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Regulation of Algorithmic Tools in the United States

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Regulation of Algorithmic Tools in the United States

Christopher S. Yoo* and Alicia Lai**

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〈Abstract〉

Policymakers in the United States have just begun to address regulation of artificial intelligence technologies in recent years, gaining momentum through calls for additional research funding, piece-meal guidance, proposals, and legislation at all levels of government. This Article provides an overview of high-level federal initiatives for general artificial intelligence (AI) applications set forth by the U.S. president and responding agencies, early indications from the incoming Biden Administration, targeted federal initiatives for sector-specific AI applications, pending federal legislative proposals,

and state and local initiatives. The regulation of the algorithmic ecosystem will continue to evolve as the United States continues to search for the right balance between ensuring public safety and transparency and promoting innovation and competitiveness on the global stage.

I. Introduction

The U.S. approach to regulating algorithmic decision-making is characterized by a reliance on soft standards and certifications. Rather than a unified set of strict regulations or sector-specific rules, the U.S. president, federal agencies, individual states, and local governments have proposed piecemeal legislation to promote research, create task forces, mandate reports and recommendations, and pursue other forms of light-touch regulation.

As a preliminary matter, the United States has publicly committed to broad principles on artificial intelligence (AI) development and cooperated through international initiatives. In May 2019, the United States, United Kingdom, European Union,

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Korea, and other countries signed onto the Organisation for Economic Co-operation and Development (OECD) Principles on Artificial Intelligence¹⁾ to endorse AI that is “innovative and trustworthy and that respects human rights and democratic values.” Specifically, the agreement calls upon these countries to: (1) invest in AI research and development, (2) foster a digital ecosystem for AI, (3) shape an enabling policy environment for AI, (4) build human capacity and prepare for labor market transformation, and (5) cooperate internationally for trustworthy AI.²⁾ Although these are mere recommendations, the OECD periodically reports upon the comparative state of AI regulation in each country to G20 leaders, adding some teeth - in the form of public accountability - to the agreement.³⁾ These sentiments build upon prior international initiatives such as the 2018 Declaration on Ethics and Data Protection in Artificial Intelligence that endorsed “a set of guiding principles as its core values to safeguard human rights in the development of AI.”⁴⁾

More recently, the United States has joined international initiatives on AI innovation. In June

2020, fourteen countries (including the United States, United Kingdom, and Korea) and the European Union jointly create the Global Partnership on Artificial Intelligence (GPAI) to promote responsible AI grounded in “human rights, inclusion, diversity, innovation, and economic growth.”⁵⁾ GPAI is supported by the OECD and seeks to bring together leading experts to collaborate in working groups on four topics: (1) responsible AI, (2) data governance, (3) the future of work, and (4) innovation and commercialization.⁶⁾ In September 2020, the United States and United Kingdom signed the US-UK Science and Technology Agreement, renewing a 2017 agreement to further cooperate in AI research and development in order to advance a shared vision of an AI research ecosystem that promotes mutual wellbeing, prosperity, and security.⁷⁾ The two countries intend to take stock of existing bilateral science and technology cooperation and multilateral cooperation frameworks, recommend priorities for future cooperation, coordinate programming of relevant activities across sectors, and promote technical AI research and development.⁸⁾

1) Org. for Econ. Co-operation & Dev., Recommendation of the Council on Artificial Intelligence (May 21, 2019), available at <https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0449>.

2) *Id.*

3) See, e.g., Org. for Econ. Co-operation & Dev., Examples of AI National Policies: Report for the G20 Digital Economy Task Force (2020), available at <https://www.mcit.gov.sa/sites/default/files/examples-of-ai-national-policies.pdf>.

4) Int'l Conf. of Data Protection & Privacy Comm'rs, Declaration on Ethics and Data Protection in Artificial Intelligence (Oct. 23, 2018), available at https://www.privacyconference2018.org/system/files/2018-10/20180922_ICDPPC-40th_AI-Declaration_ADOPTED.pdf; see also Int'l Conf. of Data Protection & Privacy Comm'rs, Working Group on Ethics and Data Protection in Artificial Intelligence: Report on 2019 Activities: 2019-2021 Forward Looking Plan (2018), available at <http://globalprivacyassembly.org/wp-content/uploads/2019/11/WG-on-Ethics-and-Data-protection-in-AI-Activity-report-41st-ICDPPC.pdf>.

5) Joint statement from founding members of the Global Partnership on Artificial Intelligence (June 15, 2020), available at <https://www.gov.uk/government/publications/joint-statement-from-founding-members-of-the-global-partnership-on-artificial-intelligence/joint-statement-from-founding-members-of-the-global-partnership-on-artificial-intelligence>.

6) *Id.*

7) Media Note, Office of the Spokesperson, U.S. Dep't of State, Declaration of the United States of America and the United Kingdom of Great Britain and Northern Ireland on Cooperation in Artificial Intelligence Research and Development: A Shared Vision for Driving Technological Breakthroughs in Artificial Intelligence (Sep. 25, 2020), available at <https://www.state.gov/declaration-of-the-united-states-of-america-and-the-united-kingdom-of-great-britain-and-northern-ireland-on-cooperation-in-artificial-intelligence-research-and-development-a-shared-vision-for-driving/>.

8) *Id.*

Over the last several years, the United States has seen a plethora of directives from the president, federal agencies, state governments, and local governments. These proposals range from broad prescriptions to sector-specific applications that occasionally overlap or conflict and some of which became enacted law while others have languished as non-enforced proposals for years.

The following sections offer a descriptive account of the major U.S. initiatives on the regulation of AI over the last half decade. Section II covers federal initiatives that broadly apply to AI technologies as a whole, including the President’s Executive Order and other White House memorandum, subsequent responses by the Office of Management and Budget (OMB) and the National Institute for Standards and Technology (NIST), and early indications from the incoming Biden Administration. Section III details federal initiatives by federal agencies that apply to specific AI applications, including regulatory frameworks by the Food & Drug Administration and the Department of Transportation. Section IV reviews pending federal legislation. Section V describes state and local initiatives, many of which have been enacted into law. We conclude with a few overarching trends in AI regulation in the United States.

II. Federal Initiatives for General AI Applications

1. Presidential Directives

In February 2019, the President signed Executive Order 13859 on Maintaining American Leadership in Artificial Intelligence.⁹⁾ The order

broadly shepherds federal agencies towards a coordinated federal strategy, the American AI Initiative. The initiative is guided by several objectives: to (1) promote sustained investment in AI R&D in collaboration with industry, academia, international partners, (2) enhance access to high-quality and fully traceable federal data, models, and computing resources, as well as reduce barriers to the use of AI technologies to promote innovative applications and protect American values, (3) set AI governance standards that minimize vulnerability to attacks from malicious actors and incentivize innovation, (4) build an AI workforce by training the next generation of American AI researchers and users through apprenticeships, skills programs, and educational curriculum, and (5) promote the international advantage of the United States in AI and protect critical national security technology against strategic competitors and foreign adversaries.¹⁰⁾ The order creates the National Science Technology Council Select Committee on Artificial Intelligence (Select Committee) to coordinate the initiative.¹¹⁾

Specifically, to invest in AI research and development, the order directs federal agencies to consider AI an agency priority when developing budget proposals and planning for the use of funds in Fiscal Year 2020 and onwards.¹²⁾ Prioritization of AI should be consistent with R&D policy memoranda set forth by the OMB and the Office of Science and Technology Policy (OSTP).¹³⁾

9) Executive Order No. 13859, Maintaining American Leadership in Artificial Intelligence, 84 Fed. Reg. 3967 (Feb. 11, 2019), available at <https://www.whitehouse.gov/presidential-actions/executive-order-maintaining-american-leadership-artificial-intelligence/>.

10) *Id.* at § 1.

11) *Id.* at § 3.

12) *Id.* at § 4.

Public-private collaborations in AI research are encouraged.¹⁴⁾

To unleash AI resources, the order directs agencies to identify opportunities to increase the non-federal AI research community's access and use of federal data and models in a manner that benefits that community in a way that protects safety, security, privacy, and confidentiality.¹⁵⁾ It instructs OMB to publish a notice in the *Federal Register* inviting the public to make requests for access or quality improvements for federal data and models that would improve AI R&D and testing; it instructs the Select Committee to submit a report making recommendations on better enabling the use of cloud computing resources for federally funded AI R&D.¹⁶⁾

To set AI governance standards for the regulation of AI applications, the order instructs the Director of the OMB - in coordination with the Director of OSTP, the Director of the Domestic Policy Council, and the Director of the National Economic Council - to submit a memorandum on regulatory and non-regulatory approaches and ways to reduce barriers to using AI.¹⁷⁾ To ensure public trust in the development of AI, a draft version of the memorandum must be released for public comment before it is finalized.¹⁸⁾ The order also charges the NIST with issuing a plan for developing technical standards for reliable, robust, and trustworthy AI systems.¹⁹⁾ Both these memoranda will be discussed further below.²⁰⁾

To build an AI workforce, the order directs

research and educational grantmaking agencies to prioritize AI at the high school, undergraduate, graduate, training programs, and faculty levels.²¹⁾ Although the order broadly lauds AI education and workforce training, it does not allocate any additional federal funding to these goals.

To engage strategically on the international stage, the order implements the 2019 National Security Presidential Memorandum (NSPM) on *Protecting the United States Advantage in Artificial Intelligence and Related Critical Technologies*.²²⁾

The executive order reflects an aspirational U.S. goal of international AI leadership, to set the standard for the regulation of AI for the rest of the world. In the *American Artificial Intelligence Initiative: Year One Annual Report*, published in February 2020, OSTP states that it believes the U.S. has “made significant progress on achieving the objectives of this national strategy.”²³⁾ It further asserts that while maintaining a robust AI R&D ecosystem requires federal investments and policies to promote cooperation, the federal government “cannot - and should not - be the primary driver of United States innovation.”²⁴⁾ However, the government will continue to play a “critical role in providing targeted R&D funding to support long-term fundamental research driving future technological breakthroughs, guiding the portfolio of R&D investments, using its resources to procure and adapt commercial AI capabilities for government missions, coordinating cross-agency AI

13) *Id.*

14) *Id.*

15) *Id.* at § 5.

16) *Id.*

17) *Id.* at § 6.

18) *Id.*

19) *Id.*

20) See *infra* Section II.B-.C.

21) *Id.* at § 7.

22) *Id.* at § 8.

23) White House Office of Sci. & Tech. Pol'y, *American Artificial Intelligence Initiative: Year One Annual Report* iii (Feb. 2020), available at <https://www.whitehouse.gov/wp-content/uploads/2020/02/American-AI-Initiative-One-Year-Annual-Report.pdf>.

24) *Id.*

investments, and leveraging federal resources to accelerate AI R&D and adoption.”²⁵⁾

Apart from the broad directives of the executive order, the Trump Administration has also issued several directives regarding specific AI applications. In 2017, the President signed a Presidential Memorandum for the Secretary of Transportation directing the Secretary to establish an unmanned aircraft system (UAS) integration pilot program (IPP).²⁶⁾ The Secretary did so, with the Federal Aviation Administration identifying major drone safety and security issues in a subsequent proposal.²⁷⁾

In 2018, President Trump signed a new National Security Strategy broadly calling for increased military and border security.²⁸⁾ The White House cites to the Department of Defense’s National Defense Strategy, which suggests investment in military AI applications, quantum information science, and strategic computing.²⁹⁾ U.S. defense agencies have subsequently spurred momentum for the use of AI in national security matters, including establishing the Joint Artificial Intelligence Center to focus on the use of AI in key defense missions.³⁰⁾

Additionally, in 2018, the President unveiled a National Strategic Plan on Advanced Manufacturing that broadly supports developing new standards for AI and identifying best practices to provide consistent availability, accessibility, and utility of manufacturing data within and across industries.³¹⁾

In 2020, the President issued a Call to Action to the Tech Community on New Machine Readable COVID-19 Dataset, asking the tech community to develop AI tools to analyze the COVID-19 Open Research Dataset (CORD-19) gathered by the Allen Institute for AI, Chan Zuckerberg Initiative, Georgetown University’s Center for Security and Emerging Technology, Microsoft, and the National Library of Medicine.³²⁾

2. Office of Management and Budget (OMB)

OMB implemented the Executive Order’s directive to submit a memorandum on regulatory approaches to AI³³⁾ by publishing its *Draft of Guidance for Regulation of Artificial Intelligence Applications* in January 2020.³⁴⁾ The Draft Guidance seeks to support the U.S. approach to free markets, federalism, regulatory practices, and

25) *Id.*

26) White House, Presidential Memorandum for the Secretary of Transportation (Oct. 25, 2017), *available at* <https://www.whitehouse.gov/presidential-actions/presidential-memorandum-secretary-transportation/>.

27) Fed. Aviation Admin., *Unmanned Aircraft Systems, Policy Document Library*, *available at* https://www.faa.gov/uas/resources/policy_library/ (last visited Nov. 11, 2020).

28) White House, National Security Strategy (Dec. 2017), *available at* <https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905.pdf>.

29) U.S. Dep’t of Defense, Summary of the 2018 National Defense Strategy (2018), *available at* <https://dod.defense.gov/Portals/1/Documents/pubs/2018-National-Defense-Strategy-Summary.pdf>.

30) U.S. Dep’t of Defense, Joint Artificial Intelligence Center, <https://dodcio.defense.gov/About-DoD-CIO/Organization/JAIC/> (last visited Nov. 11, 2020).

31) White House, National Strategic Plan on Advanced Manufacturing (Oct. 2018), *available at* <https://www.whitehouse.gov/wp-content/uploads/2018/10/Advanced-Manufacturing-Strategic-Plan-2018.pdf>.

32) News Release, White House Office of Sci. & Tech. Pol’y, Call to Action to the Tech Community on New Machine Readable COVID-19 Dataset (Mar. 16, 2020), *available at* <https://www.whitehouse.gov/briefings-statements/call-action-tech-community-new-machine-readable-covid-19-dataset/>.

33) *See supra* notes 17–18 and accompanying notes.

34) Office of Mgmt. & Budget, Draft of Guidance for Regulation of Artificial Intelligence Applications (Jan. 2020), *available at* <https://www.whitehouse.gov/wp-content/uploads/2020/01/Draft-OMB-Memo-on-Regulation-of-AI-1-7-19.pdf>.

innovation incentives.³⁵⁾ In particular, the Draft Guidance cautions agencies to “avoid a precautionary approach that holds AI systems to such an impossibly high standard that society cannot enjoy their benefits.”³⁶⁾ The U.S. government treats innovation as a high priority, animated by the promise of AI deployment “to improve safety, fairness, welfare, transparency, and other social goals.”³⁷⁾

Agencies may use their authority to address “inconsistent, burdensome, and duplicative State laws that prevent the emergence of a national market” when a national standard is essential.³⁸⁾ The Draft Guidance sets forth ten principles for agencies to consider when formulating regulatory and non-regulatory approaches for AI in the private sector: (1) public trust in AI, (2) public participation, (3) scientific integrity and information quality, (4) risk assessment and management, (5) benefits and costs, (6) flexibility, (7) fairness and non-discrimination, (8) disclosure and transparency, (9) safety and security, and (10) interagency coordination.³⁹⁾ In subsequent interviews with agency representatives, the Deputy U.S. Chief Technology made clear that the Draft Guidance is deliberately broad, explaining that “these principles are intentionally high-level. Federal agencies will implement the guidance in accordance with their sector-specific needs. We purposefully want to avoid top-down, one-size-fits-all blanket regulation, as AI-powered technologies reach across vastly different industries.”⁴⁰⁾

35) *Id.* at 1.

36) *Id.* at 2.

37) *Id.*

38) *Id.*

39) *Id.* 3–6.

40) Jory Heckman, *White House releases ‘first of its kind’ set*

The Draft Guidance further permits creative strategies besides traditional regulations. Agencies may adopt non-regulatory approaches such as sector-specific policy guidance (i.e., voluntary incentive frameworks in collaboration with industry), pilot programs and experiments (i.e., waivers and exemptions as safe harbors for specific AI applications), and voluntary consensus standards (with private-sector conformity assessment programs as a preliminary default).⁴¹⁾ The Draft Guidance gives several examples of actions that agencies can take beyond the rulemaking process to support an environment that facilitates the use and acceptance of AI. It encourages reducing barriers to AI deployment and use: first by increasing accessibility, discoverability, and usability of federal data and models and second by communicating about the benefits and risks of AI in requests for information (RFIs) in the Federal Register in a manner that facilitates trust and understanding of AI.⁴²⁾ It also encourages cooperation with international bodies who embrace approaches consistent with American values in innovation, privacy, civil rights, and civil liberties.⁴³⁾

3. National Institute of Standards and Technology (NIST)

In response to the executive order’s charge to issue a plan for developing AI standards,⁴⁴⁾ NIST

of binding AI principles for agency regulators, Fed. News Network (Jan. 7, 2020), available at <https://federalnewsnet.com/artificial-intelligence/2020/01/white-house-releases-first-of-its-kind-set-of-binding-ai-principles-for-agency-regulators/> (interview with U.S. Chief Technology Officer Michael Kratsios and Deputy U.S. Chief Technology Officer Lynne Parker).

41) Office of Mgmt. & Budget, *supra* note 34, at 7.

42) *Id.* at 7–8.

43) *Id.* at 10.

44) See *supra* note 19 and accompanying text.

prepared *A Plan for Federal Engagement in Developing Technical Standards and Related Tools*, which was published in August 2019.⁴⁵⁾ The plan identifies nine areas of AI in need of standardization: (1) concepts and terminology, (2) data and knowledge, (3) human interactions, (4) metrics, (5) networking, (6) performance testing and reporting methodology, (7) safety, (8) risk management, and (9) trustworthiness.⁴⁶⁾ The plan asks the federal government to commit to deeper, consistent, long-term engagement in AI standards development activities to help the United States speed the pace of reliable, robust, and trustworthy AI technology development.⁴⁷⁾ It emphasizes that U.S. global leadership in AI depends upon the federal government playing an active role in driving AI standards development and adoption.⁴⁸⁾

The NIST plan offers four sets of practical recommendations. First, it advises bolstering AI standards-related knowledge, leadership, and coordination among agencies to maximize effectiveness and efficiency.⁴⁹⁾ It advises that the National Science and Technology Council Machine Learning/Artificial Intelligence Subcommittee designate a Standards Coordinator to gather and share AI standards-related strategies, roadmaps, terminology, use cases, and best practices.⁵⁰⁾ The federal government should also make maximum use of existing standards broadly adopted by industry sectors, reinforce federal policies, and be flexible in selecting AI standards that adapt to the

rapid pace of AI developments.⁵¹⁾ The government should also grow a cadre of federal staff with relevant skills and training, providing them with a clear career and promotion path.⁵²⁾

Second, the NIST plan recommends promoting focused research to understand and adopt “trustworthy” AI.⁵³⁾ The plan sets forth seven dimensions of trustworthiness: accuracy, resiliency, safety, reliability, objectivity, security, and explainability.⁵⁴⁾ It is important to develop metrics and data sets to assess these dimensions.⁵⁵⁾ The federal government should also conduct research to inform standardization of risk management strategies.⁵⁶⁾

Third, the plan encourages the federal government to support and expand public-private partnerships to develop AI standards and related tools, particularly consensus standards.⁵⁷⁾ Private organizations are crucial for standard-setting: broader data discovery of federal government data can enable more widespread training and use of AI; non-traditional collaborative models, such as open source projects and open data initiatives, can advance standards development.⁵⁸⁾ In these partnerships, the federal government may lead or monitor in whichever way is best to foster collaborative environments for creative problem-solving of standards development.⁵⁹⁾

Fourth, the plan recognizes that engaging with international parties can “champion U.S. AI standards priorities” around the world.⁶⁰⁾

45) Nat’l Inst. of Standards & Tech., *A Plan for Federal Engagement in Developing Technical Standards and Related Tools* (2019), available at https://www.nist.gov/system/files/documents/2019/08/10/ai_standards_fedengagement_plan_9aug2019.pdf.

46) *Id.* at 3, 11.

47) *Id.* at 22.

48) *Id.* at 3.

49) *Id.* at 4–5, 22.

50) *Id.* at 5, 22.

51) *Id.*

52) *Id.*

53) *Id.* at 5, 22.

54) *Id.* at 8.

55) *Id.* at 4, 23.

56) *Id.* at 5, 23.

57) *Id.* at 5–6, 23.

58) *Id.* at 5, 19, 23.

59) *Id.* at 6, 23.

60) *Id.* at 6, 24.

Strategically engaging with other countries with similar priorities can help advance U.S. economic and national security.⁶¹⁾

The NIST plan largely envisions a sector-specific approach. These prescriptions ask individual agencies to tailor their AI standards to the specific AI application at issue. The NIST plan specifically lauds two federal agencies for being “ahead of the curve” in examining the use and impact of AI on setting AI standards: the Department of Transportation report, *Preparing for the Future of Transportation: Automated Vehicles 3.0*, as well as the Food and Drug Administration report, *Proposed Regulatory Framework for Modification to Artificial Intelligence/Machine Learning-Based Software as a Medical Device*.⁶²⁾ Other agencies should follow suit to engage in standard-setting: identify how AI technologies can be used to further the agency’s mission; know existing statutes and polices related to standard-setting; conduct a “landscape scan and gap analysis” to identify standards and tools that need to be developed; use appropriate standards if they exist; engage in the development of standards if they do not exist.⁶³⁾

In August 2020, a year after the original plan was published, NIST released the first draft of *Four Principles of Explainable Artificial Intelligence*.⁶⁴⁾ It largely tracks on the original NIST plan, but also elaborates on the “explainability” requirement of AI. The plan clarifies four principles for explainable AI: (1)

explanation (the AI must supply evidence for its outputs, whether as self-explainable models, global explainable AI algorithms, or per-decision explainable AI algorithms); (2) meaningfulness (the recipient must understand this explanation); (3) explanation accuracy (the explanation must correctly reflect the system process); and (4) knowledge limits (the AI must identify cases it was not approved to operate).⁶⁵⁾ The report recognizes that because one-size-fits-all explanations do not exist, different users will require different types of explanations, including user benefit, societal acceptance, regulatory and compliance, system development, and owner benefit.⁶⁶⁾

4. Early Indications from the Biden Administration.

The incoming Biden Administration has not provided clear plans for its policy with respect to algorithms. Many observers remain hopeful that artificial intelligence will receive more research support than during the Trump Administration.⁶⁷⁾

The policy documents released by the Biden-Harris Campaign during the past election contained a few scattered references to artificial intelligence. The campaign proposed increasing federal R&D funding for “breakthrough technologies” such as electric vehicle technology, lightweight materials, 5G, and artificial intelligence.⁶⁸⁾ It also “[c]ommit[ted] to future

61) *Id.*

62) *Id.* at 21.

63) *Id.* at 20.

64) Nat’l Inst. of Standards & Tech., *Four Principles of Explainable Artificial Intelligence* (Aug. 2020), available at <https://www.nist.gov/system/files/documents/2020/08/17/NIST%20Explainable%20AI%20Draft%20NISTIR8312%20%281%29.pdf>.

65) *Id.* at 2–4.

66) *Id.* at 4–5.

67) Jonathan Vanian, *What a Biden–Harris administration means for artificial intelligence*, *Fortune* (Nov. 10, 2020), available at <https://fortune.com/2020/11/10/biden-harris-administration-artificial-intelligence/>.

68) *The Biden Plan to Ensure the Future Is “Made in All of America” by All of America’s Workers*, Biden Harris,

purchases in advanced industries like cutting-edge telecommunications and artificial intelligence” to create jobs and protect intellectual property and national security.⁶⁹⁾ Other key documents called for a new federal credit agency that would “ensure the algorithms used for credit scoring don’t have discriminatory impacts.”⁷⁰⁾

Internationally, the campaign called for equipping U.S. citizens to succeed in a global economy by investing R&D in artificial intelligence and other technologies and by “ensur[ing] the technologies of the future like AI are bound by laws and ethics and promote greater shared prosperity and democracy” and to “shape the future rules of the road” on those technologies “so they continue to reflect democratic interests and values.”⁷¹⁾ It also called for a global “Summit for Democracy” that would call for participants to “make concrete pledges for how they can ensure their algorithms and platforms are not empowering the surveillance state, facilitating repression in China and elsewhere, spreading hate, spurring people to violence, and remaining susceptible to misuse.”⁷²⁾

Prior statements by Vice President-elect Kamala Harris have noted potential problems applying artificial intelligence, such as facial recognition technologies, in criminal justice and housing.⁷³⁾ Only time will tell how these statements will

translate into future policy.

III. Federal Initiatives for Sector-Specific AI

Even prior to the President’s 2019 executive order, some federal agencies provided regulatory guidance for sector-specific AI applications. Unsurprisingly, the two leading agencies are the ones identified by the NIST plan on AI standards as being ahead of the curve: The Food and Drug Administration (FDA) and the Department of Transportation (DOT).⁷⁴⁾

1. Food and Drug Administration (FDA)

Recognizing that the traditional paradigm of medical device regulation was not designed for adaptive AI technologies that can learn over time to continuously improve healthcare, the FDA sets forth a new regulatory framework, *The Proposed Regulatory Framework for AI-based Software as a Medical Device, in February 2019*.⁷⁵⁾ The emphasis on “software as a medical device” (SaMD) reflects how medical devices, defined as diagnostics and treatments that affect the structure or function of the body aside from through chemical actions/drugs, have been shifting away from being exclusively hardware to include software.⁷⁶⁾ A few months later, the FDA

<https://joebiden.com/made-in-america/> (last visited November 12, 2020).

69) *Id.*

70) *Economic Unity Task Force Recommendations*, Biden-Sanders Unity Task Force Recommendations at 74, <https://joebiden.com/wp-content/uploads/2020/08/UNITY-TASK-FORCE-RECOMMENDATIONS.pdf>.

71) *The Power of America’s Example: The Biden Plan for Leading the Democratic World to Meet the Challenges of the 21st Century*, Biden Harris, <https://joebiden.com/americanleadership/> (last visited November 12, 2020).

72) *Id.*

73) Vanian, *supra* note 67.

74) See *supra* note 62 and accompanying text.

75) Food & Drug Admin., Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD): Discussion Paper and Request for Feedback (Feb. 2019), available at <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device> [hereinafter FDA SaMD Framework].

76) *Id.* at 2.

reaffirmed this approach in their Draft Guidance for *Clinical Decision Support Software* by extending a similar regulatory framework to clinical decision support (CDS) technologies: software designed to aid clinical decision-making with “person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.”⁷⁷⁾

The framework for both these novel technologies incorporates the International Medical Device Regulators Forum (IMDRF) SaMD Framework for Risk Categorization, the FDA’s benefit-risk framework, and the FDA’s Digital Health Software Precertification Program.⁷⁸⁾ These medical technologies are categorized into different levels of risk based on two major factors: first, the state of healthcare situation (critical, serious, non-serious); second, the significance of information provided by the software to the healthcare decision (treat or diagnose, drive clinical management, or inform clinical management).⁷⁹⁾

For CDS technologies, the framework specifies that low-risk software - such as programs for non-serious conditions or programs where users can independently check the basis for the programs’ recommendations - are driven through the more permissive 501(k) approval pathway.⁸⁰⁾ High-risk software—such as programs for critical situations, programs for diagnosing positive cases,

or machine learning-based algorithms—are driven through the more restrictive de novo approval pathway.⁸¹⁾ For SaMD, the framework does not explicitly specify the precise implication of the risk level of the technology, but discussion of varying risk levels in the proposal suggests that risk plays some role in how strictly SaMD is regulated.⁸²⁾

This FDA regulatory framework emphasizes risk-differentiation to promote innovation in low-risk software, with the impact on innovation for higher-risk software being much less clear.

2. Department of Transportation (DOT)

DOT has also published its framework for unifying federal policy for autonomous vehicles, *Ensuring American Leadership in Automated Vehicle Technologies*.⁸³⁾ It sets forth ten voluntary principles for large-scale deployment of autonomous vehicles (AVs) to further three primary goals. To protect the physical safety of users and communities, including vehicle operators, vehicle occupants, pedestrians, bicyclists, motorcyclists, and other travelers, the DOT commits to: (1) prioritizing safety, (2) emphasizing security and cybersecurity, (3) ensuring privacy and data security, and (4) enhancing mobility and accessibility.⁸⁴⁾ To promote efficient markets for investment and innovation, the DOT commits to: (5) remaining technology neutral, (6) protecting American innovation and creativity, and (7)

77) Food & Drug Admin., *Clinical Decision Support Software: Draft Guidance for Industry and Food and Drug Administration Staff 5* (Sep. 2019), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software> [hereinafter FDA CDS Guidance]

78) *Id.* at 6–7; FDA SaMD Framework, *supra* note 75, at 3.

79) FDA CDS Guidance, *supra* note 77, at 13–18; FDA SaMD Framework, *supra* note 75, at 4–5.

80) FDA CDS Guidance, *supra* note 77, at 16.

81) *Id.*

82) FDA SaMD Framework, *supra* note 75, at 12.

83) U.S. Dep’t of Transp., *Ensuring American Leadership in Automated Vehicle Technologies* (Jan. 2020), available at <https://www.transportation.gov/sites/dot.gov/files/docs/policy-initiatives/automated-vehicles/360956/ensuring-americanleadershipav4.pdf>.

84) *Id.* at 4.

modernizing regulations.⁸⁵) To facilitate coordinated efforts between federal, state, local, tribal, territorial, and international governments, the DOT commits to: (8) promoting consistent standards and policies, (9) ensuring a consistent federal approach, and (10) improving transportation system-level effects.⁸⁶) This unification of high-level guidance is meant to reduce uncertainty for state and local governments, innovators, and stakeholders.

The remainder of the DOT report is devoted to describing government activity regarding autonomous vehicles and encouraging opportunities for collaboration. A wide span of federal agencies currently undertake projects supporting a multitude of autonomous vehicle goals: safety (National Transportation Safety Board and modal agencies such as the National Highway Traffic Safety Administration, Federal Motor Carrier Safety Administration, Federal Transit Administration, and Federal Highway Administration), freedom of mobility (Department of Health and Human Services, Department of Interior, National Council on Disability, and others), fundamental research (Department of Agriculture, Department of Defense, U.S. Postal Service, and others), security and cybersecurity (Department of Homeland Security, and others), infrastructure (Department of Energy and others), and spectrum and connectivity (NIST and others).⁸⁷)

Following the publication of the DOT guidance, the National Highway Traffic Safety Administration implemented the Automated Vehicle Transparency and Engagement for Safe Testing (AV TEST) Initiative in July 2020.⁸⁸) AV

TEST is a publicly accessible online tool to track AV testing and safety data. Participants in the initiative are stakeholders in on-road testing of automated vehicles in the United States, including developers, testers, operators, manufacturers, states, and other governmental entities.⁸⁹) Its goal is to increase transparency and public trust, in line with the DOT guidance.⁹⁰) It is entirely voluntary whether a participant decides to join, as well as how much information to submit.⁹¹) Thus far, this initiative has been adopted by fourteen states (Arizona, California, Colorado, Florida, Georgia, Maryland, Michigan, New Jersey, New York, Ohio, Texas, Utah, Virginia, and Washington) and nine companies (Beep, GM, LM Industries Group, NAVYA, NHTSA Records, Nuro, Toyota, Uber, and Waymo).⁹²)

IV. Federal Legislative Proposals

Lawmakers in both the House and the Senate are exploring various legislative approaches, with many bipartisan federal bills introduced over the last several years regarding AI, machine learning, and their applications. These bills go further to delineate specific strategies than the President's executive order, which only offers broad calls for greater coordination and investment in AI research

⁸⁵) *Id.* at 4–5.

⁸⁶) *Id.* at 5.

⁸⁷) *Id.* at 8–26.

⁸⁸) Nat'l Highway Traffic Safety Admin., AV TEST Initiative, available at <https://www.nhtsa.gov/automated-vehicles-safety/av-test-initiative-tracking-tool> (last visited Nov. 10, 2020).

⁸⁹) *Id.*

⁹⁰) Press Release, Nat'l Highway Traffic Safety Admin., U.S. Transportation Secretary Elaine L. Chao Announces Launch of AV TEST Online Tracking Tool (Sep. 2, 2020), available at <https://www.nhtsa.gov/press-releases/av-test-initiative-tracking-tool-launch>.

⁹¹) *Id.*

⁹²) AV TEST Initiative, *supra* note 88.

without specifying any additional funding or specific mechanisms for doing so. Most have not yet been enacted.

The Growing Artificial Intelligence Through Research Act (GrAIR) was introduced in the House in 2019 as a bipartisan initiative.⁹³⁾ It directs the President to implement a “National Artificial Intelligence Initiative” to invest in AI research, increase skilled workers to develop a workforce pipeline, and promote data-sharing between the federal government and private and academic organizations.⁹⁴⁾ The Act would establish an “Interagency Committee on Artificial Intelligence,” chaired by the NIST Director, the Director of the National Science Foundation, and the Secretary of Energy, with representatives from over a dozen federal agencies.⁹⁵⁾ The Act also includes a provision instructing the NIST Director to establish standards and support collaborative ventures with public or private sector entities, including institutions of higher education, national laboratories, and private industry.⁹⁶⁾ Additionally, the Act entrusts the Director of the National Science Foundation to implement a research and education program on AI and engineering, awarding to grants to establish up to five multidisciplinary research and education centers.⁹⁷⁾ The Secretary of Energy is to carry out a research program on AI to provide public and private organization with computing hardware and software. Altogether, the bill sets forth a strategic plan to invest \$1.6 billion over ten years in AI.⁹⁸⁾

93) GrAIR Act, H.R. 2202, 116th Cong. (introduced Apr. 10, 2019), available at <https://www.congress.gov/bill/116th-congress/house-bill/2202/text>.

94) *Id.*

95) *Id.*

96) *Id.*

97) *Id.*

98) *Id.*

A companion bill entitled the Artificial Intelligence Initiative Act (AI-IA) was subsequently introduced in the Senate with only minor modifications on the GrAIR Act.⁹⁹⁾ The AI-IA largely proposes a similar plan: the Department of Energy is to select five institutions to serve as AI R&D Centers, the National Science Foundation is to select five institutions to serve as AI Education and Research Centers including a K-12-focused institution, and NIST is to develop standards and metrics on cybersecurity, algorithmic accountability, algorithmic explainability, and algorithm trustworthiness.¹⁰⁰⁾ The AI-IA would allocate \$2.2 billion over the next five years towards this national AI strategy to accelerate R&D to match other global economic powers.¹⁰¹⁾ Neither the GrAIR nor the AI-IA have yet been enacted into law.

Legislators have since expanded their efforts from regulating the AI private sector to regulating the use of AI in government decision-making. The AI in Government Act of 2020 seeks to advance innovative and competent uses of AI by the federal government to benefit the public.¹⁰²⁾ The bipartisan bill would create an AI Center of Excellence for the study of “economic, policy, legal, and ethical challenges” of federal AI use and establish practices for “identifying, assessing, and mitigating” bias.¹⁰³⁾ The center would regularly convene individuals from federal agencies,

99) Artificial Intelligence Initiative Act, S. 1558, 116th Cong. (introduced May 21, 2019), available at <https://www.congress.gov/bill/116th-congress/senate-bill/1558>.

100) *Id.*

101) *Id.*

102) AI in Government Act of 2020, H.R. 2575, S. 1363, 116th Cong. (introduced Dec. 19, 2019), available at <https://www.congress.gov/bill/116th-congress/house-bill/2575/text?q=%7B%22search%3A%5B%22H.+R.+2575%22%5D%7D&r=1&s=5>.

103) *Id.*

industry, federal laboratories, nonprofit organizations, academia, and others to discuss recent AI developments.¹⁰⁴⁾

Other federal legislation remains largely confined to task forces proposals at the discussion phase. The National AI Research Resource Task Force Act of 2020 proposes convening a task force of technical experts in academia, government, and industry.¹⁰⁵⁾ The task force would develop a plan for the U.S. to build, deploy, govern, and sustain a national research cloud that would provide “access to compute resources, co-located with publicly available, artificial intelligence-ready government and nongovernment data sets and a research environment with appropriate educational tools and user support” for students and researchers.¹⁰⁶⁾

Furthermore, AI-related provisions have been attached to a broad range of legislative proposals. The Future Defense Artificial Intelligence Technology Assessment (Future DATA) Act would task the Secretary of Defense and the Joint Artificial Intelligence Center with issuing a report to Congress on the Pentagon’s AI strategy.¹⁰⁷⁾ The Armed Forces Digital Advantage Act would task the Under Secretary of Defense for Personnel and Readiness with developing a policy to “promote and maintain digital engineering as a core competency of the Armed Forces.”¹⁰⁸⁾ Both these

proposals have been incorporated as provisions of the recently enacted National Defense Authorization Act.¹⁰⁹⁾ Additionally, the Artificial Intelligence Job Opportunities Act of 2019 would mandate that the Secretary of Labor submit a report to Congress on the impact of AI on employment, education, and the workforce.¹¹⁰⁾ The Commercial Facial Recognition Privacy Act would prohibit private entities from using facial recognition technology to collect facial recognition data without user consent, or from sharing facial recognition data with an unaffiliated third party without user consent.¹¹¹⁾ The Algorithmic Accountability Act would require corporations to conduct data impact assessments of high-risk automated decision systems for accuracy, fairness, bias, discrimination, privacy, and security; it also mandates that companies fix flawed algorithms that result in “inaccurate, unfair, biased, or discriminatory decisions” on consumers.¹¹²⁾

Several pieces of proposed legislation are particularly concerned with the protection of consumer data and privacy. The Consumer Online Privacy Rights Act (COPRA) requires companies to conduct impact assessments if they use

104) *Id.*

105) National AI Research Resource Task Force Act of 2020, H.R. 7096, 116th Cong. (introduced June 4, 2020), *available at* <https://www.congress.gov/bill/116th-congress/house-bill/7096/text>.

106) *Id.*

107) Future Defense Artificial Intelligence Technology Assessment (Future DATA) Act, H.R. 2432, 116th Cong. (introduced Jan. 28, 2019), *available at* <https://www.congress.gov/116/bills/hr827/BILLS-116hr827ih.pdf>.

108) Armed Forces Digital Advantage Act, S. 1471, 116th

Cong. (introduced May 15, 2019), *available at* <https://www.govtrack.us/congress/bills/116/s1471>.

109) National Defense Authorization Act for Fiscal Year 2020, S. 1790, 116th Cong. (Dec. 20, 2019), *available at* <https://www.congress.gov/bill/116th-congress/senate-bill/1790>.

110) Artificial Intelligence Job Opportunities Act of 2019 (AI JOBS Act), H.R. 827, 116 Cong. (introduced Jan. 28, 2019), *available at* <https://www.congress.gov/116/bills/hr827/BILLS-116hr827ih.pdf>.

111) Commercial Facial Recognition Privacy Act, S. 847, 116th Cong. (introduced Mar. 14, 2019), *available at* <https://www.congress.gov/116/bills/s847/BILLS-116s847is.pdf>.

112) Algorithmic Accountability Act, S. 1108, H.R. 2231, 116th Cong. (introduced Apr. 10, 2019), *available at* <https://www.congress.gov/bill/116th-congress/senate-bill/1108>.

algorithms to determine eligibility for “housing, education, employment, or credit opportunities” or access to “any place of public accommodation.”¹¹³⁾ The Data Protection Act would create a new federal agency to regulate the collection, maintenance, use, processing, storage, and dissemination of information.¹¹⁴⁾ This is by no means an exhaustive list of proposed federal legislation, particularly given the pervasiveness with which algorithms and automated decision-making permeate each sector.

V. State and Local Initiatives

State and local governments have been noticeably proactive in the legislative process, enacting a multitude of laws restricting the use of specific AI applications by the private sector as well as by government entities.

a preliminary matter, many states and cities - including Alabama, Vermont, Washington, and New York City - have established task forces generally consisting of representatives from city agencies, private sector, and research communities,¹¹⁵⁾ and California has pending legislation to the

same effect.¹¹⁶⁾ The committees are to produce reports on a variety of AI issues, including the uses, risks, benefits, and legal implications associated with the development and deployment of AI by state or local businesses.

States and local governments have also enacted sector-specific AI regulations that are often stricter than their federal counterparts. Facial recognition technologies have elicited a number of regulations: In 2020, Washington state enacted a statute creating a legal framework by which agencies may use facial recognition technologies to the benefit of society - for example, by assisting agencies in locating missing persons - but prohibits uses that “threaten our democratic freedoms and put our civil liberties at risk.”¹¹⁷⁾ Maryland passed a bill prohibiting the use of facial recognition technologies during job interviews without the applicant’s consent.¹¹⁸⁾ San Francisco passed a bill strictly banning any use of facial recognition technologies by the city police or city officials, departments, boards, or commissions over concerns for civil liberties.¹¹⁹⁾

Video assessments have also been restricted: Illinois passed a bill requiring employers to disclose to job candidates in writing when they use AI to assess job interviews, explain how the AI works, and obtain prior written consent.¹²⁰⁾

113) Consumer Online Privacy Rights Act, S. 2968, 116th Cong. (introduced Dec. 3, 2019), *available at* <https://www.congress.gov/bill/116th-congress/senate-bill/2968/text>.

114) Data Protection Act, S. 3300, 116th Cong. (introduced Feb. 13, 2020), *available at* <https://www.congress.gov/bill/116th-congress/senate-bill/3300/text>.

115) An Act Establishing the Alabama Commission on Artificial Intelligence and Associated Technologies, No. 269 (Ala. 2019), <https://arc-sos.state.al.us/ucp/B19148AA.AEM.pdf>; An Act Relating to the Creation of the Artificial Intelligence Task Force, 2018 Vt. Acts & Resolves 264; An Act relating to the use of facial recognition services; adding a new chapter to Title 43 RCW; providing an effective date; and providing an expiration date, ch. 257, § 10, 2020 Wash. Sess. Laws 1847, 1852-53; N.Y.C. Local Law No. 49 (N.Y.C. 2018), *available at* <https://www1.ny>

[c.gov/site/adstaskforce/about/about-ads.page](https://www1.ny.gov/site/adstaskforce/about/about-ads.page).

116) A.B. 1576, Reg. Sess. (Cal. 2019), *available at* https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201920200AB1576.

117) Wash. Rev. Code §§ 43.003.0001-.0012. Previous statutes allowed the Department of Motor Vehicles to implement a facial recognition matching system, *id.* § 46.20.037, and prohibited traffic cameras from using any facial recognition technology, *id.* § 46.63.170-.174.

118) Md. Code Ann., Lab. & Empl. § 3-717.

119) S.F. Admin. Code §§ 19B.1-.8 (Ord. 107-19), *available at* https://codelibrary.amlegal.com/codes/san_francisco/latest/sf_admin/0-0-0-47320.

120) 820 Ill. Comp. Stat. 42/1 to 42/15.

Autonomous vehicles are permitted only in limited circumstances: Washington state passed a bill outlining a legal framework for use of personal delivery devices,¹²¹⁾ and Pennsylvania has a bill pending that would authorize specific routes for AV shuttles.¹²²⁾ On the other hand, Florida enacted law permitting fully automated vehicles on public roads.¹²³⁾

Legislation on smart speakers and ambient listening devices are also pending: the California State Assembly passed a bill that is now pending before its State Senate that would require user consent to retain voice recordings and bans manufacturers from sharing command recordings with third parties.¹²⁴⁾

U.S. AI policy is likely to weigh the potential benefits of innovation as far greater than the potential costs. After all, algorithmic tools often provide significant improvements in accuracy, consistency, speed, and capacity than the human baseline - and an overly precautionary approach would deprive society of those advancements. The regulation of the algorithmic ecosystem will continue to evolve as the United States continues to search for the right balance between ensuring public safety and transparency and promoting innovation and competitiveness on the global stage.

VI. Conclusion

The fledging state of federal legislation for algorithmic decision-making in the United States makes it difficult to discern explicit trends in regulation, though the approach of the federal government is thus far consistent with its light-touch, pro-innovation approach in other high-tech areas. State governments have shown more interest in regulating algorithmic decision-making, enacting a multitude of sector-specific laws restricting the use of particular AI technologies. Despite a growing awareness of potential complications arising from algorithms,

121) Wash. Rev. Code §§ 46.75.010–.060, 46.61.055, 46.61.240–.269, 46.61.36546.61,710–.733.

122) H.B. 1078, Gen. Assemb., Reg. Sess. (Pa. 2019), *available at* <https://www.legis.state.pa.us/CFDOCS/billInfo/billInfo.cfm?syearch=2019&slnd=0&body=H&type=B&bn=1078>.

123) Fla. Stat. § 316.85.

124) A.B. 1395, 2019–2010 Reg. Sess. (Cal. 2019), *available at* <https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?billId=201920200AB1395>.

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