 2 (2021) ("Stroke is the second leading cause of death worldwide with an annual mortality of about 5.5 million. Early identification of acute stroke is critical for initiating prompt intervention to reduce morbidity and mortality.").

[97] *Id.* ("Neuroimaging is an important tool for the detection, characterization, and prognostication of acute strokes, including ischemic and hemorrhagic subtypes. Artificial intelligence (AI) technology is a rapidly burgeoning field, providing a promising avenue for fast and efficient imaging analysis. AI applications for imaging of acute cerebrovascular disease have been implemented, including tools for triage, quantification, surveillance, and prediction.").

[98] *Id.* at 4 ("To address these challenges, many publicly available imaging datasets are now available for ML in stroke. These datasets are valuable because they are already anonymized, postprocessed, and annotated, and they can be used for testing and comparing algorithms in diagnosing ischemic stroke and hemorrhage.").

[99] Fuk-Hay Tang et al., *An Image Feature Approach for Computer-Aided Detection of Ischemic Stroke*, 41 COMPUTS. BIOLOGY & MED. 529, 533–36 (2011).

[100] Yishu Fan, Zhenshan Song & Menqi Zhang, *Emerging Frontiers of Artificial Intelligence and Machine Learning in Ischemic Stroke: A Comprehensive Investigation of State-of-The-Art Methodologies, Clinical Applications, and Unraveling Challenges*, 14 EPMA J. 645, 650 (2023).

[101] *Id.* at 657.

[102] *See, e.g.*, Liang Chen et al., *Fully Automatic Acute Ischemic Lesion Segmentation in DWI Using Convolutional Neural Networks*, 15 NEUROIMAGE 633 (2017); *see also, e.g.*, Ying Lui et al., *Artificial Intelligence in Ischemic Stroke Images: Current Applications and Future Directions,* 15 FRONT NEUROLOGY 1 (2024); *see also* Koska İÖ et al., *Artificial Intelligence in Stroke Imaging: A Comprehensive Review*, 55 EURASIAN J. MED. S91 (2023).

[103] *See* Vida Abedi et al., *Novel Screening Tool for Stroke Using Artificial Neural Network*, 48 STROKE 1678 (2017).

[104] *See* Zhicai Chen et al., *Novel Prehospital Prediction Model of Large Vessel Occlusion Using Artificial Neural Network*, 10 FRONTIERS AGING NEUROSCIENCE 1, 5 (2018).

hemorrhages.[105] Another study employed a more user-friendly AI model to combat some of the uncertainty behind the model's "black box" nature. The AI model emphasized readable diagrams and digestible predictive models to detect and classify ICH, which resulted in favorable performance at similar levels to experts in the field.[106] Further, a machine learning model was used to identify the risk of future brain bleeds with high accuracy, and the results indicate further potential for AI systems to engage in the triaging of ICH patients through more efficient and effective identification methods.[107]

4. Vascular Surgery

In the field of vascular surgery, breakthroughs in AI technology have led to its increased use in "vascular diagnostics, perioperative medicine, risk stratification, and outcome prediction."[108] AI has contributed to the field of vascular diagnosis by employing noninvasive techniques to determine the severity of risk-related factors for diseases such as peripheral artery disease.[109] For example, in one study, a deep learning model was created and evaluated against traditional methods for the detection of peripheral artery disease (the "ankle-brachial index").[110] The deep learning model showed superior performance, indicating that AI systems could lead to more efficient and effective methods of diagnosis that could determine the risk of peripheral artery disease before the occurrence of symptoms.[111]

AI methods have also been used to examine patients that present with abdominal aortic aneurysm and help develop treatment plans before a clinician operates, showing the potential for AI systems to further contribute to the pre-operative management of such diseases through effective data management techniques.[112] One study that examined the use of AI to analyze pulse waveforms showed the AI system's aptitude in identifying peripheral artery disease when compared to traditional detection methods.[113]

The strength of AI systems in this field lies in their ability to objectively analyze massive amounts of data, calculate various risks in a patient's treatment plan, and provide alternative

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[105] *See* Sasank Chilamkurthy et al., *Deep Learning Algorithms for Detection of Critical Findings in Head CT Scans: A Retrospective Study*, 392 LANCET 2388, 2396 (2018).

[106] *See* HyunKwang Lee et al., *An Explainable Deep-Learning Algorithm for The Detection of Acute Intracranial Haemorrhage from Small Datasets*, 3 NAT. BIOMEDICAL ENG'G. 173, 179 (2019).

[107] *See* Jinjin Liu et al., *Prediction of Hematoma Expansion in Spontaneous Intracerebral Hemorrhage Using Support Vector Machine*, 43 EBIOMEDICINE 454, 458 (2019).

[108] Uwe M. Fischer et al., *Current Applications of Artificial Intelligence in Vascular Surgery*, 34 SEMIN. VASCULAR SURGERY 268, 268–69 (2021) ("Although research and development of AI in healthcare is being conducted in many medical subspecialties, only few applications have been implemented in clinical practice. This is true in vascular surgery, where applications are mostly in the translational research stage. These AI applications are being evaluated in the realms of vascular diagnostics, perioperative medicine, risk stratification, and outcome prediction, among others.").

[109] *Id.* at 269 ("AI can accurately predict which patients are at risk and need of intervention using imaging platforms. Even before the need for an intervention, AI offers methods of diagnosing the severity of vascular pathology such as peripheral artery disease (PAD) based on analysis of noninvasive diagnostics.").

[110] *See* Soojo Kim et al., *Detection and Severity Assessment of Peripheral Occlusive Artery Disease via Deep Learning Analysis of Arterial Pulse Waveforms: Proof-of-Concept and Potential Challenges*, 8 FRONTIERS IN BIOENG'G & BIOTECH. Article 720, at 7 (2020).

[111] *Id.*

[112] Juliette Raffort et al., *Artificial Intelligence in Abdominal Aortic Aneurysm*. 72 J. VASCULAR SURGERY 321, 321 (2020).

[113] *See* Kim et al., *supra* note 110, at 7.

solutions to mitigate those risks on an individual patient level.[114] In peripheral artery disease risk stratification, an AI system's ability to quickly mine data for training purposes allows the AI system to develop models that accurately assess current client data and identify risk factors for disease incidence and mortality.[115] One such study used AI to predict whether infections might occur at certain sites after vascular surgery, resulting in high prediction rates for the AI model.[116]

5. Ophthalmology

Ophthalmologists are already heavily reliant on images and high-quality data at baseline, creating great potential for the future development of AI technology.[117] The field of ophthalmology has already seen advancements of AI technology in combating eye diseases such as "diabetic retinopathy, age-related macular degeneration, and retinopathy of prematurity."[118] AI systems can be used in diabetic retinopathy for more efficient and effective identification of the disease across larger populations, while reducing the resources needed to complete such a monumental undertaking as a routine screening exam for the nearly 40 million people with diabetes mellitus in the United States.[119] Studies have shown that AI assistance in the diagnosis of diabetic retinopathy has led to significantly more accurate diagnoses, which can lead to earlier treatment and greater preservation of vision.[120]

The FDA has already approved an AI-enabled medical device developed for the detection of diabetic retinopathy and related diseases, indicating a promising future for the further regulatory approval of similar AI-related devices.[121] Deep learning models can classify age-related macular degeneration by analyzing images from historical data, comparing them to images of current patients, and identifying appropriate boundaries for the search for retinal lesions.[122] As with other medical conditions, earlier diagnosis can lead to earlier treatment, delaying progression of disease while preserving vision.

Deep learning models have also been used to triage patients with symptoms of macular

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[114] Fischer et al., *supra* note 108, at 270 ("Although clinical applications are in their infancy the ability to analyze large amounts of patient data in an unbiased fashion enables AI to determine patient risk for the perioperative period providing tools to individualize and thus optimize patient care.").

[115] Elsie Gyang Ross et al., *The Use of Machine Learning for the Identification of Peripheral Artery Disease and Future Mortality Risk*, 64 J. VASCULAR SURGERY 1515, 1515 (2016).

[116] *See* Frank M. Davis et al., *Predictors of Surgical Site Infection After Open Lower Extremity Revascularization*, 65 J. VASCULAR SURGERY 1769, 1770 (2017).

[117] Santosh G. Honavar, *Artificial Intelligence in Ophthalmology – Machines Think!*, 70 INDIAN J. OPHTHALMOLOGY 1075, 1076–77 (2022) ("Ophthalmology, being an image-based and data-rich specialty of medicine, possibly has the widest scope for the application of AI.").

[118] *Id.* at 1076 ("The most promising AI tools are currently in the field of the retina—for diabetic retinopathy (DR), age-related macular degeneration (AMD), and retinopathy of prematurity (ROP). There are AI models applicable to glaucoma, keratoconus, cataract, and other anterior segment diseases and oculoplastic surgery.").

[119] Michael D. Abràmoff et al., *Improved Automated Detection of Diabetic Retinopathy on a Publicly Available Dataset Through Integration of Deep Learning*, 57 INVESTIGATIVE OPHTHALMOLOGY & VISUAL SCI. 5200, 5200 (2016).

[120] *See* Daniel Shu Wei Ting et al., *Development and Validation of a Deep Learning System for Diabetic Retinopathy and Related Eye Diseases Using Retinal Images from Multiethnic Populations with Diabetes*, 318 JAMA 2211, 2222 (2017).

[121] Michael D. Abràmoff et al., *Pivotal Trial of an Autonomous AI-Based Diagnostic System for Detection of Diabetic Retinopathy in Primary Care Offices*, 1 NPJ DIGIT. MED. Article 39, at 1 (2018).

[122] Daniel Shu Wei Ting et al., *Development and Validation of a Deep Learning System for Diabetic Retinopathy and Related Eye Diseases Using Retinal Images from Multiethnic Populations with Diabetes*, 318 JAMA 2211, 2219–20 (2017).

degeneration with results at the same level as experts in the field and without constant human intervention.[123] A study using a deep learning system showed extreme aptitude in the detection of retinopathy of prematurity, correctly identifying the disease at the same level of specificity as multiple experts in the field and correctly identifying levels of risk and highlighting the importance of monitoring the activity of the disease over time.[124]

The evolution and implementation of AI in medicine has shown promise in making medical processes more efficient and effective, even as compared to medical experts. Profound innovations in colonoscopy, PCI, stroke and ICH, vascular surgery, and ophthalmology suggest that AI could lead to even more effective diagnostic and therapeutic options in the future.

However, there is concern about whether AI might supplant physicians in some areas of medicine.[125] A common sentiment amongst speculators of the AI development industry is the fear of data misuse and misinformation when collecting data for the training of AI models and improperly using that data to generate biased results.[126] These concerns are echoed by industry leaders and government officials as being a potential setback for the smooth implementation of AI models in various industries.[127]

The health care industry, in particular, has an interest in ensuring the ethical and accurate use of patient data, indicating the need for AI regulation that forces AI development and training to adhere to HIPAA standards and other patient-protection laws.[128] As AI technology continues to advance, regulators need to develop best practices that allow for innovations in the provision of care while carving out clear roles for physicians and imposing safeguards against patient harm.

V. THE FUTURE OF AI IN PHARMACEUTICALS AND DIAGNOSTIC MEDICINE

As AI technology related to the discovery and development of new drugs matures and becomes more complex, its uses will also grow in scope and become more effective.[129] Corporations with interests in pharmaceutical advancements are excited about the opportunity for

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[123] Honavar, *supra* note 117, at 1077 ("DL is now used to triage patients with macular pathologies (choroidal neovascularization, macular edema, drusen, geographic atrophy, epiretinal membrane, vitreomacular traction, macular hole, central serous chorioretinopathy, etc.), for triage and referral (urgent, semi-urgent, routine, observation) in the setting of an unsupervised virtual clinic with accuracy comparable to that of experts.").

[124] James M. Brown et al., *Automated Diagnosis of Plus Disease in Retinopathy of Prematurity Using Deep Convolutional Neural Networks*, 136 JAMA OPHTHALMOLOGY 803, 806–08 (2018).

[125] *See, e.g.*, Sarah C. Jull & Joseph J. Fins, *Echoes of Concern – AI and Moral Agency in Medicine*, 9 JAMA CARDIOLOGY 955 (2024).

[126] Eyal Lotan et al., *Medical Imaging and Privacy in the Era of Artificial Intelligence: Myth, Fallacy, and the Future*, 17 J. AM. COLL. RADIOLOGY 1159, 1159–62 (2020).

[127] *See* Exec. Order No. 14,110, 3 C.F.R. § 14,110 (2024) (revoked by Exec. Order No.14,148, 90 Fed. Reg. 8237 (Jan. 20, 2025) [hereinafter Biden AI Executive Order].

[128] *See* W. Nicholson Price II, *Problematic Interactions Between AI and Health Privacy*, 2021 UTAH L. REV. 925, 936 (2021) ("The relationship between health privacy and the development of big data and health AI is dysfunctional now, but the rewards to getting it right are potentially immense."); *see also* Barbara J. Evans, *The HIPAA Privacy Rule at Age 25: Privacy for Equitable AI*, 50 FLA. ST. U. L. REV. 741, 802 (2023) ("Parties who control AI/ML [clinical decision support] tools—whether they are researchers, software developers/vendors, or health care providers that use the software—should be subject to strong information fiduciary duties in their handling of personal information used in these systems.").

[129] Morgan Stanley, *Why Artificial Intelligence Could Speed Drug Discovery* (Sept. 9, 2022), https://www.morganstanley.com/ideas/ai-drug-discovery [https://perma.cc/R7B2-B93J].

AI to reduce research costs and expedite drug development.[130] Morgan Stanley posited that "modest improvements in early-stage drug development success rates enabled by the use of artificial intelligence and machine learning could lead to an additional 50 novel therapies over a 10-year period, which could translate to a more than $50 billion opportunity."[131] Investment in AI-enabled drug discovery has reached incredible heights in the past few years: in 2021, such funding surpassed previous years, exceeding more than $5 billion.[132]

Corporate success and funding are not the only indicators of AI's potential in pharmaceutical development: MIT Technology Review recognized the importance of AI in the drug discovery field as one of the most significant technological advancements in recent years.[133] Advancements in technologies such as nanomedicines outline the horizon as AI becomes more sophisticated. Nanomedicine employs the use of nanotechnology alongside traditional methods of patient care to develop more efficient and effective methods for the diagnosis and treatment of certain diseases; the technology has become increasingly important in recent years because of the greater efficacy of treatment methods.[134] The combination of AI and nanotechnology could provide solutions to problems in areas of drug discovery and development that have historically seen the greatest numbers of failed studies.[135]

In diagnostic medicine, machine learning techniques are uniquely poised to make significant contributions in precision medicine, which relies on patient characteristics to make informed decisions about what types of treatments would best suit that specific patient.[136] Initial challenges have hindered AI technology in this field as opposed to other industries, but current uses and anticipated advancements in AI technology's ability to reliably analyze images, both as training data and in real-time, indicate the potential for AI techniques to be used widely in the areas of medicine that revolve around a clinician's analysis of photographs and videos.[137]

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[130] *Id.*

[131] *Id.*

[132] Margaret Ayers et al., *Adopting AI in Drug Discovery*, BCG (Mar. 29, 2022), https://www.bcg.com/publications/2022/adopting-ai-in-pharmaceutical-discovery [https://perma.cc/C23X-4GN9] ("The move from traditional service and software models to asset development partnerships and pipeline development has led to soaring investment. Third-party investment in AI-enabled drug discovery has more than doubled annually for the last five years, topping $2.4 billion in 2020 and reaching more than $5.2 billion at the end of 2021. These figures exclude the amounts that pharma companies are investing in their internal capabilities and investments by tech giants, which have also been active in expanding their AI investments into biology and drug research.").

[133] Quershi et al., *supra* note 24, at 15 ("MIT Technology Review named the discovery of promising drug-like molecules using AI as one of the top ten technology breakthroughs of 2020. AI tools have been around for a long time and have shown reasonable success.").

[134] Paul et al., *supra* note 23, at 90 ("Nanomedicines use nanotechnology and medicines for the diagnosis, treatment, and monitoring of complex diseases, such as HIV, cancer, malaria, asthma, and various inflammatory diseases.").

[135] *Id.* ("In recent years, nanoparticle-modified drug delivery has become important in the field of therapeutics and diagnostics because they have enhanced efficacy and treatment. A combination of nanotechnology and AI could provide solutions to many problems in formulation development.").

[136] Thomas Davenport & Ravi Kalakota, *The Potential for Artificial Intelligence in Healthcare*, 6 FUTURE HEALTHCARE J. 94, 94 (2019) ("In healthcare, the most common application of traditional machine learning is precision medicine—predicting what treatment protocols are likely to succeed on a patient based on various patient attributes and the treatment context. The great majority of machine learning and precision medicine applications require a training dataset for which the outcome variable (e.g., onset of disease) is known; this is called supervised learning.").

[137] *Id.* at 97 ("In the form of machine learning, it is the primary capability behind the development of precision medicine, widely agreed to be a sorely needed advance in care. Although early efforts at providing diagnosis and treatment recommendations have proven challenging, we expect that AI will ultimately master that domain as well. Given the rapid advances in AI for imaging analysis, it seems likely that most radiology and pathology images will be examined at some point by a machine.").

Clerical tasks, such as the generation of more specific automated patient notifications or the ability for AI to accurately dictate the notes of a clinician, could also be affected by AI, as the technology advances in its ability to detect and interpret speech and language.[138] AI technology is poised to become an effective aid to more mundane health care processes and augment a clinician's ability to recognize and interpret data; it is unlikely that AI will supplant most health care jobs, as the technology is not adept at more humanist tasks such as in-person patient communication or ideation on a grand scheme.[139] The greatest hurdles for AI to overcome in achieving widespread use in health care settings will be how it is regulated to protect against misuse, whether it appropriately trains clinicians, and whether it is sufficiently funded to ensure continued growth and actualization of envisioned AI technologies.[140]

Before AI is deployed for widespread use in pharmaceutical development and diagnostic medicine, however, there are a number of challenges that must be addressed.[141] These challenges include "data representation, data labeling, disparity among labels, small sample size, data privacy, ethical concerns, learning paradigms, and model interpretations."[142] The crux of these issues is the safety of the proposed systems and the ability of clinicians to accurately employ and adequately understand the technology.[143] Some hypothesize that AI techniques could be more efficiently trained and become more effective at detecting and synthesizing solutions for complex problems in the drug development field through unsupervised learning techniques, which would also require less human intervention.[144] Reinforcement Learning may also be an effective way to combat these challenges because it would enable the AI system to become more efficient at problem-solving through a trial and error process. In order to do so, new evaluation techniques would need to be developed to ensure the accuracy of the AI's outputs.[145]

Sufficiency in data quantity will also be an important hurdle for those wishing to use AI for pharmaceutical research, as limited data sets will likely lead to flawed interpretation by the

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[138] *See* MCKINSEY GLOBAL INST., *A Future that Works: Automation, Employment, and Productivity* (Jan. 2017), https://www.mckinsey.com/~/media/mckinsey/featured%20insights/Digital%20Disruption/Harnessing%20automation%20for%20a%20future%20that%20works/MGI-A-future-that-works-Executive-summary.ashx [https://perma.cc/XGT8-DL9W].

[139] THOMAS DAVENPORT & JULIA KIRBY, ONLY HUMANS NEED APPLY: WINNERS AND LOSERS IN THE AGE OF SMART MACHINES (Harper Business 2016).

[140] Thomas Davenport & Ravi Kalakota, *The Potential for Artificial Intelligence in Healthcare*, 6 FUTURE HEALTHCARE J. 94, 97 (2019) ("The greatest challenge to AI in these healthcare domains is not whether the technologies will be capable enough to be useful, but rather ensuring their adoption in daily clinical practice. For widespread adoption to take place, AI systems must be approved by regulators, integrated with EHR systems, standardised to a sufficient degree that similar products work in a similar fashion, taught to clinicians, paid for by public or private payer organisations and updated over time in the field.").

[141] Quershi et al., *supra* note 24, at 14.

[142] *Id.* ("Many challenges exist for AI in the drug discovery domain, such as data representation, data labeling, disparity among labels, small sample size, data privacy, ethical concerns, learning paradigms, and model interpretations.").

[143] *Id.* ("The behavior of proteins and compounds can rapidly change in patients, cell lines, and tissues, which may cause a distribution shift. Therefore devising a system, learning the true representation, and labeling the data are major challenges for the success of AI in the drug discovery domain.").

[144] *Id.* at 14–15; *see also* Yao Zhang et al., *Bayesian Semi-Supervised Learning for Uncertainty-Calibrated Prediction of Molecular Properties and Active Learning*, 10 CHEM. SCI. 8154–63 (2019).

[145] Quershi et al., *supra* note 24, at 14–15 ("We also hypothesize that over-fitted machine learning models may generate a novel data-driven hypothesis, which can be validated with experimental Biologists. Reinforcement Learning (RL) can be applied to navigate through the chemical space, which chooses a set of actions to maximize the reward function. RL learning paradigm can be used to generate molecules with desired properties and design optimal treatment strategies. To deal with the imbalanced datasets, we need to obtain data balancing methods, as well as appropriate evaluation metrics.").

machine.[146] Developers and health care entities seeking to harness AI in their systems will likely incur higher costs if they wish to further develop the technology through increased data access, yet doing so would be crucial for the proper training and maintenance of the AI.[147]

Fear of AI supplanting research roles is another intimidating factor that must be overcome by companies wishing to use this technology. Researchers and employees must be informed of the actual capabilities of AI, its uses, and the continuing need for human involvement in the development and operation of AI systems to quell fears regarding job replacement.[148]

The benefits of increased use of AI in pharmaceutical research will likely outweigh the current challenges that accompany such use. AI could aid a manufacturer in creating more effective drugs, determining the best way for a drug to be administered to humans based on different characteristics, increasing quality control measures through monitoring of manufacturing processes, and decreasing the time needed to manufacture a batch of drugs through more efficient processes.[149] AI could also augment clinical trials evaluating safety and effectiveness, which may allow a drug manufacturer to optimize marketing strategies for the eventual sale of the drug.[150] Increased use of AI in drug development promises to lessen unnecessary expenditures, decrease the timeline of drug development, make drugs accessible to marginalized communities that may not have previously had access to important drugs, and provide solutions to diseases that were previously thought incurable.[151]

AI in medical diagnostics has the potential to greatly improve patient care, especially through increased availability of diagnostic data, development of more advanced AI systems, and refinement of AI compatibility with pre-existing techniques.[152] Technological advancements, such as quantum AI, may be easier to understand for most health care workers and allow for quicker display of important diagnostic information.[153]

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[146] Paul et al., *supra* note 23, at 82 ("Despite its advantages, AI faces some significant data challenges, such as the scale, growth, diversity, and uncertainty of the data.").

[147] *Id.* at 90 ("The entire success of AI depends on the availability of a substantial amount of data because these data are used for the subsequent training provided to the system. Access to data from various database providers can incur extra costs to a company, and the data should also be reliable and high quality to ensure accurate result prediction.").

[148] *Id.* ("Automation of certain tasks in drug development, manufacturing, and supply chains, clinical trials, and sales will take place with time, but these all fall under the category of 'narrow AI'; where AI has to be trained using a large volume of data and, thus, makes it suitable for a particular task. Therefore, human intervention is mandatory for the successful implementation, development, and operation of the AI platform. However, the fear of unemployment could be a myth given that AI is currently is taking over repetitive jobs, while leaving scope for human intelligence to be used for developing more complicated insights and creativity.").

[149] *Id.* ("AI can also make major contributions to the further incorporation of the developed drug in its correct dosage form as well as its optimization, in addition to aiding quick decision-making, leading to faster manufacturing of better-quality products along with assurance of batch-to-batch consistency.").

[150] *Id.* ("AI can also contribute to establishing the safety and efficacy of the product in clinical trials, as well as ensuring proper positioning and costing in the market through comprehensive market analysis and prediction.").

[151] Matthew Chun, *How Artificial Intelligence Is Revolutionizing Drug Discovery*, BILL OF HEALTH (Mar. 20, 2023), https://blog.petrieflom.law.harvard.edu/2023/03/20/how-artificial-intelligence-is-revolutionizing-drug-discovery/ [https://perma.cc/D2RH-MBPJ] ("If current trends continue, it will only be a matter of time before the drugs we take are no longer designed by people, but by machines. With the promise of lower costs and shorter development timelines, AI-enabled drug discovery holds massive potential to increase the accessibility of drugs and to treat presently incurable conditions.").

[152] Mugahed A. Al-Antari, *Artificial Intelligence for Medical Diagnostics-Existing and Future AI Technology!*, 13 DIAGNOSTICS (BASEL) 688, 689 (2023) ("The future of AI-based medical diagnostics is likely to be characterized by continued growth and development as OpenAI.").

[153] *Id.* ("More advanced AI technologies are being introduced into the research domain, such as quantum AI (QAI), to speed up the

General AI, a new type of AI technology currently in development, is expected to generate more efficient and effective methods of diagnosis while increasing the readability of the AI system, thereby making the technology's outputs more accessible to health care workers.[154] Technology in this field is already collaborative in nature, and therefore further studies of AI technology in medical diagnostics are likely to lean into the nature of the pre-existing technology. Further developments in combined technologies could boost the effectiveness of traditional diagnostic methods, which could lead to more effective AI-driven methods in the future.[155] Increased levels of development and further collaboration will only increase a health care provider's ability to provide effective patient treatment, which could lead to crucial developments in combating global problems such as the COVID-19 pandemic.[156]

The benefits of widespread AI use in pharmaceutical research and diagnostic medicine are innumerable, and with comprehensive, widespread regulation of the technology, AI could continue to safely grow and provide greater solutions to the problems that researchers and patients face regarding development of therapeutics to treat disease.

VI. EXECUTIVE ORDERS ON THE DEVELOPMENT AND USE OF AI

On October 30, 2023, President Joseph Biden issued the "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence" ("the Executive Order").[157] The Executive Order was comprehensive in its scope and addressed several important topics, such as the development of safety standards, the consideration of data privacy and security, the consideration for the civil rights of American citizens, the encouragement and incentivization of responsible development in areas of public concern, assurances to the American workforce that AI will supplement—not eliminate—jobs, the need for robust incentives to inspire AI developers, a call to lead the global push for AI development and innovation, and the development of mandatory rules to ensure the ethical deployment of AI in government settings.[158]

The Executive Order had direct consequences for the use of AI in pharmaceutical research: it set out further action points for multiple department heads and agencies and mandates that those agencies develop frameworks and standards for the future use of the technology.[159] The Executive

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conventional training process and provide rapid diagnostics models.").

[154] *Id.* ("Another concept is GAI or general AI, which is being used by different projects and companies, such as OpenAI's DeepQA, IBM's Watson, and Google's DeepMind. The goal of GAI for medical diagnostics is to improve the accuracy, speed, and efficiency of medical diagnoses, as well as provide healthcare providers with valuable insights and support in the diagnosis and treatment of patients.").

[155] Vidhya R. Umpathy et al., *Perspective of Artificial Intelligence in Disease Diagnosis: A Review of Current and Future Endeavours in the Medical Field*, 15 CUREUS 1 (2023) ("The influence of AI on medical diagnostics is anticipated to expand dramatically as healthcare systems adopt digital technology and AI algorithms continue to advance.").

[156] *Id.* at 5 ("This is due to the fact that our research demonstrates that mHealth does, in fact, significantly influence how people attend healthcare facilities in tumultuous situations like a pandemic. Some current AI methods that can hasten acceptance and enable quicker deployment throughout hospitals, medical institutions, and users at large are explored in this context. The smart healthcare revolution can be successfully fueled by ML techniques like DL, FL, and transfer learning to secure patients' privacy.").

[157] Biden AI Executive Order, *supra* note 127

[158] Biden AI Executive Order, *supra* note 127, at 75191.

[159] *Id.* Specifically, some of the mandates from the executive order that may affect pharmaceutical research are:

"the Secretary of Homeland Security, in consultation with the Secretary of Energy and the Director of the Office of Science and Technology Policy (OSTP), shall evaluate the potential for AI to be misused to enable the development or production of CBRN threats, while also

Order further required the Secretary of Commerce, National Institute of Standards and Technology, Secretary of Energy, Secretary of Homeland Security, and heads of other relevant agencies to establish further guidelines and best practices for the development of AI and for developers to conduct further testing of AI.[160] While the Executive Order did not have the full force and effect of legislation, it was a substantial step toward formal regulation of AI in America.

Following his re-election at the end of 2024, President Donald Trump revoked President Biden's AI executive order and issued his own executive order titled "Removing Barriers to American Leadership in Artificial Intelligence."[161] Trump's executive order declares the policy of the United States to "sustain and enhance America's global AI dominance in order to promote human flourishing, economic competitiveness, and national security."[162] The executive order further tasks the Assistant to the President for Science and Technology, the Special Advisor for AI and Crypto, the Assistant to the President for National Security Affairs, and the heads of the other departments and agencies to develop an action plan to achieve such policy, to determine what actions have been taken pursuant to President Biden's executive order that conflict with such policy, and to suspend, revise, or rescind such actions.[163] President Trump's executive order does not per se undo all of the progress that President Biden's executive order achieved; it remains to be seen what actions and initiatives developed by President Biden's executive order will be curtailed, i.e., which of these are contrary to President Trump's AI policy. As the action plan must be developed and submitted to President Trump by July 22, 2025, the discussions and ideas put forth by AI policy theorists in the next few months will be key to the infancy of AI regulation in America.

President Trump's disenfranchisement of President Biden's executive order and AI policy spells uncertainty for the future of American AI policy. It is now, more than ever, paramount that Congress and federal agencies promulgate legislation and regulatory standards for AI that fully bind corporations and citizens to properly steward the technology in order to avoid the inevitable

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considering the benefits and application of AI to counter these threats"; "the Secretary of Defense, in consultation with the Assistant to the President for National Security Affairs and the Director of OSTP, shall enter into a contract with the National Academies of Sciences, Engineering, and Medicine to conduct . . . a study that (A) assesses the ways in which AI can increase biosecurity risks, including risks from generative AI models trained on biological data, and makes recommendations on how to mitigate these risks . . . (C) assesses the ways in which AI applied to biology can be used to reduce biosecurity risks, including recommendations on opportunities to coordinate data and high-performance computing resources, and considers additional concerns and opportunities at the intersection of AI and synthetic biology that the Secretary of Defense deems appropriate"; "the Director of OSTP, in consultation with the Secretary of State, the Secretary of Defense, the Attorney General, the Secretary of Commerce, the Secretary of Health and Human Services (HHS), the Secretary of Energy, the Secretary of Homeland Security, the Director of National Intelligence, and the heads of other relevant agencies as the Director of OSTP may deem appropriate, shall establish a framework, incorporating, as appropriate, existing United States Government guidance, to encourage providers of synthetic nucleic acid sequences to implement comprehensive, scalable, and verifiable synthetic nucleic acid procurement screening mechanisms, including standards and recommended incentives "; and "to understand AI's implications for scientific research, the President's Council of Advisors on Science and Technology shall submit to the President and make publicly available a report on the potential role of AI, especially given recent developments in AI, in research aimed at tackling major societal and global challenges. The report shall include a discussion of issues that may hinder the effective use of AI in research and practices needed to ensure that AI is used responsibly for research." *Id.* at 75200–01, 75208.

[160] *Id.* at 75196.

[161] *See* Exec. Order No. 14,179, 90 Fed. Reg. 8741 (Jan. 23, 2025).

[162] *Id.* The executive order is unclear what "human flourishing" means in relation to the development of AI and AI policy. The policy primarily seems to focus on the disestablishment of President Biden's executive order and the promotion of looser AI regulation in America.

[163] *Id.*

disaster threatened by unchecked, unscrupulous development of the powerful technology.

VII. THE NEED TO REGULATE AI

The call for regulation of AI is widespread and has been echoed by a variety of key stakeholders. The average consumer is overwhelmingly concerned about the implications of AI in daily life. In a study conducted by the Pew Research Center, over 50% of those surveyed expressed concern regarding the increased prevalence of AI, with 53% expressing concern that AI would be harmful to the security of personal and private information; those who have done substantial research into AI expressed growing concerns about how AI will pervade their day-to-day lives.[164]

Corporate leaders in the AI sector also recognize the potential dangers of further development absent a defined body of regulation.[165] In May 2023, the CEO of OpenAI, Sam Altman, testified before Congress, noting the growing apprehension surrounding AI and indicating that if development and use go unchecked, it could result in extremely negative consequences.[166] Mr. Altman further stressed the importance of vetting AI for safety and implored the federal government to create an agency for the licensing of AI development, promulgation of safety regulations, and enforcement of testing requirements to ensure the long-term safety of the technology.[167]

Legislators have also been vocal about the need to regulate AI. U.S. Senator Chuck Schumer (D-NY) launched an effort to address the need for AI legislation in April 2023.[168] Senator Schumer urged his fellow members of Congress to take action, indicating that China's early-stage development of AI regulation should prompt American politicians to begin taking the technology—and its need for regulation—seriously.[169] Senator Schumer favors an expansive approach to regulating AI, but not all of his peers agree that large-form regulation is the answer to

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[164] *See* Alec Tyson & Emma Kikuchi, *Growing Public Concern About the Role of Artificial Intelligence in Daily Life*, PEW RSCH. CTR. (Aug. 28, 2023), https://www.pewresearch.org/short-reads/2023/08/28/growing-public-concern-about-the-role-of-artificial-intelligence-in-daily-life/ [https://perma.cc/UQY6-7KMC] ("Overall, 52% of Americans say they feel more concerned than excited about the increased use of artificial intelligence . . . . Those who have heard a lot about AI are 16 points more likely now than they were in December 2022 to express greater concern than excitement about it. Among this most aware group, concern now outweighs excitement by 47% to 15%. . . . Overall, 53% of Americans say AI is doing *more to hurt than help* people keep their personal information private.").

[165] *See* Blair Levin & Larry Downes, *Who Is Going to Regulate AI?*, HARV. BUS. REV. (May 19, 2023), https://hbr.org/2023/05/who-is-going-to-regulate-ai [https://perma.cc/8W7R-PE88].

[166] *Id.* ("Testifying before Congress on May 16, OpenAI chief executive Sam Altman said it was time for regulators to start setting limits on powerful AI systems. 'As this technology advances we understand that people are anxious about how it could change the way we live. We are too,' Altman told a Senate committee. 'If this technology goes wrong, it can go quite wrong,' he said, claiming it could do 'significant harm to the world.' He agreed with lawmakers that government oversight will be critical to mitigating the risks.").

[167] Matt O'Brien, *ChatGPT Chief Says Artificial Intelligence Should be Regulated by a US or Global Agency*, ASSOCIATED PRESS (May 16, 2023), https://apnews.com/article/chatgpt-openai-ceo-sam-altman-congress-73ff96c6571f38ad5fd68b3072722790 [https://perma.cc/H784-7PGZ] ("Altman proposed the formation of a U.S. or global agency that would license the most powerful AI systems and have the authority to 'take that license away and ensure compliance with safety standards.'").

[168] *Schumer Launches Major Effort to Get Ahead of Artificial Intelligence*, SENATE DEMOCRATS: NEWSROOM (Apr. 13, 2023), https://www.democrats.senate.gov/newsroom/press-releases/schumer-launches-major-effort-to-get-ahead-of-artificial-intelligence [https://perma.cc/U7J8-NRRP] ("*Today, Senate Majority Leader Chuck Schumer (D-NY) launched a first-of-its-kind effort to advance and manage one of the fastest moving, and most consequential industries across the globe: artificial intelligence (AI).*").

[169] *Id.* ("For months now, Leader Schumer has been discussing and circulating a high-level framework that outlines a new regulatory regime for artificial intelligence, engaging leading artificial intelligence experts to help inform the proposal. Leader Schumer believes the Chinese Communist Party's release this week of their own approach to regulating AI is a wake-up call to the nation and urgent action is required for the U.S. to stay ahead of China and shape and leverage this powerful technology.").

the AI problem.

Senator Ted Cruz (R-TX) cautions against a "regulatory superstructure," arguing that doing so could weaken the standing of AI developers and users in America.[170] Senator Cruz instead promotes a looser approach that would enable individuals and companies to continue innovating with the technology, making America more appealing for corporations than other countries with more stringent technology regulations.[171] Legislators may agree that AI needs to be regulated, but the method of doing so remains a point of contention.

As the calls for regulation increase and the sophistication and prevalence of AI in all aspects of our society continue to grow, it becomes more apparent that a solid regulatory framework must be put into place to ensure the safe and responsible development and use of AI while insulating the promising medical uses of AI described *supra*. With no official federal legislation or widespread regulation in effect, the rampant and unchecked growth of AI will continue to induce anxiety among consumers, legislators, and corporate leaders alike. Using President Biden's executive order as a framework, legislators must take the initiative to develop comprehensive AI legislation—the power to regulate the controversial technology must be vested in a policy-making federal entity.

VIII. WHO SHOULD REGULATE AI?

To discuss a path to the regulation of AI, it will first be important to understand how AI might be regulated and who has the best qualifications for regulating the fast-growing technology.

As seen across the globe, countries are scrambling to enact AI protections and frameworks for safe development and innovation: China has developed stopgap regulations for managing the technology until more lasting laws are created, the European Union is close to fully adopting AI legislation, Japan is considering less stringent AI regulations, and the United States is seeking input from interested parties in order to develop more informed policy.[172] Taking into account the various approaches from the countries that have already acted, onlookers have identified five frameworks for regulating AI: Risk-Based Law, Voluntary Codes of Conduct, Tech-Based Law, Regulations of Speech, and Efforts for Global Cooperation.[173]

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[170] Press Release, Ted Cruz, U.S. Senate Comm. on Com., Sci., & Transp., AI Has Opportunity to Improve Lives, Spur Economic Growth, and Create New Jobs (Sept. 12, 2023), https://www.commerce.senate.gov/2023/9/sen-cruz-ai-has-opportunity-to-improve-lives-spur-economic-growth-and-create-new-jobs [https://perma.cc/CYK6-74MB].

[171] *Id.* ("With AI, I'm afraid that we are allowing history to repeat itself – only this time, we are following our European counterparts, who made a mistake with their early regulation of the internet. You can't read the news today without encountering Terminator-style fearmongering about AI building a weapon of mass destruction or developing sentience that will destroy humans.").

[172] Alessandro Parodi & Amir Orusov, *Governments Race to Regulate AI Tools*, REUTERS (Dec. 7, 2023), https://www.reuters.com/technology/governments-race-regulate-ai-tools-2023-10-13/ [https://perma.cc/ASE5-K57R].

[173] Cecelia Kang & Adam Satarino, *Five Ways A.I. Could Be Regulated*, N.Y. TIMES (Dec. 6, 2023), https://www.nytimes.com/2023/12/06/technology/artificial-intelligence-regulation.html [https://perma.cc/D726-QYW2] ("Though their attempts to keep up with developments in artificial intelligence have mostly fallen short, regulators around the world are taking vastly different approaches to policing the technology. The result is a highly fragmented and confusing global regulatory landscape for a borderless technology that promises to transform job markets, contribute to the spread of disinformation or even present a risk to humanity.").

Risk-based regulations would create distinct levels of regulation, according to predetermined levels of risk, by which each AI tool would then be assessed.[174] Voluntary Codes of Conduct, such as those agreed to by several American corporations in July 2023, would include security testing, further consideration of programming bias and data privacy, collaboration with governments to increase transparency about risks, and contribution of corporations in addressing societal issues.[175] Formal technology-based laws would include legislative involvement from bodies such as the U.S. Congress to enact broad legislation and vest regulatory authority in a single government agency.[176] Some countries, such as China, are focused on regulations regarding speech, misinformation, content labeling, and verification of "true and accurate" content.[177] Finally, the most effective and widespread AI regulation would likely come from global cooperation, but efforts to move in that direction have yielded little to date.[178]

The second consideration is which regulatory entity would have the best chance of keeping up with the fast-paced, complex technology: should corporate entities be left to self-govern, with national stewardship guidelines and voluntary codes of conduct for guidance? Should state governments be allowed to promulgate their own standards without a federal basepoint for ensured consistency? Should multiple federal agencies have the power to promulgate regulation specific to their industries? Should an existing agency be vested with the authority to create AI regulation? Or should a new federal agency be created with the sole purpose of regulating AI and enforcing AI policies and practices?

In light of the consensus from AI developers and other leaders in the American technology industry that they would prefer some sort of official regulation of AI over self-governance, leaving the oversight of AI technology to industry would be a major mistake. Leaders in the AI development industry, like Sam Altman, the CEO of OpenAI, have been clear about the increasing need for comprehensive AI regulation to address the growing concerns of the public and the potential for unethical and unsafe AI development. In May 2023, Microsoft President Brad Smith endorsed a set of proposed AI regulations and claimed that corporations and governments need to quickly coordinate in order to combat the high rate of growth in the AI industry and the potential for harm that comes with unregulated AI.[179] Elon Musk, Bill Gates, and Mark Zuckerberg all testified before Congress in September 2023 regarding the need for comprehensive AI

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[174] *Id.* The European Union's approach to regulating AI would assign individual AI tools to one of four categories and would place the heaviest restrictions on the riskiest AI tools.

[175] Michael Shear et al., *Pressured by Biden, A.I. Companies Agree to Guardrails on New Tools*, N.Y. TIMES (July 21, 2023), https://www.nytimes.com/2023/07/21/us/politics/ai-regulation-biden.html [https://perma.cc/U7H3-6929].

[176] Cecelia Kang, *2 Senators Propose Bipartisan Framework for A.I. Laws*, N.Y. TIMES (Sept. 7, 2023), https://www.nytimes.com/2023/09/07/technology/artificial-intelligence-framework-senate.html [https://perma.cc/N583-FPUQ].

[177] Matt Sheehan, *China's AI Regulations and How They Get Made*, CARNEGIE ENDOWMENT FOR INT'L PEACE (July 10, 2023), https://carnegieendowment.org/research/2023/07/chinas-ai-regulations-and-how-they-get-made [https://perma.cc/SU28-CMDF].

[178] Kang & Satariano, *supra* note 172 (stating that an international agency akin to the International Atomic Energy Agency has been proposed, but that geopolitical distrust and world events have largely stalled the possibility of harmonious, international cooperation).

[179] David McCabe, *Microsoft Calls for A.I. Rules to Minimize the Technology's Risks*, N.Y. TIMES (May 25, 2023), https://www.nytimes.com/2023/05/25/technology/microsoft-ai-rules-regulation.html [https://perma.cc/ZRX2-LAXJ] (indicating that Microsoft President Brad Smith stated that "Companies need to step up" and "government needs to move faster" in dealing with AI regulation).

regulation—this historic meeting between corporate leaders and legislative authorities indicated a joint acknowledgement between the public and private sectors that AI needed to be regulated to prevent catastrophe.[180] There is substantial consensus from the private sector that AI should be subject to some sort of formal regulation, which indicates that a model of self-governance and voluntary codes of conduct are not the path that should be chosen for the regulation of AI in America.

In the absence of federal legislation, state legislators have been quick to pass their own piecemeal laws concerning AI, typically addressing topics such as racial bias in hiring, sex-based bias in algorithmic training, and other civil rights-related topics.[181] According to *The New York Times*, 36 states had enacted a form of legislation regarding AI by July 2023, broadly anticipating the potential harms that may come with further development and use of the technology.[182] States that have promulgated some form of AI legislation have done so with good intentions—yet such a fragmented system would undoubtedly create a heterogeneous regulatory infrastructure that would lead to increased corporate and consumer confusion, flight of AI developers and sellers from certain states to others, and inter-state litigation issues and forum-shopping for the most favorable jurisdictions to engage in legal battles. To avoid these unfavorable outcomes and potential setbacks, regulating AI in America requires a federal approach, such that corporate and consumer confusion is kept to a minimum and legal conflicts are kept within one body of law.

A number of federal agencies have already expressed a desire to have regulatory authority over AI. The Department of Commerce opened an inquiry into whether audits and certifications for AI systems should be implemented as an enforcement tool and questioned which federal body should be responsible for assessing, certifying, and auditing AI developers for certification.[183] The Chair of the Federal Trade Commission ("FTC") claims the FTC should be granted regulatory authority over AI because the FTC already has jurisdiction to regulate large language models and

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[180] *See Tech Industry Leaders Call for AI Regulation in Historic Capitol Hill Summit*, GENEVA INTERNET PLATFORM DIGWATCH, (Sept. 14, 2023), https://dig.watch/updates/tech-industry-leaders-call-for-ai-regulation-in-historic-capitol-hill-summit [https://perma.cc/7QJY-99VK] ("Tech industry leaders, including Elon Musk, Mark Zuckerberg, and Bill Gates, convened at Senate Majority Leader Chuck Schumer's inaugural AI Insight Forum to address the pressing requirement for AI regulation. With more than 60 senators in attendance, the closed-door summit underscored the urgency of enacting legislation to govern the rapidly advancing field of AI. Elon Musk expressed apprehensions about AI's potential to harm humanity and advocated for the establishment of a federal AI department. Sam Altman, the CEO of OpenAI, who had previously endorsed the need for regulation, echoed the necessity of government leadership in this regard. Schumer, invigorated by the discussions, highlighted the unanimous consensus among participants that government involvement is essential for AI regulation, despite their differing viewpoints.").

[181] Courtney Rozen, *Regulate AI? Here's What That Might Mean in the US: QuickTake*, BLOOMBERG NEWS (July 27, 2023), https://www.bloomberglaw.com/bloomberglawnews/antitrust/X1MKAM9G000000 [https://perma.cc/J3HU-CFA8] ("Generally speaking, state officials are working faster than national leaders in applying limits to AI, particularly with regard to civil rights. New York in July began enforcing requirements to tackle racial bias in the algorithms employers use to filter job applicants. Connecticut officials that use AI systems must verify they don't put women at a disadvantage, under a new law enacted in June. In California, lawmakers have slowed their effort to put guardrails around artificial intelligence, in part because of a poor fiscal climate and opposition from business interests.").

[182] *Id.* ("As of late July, at least 275 measures mentioning AI had been introduced in 36 states and the District of Columbia in the most recent legislative session, according to Bloomberg Government. New York and Virginia had the most pending bills referencing AI.").

[183] Levin & Downes, *supra* note 165 ("At the Department of Commerce, the National Telecommunications and Information Administration (NTIA) has opened an inquiry about the usefulness of audits and certifications for AI systems. The agency has requested comments on dozens of questions about accountability for AI systems, including whether, when, how, and by whom new applications should be assessed, certified, or audited, and what kind of criteria to include in these reviews.").

AI could increase already-existing problems in the technology sector, such as "collusion, monopolization, mergers, price discrimination, and unfair methods of competition."[184] In compliance with President Biden's Executive Order, the National Institute of Standards and Technology ("NIST") developed and released a Risk Management Framework for the use of AI by interested organizations.[185] The framework focuses on the unique risks created or exacerbated by the use of AI and suggests actions that organizations can take to manage those risks.[186]

Decentralized AI regulation across multiple federal agencies may seem like an intuitive option because of the potential for hyperspecialized regulation for each industry, but in practice the inevitable inconsistencies in levels of regulation across industries would lead to consumer and corporate confusion, problems with data privacy and security allowances, issues regarding data sharing between industries, the risk of industry-specific biases being programmed into AI technology that operates across industry lines, and ethical issues regarding the development and use of AI for certain industries, such as the military.

If the federal government were to vest an existing agency with the authority to regulate AI, an ideal candidate to undertake that challenge could be the Department of Commerce. Having already taken steps to determine whether auditing and licensure, the Department of Commerce could be in enforcing AI regulation and proposed voluntary standards for the development of AI, would have a head start in the information-gathering phase of creating regulation. That said, the Department of Commerce may not currently have the authority to regulate AI or the necessary backing to secure control of the regulatory process through new legislation.[187]

Situated within the Department of Commerce, NIST would be an appropriate regulatory body to shepherd in a new age of AI policymaking and governance, given its extensive research into the inherent risks of widespread AI usage and its work in developing management solutions tailored for organizations seeking to combat those risks.[188] Having completed research and considered management options for topics ranging from data privacy, intellectual property, and information security to environmental impacts, harmful speech, and homogenization, NIST seems like an ideal candidate to turn its ideation into regulatory decision-making.[189]

In order for any of the entities desiring the power to regulate AI to obtain that power, Congress would need to unambiguously bestow that power upon them via federal legislation. Congress could also create a new federal agency, exclusively tasked with creating and enforcing

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[184] *Id.* ("Federal Trade Commission Chair Lina Kahn, meanwhile, is taking a different approach, claiming her agency already has jurisdiction over LLMs, and rattling the agency's anti-competitive and consumer protection sabers in the direction of the new technology.").
[185] NAT'L INST. OF STANDARDS & TECH., NIST AI 600-1, ARTIFICIAL INTELLIGENCE RISK MANAGEMENT FRAMEWORK: GENERATIVE ARTIFICIAL INTELLIGENCE PROFILE 1 (2024), https://nvlpubs.nist.gov/nistpubs/ai/NIST.AI.600-1.pdf [https://perma.cc/G2N4-EM4C].
[186] *Id.*
[187] Levin & Downes, *supra* note 165 ("Among the federal proposals, credit the Department of Commerce for asking the right questions. But it is unclear whether Secretary Gina Raimondo has the legal authority to create a sustainable certification process, or the political clout to get the tech industry to support NTIA's efforts. Further, as the Department acknowledges, its inquiry is only part of the larger White House effort to create a trusted environment for AI services, an objective that would require previously unseen levels of coordination and cooperation across numerous government silos.").
[188] *See generally* NAT'L INST. OF STANDARDS & TECH., *supra* note 185.
[189] *See id.* at 3.

regulations for AI and AI-enabled technology. Members of Congress, specifically Senators Elizabeth Warren (D-MA) and Lindsey Graham (R-SC), have called for a "nimble, adaptable, new agency with expertise, resources and authority to" regulate AI.[190] Amidst the recent upheaval in American politics, however, the possibility of a brand-new agency to preside solely over AI and other emergent technologies is an unlikely scenario. It may be more palatable, then, to turn to an already-established federal agency to assume the responsibility of AI regulation and stewardship.

In deciding which entity should be granted regulatory authority for AI, Congress should carefully consider whether it would be appropriate to choose an existing agency as opposed to establishing a new federal agency that would be solely focused on regulating the quickly growing technology. Any federal agency dedicated to this purpose—new or old—would need to be given widespread and specific authority to monitor the development of AI, to generate policy, to staff the agency with proper personnel to be able to keep up with the fast-paced industry, and to promulgate effective regulatory standards.

IX. TOWARD FEDERAL REGULATION OF MEDICAL AI

The 2023 Executive Order gave federal legislators a strong starting point for determining what factors should be taken into consideration when approaching AI legislation. Congress must now collect a wide array of data regarding the needs of interested parties to develop and pass comprehensive, industry-crossing legislation that both establishes a baseline for the safe and responsible use of AI and directs a federal entity to create and enforce regulations in a quickly growing industry.

Congress should continue to consult industry leaders and other experts in the fields of AI, AI technology, and emergent technology policymaking to develop legislation that will properly affect the AI industry while creating safeguards against improper development and use. The federal entity that is vested with the power to regulate AI and enforce those regulations should be staffed with proper experts in the technology industry to monitor the actions of AI developers and users. This federal entity must also work with interested parties to promulgate ethics guidelines for the development of AI and AI-enabled technology, mechanisms to control the growth of AI and AI-enabled technology across industry lines, and regulations for the intra- and inter-industry use of AI that consider data privacy and sharing, misinformation, unlawful development, and other concerns regarding unregulated AI. In addition, the entity must develop means by which it will enforce its regulations, such as mandatory licensing for the development and sale of AI, third-party auditing, and civil or criminal liability for violation of regulations.

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[190] Lindsey Graham & Elizabeth Warren, *When It Comes to Big Tech, Enough Is Enough*, N.Y. TIMES (July 27, 2023), https://www.nytimes.com/2023/07/27/opinion/lindsey-graham-elizabeth-warren-big-tech-regulation.html [https://perma.cc/94M9-RMJP] ("For more than a century, Congress has established regulatory agencies to preserve innovation while minimizing harm presented by emerging industries. In 1887 the Interstate Commerce Commission took on railroads. In 1914 the Federal Trade Commission took on unfair methods of competition and later unfair and deceptive acts and practices. In 1934 the Federal Communications Commission took on radio (and then television). In 1975 the Nuclear Regulatory Commission took on nuclear power, and in 1977 the Federal Energy Regulatory Commission took on electricity generation and transmission. We need a nimble, adaptable, new agency with expertise, resources and authority to do the same for Big Tech.").

Federal legislators have already been gathering the requisite information needed to develop comprehensive, industry-crossing legislation by inviting industry leaders to share their opinions on how AI should be regulated in America. OpenAI CEO Sam Altman reaffirmed his commitment to AI regulation, stating that the AI industry "needs government to lead," but that the industry "looks forward to partnering with [the federal government]" on AI regulation.[191] Elon Musk added his voice to the call for regulation, calling unregulated AI "potentially harmful to all humans everywhere" and calling for the power to regulate AI to be vested in a new federal department of AI.[192] The White House has offered independent research, developed safety standards, and called for further action. The Executive Order clearly outlines future steps the federal government can take in efforts to collect data, opines as to how AI should be managed, and creates categories of standards that Congress can build upon to develop a legislative framework for future regulation.

Federal legislators will have a tough decision to make as to whether to vest the regulatory authority for AI in an already-existing federal agency or to create a brand-new agency focused exclusively on regulating AI and enforcing those regulations. The challenges of regulating AI stem from the fast-paced growth of the technology, its increased use by the general public and corporate entities, uncertainty with regard to data privacy and sharing considerations, the potential for unethical use of AI in certain industries such as police forces and the military, and the general apprehension that AI may evolve into an unmanageable force that thinks and acts on its own.

In evaluating existing agencies for the right fit for governance over AI regulation, Congress should search for an agency that has a proven record of regulating modern, complex technologies, indicated its willingness and capability to work with other federal agencies to promulgate inter-industry regulations and standards, and expressed an interest in assuming the responsibility of regulating AI. A prudent solution would be for Congress to first enact widespread, industry-crossing legislation that sets a legislative framework for future regulation, then to vest regulatory authority over AI to NIST.

NIST is a highly qualified candidate to be the ultimate regulatory decisionmaker on AI policy in America for a number of reasons: (1) its recent success with developing standards, guidelines, best practices, and other resources for cybersecurity practices throughout interested industries shows its ability to develop regulation for modern, complex technologies and issues,[193] (2) its development of inter-industry standards and initiatives, such as through its Standards and Conformity Assessment Training for other federal agencies and its Interagency Committee on Standards Policy, will aid in its efforts to develop industry-spanning AI regulation and coordinate

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[191] Maria Curi & Ashley Gold, *Musk, Other Tech Giants Agree Legislation Needed to Regulate AI*, AXIOS (Sept. 13, 2023), https://www.axios.com/2023/09/13/ai-insight-forum-senate-regulation [https://perma.cc/VE6K-93RL] ("OpenAI CEO Sam Altman, who previously appeared before Congress and called for regulation, said in prepared remarks per the Washington Post: 'We need government to lead, and we look forward to partnering with you.'").

[192] *Id.* ("Tesla CEO and X owner Musk said after the summit that AI development 'is potentially harmful to all humans everywhere,' and called for a federal department of AI.").

[193] *See* Christine Moundas et al., *HHS OCR and NIST Revamp Cybersecurity Guidance for the Health Care Industry*, ROPES & GRAY (Mar. 12, 2024), https://www.ropesgray.com/en/insights/alerts/2024/03/hhs-ocr-and-nist-revamp-cybersecurity-guidance-for-the-health-care-industry [https://perma.cc/ZAD3-3W2M].

needs and stewardship efforts between federal agencies, and (3) NIST has been active in initial and recent efforts to develop AI regulation in America. With AI permeating medicine and patient information being used to train such models to increase their effectiveness, it will also be important for privacy laws and security systems to be suitably updated.[194]

From a health care standpoint, NIST has proven that it can take into account the interests of the health care industry while also developing responsible regulations for technology affecting the industry. Take, for example, the cooperation between NIST, HHS, and the Office for Civil Rights to develop and implement standards and best practices in relation to NIST's more overarching Cybersecurity Framework.[195] NIST's past and present cooperation with agencies that will be directly impacted by AI regulation will allow NIST to use those pre-existing channels of communication to receive quick, accurate feedback from those agencies while enabling NIST to develop holistic, thoughtful regulations. Finally, NIST's extensive research into AI and potential AI policy evidences the agency's desire and capability to oversee AI regulation in America. NIST's development of the U.S. AI Safety Institute to evaluate the risk of AI to businesses and the public, promote safe and responsible research standards, and develop a framework for proper stewardship of the technology demonstrates its ability to quickly assume the role should Congress vest it with the power to regulate AI.[196]

NIST will need to be given adequate resources for staffing, monitoring further developments in AI, monitoring AI use across all industries, fast-tracking regulations to combat innovative AI developments, and maintaining enforcement authority for AI development and AI use. After funding is secured for initial staffing, monitoring, policymaking, and enforcement concerns, NIST can begin to accrue its own funds through licensing or taxation programs. Licenses to develop or sell AI could generate a substantial amount of revenue for NIST as long as the funds are not siphoned away to meet the demands of other agencies or unrelated priorities. The AI arm of NIST could also become self-sufficient through a sales tax on the deployment of AI across industries. Price increases that come with a taxation scheme could also serve to slow the growth of AI, at least in the short term.

In determining the appropriate standards for AI regulation, NIST will need to further consult experts in the field of AI development, experts in other effected industries, and the legislative framework that grants regulatory authority over AI to NIST, while considering safety concerns and the opinions of the public. Consultation of AI industry experts will lead to lessened monitoring costs for the AI development industry and lead to more succinct and appropriate regulation for AI development. Similarly, consultation of experts from effected industries that use

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[194] Jacob Hansen et al., *Updating HIPAA Security to Respond to Artificial Intelligence*, J. OF AHIMA (Nov. 13, 2023), https://journal.ahima.org/page/updating-hipaa-security-to-respond-to-artificial-intelligence [https://perma.cc/KB9E-UW38].

[195] Moundas et al., *supra* note 193 (This cooperation between the Department of Health and Human Services, the Office for Civil Rights, and the National Institute of Standards and Technology was a part of President Joseph Biden's National Cybersecurity Strategy to further develop responsible cybersecurity practices in the United States.).

[196] Will Henshall, *Biden Economic Adviser Elizabeth Kelly Picked to Lead AI Safety Testing Body*, TIME (Feb. 7, 2024), https://time.com/6692176/elizabeth-kelly-ai-safety-institute-director/ [https://perma.cc/9CGY-QCXL].

AI and AI-enabled technologies will lead to mitigated monitoring costs of those industries and will enable NIST to create more consistent regulation that will directly meet the needs of each industry.

While the legislative framework that grants NIST the power to regulate AI would also normally allow the agency some leeway to interpret the legislation and make informed decisions within that framework, the United States Supreme Court's landmark decision in *Loper Bright Enterprises et al. v. Department of Commerce et al.* casts some doubt on a federal agency's ability to interpret its authorizing statute's language.[197]

The decision in *Loper Bright* centered primarily around whether federal agencies should continue to be granted "Chevron Deference," or deference to the agency on its interpretation of its authorizing statute.[198] The Supreme Court determined that "courts need not, and under the Administrative Procedure Act ("APA") may not, defer to an agency interpretation of the law simply because a statute is ambiguous."[199] This decision directly affects how new legislation will need to be written and how agencies will need to make sure to clearly act within the confines of the authorizing statute's language.

It is unclear exactly what post-*Loper* statutory creation and interpretation will look like, but this decision makes the AI statutory language that much more important. Given how quickly AI technology changes and advances, there will likely be regulatory problems that need swift and decisive action, giving rise to the increased likelihood of challenges to any future AI statute.

Once regulation has been developed and put into place, NIST will need enforcement techniques to ensure ethical compliance with the regulations and establish penalties for noncompliance. NIST should develop certification requirements for potential AI developers and AI sellers; such requirements will make it easier to detect unscrupulous actors in the AI industry, as well as create a stream of income for NIST. Certifications can be granted on a rolling basis with periodic fees to maintain AI Developer or Seller certification.

The process by which a developer would obtain certification would require the seller to adhere to strict codes of conduct and ethical guidelines, submit to third-party auditing, and agree to substantial civil penalties if standards are not met, or in the case of willful and malicious noncompliance, criminal liability. Sellers should be held to similar standards to keep the unauthorized use of AI and AI-enabled technology to a minimum. Certifications would also help to alleviate the fears of onlookers and users of AI, as the potential for unscrupulous actors in the AI development industry or marketplace would likely be reduced.

To keep misinformation about certification to a minimum, NIST should also maintain a list of certified AI developers and sellers to be made public to interested parties. Random audits of AI developers and sellers should be conducted to ensure good faith compliance with the promulgated regulations. Civil and criminal penalties would be an effective deterrent to would-be noncompliers,

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[197] *See* Loper Bright Enterprises v. Raimondo, 603 U.S. 369 (2024).
[198] *See id*.
[199] *Id*. at 2273.

but the power to create such penalties would need to be either granted to NIST by its enacting legislation or created and maintained by Congress separately from NIST. For penalties to have a deterrent effect, they must be substantial enough and must not be subject to enforcement discretion on the part of NIST.

An ongoing challenge for AI regulators will be how to continue to incentivize the increased use and development of AI across all industries while also maintaining appropriate data security standards and protections against nefarious uses. Organizations may install "good practice" guidelines to help curtail some of these concerns on their own initiative, but for the other AI users that fail to do so, and for a large swath of the consumer public, any future AI regulatory body will need to create effective incentives to do so. For instance, proper use above and beyond certain standards may lead to favorable treatment of certain organizations when bidding for government contracts, while improper use of the technology could lead to criminal sanctions if the authorizing legislation dictates as such. The coming years will be illustrative of how AI governance will be handled, and proper controls on the technology and those who develop and use it will be crucial to harmonious regulation.

X. Conclusion

Breakthroughs in rapidly growing sectors have reduced the time and funding needed to complete tasks in crucial fields such as pharmaceutical discovery and development. AI has the potential to generate breakthroughs in all stages of drug development, potentially enabling the discovery and development of treatments for previously incurable afflictions. Machine learning, specifically deep learning methods, has proven to make diagnostic techniques in clinical medicine more efficient in time and labor while also increasing the efficacy of clinicians through the bolstering of traditional techniques. Challenges in data representation, data labeling, small sample sizes, data privacy, ethical concerns, and interpretation of models present barriers for AI developers and interested clinicians to overcome when further developing AI technology in the pharmaceutical and medical diagnostics industries.

The first steps toward comprehensive federal legislation and regulation have been taken via Congress's interaction with industry leaders and President Biden's Executive Order. To promote informed, responsible regulation, Congress should vest regulatory authority in NIST, an existing agency with a proven record of developing regulations for complex technologies amongst myriad affected industries, in order to ensure safety and harmony for AI use across all industries.