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LEARNING FROM EMERGING TECHNOLOGY GOVERNANCE FOR GUIDING QUANTUM TECHNOLOGY

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ABSTRACT

Quantum technology is often described as the "next big thing." But the past few decades have brought us a series of next big things in technology, and we have accumulated enough experience now to start to extract some lessons and recommendations from our recent history of technology governance. That is what this article seeks to do. It first explains what quantum governance is and why people expect it to be such a big deal. The article then describes the existing. Limited regulations in place for quantum

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technologies, and then discusses some of the key governance challenges that quantum is expected to present. It then provides three case studies of other recent "next big thing" emerging technologies - biotechnology, nanotechnology and artificial intelligence. While each technology presents unique governance issues and challenges, the case studies extract a total of 15 lessons that may be relevant for quantum governance. The article next examines seven types of governance frameworks that have been proposed of emerging technologies by leading international and national organizations, with each type of framework providing a different emphasis, that focus on governance that is anticipatory, agile/adaptive, equitable, sustainable, soft law, coordinated and international. Finally, drawing from three technology case studies and the seven types of governance frameworks, the article identifies and discusses eight governance pillars that are common to each emerging technology and which collectively provide the foundation for effective governance, and project how these eight pillars will apply to quantum technology. These analyses provide a comprehensive roadmap, lessons and recommendations for the coming challenges of quantum technology governance.

I. INTRODUCTION

Quantum technology is often described as the "next big thing."² It may indeed be the next big thing at the present time, but it is not the first technology to be described as the next big thing. Over the past four decades, we have seen one technology after another emerge from the laboratory and become described as the next big thing, until eclipsed by the next new technology. Prominent examples of such "next big thing" technology waves include biotechnology, nanotechnology and artificial intelligence.

These previous "next big thing" technologies were and are transformative. In each case, society was confronted with a powerful new technology with uncertain benefits, risks and trajectories, for which existing regulatory systems were unprepared, having been enacted prior to the advent of the new technology. Technology developers, government regulators, and

² See, e.g.,Opto, Quantum: The Next Big Thing?, Dec. 20, 2023,

https://www.cmcmarkets.com/en/optox/quantum-the-next-big-thing; Sauvick Banerjee, Is Quantum Computing the Next Big Thing to Happen After AI?, Medium Apr. 30, 2024, https://medium.com/@sauvikbanerjjee/is-quantum-computing-the-next-big-thing-to-happen-after-ai.

policy makers were therefore challenged to develop or adapt governance frameworks for each of these new emerging technologies.³

In the United States, the governance of these new technologies has been characterized by adapting existing statutes and regulatory programs to the new emerging technology, adjusted by various guidance documents, regulatory tweaks and voluntary programs created by the federal government.⁴ These federal regulatory actions were supplemented by a variety of so-called "soft law" programs that were created and administered by various private actors from industry, non-governmental organizations, think tanks, and standard-setting organizations.⁵ In addition to these two primary sources of technology governance, additional governance input was provided by state governments and international organizations such as the Organization for Economic Co-operation and Development (OECD), the World Health Organization (WHO), the World Trade Organization (WTO), and various other United Nations entities.

Each successive emerging technology revolution presented its own unique issues and controversies. Yet, there is still much to learn from the experiences in constructing governance frameworks for previous technologies, including what was attempted, what worked, what did not, and what was the impact on innovation, public perception and economic success.⁶

³ An emerging technology can be defined by five characteristics: (i) radical novelty, (ii) relatively fast growth, (iii) coherence, (iv) prominent impact, and (v) uncertainty and ambiguity. Daniele Rotolo, Diana Hicks & Ben R. Martin, *What is An Emerging Technology?*, 44 RESEARCH POLICY 1827 (2015). *See also* Gary E. Marchant & Wendell Wallach, *Introduction* in: EMERGING TECHNOLOGIES: ETHICS, LAW AND GOVERNANCE (EDS. GARY E. MARCHANT & WENDELL WALLACH) 1, 3 (2017) (emerging technologies "proceed at an accelerating pace, are not limited to a single industrial sector and present unprecedented uncertainties with respect to their risks, benefits and future developments"). ⁴ Adam Thierer, *U.S. Artificial Intelligence Governance in the Obama-Trump Years*, 2 IEEE TRANS. TECH. & SOC'Y 175, 179 (2021); Gary Marchant, *Regulating Machine Learning*, TECHREG CHRONICLE, Feb. 2023, at 1, 4-5.

⁵ A "soft law" program creates substantive expectations that are not directly enforceable by the government. Gary E. Marchant & Brad Allenby, *Soft Law: New Tools for Governing Emerging Technologies*, 73 BULL. ATOMIC SCI. 108, 108 (2017).

⁶ There is growing recognition that previous technology governance approaches can provide valuable lessons for new technologies. *See, e.g.,* Gary E. Marchant, Douglas J. Sylvester &Kenneth W. Abbott, *What Does the History of Technology Regulation Teach Us About Nano Oversight,* 37 J. LAW, MED. & ETHICS 724 (2009) [hereinafter Marchant, History of Technology Regulation]; Khara Griegr, Jonathan B. Wiener & Jennifer Kuzma, *Improving Risk Governance Strategies Via Learning: A Comparative Analysis of Solar Radiation Modification and Gene Drives*, Environment Systems & Decisions (in press), published online on June 4, 2024, at pp. 8-10,

https://link.springer.com/article/10.1007/s10669-024-09979-6; Andrew D. Maynard & Sean M. Dudley, *Navigating Advanced Technology Transitions: Using Lessons from*

For a new "next big thing" technology like quantum technology, there are important lessons from the governance of previous "next big thing" technologies such as biotechnology, nanotechnology, and artificial intelligence. That is the purpose of this article.

Part II describes quantum technology, and why it is perceived as the next big thing. Part III discusses the current regulatory status of quantum technology and describes the key governance challenges for quantum. Part IV then provides the core of this paper, summarizing the lessons for quantum governance from (1) biotechnology, (2) nanotechnology, (3) artificial intelligence. Part V describes several governance frameworks that have been proposed for emerging technologies. Part VI then elaborates on several key governance themes that emerge from the comparative analysis of "next big thing" technologies, which we describe as the "pillars" of emerging technology governance. These include (1) the role of soft law vs hard law, (2) the need for governance coordination, (3) protection of small and medium-sized enterprises, (4) stakeholder and public engagement, (5) transparency, (6) equity, (7) temporal issues for governance, and (8) international competitiveness and national security aspects. Part VII then concludes.

II. OVERVIEW OF QUANTUM TECHNOLOGY

A recent *60 Minutes* episode describe quantum technology as "a breakthrough that could transform civilization."⁷ Despite its pending revolutionary importance, few people understand this complex technology. Quantum technology is a rapidly advancing field that leverages the peculiar principles of quantum mechanics to create new applications in computing, communication, sensing, and more. Quantum computers use qubits⁸ that can exist in multiple states simultaneously, offering unprecedented

Nanotechnology, 18 NATURE NANOTECHNOLOGY 1118 (2023); Sara E. Berger & Francesca Rossi, Addressing Neuroethics Issues in Practice: Lessons Learnt by Tech Companies in AI Ethics, 110 NEURON 2052 (2022).

⁷ Scott Pelley, 60 Minutes, *Google, IBM Make Strides Toward Quantum Computers that May Revolutionize Problem Solving,* 60 MINUTES (CBS), July 28, 2024,

https://www.cbsnews.com/news/quantum-computing-google-ibm-advances-60-minutes-transcript/.

⁸ A "qubit" "or quantum bit" is the quantum equivalent of a standard computer "bit," but unlike a standard bit that can only exist in two states (0 or 1), a qubit can exist in multiple states expressed as a probability of being 0 and a probability of being 1, which results in exponentially more information being stored than with standard computer bits.

Congressional Research Service (CRS), Quantum Computing: Concepts, Current States, and Considerations for Congress 2 (Sept. 7, 2023),

computational speed for certain problems.⁹ At its core, quantum technology exploits phenomena like quantum entanglement¹⁰ and superposition¹¹ to perform complex tasks that would be impossible with classical systems.¹² Quantum represents "a completely new approach to computing."¹³

Quantum key distribution presents a method for secure communication that is theoretically immune to any kind of computational attack.¹⁴ As the field evolves, it promises to revolutionize various sectors that involve decisions that are currently too complex for existing technology, from secure data transmission to precise sensing and beyond, marking a significant leap from traditional technologies.¹⁵ This capability to undertake tasks that are not feasible with traditional technologies is known as "quantum advantage."¹⁶

The first quantum revolution, which began in the early 20th century, marked a profound shift in our understanding of physics, leading to the development of quantum mechanics.¹⁷ This revolution was driven by the

<u>explained/entanglement</u>. This property also allows qubits to scale exponentially, as two qubits "can store and process four bits of information, three can process eight, and so on." McKinsey & Co., What is Quantum Computing 2 (April 5, 2024),

¹² CRS, *supra* note __, at 2.

⁹ Congress has defined a "quantum computer" as a computer that "uses the collective properties of quantum states, such as superposition, interference, and entanglement, to perform calculations." Quantum Computer Cybersecurity Preparedness Act, P.L. 117-20 (2022).

¹⁰ Quantum "entanglement" is the capability of two or more subatomic particles to become connected ("entangled") such that they remain connected and exhibit the same behavior even when separated by vast distance. CalTech, What Is Entanglement and Why Is It Important?, <u>https://scienceexchange.caltech.edu/topics/quantum-science-</u>

https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-is-quantum-computing.

¹¹ Quantum "superposition" is the phenomenon of a quantum object can exist in an undetermined state, vastly increasing the amount of information that can be stored in the quantum object. CRS, *supra* note __, at 18-19.

¹³ McKinsey & Co., supra note __, at 2.

¹⁴ Alexander S. Gillis, *What is Quantum Key distribution (QKD)?*, TECHTARGET.COM, (Nov. 2022), https://www.techtarget.com/searchsecurity/definition/quantum-key-distribution-QKD.

¹⁵ CRS, *supra* note __, at 2-3

¹⁶ CRS, *supra* note ____, at 2. For example, Google researchers reported in 2023 that a quantum processor with 70 qubits was able to perform in less than two minutes a complex calculation that would take the world's most powerful classical computer over 47 years to complete. Google Quantum AI and Collaborators, *Phase Transitions in Random Circuit Sampling*, <u>https://arxiv.org/html/2304.11119v2</u> (Dec. 22, 2023).

¹⁷ Daniel Garisto, *The Second Quantum Revolution*, SYMMETRY MAG, Jan 12, 2022, https://www.symmetrymagazine.org/article/the-second-quantum-

revolution?language_content_entity=und#:~:text=This%20second%20quantum%20revolut ion%20is,the%20level%20of%20individual%20particles..

need to explain phenomena that classical physics could not, such as the behavior of atoms and subatomic particles.¹⁸ It laid the groundwork for technologies that have transformed our world, including lasers, transistors, and semiconductors.¹⁹ The second quantum revolution, emerging in the 21st century, builds on this foundation, focusing on the control and manipulation of individual quantum systems.²⁰ This has opened up new possibilities in quantum computing, quantum sensing, and quantum communication, promising to revolutionize fields from cryptography to drug discovery.²¹

While quantum technology is already being applied in some industries such as financial services and drug discovery,²² technical hurdles must be overcome for the broader use of more advanced quantum technology.²³ These obstacles include the challenge of maintaining a qubit's superposition, and correcting calculation errors.²⁴ Significant progress has been made in addressing these challenges in recent years,²⁵ such that some experts are now predicting that the revolutionary impacts of quantum are now "a lot closer than people previously thought."²⁶

As quantum technology is still in its nascent stages, and its likely benefits and risks are both expected to be enormous, quantum technology provides an ideal example for applying the lessons of past emerging technologies to this new technology. When asked if society is prepared for this revolutionary technology, one expert recently replied "Definitely

¹⁸ Wolfgang P. Schleich, et al., *Quantum Technology: From Research to Application*, 122 APPL. PHYS. B 130, 5-9 (201).

¹⁹ NIST, The Second Quantum Revolution, Apr. 5, 2022,

https://www.nist.gov/physics/introduction-new-quantum-revolution/second-quantum-revolution.

²⁰ Neil C. Hughes, *The Future of Quantum Computing: Predictions for 2024 and Beyond*, TECHNOPEDIA, Nov. 1, 2023, <u>https://www.techopedia.com/future-of-quantum-computing</u>; NIST, *supra* note .

²¹ CRS, *supra* note , at 2-3.

²² Robert F. Service, Compound Interest, 384 Science 950, 953 (2024).

²³ Service, *supra* note ___, at 952-53.

²⁴ CRS, *supra* note ___, at 3. Quantum systems are more "fragile" and thus prone to errors than traditional computers because any type of environmental "noise" caused by perturbations in temperature, light, electromagnetic radiation or other factors that can induce errors in the ultra-sensitive quantum systems. *Id.* at 3-4; Service, *supra* note ___, at 952.

²⁵ For example, Quantinuum and Microsoft recently announced they had collaborated to run 14,000 experiments without a single error, a major leap forward in quantum accuracy. Frederic Lardinois, *Microsoft And Quantinuum Say They've Ushered in the Next Era of Quantum Computing*, TECHCRUNCH.COM, Apr. 3, 2024,

https://techcrunch.com/2024/04/03/microsoft-and-quantinuum-say-theyve-ushered-in-the-next-era-of-quantum-computing/

²⁶ Service, *supra* note ___, at 951.

not."²⁷ Proactive governance that is based on the lessons learned from past technological revolutions can help maximize benefits, mitigate risks, and facilitate a smooth transition into the quantum era. As quantum computing has the potential to revolutionize industries and solve complex problems, establishing global guidelines and stakeholder actions is crucial for its responsible evolution.

III. GOVERNANCE OF QUANTUM TECHNOLOGY

This section first describes the existing regulatory activity for quantum technology, and then addresses some of the broader governance challenges that quantum presents.

A. Current Regulatory Approaches

The last decade has witnessed remarkable progress in the advancement of quantum technologies, resulting in the quantum information science ecosystem having a measurable presence beyond academia and into the commercial sector.²⁸ This movement from early-stage scientific exploration and investigation into applied commercial research and development has caused governments worldwide to view quantum as a strategic technology to their economies.²⁹ Although many nations are shifting their viewpoints on the viability of quantum computing, their approach to governance - in the form of both regulation and investment remains fragmented. Some jurisdictions have yet to establish any regulations, ignoring quantum information science altogether or relegating it to fundamental research in academia. Conversely, other countries are concerned about the influence of countries like China and Russia, and are implementing comprehensive export controls and regulations restricting foreign investment. Others still are making large, strategic public investments in quantum computing to drive priorities such as hardware and technology advancement, reducing dependencies on foreign entities, and encouraging workforce development and commercialization.³⁰

As of 2024, the World Economic Forum estimates governments have invested over \$40 billion USD in quantum technologies, with China

²⁷ Pelley, *supra* note (60 Minutes interview with IBM Head of Research, Dario Gil).

 ²⁸ See Gregory T. Byrd & Yongshan Ding, *Quantum Computing: Progress and Innovation*,
 2023 IEEE Computer Soc'y 20 (2023)

²⁹ See World Economic Forum, *State of Quantum Computing 2022: Building a Quantum Economy* (2022).

³⁰ See World Economic Forum, Quantum Economy Blueprint: Insight Report, (2024).

leading the charge by investing over \$15 billion.³¹ While early-stage quantum funding was primarily through non-government investments led by academia and industry, more recently, governments are investing large amounts of money through "Strategy Legislation."³² Although this Strategy Legislation, which often includes large funding amounts, is generally characterized by broad, universally agreeable legislation, this shift towards soft-law is already influencing early-stage regulations, including driving international collaborations and partnerships, reducing dependence on foreign entities, promoting economic growth, attracting and developing top talent, and establishing these nations as leaders in the field of quantum computing.³³

While global regulations surrounding quantum technologies are still inconsistent and underdeveloped, the current state of regulations fall within three distinct categories: (1) controlling the unauthorized exfiltration of technology; (2) protecting critical cybersecurity infrastructure against the threat of cryptanalytically-relevant quantum computer (CRQC); and (3) development of a domestic quantum strategy to guide public investment.

1. Controlling the Unauthorized Exfiltration of Technology

The threat of China's "Made in China 2025" (MIC2025) policy has been the primary driver for much of the early-stage regulation of quantum. MIC2025 is a "broad set of industrial plans that aim to boost competitiveness by advancing China's position in the global manufacturing value chain, 'leapfrogging' into emerging technologies, and reducing reliance on foreign firms."³⁴ While ostensibly, China's program is focused on domestic production of high-tech products and reducing reliance on foreign technology, critics have challenged that China's ambitions rely on outright theft of U.S. intellectual property.³⁵

Although piracy and counterfeiting remain issues in China, the two newer forms of siphoning off foreign IP value are theft – often cyber theft – of extraordinarily valuable trade secrets and

³¹ See WEF, *Quantum Economy Blueprint*, at 8.

³² See National Quantum Initiative Act in the United States; the UK National Quantum Strategy; the Quantum Technologies Flagship in the European Union; and India's National Quantum Mission.

³³ See WEF, *Quantum Economy Blueprint*, at 50-54.

³⁴ See Karen M. Sutter, 'Made in China 2025' Industrial Policies: Issues for Congress,

Congressional Research Service (Mar. 10, 2023) at 1, available at

<https://crsreports.congress.gov/product/pdf/IF/IF10964>

³⁵ See USTR, Update Concerning China's Acts, Policies and Practices Related to Technology Transfer, Intellectual Property, and Innovation, (2018)

know-how, and the technology transfers required of American and other foreign companies as a condition for doing business on Chinese soil. Traditions of territoriality and sovereignty, as well as the willingness of foreign companies to trade IP for access to the Chinese market, give the latter a degree of legitimacy that outright industrial espionage lacks.³⁶

MIC2025 sparked bipartisan concerns in Congress that the existing foreign direct investment laws and the export control rules lacked the authority to adequately address the shift in Chinese investment strategy, particularly in uncontrolled investments in emerging technologies and early-stage companies.³⁷ In response to these concerns, on August 13, 2018, Congress enacted the Export Control Reform Act (ECRA)³⁸ and the Foreign Investment Risk Review Modernization Act (FIRRMA).³⁹ Both laws were intended to enhance U.S. national security in relation to technology exports and foreign investments, with a particular focus on modernizing and enhancing controls over critical and emerging technologies, including quantum.

FIRRMA expanded the authority of CFIUS, the Committee on Foreign Investment in the United States,⁴⁰ to review and address foreign investments involving critical technologies, infrastructure and sensitive data. While the term "quantum" is not explicitly mentioned in FIRRMA, enablement regulations expressly identify quantum technologies as "critical technologies." Similarly, ECRA focused on emerging and foundational technologies that are essential to national security, mandating the Department of Commerce, in coordination with other government agencies, to perform regular reviews to identify and control such technologies that are

³⁶ See Paul Goldstein, *Intellectual property and China: Is China stealing American IP*?, Stanford Law School, (2018). Available at:

https://law.stanford.edu/2018/04/10/intellectual-property-china-china-stealing-american-ip/ ³⁷ Perspectives on Reform of the CFIUS Review Process: Hearing Before the House

Subcommittee on Digital Commerce and Consumer Protection of the Committee on Energy and Commerce, 115 Cong. 43 (2d Sess. 2018) (Prepared remarks of Kevin J. Wolf), https://www.govinfo.gov/content/pkg/CHRG-115hhrg31568/html/CHRG-115hhrg31568.htm

³⁸ See Export Control Reform Act (ECRA) of 2018, Pub. L. No. 115-232, 132 Stat. 2208 (2018), Codified at 50 U.S.C. § 4801 (2024) et seq.

³⁹ See Foreign Investment Risk Review Modernization Act (FIRRMA) of 2018, Pub. L. No. 115-232, 132 Stat. 1636 (2018).

⁴⁰ CFIUS is an interagency committee that reviews foreign investments, along with mergers and acquisitions involving foreign entities, into U.S. companies for potential national security risks. CFIUS has the authority to mitigate the national security risk through legally binding restrictions on the company. CFIUS can also block the transaction from being completed if they believe the national security risk cannot be mitigated.

not otherwise subject to export controls.⁴¹ Unlike FIRRMA, ECRA specifically mentions "quantum" in the context of establishing controls on critical and emerging technologies. ERCA also requires the Department of Commerce's Bureau of Industry and Security ("BIS") to lead an ongoing interagency effort to identify "emerging" and "foundational" technologies not currently controlled but that are "essential to national security," except ECRA fails to define those key terms.

Despite both FIRRMA and ECRA being enacted in 2019, there was significant delay in developing the respective implementing regulations. In the absence of BIS regulations, the President issued a "National Strategy for Critical and Emerging Technologies," establishing a comprehensive approach for maintaining and enhancing the US's competitive edge in critical and emerging technologies. The framework focused on two pillars: (1) promotion of the national security innovation base and (2) protection of technology advantage. This Strategy was intended to address both the risks and opportunities of emerging technology, importantly also incorporated a list of twenty critical and emerging technologies including quantum information science.⁴² The list was updated in 2022 and again in 2024, further expanding quantum to include "Quantum information and Enabling Technologies." During this period of delay, the Treasury created a pilot program to review transactions in various "critical technologies." The pilot program relied on the Department of Commerce's list of critical technologies to determine which transactions needed to be reviewed by CFIUS.⁴³ "This change in procedure allow[ed] for CFIUS to place further scrutiny on emerging and foundational technologies." Although Treasury finalized its regulations on February 13, 2020, in the five years since enactment, BIS has yet to finalize its regulations for ECRA concerning emerging and foundational technologies.

⁴¹ Export control laws are administered through Department of Commerce through the Export Administration Regulations (EAR), Department of State and Department of Treasury. These laws control the export, re-export, and transfer of goods, software and technologies that have both commercial and military or proliferation applications. The EAR lists which items are subject to export controls and put them on a Commerce Control List (CCL), along with a classification number (ECCN) that determines the level of control and licensing requirements based on the item's technical characteristics, destination or enduse.

⁴² See THE WHITE HOUSE, NATIONAL STRATEGY FOR CRITICAL AND EMERGING TECHNOLOGIES (Oct. 2020), <u>https://www.hsdl.org/c/view?docid=845571</u>. (Document updated in both 2022 and 2024).

⁴³ See Emma Rafaelof, U.S.-China Econ. & Sec. Rev. Comm'n, Unfinished Business: Export Control and Foreign Investment Reforms, (June 1, 2021),

https://www.uscc.gov/sites/default/files/2021-06/Unfinished_Business-

Export_Control_and_Foreign_Investment_Reforms.pdf.

Meanwhile, several allied nations recently implemented specific export controls over quantum computers and various enabling technologies. In the spring of 2024, France⁴⁴, Spain⁴⁵, the Netherlands⁴⁶ and the United Kingdom⁴⁷ all issued pluralistic regulations. These controls identify critical component parts such as Complementary Metal Oxide Semiconductor (CMOS) integrated circuits⁴⁸; parametric signal amplifiers⁴⁹; and cryocoolers, cryowafers and similar cooling equipment.⁵⁰ These regulations also identify quantum computers⁵¹ along with specifically-designed software. These quantum computer-specific controls will likely inform the specific controls that the United States will adopt in the near future. It is critical that these global pluralistic export controls for quantum computing are collaborative and are underpinned by a coordinated approach to managing the distribution and development of quantum technologies across different allied nations.

2. Protecting Critical Cybersecurity Infrastructure

In addition to protecting and advancing quantum technologies, the US has begun to evaluate national security implications of quantum computers. In 2016, in response to the threats posed by future quantum systems, the National Institute of Science and Technology ("NIST") initiated a call to the world's cryptographers to help with "heading off a looming threat to information security: quantum computers."⁵² This initiative marked NIST's first official step to counteract the potential dangers quantum computers could pose to digital information and launched a six-year competition to develop and standardize additional public-key cryptographic algorithms. NIST's goal was to identify cryptographic methods capable of resisting attacks from a cryptanalytically-relevant

⁴⁴ https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000049120866

⁴⁵ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C 202300441

⁴⁶ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C_202300441

⁴⁷ https://www.legislation.gov.uk/uksi/2024/346/pdfs/uksi 20240346 en.pdf

⁴⁸ CMOS integrated circuits are fundamental to the development of quantum processors.

⁴⁹ These components enhance the signals in quantum computers, which are typically very weak.

⁵⁰ Most quantum computers require extremely low temperatures to operate correctly or efficiently.

⁵¹ The regulations provide explicit number of qubits that must be 'fully controlled', 'connected' and 'functional' 'physical qubits' and those qubits must have a 'C-NOT error' of less than or equal to a specific threshold, which drops as the number of qubits increases. ⁵² See https://csrc.nist.gov/news/2016/public-key-post-quantum-cryptographic-algorithms

quantum computer (CRQC).⁵³ NIST solicited public comment on "draft minimum acceptability requirements, submission requirements, and evaluation criteria for candidate algorithms."⁵⁴ More than 80 algorithms were submitted and rigorously evaluated during this process. On July 5, 2022, NIST revealed the first four quantum-resistant cryptographic algorithms chosen for future standardization.⁵⁵ NIST's candidate algorithms for standardization are: CRYSTALS-Kyber (key-establishment) and CRYSTALS-Dilithium (digital signatures); NIST also selected the signature schemes FALCON and SPHINCS+ to be standardized.⁵⁶ NIST anticipates releasing the final post-quantum cryptographic algorithms in the summer of 2024 under the new names ML-KEM, ML-DSA, FN-DSA, and SLH-DSA respectively.⁵⁷

NIST continues to explore additional algorithm candidates, in a fourth round of evaluation.⁵⁸ Meanwhile, in 2022, NIST made a specific further call for digital signature algorithm candidates, seeking to diversify the algorithms that it standardizes.⁵⁹ The current clutch of signature algorithms largely depends on the same underlying mathematical constructs, which increases the risk that a novel attack could inflict widespread damage. It will be several years before these additional signature algorithms are standardized.

As NIST's competition advanced, the US government began considering what practical steps it needed to take to protect its own cybersecurity systems. In May of 2022, President Biden issued the National Security Memorandum on Promoting United States Leadership in Quantum Computing While Mitigating Risks to Vulnerable Cryptographic Systems

⁵³ A "cryptanalytically-relevant quantum computer (CRQC)", which is US government terminology for a sufficiently powerful quantum computer. The acronym CRQC pops up in a lot of their documents, e.g. this joint CISA/NIST/NSA guidance: https://media.defense.gov/2023/Aug/21/2003284212/-1/-1/0/CSI-QUANTUM-READINESS.PDF.

⁵⁴ See National Institute of Standards and Technology, Request for Comments on Post-Quantum Cryptography Requirements and Evaluation Criteria, 81 Fed. Reg. 50,587 (Aug. 2, 2016), available at: https://www.federalregister.gov/documents/2016/08/02/2016-18150/request-for-comments-on-post-quantum-cryptography-requirements-and-evaluationcriteria

⁵⁵ Nat. Inst. of Stds. and Tech., *PQC Standardization Process: Announcing Four Candidates to be Standardized, Plus Fourth Round Candidates* (July 5, 2022), https://csrc.nist.gov/News/2022/pqc-candidates-to-be-standardized-and-round-4 ⁵⁶ Id.

⁵⁷ See Matt Swayne, *White House Advisor Says NIST To Release Post-Quantum Cryptographic Algorithms In Coming Weeks*, QUANTUMINSIDER (May 24, 2024), https://thequantuminsider.com/2024/05/24/white-house-advisor-says-nist-to-release-post-quantum-cryptographic-algorithms-in-coming-weeks/

⁵⁸ <u>https://csrc.nist.gov/Projects/post-quantum-cryptography/round-4-submissions</u>

⁵⁹ https://csrc.nist.gov/News/2022/request-additional-pqc-digital-signature-schemes

("NSM10").⁶⁰ NSM10 outlined "key steps needed to maintain the Nation's competitive advantage in quantum information science (QIS), while mitigating the risks of quantum computers to the Nation's cyber, economic, and national security."⁶¹ The President called for the creation of a whole-of-government and whole-of-society strategy to both harness the economic and scientific benefits of QIS and to deploy quantum-resistant cryptography to protect critical infrastructure and national security systems from threats posed by quantum computers. Importantly, NSM10 called upon NIST to initiate a working group with industry, including critical infrastructure owners and operators, and other stakeholders, to understand challenges of transitioning vulnerable cryptographic systems to quantum computing threats.

On December 21, 2022, the Quantum Computing Cybersecurity Preparedness Act (the Act) was signed into law,⁶² underscoring a proactive approach by the U.S. government to strengthen its cybersecurity infrastructure against future quantum threats. This legislation complements the directives of NSM10 by emphasizing the importance of migrating federal IT systems to quantum-resistant cryptographic technologies. The Act requires federal agencies to assess their current cybersecurity infrastructure and develop strategies for transitioning to quantum-resistant technologies. While the Act does not set new standards or specific timelines for adoption, it encourages the government to focus on enhancing cryptographic agility so the US remains resilient against potential quantum computing threats that could compromise sensitive defense and critical infrastructure systems and information. This flexible approach reflects the evolving nature of both the technological capabilities and threats. Moreover, the legislative framework is part of a broader strategy to push for a coordinated government-wide and industry-wide approach to cryptography that emphasizes the need for systems to be quickly and safely updated.

releases/2022/05/04/national-security-memorandum-on-promoting-united-states-leadership-in-quantum-computing-while-mitigating-risks-to-vulnerable-cryptographic-systems/.

⁶⁰ White House, National Security Memorandum on Promoting United States Leadership in Quantum Computing While Mitigating Risks to Vulnerable Cryptographic Systems (May 4, 2022), https://www.whitehouse.gov/briefing-room/statements-

 $^{^{61}}$ *Id.* at 1.

⁶² Quantum Computing Cybersecurity Preparedness Act, Public Law No: 117-260, 136 STAT. 2389 (Dec. 21, 2022).

LEARNING FROM TECHNOLOGY GOVERNANCE

3. Development of a domestic quantum strategy to guide public funding

While safeguarding intellectual property and critical infrastructure are driving regulations, the development of a domestic quantum strategy guiding public funding in order to maintain a competitive advantage also remains key to quantum governance. According to a 2023 report by McKinsey and Co., the global quantum technologies market is projected to reach \$106 billion by 2040.⁶³ Strategic investments in quantum technologies are already influencing and shaping future regulations in quantum. Currently, the quantum ecosystem both in the US and globally is facing a number of challenges; from workforce development to supply chain brittleness, and many governments have begun directing funding beyond exploratory research to address deficiencies and promote innovation while managing risks, signaling the government's priorities in quantum. In 2016, China announced the launch of is satellite Micius, which was solely dedicated to quantum information science with the aim of establishing a secure method of quantum messaging.⁶⁴ In 2018, in an effort to accelerate quantum commercialization, the European Union launched the Quantum Technologies Flagship, with EU and member states having committed more than 8 billion to quantum technologies.⁶⁵ In partial response to the European Union and Chinese investments in quantum, Congress quickly enacted the National Quantum Initiative Act (NQIA) in December 2018.⁶⁶ The NQIA established a coordinated federal program to accelerate quantum research and development for both the economic and nation security of the United States.

⁶³ See McKinsey & Company, Quantum Technology Monitor, 2023 at https://www.mckinsey.com/~/media/mckinsey/business%20functions/mckinsey%20digital/ our%20insights/quantum%20technology%20sees%20record%20investments%20progress %20on%20talent%20gap/quantum-technology-monitor-april-2023.pdf

⁶⁴ https://www.scientificamerican.com/article/china-reaches-new-milestone-in-space-based-quantum-communications/

⁶⁵ Martin Greenacre, *European industry is yet to embrace the potential of quantum technologies*, SCIENCE/BUSINESS (Mar. 26, 2024),

https://sciencebusiness.net/news/quantum-computing/european-industry-yet-embrace-potential-quantum-technologies. .

⁶⁶ National Quantum Initiative Act, Public Law No: 115-368, 132 Stat. 5092 (Dec. 21, 2018).

Up until that point, the US had been providing funding and support, but without consistency or strategy.⁶⁷ The Act authorized over \$1.2 billion⁶⁸ for the first five years to support quantum research and development. Importantly, it called for the White House's Office of Science and Technology ("OSTP") to coordinate funding, thus eschewing from historic tendency to fund quantum programs through the Department of Defense.⁶⁹ Specifically, NQIA directed the Department of Energy, National Science Foundation and NIST to support the creation of Quantum Information Science research centers around the nation. NQIA aimed to facilitate the development of an ecosystem of public and private sector collaboration to advance quantum technologies, infrastructure, education and the development of a skilled workforce.

While public investment does not, in and of itself, regulate quantum, the principles and practices embedded in the NQIA and similar government strategies are influencing and shaping the behavior of the quantum ecosystem. Indeed, these funding strategies play an important role as softlaw mechanisms that guide research and development, influence private sector priorities, impact educational and workforce development, and guide international policy.

B. Challenges of Quantum Governance in the United States

1. Introduction

The infinite possibilities inherent in quantum computers can help solve many challenges in our world today. For example, there are optimization problems related to cost and distance, simulation of various natural phenomena including weather, and development of new encryption systems using complex factorization.⁷⁰ The interest in quantum technology is rapidly increasing, and various countries are currently making significant investments to study the development and regulatory rules of this technology. Despite the fact that quantum technology has not fully reached

⁶⁷ Alex Knapp, *Congress Just Passed A Bill to Accelerate Quantum Computing. Here is What It Does* (Dec. 20, 2018),

https://www.forbes.com/sites/alexknapp/2018/12/20/congress-just-passed-a-bill-to-accelerate-quantum-computing-heres-what-it-does/

⁶⁸ Note, in addition to NQIA funds, quantum technology projects are still supported by the Department of Defense under its Research, Development, Test, and Evaluation (RDT&E) budget, now exceeds \$100 billion annually. In 2021, the DOD "2021 budget estimates for RDT&E mention the word "quantum" on 27 pages of the 1094-page document.

⁶⁹ See generally CHRIS JAY HOOFNAGLE AND SIMON GARFINKEL, LAW AND POLICY FOR THE QUANTUM AGE (2021).

⁷⁰ Mauritz Kop, *Establishing a Legal-Ethical Framework for Quantum Technology*, YALE J. OF L. & TECH., THE RECORD, (Mar. 30, 2021),

the commercialization stage, predicting the complex impacts when combined with other technologies is not entirely impossible because of its practical value in various fields.⁷¹ Additionally, since quantum computers operate in a completely different manner from classical computing methods, they cannot entirely replace current computers and are instead expected to function in a complementary manner.⁷² In this emerging technology, through a review of existing research materials on the regulation of quantum technology, we aim to identify the most challenging tasks currently faced by policymakers and lawyers in each field.

2. Governance of Private Actors

One of the important features of the U.S. quantum industry is the establishment of an industry-led consortium, QED-C, which is focused on revitalizing and growing the quantum industry around this consortium. While similar consortia exist in other countries (Europe, Japan, Canada), the U.S.'s QED-C is different in that it focuses on identifying supply chain dependencies and commercialization.⁷³

Developing quantum computer technology is not an easy task, but currently, various companies are showing great interest in commercializing this technology, and many discussions have already taken place on how to use existing tools. Based on these developments, it appears that various barriers to quantum technology are being broken down. However, due to the nature of this field, there is a lack of specialized personnel. Many quantum technologies are developing around corporate research centers so training of experts mostly reflects the needs of companies and their customers.⁷⁴The first challenges in the private sector are that the interests in quantum technology could be biased toward one side. Balance between private investment and public benefits are essential to overcome this obstacle. There are several societal structural issues that hinder the development of governance on quantum technology. The biggest issue among these is the shortage of personnel. Although quantum technology is expected to be

content/uploads/2023/11/TTLF-WP-107-KiesowBambauerGuhaFleming.pdf.

⁷¹ David Atkinson, *Quantum Computing: The Promises and Potential Perils*, 37 THE COMP. & INTERNET L. 4, 6 (2020).

⁷² Id. at 4.

 ⁷³ Hodan Omaar, *The U.S. Approach to Quantum Policy*, CENTER FOR DATA INNOVATION, REPORT 19 (Oct. 10, 2023), https://www2.datainnovation.org/2023-us-quantum-policy.pdf.
 ⁷⁴ Elif Kiesow Cortez, Jane Bambauer, *et al.*, A Quantum Policy and Ethics Roadmap: Towards a Transatlantic View on Responsible Innovation, STANFORD-VIENNA TRANSATLANTIC TECH. L. F., (2023), https://law.stanford.edu/wp-

widely applied across various sectors, there is a significant lack of experts to meet the interest and needs in this field. Working in the quantum technology field requires a lot of preparation time and stages, so according to basic economic principles, it is difficult to see an increase in supply or applicants based on demand alone.⁷⁵ The shortage of quantum technology experts is seen as the biggest obstacle to the quantum technology industry. To address this challenge, quantum technology companies are making various efforts. One of the most notable efforts is that quantum technology companies are focusing on advancing quantum technology through partnerships with university research institutions and programs at universities, rather than relying solely on the labor market.⁷⁶ It is also anticipated that supply chains of big high-tech firms in the United States will soon seek cheaper labor overseas.⁷⁷

3. *Governance of the public sectors*

Although quantum computers may seem highly futuristic, many countries around the world are already investing substantial public funds into quantum research. The EU has decided to invest approximately \$100 million in the quantum computing industry over the next decade, while China has already invested \$11.4 billion in quantum research facilities and is currently ahead of other countries in quantum research.⁷⁸ Currently, the United States is also keeping pace with these developments by formulating strategies for a strategic approach to the quantum information industry since 2016 and continuing these efforts to the present day.

Under President Obama, a report titled "Advancing Quantum Information Science: National Challenges and Opportunities" was released in 2016, presenting the following three principles: (1) Establish stable policies that can capture new opportunities and restructure when obstacles arise, (2) Invest in targeted areas or time-limited programs to achieve specific and measurable goals, and (3) Regularly evaluate and monitor federal investments in the Quantum Information Science field.⁷⁹ In addition, through The CHIPS and Science Act of 2022, the legislature established the following foundations to enhance its influence on quantum technology. First, it authorizes research and development on quantum networking

⁷⁵ Elif Kiesow Cortez et al., *supra* note 62, at 16.

⁷⁶ Richard D. Taylor, *Quantum Artificial Intelligence: A "Precautionary" U.S. Approach?*, 44 J. OF TELECOMM. POL'Y 1, 8 (July 20, 2020).

⁷⁷ Id. at 9.

⁷⁸ David Atkinson, *Quantum Computing: The Promises and Potential Perils*, 37 COMP. & INTERNET LAWYER 4, 7 (Jan. 2020).

⁷⁹ Hodan Omaar, *supra* note 61, at 2.

infrastructure. Second, it directs the National Institute of Standards and Technology (NIST) to develop standards for quantum networking and communication. Third, it supports the integration of Quantum Information Science into STEM curricula to provide research access to quantum computing resources through Department of Education programs.⁸⁰

Some scholars argue that to supply the workforce needed for such quantum technology, the government should step in and enhance STEM-related skills in the K-12 education curriculum and supplement educational policies so that this experience can continue through to graduate school.⁸¹ Secondly, if quantum technology is left to the market, investors are more likely to use the technology for managing the portfolios of wealthy individuals rather than addressing energy management or climate change solutions. Therefore, it is necessary for the federal government to identify socially valuable issues, provide the necessary resources, and secure commitments for public investment.⁸²

Many of the concerns associated with quantum computer technology arise when it is combined with artificial intelligence technology. This is because the unintended biases of artificial intelligence may operate, leading to unexpected optimization conclusions in areas such as financial predictions and modeling, or prioritizing the interests of AI users over societal benefits.⁸³

4. Governance for International Collaboration

Since the U.S. quantum industry is developing around individual companies, the most notable aspect of U.S. quantum computer development is the supply chain issue. These supply chain issues could lead to disruptions in the supply of raw materials related to quantum computers within the next few years, which would be difficult to resolve without relying on allied nations.⁸⁴ It is particularly concerning that China accounts for 60% of rare earth mining, 85% of rare earth processing, and 92% of rare earth magnet production.⁸⁵ To stabilize this supply chain, it is necessary to cooperate with allied governments and continuously track policy changes.⁸⁶ Quantum technologies are growing in a geopolitical environment, highlighting the importance of cooperation and exchange among likeminded countries. Particularly, as challenges persist in defense or

⁸⁰ Id. at 3.

⁸¹ Elif Kiesow Cortez et al., *supra* note 62, at 7.

⁸² Id. at 9.

⁸³ Id. at 8.

⁸⁴ Hodan Omaar, *supra* note 61, at 19.

⁸⁵ Id.

⁸⁶ Id. at 23.

technological competition originating from China, establishing governance principles for international cooperation on the advancement of quantum technologies is crucial.⁸⁷

First, considering that the research leaders of major companies leading quantum research in the United States hail from foreign countries such as Australia, Germany, and Canada, it would be beneficial to pave the way for foreign talents to contribute to the U.S. industry in order to stimulate and activate the quantum industry within the United States.⁸⁸ Second, it is necessary to control the export and exchange of quantum computing technology. Currently, excessive export and import controls could suppress domestic growth in the quantum industry. While specific discussions are not underway, in the long term, trade regulations will undoubtedly be necessary to thwart China's ambitious technological competition.⁸⁹

5. Governance for National Security

Another potential of quantum computers lies in revolutionizing communication technology and excelling in cryptography. However, the powerful encryption systems of quantum computers also mean that hacking or espionage activities against the currently maintained encryption systems could occur.

This privacy crisis is noteworthy when individual hackers use quantum computer communication technology for personal, financial, or political motives, or when national security threats arise from competing countries. Among these concerns, first, the most alarming is the "Intercept now, decrypt later" attack. Under this threat, the data and communications we are producing today, or we have already produced, will be stored in RSA-encrypted from and decrypted by Post Quantum Cryptography (PQC).⁹⁰ It is pivotal to prevent a massive failing of current data protection and breaches of privacy. Secondly, quantum-based decryption could cause very strong privacy of communication which may benefits criminals or enemies when they use the same technology as the law enforcement or intelligence will face "going dark" problem. Going dark problems arise when our communication moves from centralized encryption to device-side end-to-end, including all communications on Apple devices.⁹¹ If a telecommunications company does not possess decryption keys or if all

⁸⁷ Id.

⁸⁸ Id. at 16.

⁸⁹ Id. at 24.

⁹⁰ Cortez at al., *supra* note 62, at 10.

⁹¹ *Id.* at 11.

back channels enabling access to customers' communication contents are closed, even with a warrant issued, it would likely be futile. This would create inconvenience necessitating diplomatic means to view communications abroad. ⁹²

Lastly, the Department of Commerce's Bureau of Industry and Security (BIS) is also making efforts to regulate the export of sensitive technologies related to quantum technology for U.S. security. In 2021, BIS proposed adding a new Export Control Classification Number (ECCN) to control the export of electrical assemblies and components related to quantum computers.⁹³

6. *Governance in Ethical Perspectives*

Quantum computing is not yet a major part of mainstream industries, and most of the technological research is conducted for scientific purposes.⁹⁴ Furthermore, since the financial and technical capabilities to implement applications such as quantum computers and quantum AI are limited to a few companies, it currently seems most appropriate to create data governance for quantum computers.⁹⁵ However, predicting whether the fields of quantum information technology or quantum artificial intelligence will turn out positively or negatively in terms of their potential and impact is still difficult.

To address these dilemmas, some scholars advocate for a shared and collective form of governance rather than regulatory authority being centralized in one institution. They argue that regulation should move towards shared authority or encourage self-regulation through concepts like "policy space."⁹⁶

Another reason why we need to discuss the moral rules of quantum technology is that China is leading in this field. Some scholars argue that it is necessary to establish rules that can be universally applied worldwide because the funding systems and rules, and habitus of countries like China may differ from those of other countries.⁹⁷ They argue that, just as AI technology impact assessments were created through public-private efforts, the impact of quantum technology on ethics, law, and society should be continuously monitored. They emphasize that democratic norms and

⁹² Id.

⁹³ Omaar, *supra* note 61, at 24.

⁹⁴ Luigi Bruno & Isabella Spano, *Post Quantum Encryption and Privacy Regulation: Can the Law Keep the Pace with Technology*? 2021 EUR. J. PRIV. L. & TECH.72 (2021).

⁹⁵ Taylor, *supra* note 67, at 9.

⁹⁶ *Id*. at 10.

⁹⁷ Kop et al., , *supra* note 58, at 9.

standards, philanthropic values, and an incentive-reward perspective must be considered in such impact analyses.⁹⁸

Many ethics-promoting regulations are based on the premise that an existential threat may arise when quantum computers and AI are combined.⁹⁹ It is concerned that AI might gain free will or be used in an arms race. Discussing these risks at this point may be premature, but if such events occur, they could cause irreversible harm, so it is meaningful to discuss them with precaution.¹⁰⁰ The precautionary principles were already declared in the 1992 United Nations Rio Declaration, which stated that technology should be developed in a way that ensures human safety, secures resources for future generations, and does not violate human rights.¹⁰¹ The characteristic of these principles is that they regulate scientific uncertainty or the unknown, so they must be able to encompass international public law or various fields of science.¹⁰² Physicists also say that using quantum computers to accurately predict the future or the emergence of AI with free will is almost impossible based on the theory of chaotic behavior.¹⁰³

7. Conclusion on Governance Challenges

Quantum technology is a technology with the potential to solve unknown problems and can be applied to various areas of our lives and nature. However, such new technology always presents our society with new challenges and opportunities, and someone needs to take responsibility for the accompanying risks. To address the social challenges posed by quantum technology, it is crucial to establish a robust legal-ethical framework. To maximize the benefits of quantum technology while avoiding and minimizing potential harms for the progress of humanity, we must begin discussions and address potential risks at this moment. In developing quantum technology, one key aspect is creating new norms that incorporate the demands of scientists, policymakers, business people, and the public, ensuring that transparent decision-making processes are established so that the technology can contribute to the common good. Since our resources are limited, it will also be necessary to avoid

⁹⁸ Id. at 11.

⁹⁹ Id. at 8.

¹⁰⁰ Taylor, *supra* note 67, at 9.

¹⁰¹ Atkinson, *supra* note 59, at 11.

¹⁰² Taylor, *supra* note 67, at 9.

¹⁰³ Rachel Gutman-Wei, *Could Quantum Computing Be the End of Free Will*?, THE ATLANTIC 2 (June 30, 2018),

https://www.theatlantic.com/technology/archive/2018/06/quantum-computing-free-will/564215/.

unnecessary arms races and technological competition and to establish longterm welfare plans that allow for the sustainable use of Earth's resources.

Among the various issues discussed, developing encryption that protects individual privacy is an immediate potential threat, making it necessary to take overall efforts to mitigate such social risks. Additionally, because the advancement of quantum technology requires substantial financial investment, it is essential to ensure that the general public receives and perceives the benefits of quantum technology. Finally, it is crucial to remember that robust international cooperation is essential in using and advancing quantum technology.

IV. LESSONS FROM OTHER EMERGING TECHNOLOGIES

A. Lessons from Biotechnology Governance

Biotechnology was seen as the next big thing in the 1970s and 1980s as genetic engineering moved from laboratory experiments to commercial development of biotechnology drugs and foods. At the time, the concept of moving genes from one species to another seemed very exotic and unnatural, possibly presenting great and uncertain risks. Subsequent research and knowledge have revealed that gene movement between species is not such a novel phenomena, and in fact it occurs quite often in nature.¹⁰⁴ At the time the gene engineering technology was getting off the ground in the 1970s and 1980s, however, the fears and anxiety about creating an "Andromeda Strain" by moving genes between species was quite intense and broad in the population.¹⁰⁵

In response to the fears and controversy over genetically engineering, and to head off numerous federal and state draft bills that would strictly regulate biotechnology,¹⁰⁶ the U.S. Executive branch put in place a "Coordinated Framework for the Regulation of Biotechnology" in 1986.¹⁰⁷

¹⁰⁴ See, e.g., Michael Marshall, *Plants Routinely Swap DNA*, NEW SCIENTIST, May 1, 2021, at 11; Julia Van Etten & Debashish Bhattacharya, *Horizontal Gene Transfer in Eukaryotes: Not If, But How Much*?, 36 TRENDS IN GENETICS 915 (2020); Alan McHughen, *Fatal Flaws in Agbiotech Regulatory Policies*, 25 NATURE BIOTECH. 725, 725 (2007).

¹⁰⁵ Paul Berg & Maxine F. Singer, *The Recombinant DNA Controversy: Twenty Years Later*, 92 PROC. NAT'L ACAD. SCI. 9011, 9011 (1995).

¹⁰⁶ See Stanley Abramson & Karen Carr, *A Bounty of Benefits*, Environmental Forum, Nov./Dec. 2022, at 24,26 (describing factors and context that lead to adoption of the Coordinated Framework).

¹⁰⁷ Office of Science & Technology Policy (OSTP), Coordinated Framework for the Regulation of Biotechnology, 51 Fed. Reg. 23302 (1986). For a discussion of the adoption

The Coordinated Framework allocated regulatory responsibility for biotechnology products to existing agencies using their existing statutory authorities.¹⁰⁸

The Coordinated Framework has remained in effect to the present time, with some relatively minor updates in 1992¹⁰⁹ and 2017.¹¹⁰ As experience with genetically modified products has accumulated over the past forty years, there has been growing confidence in the relative safety of the genetically modified products produced to date.¹¹¹ The U.S. National Academy of Sciences and other prestigious scientific organizations have concluded that genetically modified products are no more risky than their conventional equivalents.¹¹² The agencies have started to relax some of their requirements for some genetically modified products, especially gene edited products that involve relatively minor genetic changes that are likely to occur

and operation of the Coordinated Framework, see Alan Sachs, *Adapting Federal Regulatory Approaches to Advances in Agricultural Biotechnology*, 80 MD. L. REV. ONline 26 (2021).

¹⁰⁸ The government gave two reasons for this reliance on existing agencies and statutes. First, the use of existing statutes "could provide more immediate regulatory protection and certainty for industry." OSTP, *supra* note ___, at 23,303. Second, the wide range of genetically engineered products precluded regulation by a single agency or statute. *Id*. ¹⁰⁹ Office of Science & Technology Policy, Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992).

¹¹⁰ Modernizing the Regulatory System for Biotechnology Products: Final Version of the 2017 Update to the Coordinated Framework for the Regulation of Biotechnology (2017), https://www.epa.gov/sites/default/files/2017-

^{01/}documents/2017_coordinated_framework_update.pdf.

¹¹¹ Abramson & Carr, *supra* note ___, at 25 ("biotechnology has produced benefits that have flowed to society without any evidence of adverse health or environmental effects. It is a fair question to ask how many other new technologies can point to such an enviable track record.").

¹¹² See, e.g., NATIONAL ACADEMIES OF SCIENCE, ENGINEERING & MEDICINE, GENETICALLY-ENGINEERED CROPS: PAST EXPERIENCE AND FUTURE PROSPECTS 19 (2016) ("On the basis of its detailed examination of comparisons between currently commercialized GE and non-GE foods in compositional analysis, acute and chronic animal-toxicity tests, long-term data on health of livestock fed GE foods, and epidemiological data, the committee concluded that no differences have been found that implicate a higher risk to human health safety from these GE foods than from their non-GE counterparts."); NATIONAL RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 43 (2000) ("There is no strict dichotomy between, or new categories of, the health and environmental risks that might be posed by transgenic and conventional pest-protected plants."); NATIONAL RESEARCH COUNCIL, ENVIRONMENTAL EFFECTS OF TRANSGENIC PLANTS 49 (2002) (reaffirming the finding that "the transgenic process presents no new categories of risk compared to conventional methods of crop improvement")..

naturally.¹¹³ But for most genetically engineered products, the Coordinated Framework remains in effect, and the regulatory experience under the framework provides a number of lessons for technology governance.

Here are eight lessons for technology governance learned from the history of biotechnology regulation in the United States:

1. Be Careful What You Ask For – The Coordinated Framework was adopted in part at the request of industry, who actively lobbied for federal regulation.¹¹⁴ Companies were concerned about the proliferation of state legislative proposals, many of which would impose relatively draconian and inconsistent requirements on industry.¹¹⁵ In addition, federal regulation was perceived as a helpful step to address the public apprehension about genetic engineering. Yet once in place, the regulatory framework has been resilient to serious efforts to relax or reform regulatory requirements that no longer are scientifically justified.¹¹⁶ The Obama,¹¹⁷ Trump¹¹⁸ and Biden¹¹⁹ administrations all issued Orders stating that biotechnology is

¹¹³ See, e.g., USDA, Movement of Certain Genetically Engineered Organisms: Final Rule, 85 Fed. Reg. 29790 (2020); EPA, Final Rule, Pesticides; Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived From Newer Technologies, 88 Fed. Reg. 34756 (May 31, 2023).

¹¹⁴ Mark Crawford, *Biotech Companies Lobby for Federal Regulation*, 248 SCIENCE 546 (1990).

¹¹⁵ *Id.* ("We are concerned that 50 different states are going to come out with different sets of regs if the feds do not get their act together.") (quoting Pamela J. Bridge, American Association of Biotechnology Companies).

¹¹⁶ See Jennifer Khan, Learning to Love GMOs, N.Y. TIMES MAG., July 20, 2021 (regulatory system based on earlier lack of knowledge has persisted because of "powerful anti-GMO campaign" resulting ins situation where we are "stuck in a closed loop") ¹¹⁷ Executive Office of The President, Memorandum for Heads of Food and Drug Administration, Environmental Protection Agency, and Department of Agriculture, "Modernizing the Regulatory System for Biotechnology Products 2 (July 2, 2015), <u>https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/modernizing_the_r</u> <u>eg_system_for_biotech_products_memo_final.pdf</u> (current biotechnology regulatory system creates uncertainty about agency jurisdiction, lack of predictability of timeframes for review, and other processes have imposed unnecessary cost and burdens on small and

mid-sized companies and academics).

¹¹⁸ Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products, Executive Order 13874, 84 Fed. Reg. 27899, 27900 (June 14, 2019) (agencies are instructed to "identify relevant regulations and guidance documents ... that can be streamlined to ensure that products of agricultural biotechnology are regulated ... in a timely and efficient manner and to "exempt low-risk products from ... undue regulation").

¹¹⁹ Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy, Executive Order 14081, 87 Fed. Reg. 56849, 56850 (Sept. 15, 2022) (recognizing need to "clarify and streamline regulations in service of a

critical to the nation's economic future but the current regulatory framework is unduly burdensome and restrictive. Despite these instructions to pull back or simplify some of the Coordinated Framework's regulatory requirements, the agencies have only managed to make minor adjustments that do not fix the problem of outdated and unnecessarily restrictive regulatory barriers to innovation.

2. Stringent Regulation Can Favor Big Companies and Exclude Mid- and Small-Sized Businesses - The Coordinated Framework imposes substantial regulatory costs on the approval of a genetically modified product, with the direct regulatory costs exceeding \$35 million, and the total product development costs exceeding \$100 million.¹²⁰ Navigating the regulatory labyrinth almost imposes a significant delay, which can extend the product development period by an additional decade.¹²¹ These costs and delays can only be afforded by large multinational companies developing commodity crops.¹²² As Ingo Potrykus, creator of Golden Rice, stated, "[t]he present reality is that of a *de facto* monopoly for the use of the technology by a few financially potent companies with industrial crops and projects that promise a return of not less than USD 100 million."123 The effect of this regulatory burden has been to extinguish most academic, humanitarian and small and medium-size business biotechnology products.¹²⁴ The lesson from this example is that it is important to design regulatory frameworks that

¹²¹ Jose Rafael Prado et al., *Genetically Engineered Crops: From Idea to Product*, 65 ANN.
 REV. PLANT BIO. 769, 779 (2014) ("Bringing a new GE crop product to the commercial market can be a challenging, long-term and expensive enterprise, costing an estimated average of USD 136 million and 13 years from product concept to product launch.").
 ¹²² Khan, *supra* note __ ("only half a dozen companies in the world" can afford the costly regulatory gauntlet to commercialize a genetically modified crop); Council for Agricultural Science and Technology (CAST). 2018. Regulatory Barriers to the Development of Innovative Agricultural Biotechnology by Small Businesses and Universities. Issue Paper 59, https://cast-science.org/publication/regulatory-barriers-to-the-development-of-innovative-agricultural-biotechnology-by-small-businesses-and-universities/.
 ¹²³ Ingo Potrykus, *Unjustified Regulation Prevents Use of GMO Technology for Public Good*, 31 TRENDS IN BIOTECH. 131, 133 (2013).

science- and risk-based, predictable, efficient, and transparent system to support the safe use of products of biotechnology").

¹²⁰ AgBioInvestor, Time and Cost to Develop a New GM Trait, April 2022, available at <u>https://croplife.org/wp-content/uploads/2022/05/AgbioInvestor-Trait-RD-Branded-Report-Final-20220512.pdf</u>; Nicholas Kalaitzandonakes, Julian M Alston & Kent J Bradford, *Compliance Costs for Regulatory Approval of New Biotech Crops*, 25 NATURE BIOTECHNOLOGY 509, 509-510 (2007).

¹²⁴ *Id.*; Council for Agricultural Science & Technology (CAST), Regulatory Barriers to the Development of Innovative Agricultural Biotechnology by Small Businesses and Universities, CAST Issue Paper No. 59, March 2018, https://www.cast-science.org/wp-content/uploads/2018/12/CAST IP59 Biotech Regs CCE3A1D779985.pdf.

universities, public interest projects, and small/medium companies can afford.

3. Direct Consumer Benefits are Critical for Public Support: The first generation of genetically modified crops were engineered with input traits, which made the crops easier or cheaper to grow.¹²⁵ These included traits such as herbicide resistance or pest resistance.¹²⁶ These input traits were selected for two primary reasons. First, the input traits appeal to farmers, who are the initial customers in the product chain who must be persuaded to purchase genetically modified seeds. Second, because the final food products from crops engineered with input traits will be substantially similar if not chemically identical to non-engineered equivalents, the public will have no need to be concerned about new properties or risks. This calculus overlooked, however, extensive research on public risk perception, which found that the public's views on technology risks inevitably link the perceived risks and benefits of a technology, which are inversely correlated.¹²⁷ If perceptions of risk go up, perceptions of benefits go down.¹²⁸ Alternatively, if perceptions of benefits go up, perceptions of risk go down.¹²⁹ It is as if risks and benefits are connected by a teeter-totter balance in the public's perception. So if the public perceives no benefits from genetically modified products, it will find any risks, no matter how small or hypothetical, to be unacceptable.¹³⁰ If biotechnology companies started with products that increased the nutritional value or improved the taste of their foods,¹³¹ it is likely that the public would have been much more

¹²⁶ Rebecca Bratspies, Some Thoughts on the American Approach to Regulating Genetically Modified Organisms, 16 KANSAS J. L. & PUB. POL'Y 101, 112 (2007).
 ¹²⁷ Paul Slovic, Trust, Emotion, Sex, Politics, and Science: Surveying the

¹²⁵ *Cis-editing for All,* 42 NATURE BIOTECH. 821 (2024) ("The public has viewed GM crops with suspicion, if not outward rejection. Most GM crops were ultimately developed by large agricultural companies..., and their benefits – resistance to insects, viruses and herbicides – accrued to farmers rather than consumers.").

Risk-Assessment Battlefield, 19 RISK ANALYSIS 689, 695 (1999); Angela Bearth, Caitlin Drummond Otten & Alex Segre Cohen, *Consumers Perceptions and Acceptance of Genome Editing in Agriculture: Insights from the United States of America and Switzerland*, 178 FOOD RES. INT'L 113982, at 2, 27 (2024); Chad M Baum et al., *Show Me the Benefits! Determinants of Behavioral Intentions Towards CRISPR in the United States*, 107 FOOD QUALITY PREFERENCE 104842, at 8-9 (2023).

¹²⁸ Slovic, *supra* note ___, at 695.

¹²⁹ Id.

¹³⁰ Khan, *supra* note ___("I mean, if you think there might be a risk, and there's no benefit to you, why even consider it?") (quoting Cathie Martin, developer of the purple tomato). ¹³¹ Such second-generation improved genetically modified foods are now entering the market. *See* Khan, *supra* note ___(describing commercialization of new food products that directly appeal to consumers such as cancer-fighting purple tomatoes and better tasting mustard greens).

supportive of the introduction of genetically engineered foods.¹³² The lesson is that it is important to develop and emphasize qualities or applications of a new technology that provide clear consumer benefits.

Transparency Is Important for Public Trust: Similar and 4. complementary to the importance of genuine public engagement to enhance public trust is the critical role of transparency¹³³. The public senses and is suspicious of industry secrecy, especially as it relates to their safety and welfare. For many years, the biotechnology industry vigorously opposed the mandatory labeling of genetically modified foods.¹³⁴ The reasons for this opposition seemed sound - mandatory labeling would stigmatize and falsely portray genetically modified foods as somehow more dangerous than conventional foods,¹³⁵ and the anti-biotech groups would use the mandatory labeling to try to indirectly ban genetically modified foods, as they had achieved in Europe.¹³⁶ There the anti-biotech groups successfully lobbied European regulators to require mandatory labeling of genetically modified foods supposedly to promote consumer "choice," but then turned round and threatened to boycott any grocery store that carried products labeled as genetically modified.¹³⁷ This had the effect of a de facto ban on genetically modified foods, and it became impossible to find or buy any such products in most European countries.¹³⁸ U.S. supporters of mandatory labeling told their followers that a mandatory label could likewise be used to indirectly ban genetically modified foods in the United States.¹³⁹ However, the industry's opposition to mandatory labeling became the primary focus of the budding anti-biotech campaign in the United States, which quickly and steadily built momentum based on the claims that the industry was trying to hide its products from the public.¹⁴⁰ As a *Business Week* article stated, "by blocking

¹³⁶ European Union, Council Regulation No. 1830/2003, Concerning the Traceability and Labeling of Genetically Modified Organisms and the Traceability of Food and Feed Products Produced from Genetically Modified Organisms, 2003 O.J. (L 268) 24, 24.
 ¹³⁷ Gary Marchant, *Counterpoint: The Case Against Mandatory Labeling of GE Food*,

NATURAL RESOURCES & ENV'T (ABA), Fall 2013, at 11, 13; Thwarting Consumer Choice, *supra* note ___, at 33-34; Gary E. Marchant & Guy A. Cardineau, *The Labeling Debate in the United States*, 4 GM CROPS AND FOOD BIOTECHNOLOGY 126, 132 (2013).

¹³⁹ Marchant & Cardineau, *supra* note __, at 132 (providing examples of this "Trojan Horse" strategy)."; Thwarting Consumer Choice, *supra* note __, at 34-35.

¹³² Bratspies, *supra* note ___, at 112.

¹³³ Bratspies, *supra* note , at 103.

¹³⁴ GARY E. MARCHANT, GUY A. CARDINEAU & THOMAS P. REDICK, THWARTING CONSUMER CHOICE: THE CASE AGAINST MANDATORY LABELING FOR GENETICALLY MODIFIED FOODS 13-16 (2010) (hereinafter "Thwarting Consumer Choice").

¹³⁵ *Id.* at 60-61.

¹⁴⁰ Marchant & Cardineau, *supra* note , at 127-129.

grassroots attempts to put advisory labels on food, the food and biotech industries look as if they have something to hide."¹⁴¹ Eventually, the State of Vermont and then the U.S. Congress did mandate labeling of bioengineered foods,¹⁴² and companies putting the labels on their products encountered only consumer indifference and lack of concern.¹⁴³ In fact, the results of the first labeling requirement in Vermont showed that labeling genetically modified foods *increased* consumer trust in genetically modified foods.¹⁴⁴ The lesson from this example is that transparency increases public confidence in a technology, whereas lack of transparency exacerbates consumer concerns and fears.

Use of Existing Statutes and Agencies is Workable: Another 5. lesson from the biotechnology regulatory experience is that existing agencies and statutes can be used to regulate a new technology. This is true even when those existing statutes and agencies were created long before the technology and were never intended to address the new technology. When a new and important technology comes into focus, there is often a rush to introduce new legislation and create new specialized agencies. But creating a brand new regulatory infrastructure is time-consuming and controversial, and tends to not succeed in the United States governmental system. The default option then becomes regulating the new technology by existing agencies using existing statutes, a pattern that was followed by biotechnology as well as by other technologies such as nanotechnology, the internet and (so far at least) artificial intelligence. As Bennett Moses has argued, attempts at bespoke legislative enactments (sui generis rules) are risky, and it is usually preferred to use the broader existing regulatory enactments instead.¹⁴⁵ For biotechnology regulation in the United States, the existing regulatory authorities have worked quite well, with minor problems such as some specific applications (e.g., genetically engineered animals) not easily falling into existing regulatory categories, and some examples of duplicative regulation for some products.¹⁴⁶ Notwithstanding these issues, the lesson

¹⁴¹ Julie Forster, *GM Foods: Why Fight Labeling*?, BUSINESS WEEK, Nov. 11, 2002, 44.

¹⁴² National Bioengineered Food Disclosure Standard, 7 U.S.C. § 1639 (2016).

¹⁴³ Dave Fusaro, *GMO/BE Labeling: Maybe It Won't Hurt*, FOOD PROCESSING, April 19, 2019, at 24, 25.

¹⁴⁴ Jane Kolodinsky & Jayson L. Lusk, *Mandatory Labels Can Improve Attitudes Towards Genetically Engineered Food*, 4 SCI. ADVANCES eaaq1413 (2018).

¹⁴⁵ Lyria Bennett Moses, Sui Generis *Rules, in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT: THE PACING PROBLEM 77, 77-94 (Gary E. Marchant et al. eds., 2011).

¹⁴⁶ Bratspies, *supra* note ___, at 121; Jennifer Kuzma, *A Missed Opportunity for U.S. Biotechnology Regulation*, 353 SCIENCE 1211, 1211 (2018).

from biotechnology is that existing regulatory authorities can often suffice to provide an acceptable regulatory framework.

International Regulatory Differences Can Grow and Become 6. Irreconcilable: As a new emerging technology develops, there are frequent calls for international harmonization of governance.¹⁴⁷ Unfortunately, in the case of biotechnology, important national differences emerged, especially between the United States and European Union (EU).¹⁴⁸ In contrast to the U.S. regulatory approach, the EU required mandatory labeling of genetically modified crops, and put in place an extremely restrictive sui generis rule for genetically modified products that all but eliminated biotechnology foods from the European market (with the exception of imported animal feed).¹⁴⁹ This led to intense trade disputes between the United States and the EU, which culminated in a World Trade Organization case filed by the United States against the EU.¹⁵⁰ Although the U.S. won that case, the EU mostly refused to comply with the decision, and the trade hostilities continued and strengthened.¹⁵¹ This created a major fracture in the otherwise close U.S.-EU relationship, as noted by two legal scholars:

The transatlantic GMO dispute has brought into conflict two longtime allies, economically interdependent democracies with a long record of bilateral and multilateral cooperation in both economics and security. Yet the dispute has developed into one of the most bitter and intractable transatlantic and global conflicts, resisting efforts at resolution in bilateral networks and multilateral regimes alike, and resulting in a bitterly contested legal battle before the WTO.¹⁵²

¹⁴⁷ Marchant, History of Technology Regulation, *supra* note ___, at 729.

¹⁴⁸ David Zilberman et al., *Continents Divided: Understanding Differences Between Europe and North America in Acceptance of GM Crops*, 4 GM CROPS & FOOD BIOTECH. IN AGRICULTURE AND THE FOOD CHAIN 202, 206 (2013).

¹⁴⁹ *Id.;* Robert Paarlberg, *The Trans-Atlantic Conflict Over "Green" Farming*, 108 FOOD POLICY 102229 (2022).

¹⁵⁰ Samuel A. Blaustein, *Splitting Genes: The Future of Genetically Modified Organisms in the Wake of the WTO/Cartagena Standoff*, 16 PENN. STATE ENTL. L. REV. 367 (2008); Congressional Research Service, Agricultural Biotechnology: The U.S.-EU Dispute, April 8, 2010,

 $https://www.everycrsreport.com/files/20100408_RS21556_90ae3bd461abd7d052d2e3dd5e1cdeb3b86a071f.pdf.$

¹⁵¹ Id.

¹⁵² MARK A. POLLACK & GREGORY C. SHAFFER, WHEN COOPERATION FAILS: THE INTERNATIONAL LAW AND POLITICS OF GENETICALLY MODIFIED FOODS 2 (2009).

The lesson from this unfortunate conflict is that regulatory harmonization for a new technology is important to pursue at the outset, because once major differences arise, path dependency and national pride will block future attempts at reconciliation.

7. Some Voluntary "Soft Law" Programs Can Succeed: Although the regulation of genetically modified foods in the United States has mostly involved traditional hard law regulation, there have been elements of voluntary commitments or "soft law." To begin with, the Pew Initiative on Food and Biotechnology attempted to negotiate a consensus framework for biotechnology governance among 18 stakeholders representing the major industry, non-governmental organization and academic interests in biotechnology.¹⁵³ The Stakeholder Forum met for two years and made significant progress, but were ultimately unable to "reach agreement on the full range of issues in sufficient detail to achieve its goal," and concluded that releasing "an imprecise or incomplete package of recommendations would not serve a useful purpose."¹⁵⁴ Although this initiative to develop a consensus "solution" to the issue of biotechnology governance did not succeed, it came close, and one wonders how the subsequent history of two decades of conflict and controversy might have been avoided if a collaborative agreement had been reached.

Even though the Pew initiative failed, soft law does exist in the biotechnology governance framework. In particular, the FDA has implemented as "prudent practice" a voluntary consultation process in which developers of genetically modified foods voluntarily submit a dossier of requested safety data to FDA for pre-market safety review.¹⁵⁵ In 1996 FDA made this voluntary consultation more concrete by putting out a guidance on this "voluntary" consultation process, stating its goal was to allow FDA scientists to identify unresolved safety questions and as a means to further consumer trust. ¹⁵⁶ FDA proposed to make this voluntary consultation process

¹⁵³ Pew Initiative on Food and Biotechnology, The Stakeholder Forum on Agricultural Biotechnology: An Overview of the Process (May 2003), Pew Initiative on Food and Biotechnology, The Stakeholder Forum on Agricultural Biotechnology: An Overview of the Process.

¹⁵⁴ *Id.* The Pew stakeholder process for biotechnology is reviewed in Donald L. Uchtmann, *Agricultural Biotechnology Regulation: The Pew Initiative and Its Stakeholder Forum*, 9 DUKE J. AGRICULTURAL LAW 53 (2004).

¹⁵⁵ This voluntary consultation process was first recognized in the FDA's 1992 "Statement of Policy" for genetically modified foods. FDA, Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 22991 (May 29, 1982).

¹⁵⁶ FDA, Guidance of Industry: Consultation Procedures for FDA's 1992 Statement of Policy for Foods Derived from New Plant Varieties (1996, revised Oct. 1997),

a mandatory rule in January 2001 in the final days of the Clinton Administration, but this proposal was never finalized.¹⁵⁷ Even though this consultation process remained "voluntary" until the present day,¹⁵⁸ every company that has introduced GM foods into the market has voluntarily conformed with the consultation process.¹⁵⁹ In February 2024, the FDA extended the pre-market consultation and meeting process to gene-edited foods, again emphasizing that the process is voluntary.¹⁶⁰ It is likely that biotechnology companies perceive that failing to follow this recommended voluntary consultation process would undermine trust by regulators and the public, demonstrating that voluntary "soft law" programs that are in the regulated parties' interest to conform can be successful.

B. Lessons from Nanotechnology Governance

The emergence and regulatory evolution of nanotechnologies–the science of the small¹⁶¹–provides valuable insights into the ways in which quantum technologies may be governed. And by whom. A largely nascent technology at the time, nanotechnologies became the focus of intense scientific, regulatory, and societal debate in 2004 with the release of the United Kingdom's Royal Society and Royal Academy of Engineering's (RS-RAE) report on the opportunities and potential raised by the platform technology.¹⁶² While the comprehensive report documented the potential

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-consultation-procedures-under-fdas-1992-statement-policy-foods-derived-new-plant.

¹⁵⁷ FDA, Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706 (Jan. 18, 2001).

¹⁵⁸ The history, implementation and legal status of this voluntary consultation process is reviewed in Edward L. Rubin & Joanna K. Sax, *Administrative Guidance and Genetically Modified Food*, 60 ARIZONA L. REV. 539 (2018), which asserts that the consultation process was "voluntary in name, but virtually compelled in fact." *Id.* at 562.

¹⁵⁹ Gregory Conko et al., *A Risk-Based Approach to the Regulation of Genetically Engineered Organisms*, 34 NATURE BIOTECH. 493, 496 (2016).

¹⁶⁰ FDA, Foods Derived from Plants Produced Using Genome Editing: Guidance for Industry 11-18 (Feb. 2024), https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-foods-derived-plants-produced-using-genome-editing.

¹⁶¹ CBS Interview with John Rennie, Editor-in-Chief, Scientific American, *Nanotechnology: The Science of Small*, CBS NEWS (Aug. 30, 2001 2:25 AM),

https://www.cbsnews.com/news/nanotechnology-the-science-of-small/.

¹⁶² ROYAL SOC. & ROYAL ACAD. OF ENG., NANOSCIENCE AND NANOTECHNOLOGIES: OPPORTUNITIES AND UNCERTAINTIES (2004). For a critique of the recommendations aimed specifically at regulatory activities see generally, Diana M. Bowman, *More Than a Decade On: Mapping Today's Regulatory and Policy Landscapes Following the Publication of Nanoscience and Nanotechnologies: Opportunities and Uncertainties*, 11 NANOETHICS 169 *et seq.* (2017).

benefits of nanotechnologies across many different sectors, and highlighted the significant investment by governments, it also shed light onto the many uncertainties posed by the technology in relation to scientific risk.¹⁶³ Its publication elicited robust responses from public and private actors,¹⁶⁴ along with non-governmental organizations (NGOs) and arguably served as a catalyst for shaping the governance landscape. In this section, we examine four overarching lessons from nanotechnologies that we argue are most relevant to quantum technologies.

1. Synergistic development of the science and the governance tools.

A key differential between nanotechnologies and other earlier emergent technologies, such as biotechnologies discussed above in Section IV (A) above, is the timing in which different governance initiatives were developed and deployed. As noted by Levi-Faur and Comaneshter,

.... unlike other cases where the discussion of the associated risks has followed the development of new technologies, the discussion on the proper regulatory framework for the governance of nanotechnology is accompanying the development of the technology and the associated products themselves.¹⁶⁵

This co-evolution saw a myriad of tools behind deployed and ranged from, for example, certification systems, ¹⁶⁶ voluntary data call ins, ¹⁶⁷ codes of

¹⁶⁷ See Department of Environment Food and Rural Affairs (Defra), UK Voluntary Reporting Scheme for Engineered Nanoscale Materials, Sept., 2006,

¹⁶³*Id.* at 35–50.

¹⁶⁴ See Dexter Johnson, *Five Years After Release of Royal Society's Nanotech Report*, IEEE SPECTRUM (Aug. 4, 2009), https://spectrum.ieee.org/five-years-after-the-release-of-royal-societys-nanotech-report.

¹⁶⁵ D. LEVI-FAUR & H. COMANESHTER, THE RISKS OF REGULATION AND THE REGULATION OF RISKS: THE GOVERNANCE OF NANOTECHNOLOGY 149, 151 (Graeme Hodge, Diana Bowman, and Karinne Ludlow, eds. 2007).

¹⁶⁶ Origin of nanoMark, TAIWAN NANOTECHNOLOGY IND. DEV. ASS'N,

http://www.tanida.org.tw/nanomark_e.php?nm=markIntroduction_e

http://www.defra.gov.uk/ENVIRONMENT/nanotech/policy/pdf/vrs-nanoscale.pdf. Dep't of Health & Ageing NICNAS, No. C 10, AUSTL. GOv'T GAZETTE CHEM., Oct. 7, 2008, at 8,

https://nanotech.law.asu.edu/Documents/2009/07/2008oct_whole_165_2476.pdf [https:// perma.cc/S7JC-DNNU].News Release, U.S. Env't. Prot. Agency, EPA Invites Public Participation in Development of Nanotechnology Stewardship Program (Oct. 18. 2006), https://archive.epa.gov/epapages/news

roomarchive/newsreleases/0edb5f39e2ed3c428525720b00629872.html;

Austl. Gov't Dep't of Health, Nanomaterials-Findings and Calls for Information-

conduct, risk frameworks and positive and negative labeling. Many of these initiatives gained little traction, with the Bowman having argued that the voluntary data-calls being "failed to achieve their objectives", ¹⁶⁸ and other activities being classified as a form of "window-dressing". ¹⁶⁹ Not surprisingly, many of these attempts to shape the governance disappeared nearly as quickly as they appeared, allowing industry to coalescence around a handful of tools. These include high profile tools such as BASF's Code of Conduct and the Environmental Defense-DuPont's Risk Framework for Nanomaterials, both of which seemingly benefitted from sizeable funding, excellent branding and marketing, and the legitimacy of two of the world's largest chemical company brands.

Multi-lateral actors also played a role in shaping the early governance landscape and have arguably had the more significant impacts on the shaping the governance ecosystem. In June 2005 the International Organization for Standardization (ISO) established its first Technical Committee (TC) for nanotechnologies, ISO/TC 229 – *Nanotechnologies*, to provide a global umbrella for the development of consensus-based standards. Provided with a broad mandate to produce standards for:

terminology and nomenclature; metrology and instrumentation, including specifications for reference materials; test methodologies; modelling and simulations; and science-based health, safety, and environmental practices¹⁷⁰

the consensus-based body has gone on to produce 110 standards, with a further 26 in development.¹⁷¹ While these standards are voluntary in nature, the very fact that they are developed by industry to address gaps in industry accelerates their uptake. Moreover, as evidenced by the ISO 14,000 family of standards for environmental management, standards may serve to create a de facto regulatory regime.¹⁷² As such, despite some concerns over the

ets/chemical-name/nanomaterials-findings-and-calls-for-]nformation [https://web.archive.org/web/20

- ¹⁶⁸ Diana M. Bowman, The Role of Soft Law in Governing Nanotechnologies,61 JURIMETRICS J. 53, 68 (2020).
- ¹⁶⁹ Ellen-Marie Forsberg, Standardisation in the field of nanotechnology: some issues of legitimacy, 18 Science and Engineering Ethics 719, 727 (2012).

Summary: 2006 Call for Information on the Use of Nanomaterials, NAT'L INDUS. CHEMS. NOTIFICATION & ASSESSMENT SCHEME,

https://www.nicnas.gov.au/chemical-information/factshe

^{19041121193 1/}https://www.nicnas.gov.

 ¹⁷⁰ ISO/TC 229: Nanotechnologies, ISO, https://www.iso.org/committee/381983.html.
 ¹⁷¹ Id.

¹⁷² Cary Coglianese, *Environmental Soft Law as a Governance Strategy*, 61 JURIMETRICS 19 (2020).

legitimacy of the ISO standard setting process,¹⁷³ TC229's work program has and will continue to be a powerful force in shaping the governance landscape for technologies, from basic definitions through the material characterization and beyond.

The Organisation for Economic Co-operation and Development (OECD), a multi-lateral body consisting of today 38 member countries including the US, United Kingdom and many EU nations, initiated a formal program of work designed to assess the human and environment safety of certain nanomaterials used in commerce in 2006.¹⁷⁴ As noted by Visser, the scope of the OECD Working Party on Manufactured Nanomaterials (WPMN) was articulate under three work areas and ranged from, for example, classification and identification, through to test methods and risk assessment and information sharing.¹⁷⁵ A key output of the WPMN was the Testing and Assessment Programme that generated data on 11 nanomaterials for the purpose of generating data that could be then used to inform OECD testing guidelines for nanomaterials.¹⁷⁶ Despite limitations,¹⁷⁷ the dossiers created by the sponsors created new scientific knowledge for the testing of nanomaterials and advanced regulatory testing guidelines.¹⁷⁸ While it appears that the WPMN's work program has now come to a close, the data generated under its auspices is likely to inform policy and regulatory decision making for a number of years to come.

While voluntary unilateral activities may play a role in shaping the governance paradigm for quantum, one of the key lessons from nanotechnologies is the significant role that multi-lateral activities can play in shaping the ecosystem in which the technology will emerge. The

¹⁷³ Evisa Kica Diana M. Bowman, *Regulation by Means of Standardization: Key Legitimacy Issues of Health and Safety Nanotechnology Standards*, 53 JURIMETRICS 11, 38 (2012).

¹⁷⁴ Report of the OECD Workshop on the Safety of Manufactured Nanomaterials: Building Co-operation, Co-ordination and Communication 12 (2006), chrome-

 $extension://efaidnbmnnnibpcajpcglclefindmkaj/https://one.oecd.org/document/env/jm/mon o(2009)20/rev/en/pdf \,.$

¹⁷⁵ ROB VISSER, A SUSTAINABLE DEVELOPMENT FOR NANOTECHNOLOGIES: AN OECD PERSPECTIVE 320, 328-29 (Graeme A. Hodge et al. eds. 2007).

¹⁷⁶ Kirsten Rasmussen et al., Review of Achievements of the OECD Working Party on Manufactured Nanomaterials' Testing and Assessment Programme, 74 REG. TOX. & PHARM. 147, 149 (2016).

¹⁷⁷ See e.g., Steffen F. Hansen et al., A Critical Analysis of the Environmental Dossiers from the OECD Sponsorship Programme for the Testing of Manufactured Nanomaterials, 4 ENV. SCIENCE: NANO 282 (2017).

¹⁷⁸ See generally, Kirsten Rasmussen et al., Developing OECD Test Guidelines for Regulatory Testing of Nanomaterials To Ensure Mutual Acceptance of Test Data, 104 REG. TOXICOLOGY & PHARM. 74–83 (2019).

development of standards for quantum technologies will be critical to scaling the technology, and with many OECD countries looking towards quantum technologies,¹⁷⁹ the intergovernmental organization is likely to similarly play a role in harmonizing activities relating to quantum technologies.

2. The EU will not be afraid to go it alone.

The RS-RAE's report,¹⁸⁰ and that of many other scientific publications,¹⁸¹ highlighted the uncertainty of, for example, the adequacy of current risk assessment paradigms for certain nanomaterials, as well as the potential human and environmental risks that may be posed by non-biodegradable, metal nanoparticles such as carbon nanotubes and buckyballs. In response, several NGOs called on governments to introduce a moratorium on the use of nanomaterials in personal care products and food stuffs,¹⁸² while the global reinsurance company Swiss Re argued for the use of the precautionary principle.¹⁸³

¹⁷⁹ Australian Government, Leading quantum company chooses Australia as site for its groundbreaking utility scale quantum computer, Apr. 30, 2024,

https://www.industry.gov.au/news/leading-quantum-company-chooses-australia-site-itsgroundbreaking-utility-scale-quantum-computer

¹⁸⁰ ROYAL SOC. & ROYAL ACAD. OF ENG., *supra* note 177, at 74–76.

¹⁸¹ See, e.g., O. Renn, & M.C. Roco Nanotechnology and the Need for Risk Governance, 8 J. OF NANOPARTICLE RSCH. 153 (2006); Andrew Maynard. Nanotechnologies: Overview and Issues, 1 NANOTECHNOLOGY TOX.ISSUES & ENV. SAFETY (2007); C.A. Polan et al., Carbon Nanotubes Introduced into the Abdominal Cavity of Mice Show Asbestos-like Pathogenicity in a Pilot Study, 3 NAT. NANOTECHNOLOGY423–28 (2008).

¹⁸² Friends of the Earth, *Nanomaterials, Sunscreens and Cosmetics: Small Ingredients, Big Risks* 22 (2006), at 17. https://lbps6437gg8c169i0yl drtgz-wpengine.netdna-ssl.com/wp-content/uploads/wpallimport/files/archive/Nanomaterials_sunscreens_and_cosmetics.pdf [https://perma.cc/N59 G-VQWD].

¹⁸³ Swiss Reinsurance Company, Nanotechnology: Small Matter, Many Unknowns, 2004; Peter Montague, *Welcome to NanoWorld: Nanotechnology and the Precautionary Principle Imperative*, 25 MULTINATIONAL MONITOR, Sept. 2004, at 16, 18.

Against this backdrop, jurisdictions including the European Union,¹⁸⁴ Australia¹⁸⁵ and New Zealand¹⁸⁶ sought to undertake in-house or independent reviews of their existing regulatory frameworks to stress test them against new and emerging nano-applications. Each review highlighted the lack of nano-specific provisions within the legislative frameworks but suggested that most applications would fall under existing regimes, with some tweaking needed. Arguably, the proactive nature of these jurisdictions was in response to earlier introduction of GMOs, and the backlash that accompanied them.¹⁸⁷

Despite the uncertainty in what legislative action may be needed to regulate certain nanotechnology applications effectively and proportionally members of the European Parliament made a last-minute attempt to introduce nano-specific provisions during the second reading of the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation – the EU's new regulatory framework for chemical substances.¹⁸⁸ While unsuccessful, the action signaled the EU's commitment to being the first mover on introducing nano-specific legislation.

Industries and commentators alike did not have to wait for long. The passage of *Regulation (EC) No. 1223/2009 on cosmetic products (the Cosmetic Regulation)* by the European Parliament in November 2009 provided members of parliament with the opportunity to introduce nano-

¹⁸⁴ See Review of the Adequacy of Current Regulatory Regimes To Secure Effective Regulation of Nanoparticles Created by Nanotechnology: The Regulations Covered by HSE, HEALTH & SAFETY EXEC. (2006).; Q. Chaudhry et al., Final Report: A Scoping Study To Identify Gaps in Environmental Regulation for the Products and Applications of Nanotechnologies, DEFRA. SCI. & RSCH. (2006); Report of the FSA Regulatory Review, FOOD STANDARDS AGENCY (2006). The Toxicology of Nanoparticles Used in Healthcare Products, COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT (2006); Regulatory Aspects of Nanotechnologies, CHM, LONDON; EUR. COMM'N (2008). SEC(2008) 2036, EUR. COMM'N (June 17, 2008).

¹⁸⁵ K. Ludlow et al., *A Review of Possible Impacts of Nanotechnology on Australia's Regulatory Framework*, MONASH UNIV. (2007).

¹⁸⁶ C. Gavaghan & J. Moore, A Review of the Adequacy of New Zealand's Regulatory Systems To Manage the Possible Impacts of Manufactured Nanomaterials, UNIV. OF OTAGO (2011).

¹⁸⁷ See, e.g., A. Prakash& K. L. Kollman *Biopolitics in the EU and the US: A Race to the Bottom or Convergence to the Top?*, 47 INT'L STUDIES Q. 617 (2003); Y. Devos et al., *Coexistence in the EU-Return of the Moratorium on GM Crops?*, 26 NAT.

BIOTECHNOLOGY 1223 (2008); R. Hindmarsh& A. Parkinson, *The Public Inquiry as a Contested Political Technology: GM Crop Moratorium Reviews in Australia*, 22 ENVIRONMENTAL POLITICS 293–311 (2013).

¹⁸⁸ Diana M. Bowman& G. Van Calster, *Does REACH Go too far*?, 2 NAT. NANOTECHNOLOGY 525, 525 (2007).

specific provisions in legislation for the first time. In addition to providing a definition for what a "nanomaterial" was for the purposes of the Regulation, the Cosmetic Regulation introduced labeling requirements for products containing nanomaterials (Article 19(1)(g)), and placed safety data reporting requirements on the industry. The passage also signaled a shift by the EU away from transatlantic coordination on the governance of certain domains of the technology.

The recasting of the regulatory framework for food labelling provided the European Parliament with a second opportunity to introduce nano-specific provisions. The passage of Regulation (EC) No. 1169/2011 on the provision of food information to consumers (the Food Information Regulation) sought to define what a nanomaterial was for the purposes of the Regulation, and placed a requirement on industry to label foods that contain nanomaterials accordingly. Both remain law today.

In contrast, countries such as the United States articulated a regulatory pathway that would not include any new, nano-specific provisions.¹⁸⁹ Rather, existing regulatory tools such as the Special New Use Rules (SNURs) found within the Environmental Protection Agency's Toxic Substances Control Act.¹⁹⁰ This approach arguably favored industry, as well as the US government itself, which has invested over US\$43 billion nanotechnology research and development (R&D) through the National Nanotechnology Initiative alone,¹⁹¹ along with other research programs. Commentators have pointed to this inherent "balancing act" by government in terms of supporting both innovation and ensuring appropriate regulation for the technology.¹⁹²

The EU has already shown its willingness to be at the forefront of regulating other technologies that have the potential to negatively impact EU citizens wellbeing (however defined). The passage of the General Data

¹⁸⁹ *ReadoutL Advancing U.S> Leadersihop in Nanotechnology*, THE WHITE HOUSE (Mar. 6 2024), ttps://www.whitehouse.gov/ostp/news-updates/2024/03/06/readout-advancing-u-s-leadership-in-nanotechnology.

¹⁹⁰ See, e.g., J. C. Monica Jr.& J.C. Monica, *Examples of Recent EPA Regulation of Nanoscale Materials Under the Toxic Substances Control Act*, 6 NANOTECHNOLOGY L. & BUS. 388 (2009).

¹⁹¹ As of 2024, the US government had invested 42 billion USD in the NNI since its inception in 2001. This includes the 2.16 billion USD requested for 2024. *See NNI Supplement to the President's 2024 Budget*, NNI (Mar. 30, 2024), https://www.nano.gov/2024BudgetSupplement.

¹⁹² Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard, Introduction: the regulatory challenges for nanotechnologies, in *International handbook on regulating nanotechnologies* (Graeme A. Hodge, Diana M. Bowman and Andrew D. Maynard eds, 2010), p.17.

Protection Regulation (Regulation 2016/679), which created protections around EU citizen's personal data and privacy, and the Artificial Intelligence Act (AI Act), were the first comprehensive national or supranational pieces of legislation of their type. Given these precedents, we argue that the EU is more likely than not to be the first jurisdiction to pass legislation targeting quantum technologies.

3. Hype and hyperbole.

The early days of nanotechnologies were characterized as being one of both nano-hope and nano-hype. As noted above, some commentators focused on the next economic revolution which would be underpinned by nanotechnologies, while others referenced the unknown potential harms to human and environmental health.¹⁹³ Other commentators pointed to a new nano-divide and articulated ethical concerns,¹⁹⁴ while some spoke of revolutionary new treatments for cancer and other diseases.¹⁹⁵

What is clear today, more than twenty years after many of these opinions were offered up, is that many of the speculative futures offered up by experts—both optimistic and pessimistic—have not occurred. Based on the scientific data, and the real-world testing of nano-based applications in the market, risks were overhyped and promises oversold. What we have been largely given has been wrinkle and stain resistant¹⁹⁶ and stronger and more effective tennis rackets and golf clubs.¹⁹⁷ To date, there is no evidence to suggest a new wave of mesothelioma or silicosis like diseases in individuals who manufacture nanomaterials, nor—arguably apart from the nanotechnology-based vaccine for COVID-19¹⁹⁸—has the technology proven to be a panacea against disease.

This is likely to be true for quantum technologies. Scientists, policy makers and industry are likely to use the same playbook used for nanotechnologies to justify large-scale public-sector investments in

¹⁹³ ROYAL SOC. & ROYAL ACAD. OF ENG., supra note 177, at 35-49.

¹⁹⁴ R. Sparrow, *New Global Frontiers in Regulation: The Age of Nanotechnology*, NEGOTIATING THE NANODIVIDES 87, 87–107 (2007).

¹⁹⁵ R. F. Service, *Nanotechnology Takes Aim at Cancer*, 310 SCIENCE 1132, 1132–34 (2005).

¹⁹⁶ Marina E. Vance Todd Kuiken, Eric P. Vejerano, Sean P. McGinnis, Michael F. Hochella Jr, David Rejeski, and Matthew S. Hull, Nanotechnology in the real world: Redeveloping the nanomaterial consumer products inventory 6, ." *Beilstein journal of nanotechnology* 6, 1772 (2015).

 ¹⁹⁷ L. P. da Costa, *Engineered Nanomaterials in the Sports Industry*, *in* HANDBOOK OF NANOMATERIALS FOR MANUFACTURING APPLICATIONS at 309–20 (2020). NOTE – this is a smaller work contained within a larger collection so this is the proper citation format).
 ¹⁹⁸ S. Friedrichs& Diana M. Bowman, *COVID-19 May Become Nanomedicine's Finest Hour Yet*, 16 NAT. NANOTECHNOLOGY 362, 362 (2021).

quantum technologies. Billions of dollars in investment will be spent based on the framing of economic competitiveness, scientific leadership and security.¹⁹⁹ Whether or not quantum technologies live up to these promises will remain to be seen. But nanotechnologies have arguably underperformed to date.

4. Social and ethical considerations are critical for widespread acceptance

The governance journey of nanotechnologies demonstrates the increasingly important role social considerations play in the development of regulations.²⁰⁰ Burgeoning technologies like nanotechnologies, like quantum today, raised concerns over the economic, social, and ethical consequences of its application. The concern, generally, was that entities, both states and companies, who were already ahead could use the technology to reinforce their dominance, or that the technology would reinforce social inequities if there is limited input.²⁰¹ How a technology is perceived influences investment into its development and whether nanobased products are accepted depends on their perceived social costs and benefits.²⁰² As noted by David Wallace, "In the end, with or without the intervention of clear regulatory oversight, the management of technology in society is about the democratic process, defined by the consent of the people."²⁰³

In this respect, nanotechnologies were hugely successful. Nanotechnology governance stressed diversity and engagement.²⁰⁴ Despite the disappointments of voluntary programs, the inclusion of experts of stakeholders, even those outside the world of nanotechnology, provided critical perspectives.²⁰⁵ With such a diverse set of stakeholders,

¹⁹⁹ James Woodford, *Australia Places A\$1 billion Bet on Quantum Computing Firm PsiQuantum*, NEW SCIENTIST, (Apr. 20, 2024),

https://www.newscientist.com/article/2428987-australia-places-a1-billion-bet-on-quantum-computing-firm-psiquantum.

 ²⁰⁰ See Kenneth W. Abbott, Gary E. Marchant, and Elizabeth A. Corley, Soft Law Oversight Mechanisms for Nanotechnology, 52 JURIMETRICS J. 279, 282 (2012).
 ²⁰¹ Id. at 280 (citing Georgia Miller & Gyorgy Scrinis, The Role of NGOs in Governing Nanotechnologies: Challenging the 'Benefits Versus Risks' Framing of Nanotech Innovation, in INTERNATIONAL HANDBOOK ON REGULATING NANOTECHNOLOGIES 409, 414-419 (Graeme Hodge et al. eds., 2011)).

 ²⁰² See David L. Wallace, Mediating the Uncertainty and Abstraction of Nanotechnology Promotion and Control, 5 NANOTECHNOLOGY L. & BUS. 309, 311 (2008).
 ²⁰³ Id. at 312.

²⁰⁴ Andrew Maynard, *The Nanotechnology Buzz of the Past Should Inform the Way We View AI*, FAST COMPANY 4 (Oct. 3, 2023), https://www.fastcompany.com/90961294/the-nanotechnology-buzz-of-the-past-should-inform-the-way-we-view-ai. ²⁰⁵ *Id.* at 3.

nanotechnology application was both socially and economically beneficial.²⁰⁶

Forming such diverse collaboration, however, must be intentional. The public should be involved in voluntary governance programs and governments should require that private organizations include civil service organizations in their self-regulatory programs.²⁰⁷ NGOs, too, should be involved in voluntary regulatory programs.²⁰⁸ Their inclusion, and that of other stakeholders, fosters a sense of transparency and legitimacy for the technology and any voluntary framework they participate in.²⁰⁹ The good publicity and public goodwill that will come from the inclusion of diverse perspectives can also serve as positive incentives for firm participation.²¹⁰

C. Lessons from AI Governance

Artificial intelligence (AI) has been around since the 1940s,²¹¹ but it has gone through a series of rapid advances and lulls (sometimes called winters) over its 80-year history. It is only in past few years however that AI has become a priority of technology regulation and goverannce, due to advances such as machine learning and generative AI that have greatly increased the power and uptake of AI tools. While we are likely still relatively early in the era of AI technology and AI oversight, several important lessons for technology governance have already emerged.

1. The Pacing Problem is Real and Problematic

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 $^{^{206}}$ Id.

²⁰⁷ Abbott, Marchant & Corley, *supra* note 215, at 307 (citing IAN AYRES & JOHN BRAITHWAITE, RESPONSIVE REGULATION: TRANSCENDING THE DEREGULATION DEBATE (1992), at 54-60.

²⁰⁸ Steffen Foss Hansen & Joel Tickner, *The Challenges of Adopting Voluntary Health, Safety and Environment Measures for Manufactured Nano Materials*, 4 NANOTECH. L. & BUS., 341, 355 (2007) (citing Janice Mazurek, Government-Sponsored Voluntary Programs for Firms: An Initial Survey, *in* TOOLS FOR ENVIRONMENTAL PROTECTION 219 (Thomas Deitz & Paul C. Stern, eds., 2002)).

²⁰⁹ See *id.*, at 355-356; see Abbott, Marchant & Corley, *supra* note 215, at 307.

²¹⁰ Hansen & Tickner, *supra* note 223, at 356 (citing Seema Arora & Timothy N. Cason, An Experiment in Voluntary Environmental Regulation – Participation in EPA's 33/50 Program, 28(3) J. ENVT'L ECON. & MANAGEMENT 271 (1995)).

²¹¹ See STUART RUSSEL AND PETER NORVIG, ARTIFICIAL INTELLIGENCE: A MODERN APPROACH 18-19 (4th ed., 2021) (explaining that Alan Turing's theory of computation combined with early work by Warren McCulloch and Walter Pitts dating back to 1943 formed the basis of AI. The authors also note "Marvin Minsky (1969) and John McCarthy (1971)—the person credited with coining the term AI in 1956— for defining the foundations of the field based on representation and reasoning..." among many others). *Id.*

The pacing problem is the tendency of technology to advance faster than the government regulation for that technology, leaving both governance gaps and outdated regulatory provisions.²¹² This problem is at its extreme with AI, as there are new technological advances on almost a weekly basis, while regulation has struggled to move forward at all. In fact, the U.S. Congress has not enacted any binding regulatory requirements for AI, and even though dozens of bills have been introduced into Congress, the legislative body has only passed a couple general Ai bills that do not impose mandatory requirements on industry.²¹³ In the absence of national legislation, some states such as Colorado—the first state to pass an AI law²¹⁴—have proposed legislation targeting misuse of AI, but only in clearcut cases such as algorithmic discrimination and racial bias.²¹⁵

The AI case study demonstrates that traditional government regulation is not capable of keeping pace with a rapidly advancing technology such as AI (or quantum). While government regulation may eventually fill in some of the resulting governance gaps, that may not happen for many years, and in the meantime alternative forms of

²¹² Gary E. Marchant, *The Growing Gap Between Emerging Technologies and the Law, in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT: THE PACING PROBLEM 19, 22–23 (Gary E. Marchant et al. eds., 2011) [hereinafter Marchant, PACING]; World Economic Forum, Agile Regulation for the Fourth

Industrial Revolution: A Tool Kit for Regulators 6 (Dec. 2020), available at https://www.weforum.org/about/agile-regulation-for-the-fourth-industrial-revolution-a-toolkit-for-regulators.

²¹³ The first meaningful US legislation focusing on AI was the John S. McCain National Defense Authorization Act (NDAA), Pub. L. No. 115-232 § 238(g), 132 Stat. 1636, 1697-98 (2018). The AI provisions of the 2019 NDAA were primarily intended for the Department of Defense (DoD) to study, coordinate, develop, and mature AI for operationalized use and generally not intended for industry governance. Two years later Congress enacted the National Artificial Intelligence Initiative Act of 2020 (NAIIA), which was intended to maintain U.S. primacy in AI research and development, coordinate AI research efforts primarily via the National AI Advisory Committee, to develop and use trustworthy AI, and to prepare the present and future U.S. workforce for integration of AI systems across all sectors of the economy and society. The NAIIA was promulgated as part of the Div. E, William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, Pub. L. 116-283, 134 Stat. 4523, 15 USC § 9401 note. The NAIIA also imposes no mandatory requirements on private industry, but rather encourages a cooperative approach to governance. 15 U.S.C. 278h-1(c), and (d)(2) (describing the intent for collaboration between the federal government and industry to develop consensus for acceptable best practices).

²¹⁴ Chris Marr, US's First State AI Bias Law Lets Job Seekers Fight Rejections, BLOOMBERG LAW (May 22, 2024, 10:44 AM), <u>https://news.bloomberglaw.com/daily-labor-report/colorado-ai-law-lets-job-seekers-contest-employers-rejections</u>.

²¹⁵ Colo. Rev. Stat. § 6-1-1701 (2024). (Portions to take effect on Feb. 1, 2026 and entitled An Act Concerning Consumer Protections in Interactions with Artificial Intelligence Systems). *Id.*

governance are needed. These alternative governance tools include more agile and nimble soft law programs such as voluntary and partnership programs, private standards, and industry self-regulation. ²¹⁶

2. Voluntary Soft Law Approaches are Necessary but Controversial

In the absence of traditional government regulation, AI goverannce to date in the United States has consisted primarily of soft law approaches. While these soft law approaches have not been perfect (nor has any traditional regulatory program on any issue), one can hardly imagine how much harm might have been inflicted if there had not been a myriad of company ethical codes, industry standards, voluntary commitments and programs, certification programs, partnership agreements, and other voluntary programs.

An example of a government-lead soft law program is NAIIA's direction to the National Institute of Standards and Technology (NIST), part of the Department of Commerce, to create a "voluntary risk management framework for trustworthy artificial intelligence systems."²¹⁷ In January 2023 the NIST completed the Artificial Intelligence Risk Management Framework 1.0.²¹⁸ The AI RMF includes several provisions for development of trustworthy AI, assessing the AI's degree of trustworthiness, and proposes mechanisms for assessing risk for the same.²¹⁹ As noted above, however, neither the AI RMF nor the NAIIA impose any enforcement mechanisms electing instead to encourage voluntary collaboration and responsible practice.²²⁰

Another example of soft law governance of AI is that OpenAI, and many other companies including Meta, Anthropic, and Google made voluntary commitments to the White House to "promote the safe, secure,

https://doi.org/10.6028/NIST.AI.100-1 [hereinafter AI RMF]. 219 Id.

²¹⁶ Gary Marchant, Lucille Tournas & Carlos Ignacio Gutierrez, *Governing Emerging Technologies Through Soft Law: Lessons for Artificial Intelligence- An Introduction*, 61 JURIMETRICS 1, 5-9 (2020)

²¹⁷ 15 U.S.C. § 278h–1(c). (The NIST is administratively under the Department of Commerce).

²¹⁸ NAT. INST. OF STDS. AND TECH., NIST AI 100-1, ARTIFICIAL INTELLIGENCE RISK MANAGEMENT FRAMEWORK (AI RMF 1.0) (Jan. 26, 2023),

²²⁰ See, Press Release, Nat. Inst. of Stds. and Tech., NIST Risk Management Framework Aims to Improve Trustworthiness of Artificial Intelligence (Jan. 26, 2023), https://www.nist.gov/news-events/news/2023/01/nist-risk-management-framework-aims-

improve-trustworthiness-artificial.

and transparent development and use of AI technology."²²¹ For example, OpenAI asserted in its statement that it pledges to "pilot and refine concrete governance practices" tailored to OpenAI's models.²²² These voluntary commitments included many obligations that would have likely taken many years to implement through traditional legislation, but were adopted very quickly using voluntary measures.

While these and many other voluntary Ai initiatives have no doubt provided significant public benefits in reducing risks, they are criticized by many for the lack of accountability, effectiveness and credibility. In the wake of other corporate malfeasance by companies such as Boeing, Volkswagen and Theranos,²²³ many view corporate self-regulation as the "fox guarding the henhouse." For example, Helen Toner and Tasha McCauley, two former members of the OpenAI board who voted to fire Sam Altman, recently wrote "we believe that self-governance cannot reliably withstand the pressure of profit incentives" and that "[s]ociety must not let the roll-out of AI be controlled solely by private tech companies.... Governments must play an active role."²²⁴ Other notable OpenAI leaders agree. For example, executive Jan Leike joins a number of other safetyfocused personnel leaving Open AI stating that "over the past years, safety culture and processes [at OpenAI] have taken a backseat to shiny products."²²⁵

https://www.whitehouse.gov/briefing-room/statements-releases/2023/07/21/fact-sheetbiden-harris-administration-secures-voluntary-commitments-from-leading-artificialintelligence-companies-to-manage-the-risks-posed-by-ai/?utm_source=link. The companies making commitments were Amazon, Anthropic, Google, Inflection, Meta, Microsoft, and OpenAI. *Id*.

https://www.cnn.com/2024/05/17/tech/openai-exec-exits-safety-concerns/index.html.

²²¹ Press Release, OpenAI, Moving AI Governance Forward (Jul. 21, 2023), <u>https://openai.com/index/moving-ai-governance-forward/</u>. [hereinafter OpenAI Press Release] *See also*, Press Release, The White House, FACT SHEET, Biden-Harris Administration Secures Voluntary Commitments from Leading Artificial Intelligence Companies to Manage the Risks Posed by AI (Jul. 21, 2023),

²²² Id.

²²³ See e.g., G.S. Hans, *How and Why Did It Go So Wrong?: Theranos as a Legal Ethics Case Study*, 37 GA. STATE UNIV. L. REV. 427 (2021) *et seq.*, *and* Press Release, U.S. Attorney's Office, Theranos Founder Elizabeth Holmes Found Guilty of Investor Fraud (Jan. 4, 2022), https://www.justice.gov/usao-ndca/pr/theranos-founder-elizabeth-holmes-found-guilty-investor-fraud.

²²⁴ Helen Toner and Tasha McCauley, *AI firms mustn't govern themselves, say ex-members of OpenAI's board*, THE ECONOMIST (May 26, 2024), <u>https://www.economist.com/by-invitation/2024/05/26/ai-firms-mustnt-govern-themselves-say-ex-members-of-openais-board</u>.

²²⁵ Clare Duffy, *More OpenAI drama: Exec quits over concerns about focus on profit over safety*, CNN BUSINESS (May 17, 2024 4:07 PM),

Professor Roberto Tallarita recently wrote "[t]he boardroom war at OpenAI, the company behind ChatGPT, has put a spotlight on the role of corporate governance in AI safety."²²⁶ He continues, "what is likely to prove the most important technological innovation of our lifetime is currently overseen by corporate governance — the set of rules, mostly of private creation, that allocate power and manage conflicts within a corporation."²²⁷ Professor Tallarita highlights that the corporate structures of both OpenAI and Anthropic—companies who initially organized for altruistic versus profit-centric reasons—are not easily able to hold their officers accountable based on their underlying corporate structures.²²⁸ In other words, key developers of what Demis Hassabis, the Google DeepMind Chief Executive Officer (CEO), has referred to as the "most important invention humans will ever make" are faced with difficult corporate accountability systems—a fact recently highlighted by OpenAI in firing and then re-hiring CEO Sam Altman.

One measure that could be implemented, either by regulation or by non-regulatory means, would be a public reporting requirement for potentially risky activities of AI developers. For example, Section 409 of the Sarbanes-Oxley Act requires public companies to now make "real-time disclosures" on a "rapid and current basis" any "information concerning material changes in the financial condition or operations of the [stock] issuer, in plain English, which may include trend and qualitative information and graphic presentations...."²²⁹ Such a reporting requirement is not burdensome and accomplished on a simple form. However, information in the report is critical to maintain transparency and accountability—cornerstones of any corporate governance framework and, arguably, unattainable without some type of reporting apparatus.²³⁰

²²⁶ Roberto Tallarita, AI Is Testing the Limits of Corporate Governance, HARV. BUS. REV. (Dec. 5, 2023), <u>https://hbr.org/2023/12/ai-is-testing-the-limits-of-corporate-governance</u>. Also available at, <u>https://dx.doi.org/10.2139/ssrn.4693045</u>. Arguing that the law and economics of corporate governance can be used to identify emerging AI governance concerns. Prof. Tallarita outlines five lessons and warns that corporate governance cannot handle catastrophic risk. *Id*.

²²⁷ Id.

²²⁸ *Id. See also* Ted Ladd, *The Lesson Of OpenAI Is That Governance Matters*, FORBES (Dec. 15, 2023 6:00 PM), <u>https://www.forbes.com/sites/tedladd/2023/12/15/the-lesson-of-openai-is-that-governance-matters/?sh=70b5b05825e8</u>. Arguing that OpenAI should restructure its corporate model to one similar to Anthropic because OpenAI's structure—a for-profit holding company that owns a not-for-profit developer—will block OpenAI's ability to achieve its mission. *Id.*

²²⁹ 15 U.S.C. § 781.

²³⁰ Arguably, the current amended language of the Securities Exchange Act of 1934, 15 U.S.C. § 781-m could also be read to mandate such a reporting requirement for high-risk

Some type of reporting requirement would be a good starting point and also support the over-arching policy and governance goals of transparency and accountability.

A number of other indirect enforcement measures can enhance the effectiveness and credibility of soft law measures. Marchant and Guiterrez provide a "toolbox" of thirteen such types of measures, including trade association programs, insurance company risk management requirements, partnerships with non-governmental organizations, supply change product stewardship and professional society codes of ethics²³¹

A strong lesson from the AI experience is that voluntary selfregulatory measures may be helpful for internal risk management, but will not provide public trust or transparency without one or more reporting tools which ensure accountability while also functioning to assure the public that the voluntary measures are being implemented.

3. Too Many Soft Law Proposals Create Confusion

One of the reported benefits of soft law approaches is that they encourage variety and experimentation.²³² Governance is not limited to one government agency implementing one regulatory program. Rather, many types of organizations can participate in creating governance programs, and a variety of approaches can be tried, letting "a 1000 flowers bloom."²³³ However, too many soft law proposals can create a confusing mess that may be hard to gain traction and effective governance. One study showed that there were over 600 AI soft law programs by the end of 2021.²³⁴ That number has only grown since then.

It would be more effective for industry and other stakeholders to agree on one central approach earlier on and then build on that. Indeed, such an approach seemed possible with AI with the NIST AI Risk

content/uploads/sites/9/2023/06/PI_2023.06.21_Best-Worst-Digital-Life_2035_FINAL.pdf. (Reporting that many experts believe that AI tools such as ChatGPT will start with a "'let-a-thousand-flowers-bloom' strategy for a few years."). *Id.* ²³⁴ See Carlos Ignacio Gutierrez et al., *Transitioning From Ideas to Action: Trends in the Enforcement of Soft Law for the Governance of Artificial Intelligence*, 2 IEEE TRANSACTIONS ON TECH. AND SOC. 210 et seq. (Dec. 2021).

AI, especially if the company's financial position could be substantially altered as a result of the same.

²³¹ Gary Marchant & Carlos Ignacio Gutierrez, *Soft Law 2.0: An Agile and Effective Governance Approach for Artificial Intelligence*, 24 MINN. J.L. SCI. & TECH. 375, 403-424 (2023).

²³² *Id.* at 385.

²³³ Janna Anderson and Lee Rainie, *As AI Spreads, Experts Predict the Best and Worst Changes in Digital Life by 2035*, PEW RESEARCH CTR.153 (June 21, 2023), https://www.pewresearch.org/internet/wp-

assessment framework, discussed above.²³⁵ Yet, while the NIST RMF has been influential with legislators, standard-setting organizations, academic experts and many others, its formal adoption by industry has been sporadic and limited, with many major AI developers building their own AI governance frameworks.

One key adherent to the NIST model is Microsoft, which has stated that they "will implement the NIST AI Risk Management Framework and attest to alignment with it to customers."²³⁶ Microsoft has further recommended that the government require vendor "self-attestation" to the same prior to the procurement of any AI vendor products.²³⁷

Both IBM and Google have committed to following the AI RMF, but in vastly different ways than Microsoft. For example, IBM, one of the companies involved in helping to create the AI RMF, performed an internal study and concluded that IBM's "internal standards, policies, and practices are aligned with the NIST AI RMF" ostensibly making neither true commitments nor affirmative changes.²³⁸ Alternatively, Google AI's general approach appears to seek alignment of their own independent "Secure AI Framework"²³⁹ with both the AI RMF and the larger International Organization for Standardization's (ISO's)²⁴⁰ "AI Management Standard" (AIMS) promulgated under ISO/IEC 42001:2023.²⁴¹

²³⁵ See supra notes _--__ and accompanying text.

²³⁶ Microsoft Corporation, Inc., *Voluntary Commitments by Microsoft to Advance Responsible AI Innovation*, THE OFFICIAL MICROSOFT BLOG 4 (Jul. 21, 2023), https://blogs.microsoft.com/wp-content/uploads/prod/sites/5/2023/07/Microsoft-Voluntary-Commitments-July-21-2023.pdf

²³⁷ Id.

²³⁸ Heather Domin and Alina Glaubitz, *IBM's Approach to Implementing the NIST AI RMF*, IBM.COM (Sep. 26, 2023), <u>https://www.ibm.com/policy/ibms-approach-to-implementing-the-nist-ai-rmf/</u>.

²³⁹ Royal Hansen and Phil Venables, *Introducing Google's Secure AI Framework*, THE KEYWORD (Jun. 8, 2023), https://blog.google/technology/safety-security/introducing-googles-secure-ai-framework/

²⁴⁰ The ISO acronym was chosen "[b]ecause 'International Organization for Standardization' would have different acronyms in different languages (IOS in English, OIN in French for *Organisation internationale de normalisation*), its founders opted for the short form 'ISO'. The story goes that ISO is derived from the Greek word 'isos', meaning equal." *See*, Int'l. Org. for Standards, *About ISO*, <u>https://www.iso.org/about</u> (last visited Jun. 20, 2024).

²⁴¹ The full title is "Information Technology — Artificial Intelligence — Management System" promulgated under ISO/IEC 42001:2023 and is available for purchase on the ISO website at: <u>https://www.iso.org/standard/81230.html</u>. *See*, Jeanette Manfra and Nick Godfrey, *Coalfire evaluates Google Cloud AI: 'Mature,' ready for Governance, compliance*, GOOGLE CLOUD BLOG (May 30, 2024),

Key start-up companies are also electing to write their own independent governance regimes irrespective of partnerships they may have with other leading AI companies. For example, OpenAI, creators of ChatGPT, DALL·E, and Sora, and heavily financed by Microsoft,²⁴² elected to create their own "Preparedness Framework (Beta)."²⁴³ The OpenAI Framework organizes its governance mitigation system into four Tracked Risk Categories: Cybersecurity, Chemical, Biological, Nuclear, and Radiological (CBRN), Persuasion, and Model Autonomy which are then assessed against low, medium, high, and critical risk criteria.²⁴⁴ Anthropic, the Public Benefit Corporation (PBC) that invented the Claude and Opus generative LLMs, also follows their own AI governance model.²⁴⁵ Similar to OpenAI, their policy is also independent despite major funding partnerships with both Amazon and Google.²⁴⁶ Anthropic's "Responsible Scaling Policy (RSP)" is a four-tiered framework "modeled loosely after the US government's biosafety level standards" for handling biohazards.²⁴⁷

So even among the major AI developers, there is considerable variation in whether and how the NIST RMF is being implemented. Other

²⁴³ Preparedness Framework (Beta) 5, OPENAI (Dec. 18, 2023),

https://cloud.google.com/blog/products/identity-security/coalfire-evaluates-google-cloudai-mature-ready-for-governance-compliance.

²⁴² See, Dina Bass, *Microsoft Invests \$10 Billion in ChatGPT Maker OpenAI*, BLOOMBERG (Jan. 23, 2023, 7:06 AM), https://www.bloomberg.com/news/articles/2023-01-

^{23/}microsoft-makes-multibillion-dollar-investment-in-openai. See also, Tim Bradshaw, et al., How Microsoft's Multibillion-Dollar Alliance with OpenAI Really Works, FINANCIAL TIMES (Dec. 15, 2023), https://www.ft.com/content/458b162d-c97a-4464-8afc-

<u>72d65afb28ed</u>. (Discussing how Microsoft maintains a 49% ownership interest in OpenAI while investing an estimated \$13 billion over the life of the company). *See also*, Microsoft Corporation, Annual Report (Form10-K) (Jun. 30, 2023). (Describing Microsoft and OpenAI's relationship as a long-term strategic partnership).

<u>https://cdn.openai.com/openai-preparedness-framework-beta.pdf</u>. [hereinafter OpenAI Framework]

²⁴⁴ Id.

²⁴⁵ See generally, Michael R. Littenberg *et al.*, *Delaware Public Benefit Corporations*— *Recent Developments*, HARV. L. SCH. FORUM ON CORP. GOVERNANCE (Aug. 31, 2020), <u>https://corpgov.law.harvard.edu/2020/08/31/delaware-public-benefit-corporations-recent-developments/</u>. [hereinafter Anthropic]. (Outlining that a PBC shields the company's board and leadership from shareholder suit if the company is not profitable).

²⁴⁶ See, Devin Coldewey, Amazon doubles down on Anthropic, completing its planned \$4B investment, TECHCRUNCH (Mar. 27, 2024, 3:22 PM PDT),

https://techcrunch.com/2024/03/27/amazon-doubles-down-on-anthropic-completing-itsplanned-4b-investment/, and, Krystal Hu, Google agrees to invest up to \$2 billion in OpenAI rival Anthropic, REUTERS (Oct. 27, 2023, 5:21 PM), https://www.reuters.com/technology/google-agrees-invest-up-2-bln-openai-rival-anthropic-

wsj-2023-10-27/.

²⁴⁷ *Anthropic's Responsible Scaling Policy* 2, ANTHROPIC (Sep. 19, 2023), https://anthropic.com/responsible-scaling-policy.

variations in soft law implementation exist and further complicate coherent governance. For example, Stanford recently published the Artificial Intelligence Index Report for 2024 which reads "[n]ew research from the AI Index reveals a significant lack of standardization in responsible AI reporting." ²⁴⁸ The report continues by stating "[1]eading developers, including OpenAI, Google, and Anthropic, primarily test their models against different responsible AI benchmarks. This practice complicates efforts to systematically compare the risks and limitations of top AI models."²⁴⁹ Stanford's broader concern relates specifically to a lack of consistency in benchmarks that, when, if ever, reported, usually make the proposed findings inconclusive or unusable.²⁵⁰

In summary, while soft law plays an essential role in technology governance, especially in the early stages of a technology, too much variation and inconsistencies confuse and limit the effectiveness of governance. It would have been more effective if key stakeholders in the AI field could have converged on one or two key soft law programs early in the technology's development, rather than the wild west of hundreds of completing and conflicting soft law proposals we have now.

4. Fairness and Equity Are Critical for Successful Governance

Another important lesson from AI is the central importance of fairness and equity issues for the successful development of a technology and its goverannce. AI is littered with examples of biased or unfair outcomes in many different areas, including health care, employment, criminal justice, facial recognition technology, housing and financial services.

Some areas of bias, especially implicit bias, remain in healthcare and are amplified by AI. For example, a 2022 health sector review observed that though instances of provider-patient explicit racial bias have declined over time, implicit bias "remains unrelenting."²⁵¹ Such implicit sector bias has, unsurprisingly, been amplified through AI. A 2019 Center for Open Data Enterprise (CODE) study observed that the source of algorithmic bias

²⁴⁸ Stanford Univ. Human-Centered AI (HAI), Artificial Intelligence Index Report, STANFORD U. 161 (2024), <u>https://aiindex.stanford.edu/wp-</u> content/uploads/2024/05/HAI_AI-Index-Report-2024.pdf.

²⁴⁹ Id.

²⁵⁰ *Id.* at 170-71

²⁵¹ Monica B. Vela *et al.*, *Eliminating Explicit and Implicit Biases in Health Care: Evidence and Research Needs*, 43 ANNU. REV. OF PUB. HEALTH 477, 478 (2022), https://doi.org/10.1146/annurev-publhealth-052620-103528. (Ultimately finding "[n]o intervention in this review, however, achieved sustained reduction of implicit bias among health care professionals or trainees."). *Id.* at 493.

in healthcare relates primarily to the absence of "diversity in health data" resulting in data that is at "a higher risk of making a mistake."²⁵² Consequently the HHS Office of Minority Health (OMH) recommends a more diverse body of people to review and supervise the use of AI and to also introduce algorithms gradually and carefully as a "treatment plan" to mitigate bias.²⁵³

Similar issues are present in law enforcement's use of facial recognition technology (FRT). Several writers have noted substantial shortcomings of FRT especially in the context of proper identification of people from Black communities.²⁵⁴ Again, shortcomings relate mainly to training data and a lack of a full understanding of the impact of the same when deployed. An especially egregious example of this arose when the Detroit Police Department (PD) used FRT as the sole means to arrest Mr. Robert J.B. Williams resulting in him being mis-identified as a thief and detained for nearly thirty hours.²⁵⁵ Mr. Williams' civil settlement resulted in the Detroit PD agreeing to several procedural changes including mandatory corroborative investigative techniques and a complete ban on arrests based solely on FRT identification.²⁵⁶

Examples of AI bias in hiring decisions are also pervasive and are similarly tied to shortcomings in training data and deployment errors. For example, the Equal Employment Opportunity Commission (EEOC) recently settled a discrimination case for a tutoring company that deployed an Ai tool that automatically rejected "female applicants 55 or older and male applicants 60 or older" resulting in over 200 applicants being rejected based

²⁵² The Center for Open Data Enterprise (CODE), *Sharing and Utilizing Health Data for A.I. Applications: Roundtable Report* 13 HHS (2019),

https://www.hhs.gov/sites/default/files/sharing-and-utilizing-health-data-for-ai-applications.pdf.

²⁵³ See, Caleb J. Colón-Rodríguez, U.S. Dep't of Health and Human Services (HHS) Shedding Light on Healthcare Algorithmic and Artificial Intelligence Bias, HHS (July 12, 2023), https://minorityhealth.hhs.gov/news/shedding-light-healthcare-algorithmic-andartificial-intelligence-bias.

²⁵⁴ Thaddeus L. Johnson and Natasha N. Johnson, *Police Facial Recognition Technology Can't Tell Black People Apart*, SCIENTIFIC AMERICAN (May 18, 2023),

https://www.scientificamerican.com/article/police-facial-recognition-technology-cant-tellblack-people-apart/. See also, Karen Hao, A US Government Study Confirms Most Face Recognition Systems Are Racist, MIT TECH. REV. (Dec. 20, 2019),

https://www.technologyreview.com/2019/12/20/79/ai-face-recognition-racist-us-government-nist-study/.

²⁵⁵ Williams v. City of Detroit, No. 21-cv-10827 (E.D. Mich. Apr. 13, 2021).

²⁵⁶ Kashmir Hill, Facial Recognition Led To Wrongful Arrests. So Detroit Is Making Changes N.Y. TIMES (June 29, 2024),

https://www.nytimes.com/2024/06/29/technology/detroit-facial-recognition-falsearrests.html; see also, Williams v. City of Detroit, No. 21-cv-10827 (E.D. Mich. June 28, 2024).

solely on their age.²⁵⁷ One way that these AI shortcomings are being addressed are through "bias audits." For example, New York City (NYC) recently passed a law that imposed requirements on employers to audit "statistics about how often candidates of different races and sexes advance in an employer's hiring or promotion process when a particular automated tool is used" among others.²⁵⁸

Such AI audit measures are a good first step and may also address problems in how AI hiring software matches applicants with jobs. For example, LinkedIn discovered in an internal audit that their AI job matching software was biased towards men because men typically engaged more aggressively with their platform and tended to apply for jobs requiring work experience "beyond their qualifications" where women did not.²⁵⁹ To address this problem, LinkedIn deployed another separate "AI program to counteract the bias in the results in the first."²⁶⁰ Such independent audits, even if performed by a separate AI program, have yielded promising results.²⁶¹

Similar deployment and training data issues also exist in the fair housing context especially in the realm of AI "steering" buyer's choices based upon the "buyer's legally protected characteristics under federal law."²⁶² For example, Zillow discovered that their housing search and large

https://www.eeoc.gov/newsroom/itutorgroup-pay-365000-settle-eeoc-discriminatoryhiring-suit. See also, Equal Employment Opportunity Commission v. iTutorGroup, Inc., No. 1:22-cv-2565-PKC-PK (E.D.N.Y. filed May 5, 2022) (Aug. 9, 2023, joint notice of settlement and request for approval and execution of consent decree).

²⁵⁷ Press Release, U.S. Equal Emp. Opp. Comm., iTutorGroup to Pay \$365,000 to Settle EEOC Discriminatory Hiring Suit, Sep. 11, 2023,

²⁵⁸ Simon McCormack and Daniel Schwarz, *Biased Algorithms are Deciding Who Gets Hired. We're Not Doing Enough to Stop Them,* ACLU OF NEW YORK (Oct. 20, 2023), https://www.nyclu.org/commentary/biased-algorithms-are-deciding-who-gets-hired-werenot-doing-enough-stop-them. (The authors noted that in one an Ai algorithm determined that being named "Jared" and having played high school lacrosse were traits most highly associated with job success.) *Id.*

²⁵⁹ Sheridan Wall and Hilke Schellmann, *LinkedIn's job-matching AI was biased. The company's solution? More AI.*, MIT TECH. REV. (June 23, 2021),

https://www.technologyreview.com/2021/06/23/1026825/linkedin-ai-bias-ziprecruiter-monster-artificial-intelligence/

²⁶⁰ Id.

²⁶¹ See generally, Alex Engler, Auditing Employment Algorithms for Discrimination, BROOKINGS (Mar. 12, 2021), https://www.brookings.edu/articles/auditing-employment-algorithms-for-discrimination/.

²⁶²²⁶² Press Release, Zillow Group, Zillow providing open-source technology to promote fair housing in AI-powered real estate conversations, May 21, 2024,

https://investors.zillowgroup.com/investors/news-and-events/news/news-

details/2024/Zillow-providing-open-source-technology-to-promote-fair-housing-in-AI-powered-real-estate-conversations/default.aspx.

language model (LLM) software was "illegally steering" buyers to properties that were "disregarding fair housing requirements."²⁶³ In evaluating the issue, Zillow asked whether it would be illegal for a real estate agent to make purchasing recommendations based upon "protected demographic characteristic(s) of their client when making a home or neighborhood recommendation, or considers/relies upon the protected demographic characteristics of the neighborhood."²⁶⁴ In a large number of cases the answer was "yes" demonstrating their software was illegally steering clients based on their protected demographic characteristics. Consequently, Zillow recently elected to employ an additional open-source Fair Housing Classifier for LLMs to "establish guardrails to promote responsible and unbiased behavior in real estate conversations powered by LLM technology" similar to LinkedIn.²⁶⁵ Though steps to mitigate AI bias are in progress, they are slow and reactive.

These unfortunate and unfair outcomes occurred because the technology developer created and deployed their technology without expressly thinking of the potential biased and discriminatory results that would likely result. Because AI machine learning algorithms are trained on real world data, and that data is rife with biases and stereotypes, those same biases and stereotypes in the algorithmic inputs will be transferred to the algorithmic outputs.²⁶⁶ In fact, the biases and discrimination might even be exacerbated in the algorithmic outcome.²⁶⁷

The many examples of high-profile biased and discriminatory applications of AI did not just harm the reputation of the specific products and companies involved, but they also harmed the reputation of AI generally. The lesson is that fairness and equity factors must be considered at the outset and throughout technology development and will likely see success through AI audits and hiring more diverse employment teams.

²⁶³ Id.

 ²⁶⁴ Ondrej Linda *et al.*, *Navigating Fair Housing Guardrails in LLMs*, ZILLOW (Jan. 16, 2024), https://www.zillow.com/tech/navigating-fair-housing-guardrails-in-llms/.
 ²⁶⁵ AI Innovation Explored: Insights into AI Applications in Financial Services and Housing, Hearing Before the House Financial Services Committee, 118 Cong. (July 23, 2024) (Prepared Remarks of Mr. Ondrej Linda),

https://docs.house.gov/meetings/BA/BA00/20240723/117527/HHRG-118-BA00-Wstate-LindaO-20240723.pdf.

 ²⁶⁶ See generally, Lama H. Nazer et al., Bias in artificial intelligence algorithms and recommendations for mitigation, 2 PLOS DIGITAL HEALTH J. 1 (June 22, 2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10287014/pdf/pdig.0000278.pdf.
 ²⁶⁷ See e.g., Leonardo Nicoletti and Dina Bass, Humans Are Biased. Generative AI is Even Worse, BLOOMBERG (June 9, 2023), https://www.bloomberg.com/graphics/2023-generative-ai-bias/

V. TECHNOLOGY GOVERNANCE FRAMEWORKS

In addition to the technology governance lessons that are available from individual emerging technologies such as biotechnology, nanotechnology and AI, several organizations have put forward more generic governance frameworks for emerging technologies. As discussed below, some of these governance frameworks have an over-riding substantive focus, such as anticipation, agility, equity or sustainability. Others are more structural or procedural, such as frameworks emphasizing new governance/soft law, coordination bodies, or international governance. These various generic frameworks, discussed below, all provide relevant guidance for quantum governance, especially when integrated with the lessons discussed above from the individual emerging technologies.

A. Anticipatory Governance Frameworks

One set of governance frameworks focuses on anticipatory governance, which attempts to "get ahead" of the technology and to predict and manage potential risks of a technology before they occur.²⁶⁸ For example, the OECD has recently published a "Framework for Anticipatory Governance of Emerging Technologies."²⁶⁹ The document argues that the need for a general framework is needed for emerging technology governance because of the unique qualities of emerging technologies, including the political, technological and political uncertainty of the risks and benefits of emerging technologies, the tendency for emerging technologies to cut across multiple regulatory categories, the need to involve a broad range of stakeholders in cooperative governance, and the mismatch between the transboundary effects of technology and the legal jurisdictions that limit traditional government regulation.²⁷⁰ According to this Framework, anticipatory technology governance has five elements: (i) guiding values; (ii) strategic intelligence; (iii) stakeholder engagement; (iv) agile regulation, and (v) international cooperation.²⁷¹ Another framework that also emphasizes anticipation is Responsible Research and Innovation

²⁶⁸ David H. Guston, *Understanding 'Anticipatory Governance*," 44 SOCIAL STUD. SCI. 218 (2014).

²⁶⁹ OECD, Framework for Anticipatory Governance of Emerging Technologies (April 2024), https://www.oecd-ilibrary.org/fr/science-and-technology/framework-for-anticipatory-governance-of-emerging-technologies 0248ead5-en.

²⁷⁰ *Id.* at 9-10.

²⁷¹ *Id.* at 11.

(RRI), a concept developed in the European Union.²⁷² In this framework, governance actors and stakeholders intervene earlier in the innovation process to try to better align emerging technologies with societal interests.²⁷³ Much like the OECD framework, the RRI framework stresses the importance of "Upstream" engagement and deliberation. While initially developed for researchers, responsible innovation has been extended to the business sector.²⁷⁴

B. Agile Governance Frameworks

The flipside of these anticipatory frameworks, which attempt to predict and prepare for future technology impacts *before* they occur, are governance frameworks focused on *agility or adaptation*, which can quickly adjust to unanticipated developments *after* they occur. Once again, the OECD has been at the forefront of developing governance frameworks that emphasize agile governance. The OECD recently published a series of case studies that discussed the application of agile governance,²⁷⁵ and then adopted a resolution in support of agile governance.²⁷⁶ The OECD guidance calls on regulators to shift from the traditional "regulate and forget" mindset to a new "adapt and learn" paradigm.²⁷⁷ This includes building in "periodic adaptations,"²⁷⁸ experimental regulation,²⁷⁹ and a greater use of self-regulation or co-regulation.²⁸⁰ The guidance notes that given the rapidly shifting applicable governance oversight it will be important to put in place

 ²⁷² Grieger et al., *supra* note ___, at 9; Jack Stilgoe, Richard Owen & Phil Macnaghten,
 Developing a Framework for Responsible Innovation, 42 RESEARCH POLICY 1568 (2013).
 ²⁷³ Id.

²⁷⁴ Rob Lubberink et al., Lessons for Responsible Innovation in the Business Context: A Systematic Literature Review of Responsible, Social and Sustainable Innovation Practices, 9 SUSTAINABILITY 721 (2017).

²⁷⁵OECD, Case Studies on the Regulatory Challenges Raised by Innovation and the Regulatory Responses (2021), <u>https://www.oecd.org/publications/case-studies-on-the-</u> regulatory-challenges-raised-by-innovation-and-the-regulatory-responses-8fa190b5-<u>en.htm;</u> Guillermo Hernández & Miguel Amaral, Case Studies on Agile Regulatory Governance To Harness Innovation: Civilian Drones and Biosolutions, OECD Regulatory Policy Working Papers No. 18, https://www.oecd-ilibrary.org/fr/governance/case-studieson-agile-regulatory-governance-to-harness-innovation 0fa5e0e6-en.

²⁷⁶ OECD, Recommendation of the Council for Agile Regulatory Governance to Harness Innovation, OECD/LEGAL/0464, https://www.oecd.org/mcm/Recommendation-for-Agile-Regulatory-Governance-to-Harness-Innovation.pdf.

²⁷⁷ *Id.* at 9.

²⁷⁸ Id. at 12.

²⁷⁹ Id. at 14

²⁸⁰ Id. at 14.

robust mechanisms for public and stakeholder engagement "to enhance transparency, build trust and capitalize on various sources of expertise."²⁸¹

Other organizations, including the World Economic Forum²⁸² and IBM in partnership with the National Academy of Public Administration (NAPA),²⁸³ have also published frameworks for agile technology governance. The World Economic Forum report largely tracks the OECD guidance, recommending experimental regulation, sunsetting of regulations, continuous iteration of regulations, and co-regulation and self-regulation.²⁸⁴ The IBM/NAPA framework consists of 10 "agility principles" organized into three modules in the agility framework.²⁸⁵ These 10 agility principles are leadership, mission/vision, evidence, metrics, customers/public, networks, teams, innovation, speed and persistence.²⁸⁶ Implementing these 10 principles to achieve a more agile organization requires a conscious, organization-wide commitment to more agile and rapid actions.

C. Equitable Governance Frameworks

A third substantive focus of some technology governance frameworks is on *equity*. Equity has recently been recognized as a longneglected goal of technology, and for example has now been recommended as one of the key goals in evaluating new medical technologies along with goals such as improving population health, enhancing the care experience, and reducing cost.²⁸⁷ Based on this increased attention to the importance of equity, the U.S. National Academy of Sciences, Engineering and Medicine (NASEM) has recently proposed a new framework for technology

²⁸¹ *Id.* at 10.

²⁸² World Economic Forum, Agile Regulation for the Fourth Industrial Revolution: A Toolkit for Regulators (Dec. 2020),

https://www3.weforum.org/docs/WEF_Agile_Regulation_for_the_Fourth_Industrial_Revo lution_2020.pdf (hereinafter "WEF Agile Regulation"); World Economic Forum, Briefing Paper: Agile Governance for Creative

Economy 4.0 (Oct. 2019), https://www.weforum.org/publications/agile-governance-for-creative-economy-4-0/.

²⁸³IBM Center for the Business of Government & National Academy of Public Administration)NAPA), The Future of Agile Governance (2022),

https://www.businessofgovernment.org/report/future-agile-government.

²⁸⁴ WEF Agile Regulation, *supra* note __, at 12, 16, 32-34.

²⁸⁵ IBM/NAPA, *supra* note __, at 7-8.

²⁸⁶ *Id.* at 7.

²⁸⁷ Shantanu Nundy, Lisa A. Cooper & Kedar S. Mate, *The Quintuple Aim for Health Care Improvement: A New Imperative to Advance Health Equity*, 327 JAMA 521 (2022).

governance that centers on equity.²⁸⁸ The framework recognizes that "[t]here is both encouraging precedent and a disappointing lack of attention to equity in the history of technology governance in the United States."²⁸⁹

The framework begins with defining equity, which has at least eight dimensions: (a) topical equity, (b) innovator equity; (c) input equity; (d) evaluation equity; (e) deployment equity: (f) value capture equity; (g) contextual equity; and (h) attention equity.²⁹⁰ Each form of equity must be evaluated and measured in each stage of the technology innovation.²⁹¹ While the governance framework obviously must consider a variety of factors and inputs,²⁹² these equity factors should be at the forefront to ensure equitable technology development, which is critical for populationwide support and uptake of the technology. To ensure this outcome, the following "five cross-cutting imperatives underpin this new governance framework and will need to be embraced by innovators, funders, investors, purchasers, and users: (i) broadening participation and sharing responsibility to empower a wider range of stakeholders; (ii) aligning incentives to encourage equitable decision making; (iii) determining how inequities develop along technology innovation life cycles and taking responsibility for mitigating them; (iv) crafting timely guidance for pursuing equitable ends; and (v) sharpening ongoing, iterative oversight and evaluation along innovation life cycles."293

D. Sustainability Governance Frameworks

A fourth focus of technology governance frameworks is sustainability. Many emerging technologies hold great promise for a more sustainable world, but can also present sustainability challenges through greater electricity use, release of potentially hazardous materials, and other environmental disruptions. Some organizations have therefore made sustainability a core focus of technology governance frameworks. An example is the International Risk Governance Center (IRGC), which has

²⁸⁸ NASEM, Towards Equitable Innovation in Health and Medicine: A Framework (2023), https://nap.nationalacademies.org/catalog/27184/toward-equitable-innovation-in-healthand-medicine-a-framework.

²⁸⁹ *Id* at 35.

²⁹⁰ *Id.* at 46-47.

²⁹¹ *Id.* at 53-82.

²⁹² *Id.* at 19 (showing principles and commitments that are relevant to technology governance).

 $[\]frac{293}{293}$ Id. at 90.

published a series of reports focusing on the environmental sustainability of emerging technologies.²⁹⁴

This sustainability governance framework has two goals – first, to minimize the adverse sustainability impacts from an emerging technology, and second, to maximize the sustainability benefits of an emerging technology.²⁹⁵ The framework calls for anticipating potential sustainability impacts,²⁹⁶ which is difficult given the uncertainties about most emerging technologies, but nevertheless recommends ex ante, anticipatory or prospective life-cycle analysis to try to predict future sustainability impacts.²⁹⁷ The framework also recommends an adaptive governance approach to address unexpected impacts, including sequentially or iteratively updating governance plans.²⁹⁸ Finally, the framework envisions the development of resilience mechanisms for adverse sustainability impacts that are not anticipated or detected until after they occur.²⁹⁹

E. New Governance or Soft Law Governance Frameworks

Other technology governance frameworks emphasize procedural or structural aspects of the framework. For example, there are many proposals

²⁹⁴ See, e.g., IRGC, Ensuring the Environmental Sustainability of Emerging Technologies -1 (Workshop Report) (2022), <u>https://irgc.org/risk-governance/ensuring-the-environmentalsustainability-of-emerging-technologies/workshop-report/;</u> IRGC, Ensuring the Environmental Sustainability of Emerging Technologies -2 (Edited Volume) (2022), <u>https://irgc.org/risk-governance/ensuring-the-environmental-sustainability-of-emergingtechnologies/edited-volume/ (hereinafter "IRGC Edited Volume");</u> IRGC, Ensuring the Environmental Sustainability of Emerging Technologies -3 (Guidance Document) (2023), <u>https://infoscience.epfl.ch/record/302431?v=pdf</u>. [hereinafter "IRGC Guidance Document").

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²⁹⁵ IRGC Guidance Document, *supra* note , at 8.

²⁹⁶ Marie-Valentine Florin, *Introduction*, in IRGC Edited Volume, *supra* note ___, at 3, 3 "It is no longer sufficient to let people innovate and then address negative externalities We must become better at anticipating, recognizing patterns and intervening proactively, even with limited data available.").

²⁹⁷ Florin, supra note ___, at 5; IRGC Guidance Document, *supra* note ___, at 9, 19 The sustainability framework explicitly mentions that guidelines developed for responsible research and innovation may be a model for sustainability guidelines. *Id.* at 15.. ²⁹⁸ IRGC Guidance Document, *supra* note __, at 8.

²⁹⁹ IRGC Guidance Document, *supra* note ___, at 9; Rainer Sachs, *Ensuring Environmental* Sustainability of Emerging Technologies – The Case for Applying the IRGC Emerging and Systemic Risk Governance Guidelines, in IRGC Edited Volume, *supra* note ___, at 205, 211.

calling for a "*new governance*"³⁰⁰ or "*soft law*"³⁰¹ approach to technology governance. These proposals argue the traditional government regulation is not for purpose for governing fast evolving technologies, and the governance function must be distributed to other actors including industry groups, non-governmental organizations, academic and think tank experts, and certification bodies, in addition to government actors. These proposals recognize that soft law has many advantages that fit well with emerging technologies, including the ability to be rapidly adopted and amended to match the speed of emerging technologies,³⁰² the capability to address all aspects of a technology across all industries without being restricted by narrow regulatory agency jurisdictions and delegations,³⁰³ and the international application of soft law in alignment with the international properties of emerging technologies.³⁰⁴

However, new governance and soft law frameworks have a potential flaw in that they are not directly enforceable, which may allow some companies to not comply in whole or part and to use such approaches for "ethics washing."³⁰⁵ The lack of direct enforceability also undermines public confidence in such approaches.³⁰⁶ Empirical studies show that soft law programs that create appropriate incentives for industry compliance can succeed, while those that lack such incentives for conformance tend to be

 ³⁰⁰ See, e.g., Bradley C, Karkkainen, "New Governance"" in Legal Thoughts and in the World: Some Splitting as Antidote to Overzealous Lumping, 89 MINN. L. REV. 471 (2040).
 ³⁰¹ Gary E. Marchant & Brad Allenby, Soft Law: New Tools for Governing Emerging Technologies, 73 BULL. ATOMIC SCIENTISTS 108, 108 (2017); Ryan Hagemann et al., Soft Law for Hard Problems: The Governance of Emerging the Technologies in an Uncertain Future, 17 COLO. TECH. L.J. 37, 47, 68 (2018).

³⁰² Kenneth W. Abbott et al., *Soft Law Oversight Mechanisms for Nanotechnology*, 52 JURIMETRICS J. 279, 301–02 (2012); Hagemann et al., *supra* note ___, at 63–65, 104–06; WEF Agile Governance, *supra* note __, at 17 ("Soft law can be more easily updated to keep pace with technological change ...").

³⁰³ Gary Marchant, Lucille Tournas & Carlos Ignacio Gutierrez, *Governing Emerging Technologies Through Soft Law: Lessons for Artificial Intelligence- An Introduction*, 61 JURIMETRICS 1, 7 (2020).

³⁰⁴ Abbott et al, *supra* note __, at 302; WEF Agile Governance, *supra* note __, at 36 ("selfand co-regulation can support a more joined-up approach to regulation across regions and nations, by embedding common rules across jurisdictions.").

³⁰⁵ Karen Hao, *In 2020, Let's Stop AI Ethics-washing and Actually Do Something*, TECH. REV., Dec. 27, 2019, https://www.technologyreview.com/2019/12/27/57/ai-ethics-washing-time-to-act/.

³⁰⁶ Libby Maman, Yuval Feldman & David Levi-Faur, Varieties of Regulatory Regimes and Their Effect on Citizens' Trust in Firms, 30 J. EUROPEAN PUBLIC POLICY 2807 (2022); Gary E. Marchant & Kenneth W. Abbott, International Harmonization of Nanotechnology Governance Through "Soft Law" Approaches, 9 NANOTECHNOLOGY L. & BUS. 393, 398-99 (2013).

unsuccessful.³⁰⁷ To that end, a variety of indirect enforcement tools have been identified to make soft law programs more effective and credible.³⁰⁸

6. <u>Coordinated Governance Frameworks</u>

Yet another framing is to focus on coordination of governance efforts. As the number of entities both within and outside government who are involved in proposing and implementing governance initiatives proliferates, a coordination problem is created. This has created the need to focus governance on some type of coordinating entity.³⁰⁹ A variety of mechanisms have been proposed or implemented for this coordinating function, including governance coordinating committees,³¹⁰ observatories,³¹¹ multi-stakeholder coalitions,³¹² and others.³¹³

The need for coordination is a result of the broad applicability and cross-industry-cross-agency relevance of most emerging technologies. Multiple government bodies within any nation are therefore involved in the governance of given technology, creating a need for coordination within just the government. For example, for nanotechnology in the United States, the National Nanotechnology Initiative is a network of over 20 federal agencies that "enhances interagency coordination of nanotechnology R&D, supports a shared infrastructure, enables leveraging of resources while avoiding duplication, and establishes shared goals, priorities, and strategies that complement agency-specific missions and activities."³¹⁴

But the strongest need for coordination is outside government, as emergency technologies in the era of new governance and soft law spawn

³⁰⁷ Carlos Ignacio Gutierrez, Gary Marchant, Lucille Tournas, *Lessons for Artificial Intelligence from Historical Uses of Soft Law Governance – A Conclusion*, 61 JURIMETRICS 133 (2020).

³⁰⁸ Gary Marchant & Carlos Ignacio Gutierrez, *Soft Law 2.0: An Agile and Effective Governance Approach for Artificial Intelligence*, 24 MINN. J.L. SCI. & TECH. 375, 401-424 (2023).

³⁰⁹ Gary E. Marchant & Wendell Wallach, *Coordinating Technology Governance*, 31(4) ISSUES IN SCIENCE & TECHNOLOGY 43 (2015).

³¹⁰ Id.

³¹¹ OECD. OECD.AI Policy Observatory, <u>https://oecd.ai/en/</u>; Global Observatory for Genome Editing, https://global-observatory.org/.

³¹² The International Council on Nanotechnology is a now defunct example of such a multistakeholder organization that performed such a coordinating function. *See* Marchant & Wallach, *supra* note __, at 44,46.

³¹³ Marchant & Wallach, *supra* note __, at 46-47 (discussing precedents for such coordination bodies in various emerging technologies).

³¹⁴ National Nanotechnology Initiative, About the National Nanotechnology Initiative, https://www.nano.gov/national-nanotechnology-initiative.

an almost limitless array of organizations, coalitions, white papers, proposals, codes of conduct or ethics, private standards, best practices, and a myriad of other governance-related initiatives.³¹⁵ While these diverse entities and opinions cannot be harmonized, they can be harmonized by providing a place where the various s documents and proposals can all be found, and by creating opportunities for various stakeholders to meet, debate and partner on governance initiatives. These types of functions and more could be provided by a coordinating body of some type.³¹⁶ While there are many options, alternatives and challenges on how such a coordinating body could be structured, funded and operated,³¹⁷ the persistent recognition of the need for such a coordinating function in none emerging technology after another suggests the need for such a coordinating coordinated governing framework.

7. International Governance Frameworks

Finally, some frameworks emphasize *international* governance, given the international spread of most emerging technologies.³¹⁸ There are many possible rationales for international governance – one paper recently identified 10 different reasons for international technology governance (see Table 1 below), noting that a subset of these reasons are likely to apply to a given emerging technology.³¹⁹

Table 1: Ten Rationales for International Harmonization³²⁰

	Rationale for Harmonization
1	Share burden of international goal
2	Prevent unilateral advantage if others forgo unethical technology
3	Regulators benefit from economy of scale/sharing resources
4	Minimize trade disputes
5	Assure equal protection for citizens of all nations
6	Ensure safe imports
7	Discourage medical tourism
8	Provide consistent requirements for regulated entities

³¹⁵ Marchant & Wallach, *supra* note __, at 43-44.

³¹⁶ *Id.* at 44-46.

³¹⁷ *Id.* at 47-50.

³¹⁸ See, e.g., World Economic Forum, Global Technology Governance: A Multistakeholder Approach (Oct. 2019), <u>https://www.weforum.org/publications/global-technology-governance-a-multistakeholder-approach/</u> (hereinafter "WEF Global Technology Governance").

³¹⁹ Marchant & Allenby, *supra* note __, at 109.

³²⁰ Adapted from Marchant & Allenby, supra.

	Rationale for Harmonization
9	Address transboundary impacts
10	Prevent race to the bottom/risk havens

A recent World Economic Forum report noted the important need for international technology governance, which was defined "as the norms, principles, decision-making processes and institutional arrangements that set standards and create incentives for behaviors at a transnational level."³²¹ Yet, despite the need for international technology governance, there is a "deficit in global governance of technologies due to the lack of coordination in policy creation that represents shared strategies"³²² "At best," we have only "a patchwork of approaches."³²³ The report does not advocate for a "super sovereign, international authority with the power to make or enforce rules over the wishes of individual countries."³²⁴ Rather, technology governance can be global if "it materially and significantly affects the development, behavior or use of technologies across multiple countries simultaneously."³²⁵

Formal international treaties involve an enormous commitment of resources and provide limited benefits, leading to a reluctance to try to negotiate new treaties known as "treaty fatigue."³²⁶ However, there are many other forms of international governance that have become the focus of recent attention. The Organization for Economic Cooperation and Development (OECD) has identified some 14 different models for international governance.³²⁷ Most of these mechanisms are "soft law" approaches such as (i) regulatory partnerships in which two or more nations sign agreements to cooperate in promoting better quality common regulations and reducing unnecessary regulatory divergences; (ii) guidelines or codes of conduct promulgated by inter-governmental organizations such as the OECD, World Trade Organization, International Labor Organizations and many others; (iii) regional agreements by nations in a region to provide for open markets, trade cooperation, or other types of cooperation; (iv) mutual recognition agreements in which states promise to follow the legal

³²¹ WEF Global Technology Governance, *supra* note __, at 4.

³²² Id. at 7.

³²³ *Id.* at 4.

³²⁴ *Id.* at 7.

³²⁵ Id.

³²⁶ Marchant & Allenby, *supra* note __, at 110.

³²⁷ OECD, *International Regulatory Co-operation: Addressing Global Challenges*, OECD Publishing, Paris (2013), available at - https://doi.org/10.1787/9789264200463-en.

precedence and jurisprudence of the other nations in the agreement; (v) trans-governmental networks in which regulatory officials from different nations meet at regular intervals to discuss issues of common concern; (vi) international private standards promulgated by standard-setting organizations such as the ISO or IEEE; (vii) codes of conduct, professional guidelines or best practices issued by a variety of non-governmental organizations including industry trade associations, professional societies or non-governmental organizations; and (viii) information-exchange mechanisms such as online clearinghouses that allow nations to share experiences, expertise, and other technical know-how.³²⁸ One or more of these international governance mechanisms should be explored for any emerging technology.

8. Summary of Generic Technology Governance Frameworks

Despite these seven different framing and area of emphasis of these governance frameworks for emerging technologies, there are many areas of overlap between the various frameworks. Moreover, the seven frameworks are not mutually exclusive, it is possible to design a governance framework that includes several, or even all, of these seven areas of emphasis. In fact, as discussed below, all seven frameworks are relevant for quantum technology, and quantum governance can extract pertinent lessons from each of the seven frameworks.

VI. APPLYING THE LESSONS TO QUANTUM GOVERNANCE

In reviewing the governance lessons and recommendations from the three emerging technology case studies presented above (biotechnology, nanotechnology and AI), and the seven categories of emerging technology governance frameworks that have been proposed, certain governance issues come up over and over. We call these "pillars" of technology government because they are essential foundations of technology governance, and we identify and discuss eight such governance pillars below

A. Soft Law vs Hard Law

Soft law refers to guidelines, principles and declarations that are not directly enforceable by governments, whereas hard law refers to instruments

³²⁸ OECD, *supra* note 108.

that are legally enforceable by governments.³²⁹ Examples of soft law range from generally adopted industry practices to non-binding declarations of the United Nations. Examples of hard law range from local enforceable regulations to legally binding international treaties. Despite their different characteristics, governing a technology with soft law or hard law is not an either-or proposition. Any given technology will be, at any given time, governed by a mixture of soft laws and hard laws and that mixture is not static. A nascent technology can initially be governed mainly by soft law, but, as the understanding of the risks of the technology matures and the slow legislative process takes its course, hard law can become the main governance tool for the technology. Hard law regulations can adopt preexisting soft law instruments to increase compliance and public trust. The rest of this section discusses and contrasts the characteristics of soft law and hard law governance in general and describes some of the ongoing soft law efforts for the governance of quantum technologies as well as initial hard law efforts that apply to quantum technology applications.

Hard law rules have a number of advantages, which explain why they have been the presumptive form of governance in many fields. Most importantly, because they are mandatory, regulators can take enforcement measures, including imposing civil or criminal penalties, if an entity fails to comply with a hard law regulation. This ensures that all regulated entities are required to comply with the rule, even though compliance is never complete.³³⁰ Hard law rules can also engender public trust, which is an added benefit of hard law. Despite their advantages, hard law suffers from several limitations. Hard law also takes a significant amount of time to develop. In the U.S., the time taken to adopt a regulation has grown substantially over the past half century, especially when judicial review is involved (which it often is).³³¹ Lack of resources to enforce hard law regulations further limits their impact. Hard law requires strong evidence for adopting regulations, which is not always available for new technologies, and, when adopted, their effects are limited to the legal jurisdiction in which they are promulgated.³³²

³²⁹ See supra note _____ and accompanying text.

³³⁰ Daniel A. Farber, *Taking Slippage Seriously: Noncompliance and Creative Compliance in Environmental Law*, 23 HARV. ENVTL. L. REV. 297, 304–05 (1999)

³³¹ Gary E. Marchant, *The Growing Gap Between Emerging Technologies and the Law, in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL

OVERSIGHT: THE PACING PROBLEM 19, 22–23 (Gary E. Marchant et al. eds., 2011) [hereinafter Marchant, PACING]; World Economic Forum, Agile Regulation for the Fourth Industrial Revolution: A Tool Kit for Regulators 6 (Dec. 2020), available at https://www.weforum.org/about/agile-regulation-for-the-fourth-industrial-revolution-atoolkit-for-regulators.

³³² STEPHEN M. MAURER, SELF-GOVERNANCE IN SCIENCE 180 (2017).

In contrast to enforceable hard law rules, soft law includes many different types of non-enforceable instruments, including private standards, codes of conduct, principles, ethical codes, best practices, certification programs, voluntary programs, and private-public partnerships.³³³ Also. unlike hard law rules, soft law can be promoted not only by governmental entities but also by a variety of non-governmental entities, including professional associations, industry groups, individual companies, think tanks, standard-setting bodies, certification agencies, or any combination of the above.³³⁴ Despite the non-enforceability of soft law, it has a number of advantages over hard law. Soft law measures can be enacted faster without bureaucratic hurdles or court oversight.³³⁵ Soft law can also benefit from a wider circle of expertise available to the variety of entities that can be involved in enacting it.³³⁶ The voluntary nature of soft law can also be an advantage with competing soft law proposals to choose from and abide by at the risk of reputational sanctions for non-compliance.³³⁷ The lack of jurisdictional limitations is another advantage of soft law.338 On the downside, the lack of direct enforcement mechanisms is the major limitation

³³³ Gary Marchant, Lucille Tournas & Carlos Ignacio Gutierrez, *Governing Emerging Technologies Through Soft Law: Lessons for Artificial Intelligence- An Introduction*, 61 JURIMETRICS 1, 5 (2020).

³³⁴ Kenneth W. Abbott, Gary E. Marchant, and Elizabeth A. Corley, *Soft Law Oversight Mechanisms for Nanotechnology*, 52(3) JURIMETRICS, THE JOURNAL OF LAW, SCIENCE, AND TECHNOLOGY 279, 298-99 (2012).

³³⁵ Abbott, Kenneth W., Gary E. Marchant, and Elizabeth A. Corley. "Soft law oversight mechanisms for nanotechnology." Jurimetrics (2012): 279-312. note ___, at 301–02; Hagemann, Huddleston & Thierer, *supra* note ___, at 63–65, 104–06; Marchant, Tournas & Gutierrez, *supra* note ___, at 7.

³³⁶ World Economic Forum, Agile Regulation for the Fourth Industrial Revolution: A Tool Kit for Regulators 6 (Dec. 2020), available at <u>https://www.weforum.org/about/agile-regulation-for-the-fourth-industrial-revolution-a-toolkit-for-regulators</u> note ,

at 33 ("The information asymmetry between businesses and regulators means that industry is typically better placed to manage the risks from technological innovation in a way that is most efficient and effective."); MAURER, SELF-GOVERNANCE, *supra* note ___, at 179 ("Firms often possess uniquely valuable information about their internal operations, competitors' activities, and the economic and technological feasibility of standards. NGOs may similarly know more about social needs and the private sector's conduct on the ground.").

³³⁷ Gary Marchant, "Soft Law" Governance of Artificial Intelligence, AI PULSE 4 (Jan. 25, 2019) [hereinafter Marchant, AI Soft Law], <u>https://escholarship.org/uc/item/0jq252ks;</u>
Marchant, Tournas & Gutierrez, supra note ___ at 8.; Jackson, Kevin T. "Global corporate

governance: Soft law and reputational accountability." Brook. J. Int'l L. 35 (2010): 41. ³³⁸ Gary Marchant, Ann Meyer, Megan Scanlon, *Integrating Social and Ethical Concerns Into Regulatory Decision-Making for Emerging Technologies*, 11 MINNESOTA J. LAW SCIENCE & TECHNOLOGY 345-363 (2010) (government regulators often precluded from considering ethical aspects of technologies).

of soft law that adversely affects accountability. Companies can engage in "ethics washing" by purporting to adopt and follow soft law principles as cover to engage in unethical or irresponsible practices.³³⁹ The lack of direct enforcement can engender public mistrust in soft law regulations as the very companies that might be involved in creating and selling the technology at issue often play a significant role in creating and implementing soft law programs.³⁴⁰ This is compounded by the limited transparency about how and by whom soft laws are developed and implemented.³⁴¹

There are few proposals (outside of academia) for the soft law governance of quantum technologies and their applications at this time. Surveying major manufacturers of quantum computing, we could not find any readily available information about their position on quantum governance. One exception is IBM which has a blog post on responsible quantum computing.³⁴² IBM is also the only quantum computing manufacturer that contributed to the World Economic Forum's report "Quantum Computing Governance Principles" which is currently a major soft law effort for the governance of quantum computing.³⁴³ In addition, Quantinuum is a major participant in the Quantum Collaborative, which among other activities seeks to promote quantum governance, including supporting this paper.³⁴⁴ Standards activities relating to quantum computing in general are limited, but are now moving forward. IEEE has a series of quantum standards in development,³⁴⁵ and the ISO-IEC joint

³³⁹ Karen Hao, *In 2020, Let's Stop AI Ethics-Washing and Actually Do Something*, TECH. REV. (Dec. 27, 2019), <u>https://www.technologyreview.com/2019/12/27/57/ai-ethics-</u> <u>washing-time-to-act/</u>; Marchant, Tournas & Gutierrez, *supra* note __, at 9; *also* Balleisen & Esiner, supra note __, at 132.

³⁴⁰ Soft law is often perceived as self-regulation, but self- regulation is only one type of soft law. Most soft law programs include entities external to the industry being governed. For example, a recent analysis of over 600 soft law programs for AI found that government, acting in a non-regulatory role, was the leading participant in these AI soft law programs, not industry. Carlos I. Gutierrez & Gary Marchant, *A Global Perspective of Soft Law Programs for the Governance of Artificial Intelligence*, SSRN (May 28, 2021), available at https://papers.srn.com/sol3/papers.cfm?abstract_id=3855171.

³⁴¹ Marchant, Gary E., and Kenneth W. Abbott. "International harmonization of nanotechnology governance through soft law approaches." Nanotech. L. & Bus. 9 (2012):
393. note __, at 398; Marchant, Tournas & Gutierrez, supra note __, at 9.

³⁴² IBM "The era of quantum utility must also be the era of responsible quantum computing", Blog post available at <u>https://www.ibm.com/quantum/blog/responsible-quantum</u> (accessed July 2024).

³⁴³ World Economic Forum, "Quantum Computing Governance Principles", 19 January 2022, Report available at <u>https://www.weforum.org/publications/quantum-computing-governance-principles/</u> (accessed July 2024).

³⁴⁴ The Quantum Collaborative, https://quantumcollaborative.org/.

³⁴⁵ IEEE, Quantum Standards and Activities,

https://standards.ieee.org/practices/foundational/quantum-standards-activities/

technical committee standardization effort is also addressing quantum..³⁴⁶ These pending industry standards on quantum mostly relate to technical issues rather than technology governance.

B. Need for Governance Coordination

One of the challenges of regulating new technologies such as quantum computing which has both enormous power and potential while also having certain risks associated with it is that such transformative new technologies often have potential impacts and implications that transcend national borders and jurisdictions. To be clear, while the promise of quantum technologies, which leverage the principles of quantum physics to achieve unprecedented levels of performance and functionality, can enable breakthroughs in fields such as cryptography, communication, computation, sensing, and metrology, it is essential to get the governance right from the beginning and to ensure proper coordination to promote public confidence. The lessons drawn both from governance of past transformative technologies as well as an examination of the specifics of quantum technologies show that they can also pose risks and threats to security, privacy, stability, and human rights, as well as create ethical and social dilemmas within society, all of which must be addressed.³⁴⁷

Similar to the examples given earlier in this paper such as with respect to biotechnology, and the impermeable contradictions inherent in the ways that different governments around the world approached governance questions on genetically-modified foods³⁴⁸, eventually creating a conflict in approaches that could not be resolved, it is apparent that there is a need for governance coordination both within and between states.³⁴⁹ As

³⁴⁶ ISO/IEC JTC 1/WG 14, Quantum Information Technology, November 2022. Available at <u>https://jtc1info.org/sd-2-history/jtc1-working-groups/wg-14/</u> (accessed July 2024).

³⁴⁷ See supra notes ______ and accompanying text on the need set out for Governance Coordinating Committees (or GCCs) which can be used to address a wide variety of emerging technology governance issues, as discussed further by Marchant and Wallach in their paper: Gary E. Marchant & Wendell Wallach, *Coordinating Technology Governance*, 31(4) ISSUES IN SCIENCE & TECHNOLOGY 43 at 44-46 (2015).

³⁴⁸ See, e.g., the example of the case for governance coordination with respect to governance and ethical issues in the area of food and agricultural biotechnology here: Catherine Kendig, et al., *The Need for More Inclusive Deliberation on Ethics and Governance In Agricultural and Food Biotechnology*, 11:1 J. RESPONSIBLE INNOVATION 2304383 (2024).

³⁴⁹ See examples of U.S. interagency coordination with respect to governance particularly in areas of shared regulatory space as described by Freeman and Rossi, Agency Coordination in Shared Regulatory Space, 125 Harv. L. Rev. 1131 (2012), *e.g.*, at 1169-1173 describing the EPA-NHTSA Joint Rule.

we saw with the AI case study above, hundreds of different soft law initiatives were launched for that technology, creating a confusing matrix in need for coordination. The U.S. government through the Government Accountability Office itself has studied its inter-agency collaborative mechanisms, catalogued its different mechanisms for cooperation and described how it uses them for policy development and program implementation, oversight and monitoring, information sharing and communication, and building organizational capacity.³⁵⁰ Governance coordination must go beyond government though, and encompass the entire community of industry, NGO, and other governance actors. Governance coordination can take various forms, such as:

- Harmonizing standards and norms for the development, deployment, and use of quantum technologies, to foster interoperability, compatibility, and trust among different actors and systems.

- Sharing best practices and lessons learned within and across both industry and government for the design, implementation, and evaluation of quantum policies and regulations, to promote learning, innovation, and effectiveness.

- Establishing mechanisms and platforms for dialogue, consultation, and collaboration among different stakeholders, including governments, industry, academia, civil society, and international organizations, to enhance transparency, accountability, and legitimacy.

Proper governance coordination in advance also will necessarily entail balancing the trade-offs and tensions between different approaches and objectives in regulating an emerging and transformative technology such as quantum computing, such as:

- Soft law vs hard law, that is, the degree of formality, bindingness, and enforceability of the rules and standards governing quantum technologies.

- Top-down vs bottom-up, that is, the extent to which the governance process is driven by centralized authorities or decentralized actors, such as the industry itself.

- Inclusiveness vs exclusiveness, that is, the degree of participation and representation of diverse and marginalized groups and

³⁵⁰ U.S. Gen. Accounting Office, GAO-12-1002, Managing for Results, Key Considerations for Implementing Interagency Collaborative Mechanisms, 3-5 (2012)

perspectives in the governance process, including those most impacted by the new technology.

- Precaution vs innovation, that is, the level of risk aversion or risk acceptance in the development and adoption of quantum technologies.

Governance coordination is not a one-size-fits-all solution, but rather a context-dependent and dynamic process that requires constant adaptation and adjustment to the evolving quantum computing landscape and the changing needs and expectations of the stakeholders involved. We must consider the specific scenarios of each example of the development of governance coordination for a given transformative technology and determine how the lessons learned fit the instant case. The participants in the governance coordination also must work toward finding a shared vision and commitment to the common good and the public interest in determining the necessary and appropriate governance framework to apply to quantum technology, while also recognizing and respecting that there will necessarily be a diversity and pluralism of values and interests at play in the governance coordination process. Governance coordination can help foster a more responsible, workable and inclusive future for quantum technologist, characterized by public trust and acceptance as it develops and the structure is communicated with broader audiences to gain that trust, as we build a world where the opportunities and challenges of quantum technologies are addressed proactively, collectively and collaboratively by the global community.

C. Protection of Small & Medium Enterprises

Regulation can disproportionately burden small and medium-sized enterprises (SMEs). The compliance requirements and associated costs pose significant challenges that disproportionately affect SMBs, which lack the expertise, resources and flexibility that larger companies use to comply with regulations. This disparate impact can potentially stifle innovation and impede growth of SMEs, which often are on the cutting edge of new technology innovation.³⁵¹ The success of SMEs is particularly important in the quantum industry, because while large companies such as Google and IBM get much of the media attention, a survey by McKinsey & Company

³⁵¹ SMEs account for 60% of total employment and generate 50% to 60% of value added on average in OECD countries. OECD, *Small, Medium, Strong. Trends in SME Performance and Business Conditions* 3 (2017), <u>https://doi.org/10.1787/9789264275683-</u> en.

found that over 90 percent of the companies in the quantum industry had less than 100 employees.³⁵²

This disparate effect on SMEs is seen with biotechnology regulation in the United States, where the substantial costs and delays of bring a genetically modified product to market have completely eliminated all SMEs (and university researchers) from the biotechnology market.³⁵³ Only large corporations marketing commodity crops can afford the high regulatory hurdles to commercial approval, eliminating not only SMEs but also all humanitarian or niche products.³⁵⁴ Even when regulation does not completely eliminate SMEs from the market, it imposes a disproportionate burden on SMEs because they have to spread the regulatory costs over smaller revenues and fewer employees.355

Additionally, the complexity of regulatory requirements can create a significant administrative burden. SMEs often lack the specialized legal and compliance teams that larger corporations can afford. As a result, small business owners must invest time and effort into understanding and navigating complex regulations, which can be both distracting and detrimental to their primary business activities.³⁵⁶

Furthermore, regulatory compliance can stifle innovation by SMEs. Small and medium-sized enterprises are often at the forefront of technological advancements and business model experimentation. However, stringent regulations may impose constraints that limit their ability to innovate freely. As the OECD concluded, "the complexity of regulatory procedures remains the main obstacle to entrepreneurial activity" in most countries, and favors larger and incumbent companies over SMEs and startups.³⁵⁷

In response to these disparate impacts, nations have experimented with a number of approaches to try to assist SMEs, including more lenient requirements or longer lead times for SMEs, regulatory exemptions for SMEs, reviews and programs to reduce regulatory red tape, special units

³⁵² McKinsey & Company, Quantum Computing: The Time to Act is Now, Feb. 1, 2024, https://www.mckinsey.com/capabilities/mckinsey-digital/our-insights/tech-

forward/quantum-computing-the-time-to-act-is-now.

³⁵³ See supra notes _____ and accompanying text. ³⁵⁴ See supra note ____ and accompanying text.

³⁵⁵ Li Azinovic-Yang, Innovation At Every Size: Why Small Firms Struggle To Innovate In Today's Regulatory Environments, FORBES, July 22, 2024,

https://www.forbes.com/sites/columbiabusinessschool/2024/07/22/innovation-at-everysize-why-small-firms-struggle-to-innovate-in-todays-regulatory-environments/.

³⁵⁶ A study by World Bank economists found that SMEs are much more severely affected by legal obstacles than are large firms. Thorsten Beck, Asli Demirguc-Kunt & Vojislav Maksimovic Financial and Legal Constraints to Growth: Does Firm Size Matter?, 60 THE JOURNAL OF FINANCE 137, 146 (2005).

³⁵⁷ OECD, *supra* note ___, at 44.

withing regulatory agencies on small business issues, and reduced licensing requirements or costs for SMEs.³⁵⁸ Of course, SMEs can cause social harm in the same way as larger companies with powerful emerging technologies, so the efforts to protect SMEs must be balanced against the need to protect public safety and welfare.

D. <u>Stakeholder and Public Engagement</u>

In a representative democracy, the public must be engaged and listened to in critical decisions. This means that government and industry actors must show that they have taken into account a broad set of concerns and undertaken some level of consultation of and engagement with a broader set of stakeholders interested in the public interest concerns to be addressed by the proposed governance approach. Stakeholder engagement, while critical with respect to technological adoption of new governance standards, is not without its own particular risks and challenges, among which scholars have identified as complexity, uncertainty and ambiguity.³⁵⁹

Depending on the levels of complexity, uncertainty and ambiguity, these factors will necessarily affect what model of stakeholder participation should be selected to manage the risk accordingly.³⁶⁰ Given the relatively high level of ambiguity with respect to the current levels of potential risk with respect to quantum computing, this factor would argue in favor of a high level of participatory stakeholder involvement, being at the higher end of the risk elevator, and thus including actors, researchers, affected stakeholders and civil society through using instruments such as citizen advisory committees, citizen panels, consensus conferences, mediation roundtables, stakeholder meetings, and other innovative mechanisms³⁶¹

Stakeholder engagement is particularly important and challenging in soft law measures which do not invoke the mandatory administrative provisions for public input into government rulemakings. In some examples of industry self-regulation with lower levels of associated risk, stakeholder involvement has historically involved engagement of a relevant governmental agency holding a hard law function that relates to the type of soft law that the actors seek to develop. To offer a concrete example, there

³⁵⁸ OECD, *supra* note __, at 48-49.

³⁵⁹ See Ortwin Renn, Stakeholder and Public Involvement in Risk Governance, Int. J. Disaster Risk Sci. (2015), 6:8-20, at 8.

³⁶⁰ Id at 10.

³⁶¹ Id. at 15.

are several areas of industry self-regulation or where an industry has created its own soft law solutions in the United States, in which the US Federal Trade Commission ("FTC") serves as such a key stakeholder in this process.³⁶² In addition to many other specific responsibilities it has, the FTC also serves as a sort of *de facto* backstop regulator of business conduct in the United States, empowered to do so through Section 5 of the FTC Act³⁶³ to vigorously enforce the sweeping prohibition against all "unfair or deceptive acts or practices in or affecting commerce." Applying this statute, the FTC has emerged as one of the leading agencies actively supporting the development of industry self-regulation, by either serving informally or formally as that engaged stakeholder with respect to questions around how well the proposed soft law addresses public interest concerns.

The FTC's supervision of various soft law programs demonstrates how government regulators can play an important role in supporting and enhancing the credibility and effectiveness of industry self-regulation, without imposing rigid or costly hard law requirements. By engaging with the industry actors and other stakeholders, the FTC can help to balance the interests and concerns of different parties, and promote the public interest in protecting children from unhealthy food and beverage advertising.

Taking a step back to examine the broader overall context, the concept of stakeholder engagement is the process of identifying, consulting, and collaborating with those who have an interest or a stake in the development and implementation of industry self-regulation. Stakeholder engagement can help to ensure that the industry self-regulation is relevant, legitimate, effective, and accountable. Some of the benefits of stakeholder engagement are:

- It can enhance the understanding of the issues, risks, opportunities, and impacts of the industry self-regulatory effort on different groups and sectors of society, such as consumers, employees, competitors, regulators, civil society, and the environment.

- It can foster trust, dialogue, and cooperation among the industry actors and other stakeholders, and reduce the potential for conflict, resistance, or litigation.

³⁶² See, e.g., US Federal Trade Commission, Self-Regulation in the Alcohol Industry: A Review of Industry Efforts to Avoid Promoting Alcohol to Underage Consumers (1999) (available at: <u>https://www.ftc.gov/reports/self-regulation-alcohol-industry-federal-trade-commission-report-congress</u> visited July 19, 2024)

³⁶³ See Section 5(a) of the FTC Act, 15 U.S.C. Sec. 45(a).

- It can improve the quality, credibility, and acceptance of the industry self-regulation by incorporating diverse perspectives, experiences, knowledge, and feedback into its design and evaluation.

- It can increase compliance and adherence to the industry selfregulation by creating a sense of ownership, commitment, and responsibility among the stakeholders.

- It can enable the industry self-regulation to adapt and respond to changing circumstances, expectations, and needs of the stakeholders, and to address any emerging challenges or problems.

Stakeholder engagement can take different forms and levels of intensity, depending on the purpose, scope, and stage of the industry selfregulation. Some of the common methods of stakeholder engagement are:

- Information: Providing clear, accurate, and timely information to the stakeholders about the objectives, process, and outcomes of the industry self-regulation, and soliciting their views and feedback through surveys, questionnaires, interviews, focus groups, or online platforms.

- Consultation: Seeking input and advice from the stakeholders on specific aspects of the industry self-regulation, such as the identification of the problem, the formulation of the goals, the development of the standards, the monitoring of the performance, or the evaluation of the impact, through workshops, meetings, seminars, roundtables, or panels.

- Collaboration: Working together with the stakeholders on a shared or equal basis in the co-creation, co-delivery, and co-governance of the industry self-regulation, through partnerships, alliances, networks, or coalitions.

Furthermore, in addition to consulting and working with industry, in the development of successful and trusted industry self-regulation, it is helpful to also engage interested civil society organizations as well that can also identify additional issues, concerns and potential resolutions for them in working to help create accountability in the development of and deployment of trusted soft law.

E. Transparency

In recent years, transparency has been recognized as a key element in effective governance of the development and deployment of emerging technologies such as machine learning, nuclear technology and biosciences. However, its repeated absence in real-world applications of emerging technologies has been of significant concern.³⁶⁴ If society is to benefit from the advance of quantum technologies, it is crucial to ensure that development and deployment is subject to appropriate oversight, creators and users are appropriately accountable for harm, and the industry and its outputs are trusted by the public. The transformative potential of quantum technologies, coupled with their complex technical nature, make transparency all the more essential. Transparency can play a vital role in achieving these objectives by enabling informed public discourse, guiding responsible innovation, and safeguarding against potential misuse.

"Transparency" is one of the World Economic Forum's "core values" set out in its 2022 Quantum Governance Principles. "Transparency" is defined as "[u]sers, developers and regulators are transparent about their *purpose* and *intentions* with regard to quantum computing." (emphasis added)³⁶⁵ However, many governance scholars make the point that transparency must be balanced against other interests, and full transparency in every case is not possible.³⁶⁶ Therefore, the extent to which transparency is necessary is also a key issue: for example, a recent research project at Stanford on "Responsible Quantum Technologies" proposed transparency in relation to quantum as "being as open as possible, and as closed as necessary."³⁶⁷

The importance of transparency in quantum governance stems not only from the significant risks posed by the technologies, such as widespread cyber-attacks, the hiding of criminal activities from law enforcement, ubiquitous surveillance of ordinary citizens, and the development of advanced chemical and biological weaponry. Transparency is also an important tool in the hands of a society that seeks to actively

³⁶⁴ Frank Pasquale, THE BLACK BOX SOCIETY: THE SECRET ALGORITHMS THAT CONTROL MONEY AND INFORMATION, (2015); Lyria Bennett Moses & Louis de Koker, *Open Secrets: Balancing Operational Secrecy and Transparency in the Collection and Use of Data by National Security and Law Enforcement Agencies*, 41 MELB. U. L. REV. 530 (2017); Monika Zalnieriute, Lyria Bennett Moses & George Williams, *The Rule of Law and Automation of Government Decision-Making*, 82 THE MODERN LAW REVIEW 425 (2019); Simon Chesterman, *Through a Glass, Darkly: Artificial Intelligence and the Problem of Opacity*, 69 THE AMERICAN JOURNAL OF COMPARATIVE LAW 271 (2021).

³⁶⁵ WORLD ECONOMIC FORUM, *Quantum Computing Governance Principles Insight Report*, (2022), https://www3.weforum.org/docs/WEF_Quantum_Computing_2022.pdf. at 9.

³⁶⁶ Bennett Moses & de Koker, *supra* note __.at 547-551.

³⁶⁷ Mauritz Kop et al., *Towards Responsible Quantum Technology*, HARVARD BERKMAN KLEIN CENTER FOR INTERNET & SOCIETY RESEARCH PUBLICATION SERIES #2023-1 (2023) at 12, <u>https://www.ssrn.com/abstract=4393248</u> (last visited Jul 4, 2024). See also Mauritz Kop et al., *10 Principles for Responsible Quantum Innovation*, 9 QUANTUM SCIENCE AND TECHNOLOGY 035013 (2024).

shape how sociotechnical change is developed, preferably in ways that benefit humanity.

A lack of transparency can also enable a concerning concentration of quantum capabilities in the hands of a few powerful actors, such as government agencies or large technology companies, without adequate checks and balances. This raises risks of power imbalances, strategic surprises,³⁶⁸ and the privatization of key decisions that should be subject to public input and oversight.³⁶⁹

Therefore, it is essential that the development and use of quantum technologies are subject to transparency obligations to enable robust public scrutiny, deliberation, and democratic accountability, and that governance is not left solely in the hands of a narrow group. Transparency is key to ensuring that the broader public has a voice in shaping the trajectory and implementation of these technologies in line with societal values, priorities, and concerns, and in enabling an informed public discourse around the key ethical, social, political, and economic questions raised by quantum

However, achieving transparency in emerging technologies also faces significant barriers rooted in powerful institutional interests and practices. The most common barriers to transparency are concerns regarding national security, law enforcement, and commercial confidentiality. National security concerns have led to high levels of secrecy around quantum research and development, particularly in areas with potential military or intelligence applications such as cryptanalysis, sensing, and secure communications. Governments have already (particularly through dual-use export restrictions) sought to classify or restrict access to quantum technology and knowledge seen as containing a military capability, limiting public disclosure and oversight.³⁷⁰

Commercial interests in protecting intellectual property, maintaining competitive advantage and "avoiding scrutiny and/or regulation of dubious activities"³⁷¹ can also incentivize opacity³⁷² and a lack of transparency, as companies seek to safeguard their innovations and market share. While

³⁷⁰ Anstis, Leonard & Penney, *supra* note ___.

³⁶⁸ Walter Jajko, STRATEGIC SURPRISE - THE INSTITUTE OF WORLD POLITICS, (Sep. 19, 2012), <u>https://www.iwp.edu/articles/2012/09/19/strategic-surprise/</u> (last visited Jul 5, 2024).

³⁶⁹ Siena Anstis, Niamh Leonard & Jonathon W. Penney, *Moving from Secrecy to Transparency in the Offensive Cyber Capabilities Sector: The Case of Dual-Use Technologies Exports*, 48 COMPUTER LAW & SECURITY REVIEW 105787 (2023) at 13-14; Bennett Moses & de Koker, *supra* note ____ at 549..

³⁷¹ Zofia Bednarz & Kayleen Manwaring, *Keeping the (Good) Faith: Implications of Emerging Technologies for Consumer Insurance Contracts*, 43 SYDNEY L. REV. 455 (2021) at 461.

³⁷² Pasquale, *supra* note ___.

some level of protection for classified information and trade secrets may be legitimate and necessary, overly broad or blanket restrictions can hinder responsible innovation, mask potential risks and abuses, and undermine public trust.³⁷³

The technical complexity of quantum technologies presents other challenges for meaningful transparency and public engagement. The underlying principles of quantum mechanics, such as superposition, entanglement, and decoherence, can be counterintuitive and difficult to grasp for non-specialists. The mathematical and computational foundations of quantum algorithms and error correction are highly sophisticated. This inherent complexity can create barriers to public understanding and deliberation. Translating complex technical concepts and implementations into accessible and relevant terms for policymakers and the public is a key challenge,³⁷⁴ one that has been significantly highlighted in scholarship around machine learning and the use of opaque algorithms.³⁷⁵

Moreover, the hype and publicity surrounding quantum advancements can sometimes obscure the real state of the art. At the same time, the longer-term impacts and trajectories of quantum remain highly uncertain and speculative, creating further challenges for transparency, as governance frameworks should be adaptable and responsive.

Overcoming these various barriers to transparency in the quantum domain will require significant and sustained efforts from a range of actors and approaches. It is not a simple matter of choosing between complete openness or complete secrecy, but rather finding appropriate governance mechanisms and arrangements to protect legitimate interests while maximizing responsible transparency. Transparency mechanisms should be designed through inclusive, multi-stakeholder processes to build broad support and legitimacy.³⁷⁶ Key elements and initiatives to consider in developing such frameworks could include:

³⁷³ Bennett Moses & de Koker, *supra* note _____ at 540-544.

³⁷⁴ Zalnieriute, Bennett Moses & Williams, *supra* note ____ at 453; ,

 ³⁷⁵ Jenna Burrell, How the Machine 'Thinks': Understanding Opacity in Machine Learning Algorithms, BIG DATA & SOCIETY 1 (2016); Chesterman, supra note ____ at 274-277
 ³⁷⁶ Elija Perrier, The Quantum Governance Stack: Models of Governance for Quantum Information Technologies, 1 DISO 22 (2022) at 21-22. See also Elija Perrier, Ethical Quantum Computing: A Roadmap (2021) https://doi.org/10.48550/arXiv.2102.00759.

1. Ensuring that any necessary secrecy in regulation is based on clear and narrow criteria.³⁷⁷ Where full transparency is problematic, a limited form of transparency (or 'translucency') should be considered.³⁷⁸

2. Establishing mandatory or recommended disclosure policies for quantum companies and research institutions, covering areas like ethics policies, risk assessments, impact evaluations, and public engagement efforts.³⁷⁹

3. Creating and strengthening oversight mechanisms, such as empowered and technically-equipped regulatory bodies, with full access to information and the ability to conduct audits and impact assessments while handling sensitive information securely.³⁸⁰

4. Investing in multi-stakeholder engagement and deliberative processes to incorporate diverse perspectives, build public understanding, and foster trust in quantum governance, including through outreach, education, and the inclusion of civil society voices.³⁸¹

5.. Embedding ethical principles and human rights considerations into QT design and deployment from the outset, with transparency around how these are operationalized and upheld in practice.³⁸²

These initiatives are not exhaustive, but represent key elements and approaches to advancing transparency in quantum governance. They will require the active collaboration and commitment of policymakers, regulators, industry leaders, researchers, civil society groups, and international bodies. Ongoing monitoring, assessment, and adjustment of transparency approaches will be necessary as the technology and its applications mature and evolve.³⁸³

F. <u>Equity</u>

³⁸² CSIRO, FIRST QUANTUM COMPUTING GUIDELINES LAUNCHED AS INVESTMENT BOOMS, (2022), <u>https://www.csiro.au/en/news/news-releases/2022/first-quantum-computing-</u>

guidelines-launched (last visited Jan 11, 2023); Elif Kiesow Cortez et al., A Quantum Policy and Ethics Roadmap, SSRN Journal (2023),

³⁷⁷ Dennis Richardson, COMPREHENSIVE REVIEW OF THE LEGAL FRAMEWORK OF THE NATIONAL INTELLIGENCE COMMUNITY -- VOL 4: ACCOUNTABILITY AND TRANSPARENCY; ANNEXES, (2019), <u>https://www.ag.gov.au/system/files/2020-12/volume-4-accountability-and-transparency-annexes.PDF</u> (last visited Jun 24, 2024).

³⁷⁸ Bennett Moses & de Koker, *supra* n _____ at 564-569.at 36-7.

³⁷⁹ Anstis, Leonard & Penney, *supra* n at 19-21..

³⁸⁰ Richardson, *supra* n _____ at 27-28.; Bennett Moses & de Koker, *supra* n _____ at 569.

³⁸¹ Perrier, *The Quantum Governance Stack: Models of Governance for Quantum Information Technologies, supra* n ____.at 37..

https://www.ssrn.com/abstract=4507090 (last visited Jul 1, 2024).

Equity has long been a neglected or under-emphasized dimension of technology policy. Without deliberate efforts to ensure fairness and equity, the development and availability of an emerging technology will tend to unequally benefit different sub-populations based on race, gender, income, and other factors.³⁸⁴ This is the inevitable consequence of the long-standing inequalities that exist in our society. In contrast, equity is defined as "the state in which everyone has the opportunity to attain their full …potential and no one is disadvantaged from achieving this potential because of social position or other socially determined circumstances."³⁸⁵

A good illustration of this problem is provided in the discussion of artificial intelligence, *supra*.. Machine learning AI is based on historical data, which is often rife with racial and gender bias and stereotypes. There have already been numerous examples of developers releasing AI systems without expressly addressing equity issues and the result has been biased algorithms, whether it be in health care, facial recognition, criminal sentencing, employment, or numerous other applications.³⁸⁶

The lesson is clear – equity must be an explicit and central consideration in technology development and implementation. Passively allowing the status quo to prevail will often result in unfairness and discrimination. In recent initiatives, governance of emerging technologies have given greater pre-eminence to equity. For example, as discussed above, the recently proposed technology framework from NASEM centers on equity.³⁸⁷ The framework recognizes that "[t]here is both encouraging precedent and a disappointing lack of attention to equity in the history of technology governance in the United States."³⁸⁸

One partial solution to these equity issues is to ensure that the teams developing and implementing technologies are representative of the population that will be impacted by the technology.³⁸⁹ These more diverse teams will have the awareness and sensitivity to detect and prevent many of

³⁸⁴ David S. Jones et al., *Explaining Health Inequities* — *The Enduring Legacy of Historical Biases*, 390 N. ENG. J. MED 389, 393 (2024). ("Deliberate thinking and action are required to resist those narratives" that promote disparate treatment). Inequalities can affect "any populations, including individuals who identify as

Black, Latino, Native American, or LGBTQ; individuals in rural communities; individuals living in poverty; individuals with disabilities; and older persons." Nundy et al., *supra* note at E1.

³⁸⁵ National Academies of Sciences, Engineering and Medicine. Communities in Action: Pathways to

Health Equity 32 (2104), https://www.nap.edu/download/24624.

³⁸⁶ See supra notes ____ and accompanying text.

³⁸⁷ NASEM, supra note ___.

 $^{^{388}}$ *Id* at 35.

³⁸⁹ See supra notes --____and accompanying text.

the embarrassing discriminatory impacts that have afflicted technologies such as AI.

G. Temporal Issues for Governance

When contemplating an anticipated or new technology, the question of timing any legal or regulatory response comes to the fore. Discussion often begins with a reference to the "Collingridge dilemma" – act too quickly and your response may miss the target as the technological possibilities evolve; act too slowly and the technology will evolve in the absence of guidance, and technological momentum will make it difficult to guide it in a different direction.³⁹⁰ Such technological momentum is not limited to physical and digital architectures, but includes investments, planning and interests based around technological practices and trajectories.³⁹¹ There are different views on when in the innovation cycle regulatory intervention is optimized, and this may depend on the pace of innovation, the likely diffusion pattern, and the stage at which harms become apparent.³⁹² However, exploring legal and regulatory responses to new technology can begin significantly earlier,³⁹³ Consistent with the anticipatory and responsible innovation frameworks discussed above.³⁹⁴

When asking about the timing of a governance intervention, it is important to recognize the "pre-history" of technology governance. Technologies are governed *before* they exist, even in our imaginations.³⁹⁵ Law that operates at a general level, including tort law, contract law, product liability, and consumer law, creates incentives and consequences that impact discovery, investment, creation and dissemination of products and services based on new technologies. Governance, at the level of organizations involved in the emerging new sector, should incorporate compliance and risk assessment, factoring in general legal responsibilities

³⁹⁰ DAVID COLLINGRIDGE, THE SOCIAL CONTROL OF TECHNOLOGY (1980).

³⁹¹ Thomas Hughes, *Technological Momentum*, *in* TECHNOLOGY AND SOCIETY: BUILDING OUR SOCIOTECHNICAL FUTURE 137 (Leo Marx & Merritt R. Smith eds., 1994).

³⁹² Bert-Jaap Koops, *Ten Dimensions of Technology Regulation: Finding Your Bearings in the Research Space of an Emerging Discipline, in DIMENSIONS OF TECHNOLOGY* REGULATION 309 (Goodwin, M.E.A., Koops, B.J., & Leenes, R.E. eds., 2010); Gaia Bernstein, *The Paradoxes of Technological Diffusion*, 39 CONNECTICUT LAW REVIEW 59 (2006).

³⁹³ ROGER BROWNSWORD & MORAG GOODWIN, LAW IN CONTEXT: LAW AND THE TECHNOLOGIES OF THE TWENTY-FIRST CENTURY: TEXT AND MATERIALS 372 (2012). ³⁹⁴ See supra notes ____ and accompanying text.

³⁹⁵ Lyria Bennett Moses, *Regulating in the Face of Sociotechnical Change, in* THE OXFORD HANDBOOK OF LAW, REGULATION AND TECHNOLOGY 573 (Roger Brownsword, Eloise Scotford, & Karen Yeung eds., 2017).

and potential liabilities, before any technology- or sector- specific changes to law and policy.

Despite the importance of these broader laws, there is something to do as a new technology becomes imminent and then present in the world. New physical things, new possibilities for action, new ways of doing things generate "regulatory disconnection,",³⁹⁶ leading to "the pacing problem".³⁹⁷ Regulatory connection is "the connection between the regulatory environment, the technology in question and its applications.".³⁹⁸ Disconnection may arise where descriptions no longer align with the new socio-technical landscape, where there is a lack of moral fit between technological possibilities and existing constraints, and where there is a mismatch between the business models imagined at the time of regulation and current models and practices.³⁹⁹

At the point where there is regulatory disconnection, the question for policymakers is not whether they should start governing how new technologies are designed, disseminated and used, but rather what changes are required and how quickly they should be promulgated and implemented. Such changes may include clarifying any uncertainties in how the law will apply, expanding or constricting the scope of existing laws to better align with our goals in new contexts, and crafting new laws to manage new problems as well as repealing any laws rendered obsolete.⁴⁰⁰ The timing of such changes will depend on political institutions in each jurisdiction and the urgency with which they view the problem. As can be seen in the cases of earlier technologies, Europe tends to respond more quickly to technologies of concern, particularly where they are seen to threaten fundamental values. Europe has a tradition of technology assessment that survives the demise of the US Office of Technology Assessment, and the European Commission is an inbuilt bureaucracy for imagining legal possibilities.⁴⁰¹ In the United States, smaller units of government (such as cities and states) are often more agile than Congress with respect to

³⁹⁶ ROGER BROWNSWORD, RIGHTS, REGULATION AND THE TECHNOLOGICAL REVOLUTION (2008).

³⁹⁷ Marchant, *supra* note 331.

³⁹⁸ BROWNSWORD AND GOODWIN, *supra* note 393 at 371.

³⁹⁹ BROWNSWORD, *supra* note 396 at 166–167; BROWNSWORD AND GOODWIN, *supra* note 393.

⁴⁰⁰ Lyria Bennett Moses, *Recurring Dilemmas: The Law's Race to Keep Up with Technological Change*, 7 UNIVERSITY OF ILLINOIS JOURNAL OF LAW, TECHNOLOGY AND POLICY 239 (2007).

⁴⁰¹ NORMAN J. VIG & HERBERT PASCHEN, PARLIAMENTS AND TECHNOLOGY - THE DEVELOPMENT OF TECHNOLOGY ASSESSMENT IN EUROPE (2000).

legislative change, as can be seen in the context of AI regulation.⁴⁰² Executive responses in the US may be slowed by required regulatory processes, and are often supplemented by non-regulatory or voluntary initiatives at the outset of a new technology⁴⁰³

Time also comes into play in how law reforms and new laws are framed, in particular the extent to which they are scoped so that they govern a particular technology as opposed to a broader category. Examples of the former include the European Union's AI Act and prohibitions on human reproductive cloning (which do not prohibit naturally born identical twins). Examples of the latter include legal changes to better manage the governance of nanomaterials that did not create a new regulatory category but rather included particle size among the characteristics that made a chemical "new."⁴⁰⁴ Legal responses involving technological specificity suffer most from the Collingridge dilemma's prediction of obsolescence as the technological possibilities and trajectories continue to shift from expectations at the time of drafting. Broader laws are not immune – there is no such thing as a pure form of technological neutrality – but they are more robust if drafted to align with the values being preserved rather than the technological particulars of the early manifestations of the problem.⁴⁰⁵ In particular, stepping back from technological specifics in formulating law is more consistent with a dynamic view of technology.⁴⁰⁶

Turning back to organizational governance, organizations inventing, developing, investing in, disseminating and using new technologies, or planning to do so, will often seek clarity around how the legal and regulatory landscape will apply to them over time. The legal uncertainty, both as to interpretation of existing laws and as to potential legal changes, generates risk in the sense of creating uncertainty as to the achievability of objectives.⁴⁰⁷ Such organizations may seek advice, run test cases, alone or in partnership with industry bodies to create interpretative or best practice guidelines, or seek to influence the result, including through lobbying. But ultimately time creates challenges for new ventures' own governance as they seek to leverage new technologies and new business opportunities in the context of an uncertain and evolving legal and regulatory environment.

⁴⁰² MICHAEL GUIHOT & LYRIA BENNETT MOSES, ARTIFICIAL INTELLIGENCE, ROBOTS, AND THE LAW ch 10 (2020).

⁴⁰³ Marchant, *supra* note 331 at 24.

⁴⁰⁴ Ludlow et al, *supra* note Error! Bookmark not defined.

⁴⁰⁵ Bennett Moses, *supra* note 400.

⁴⁰⁶ Marchant, *supra* note 331 at 23.

⁴⁰⁷ Arto Lanamäki et al, *Editorial: Legal Compliance and the Open Texture of Law*, JOURNAL OF THE ASSOCIATION FOR INFORMATION SYSTEMS (JAIS)

⁽forthcoming).

Quantum is the newest technology where questions of how-to time legal and regulatory responses arises. In this case, it is not only those working directly with quantum technologies who face a dilemma but also those whose infrastructures are rendered vulnerable by new quantum technologies. In a situation analogous to the Y2K problem, those operating vast, complex, multi-sourced software systems need to consider reliance across systems on newly vulnerable encryption protocols. As was the case for the Y2K problem, the uncertainty is not only in obligations that may exist under statute (particularly in regulated sectors) but also interpretation of such statutes by regulators and interpretation of contractual promises by parties and, ultimately, courts. Both within the quantum sector, and in affected industries, organizations will seek to understand existing obligations and predict those that may arise over time. Government will also need to consider whether laws need to be enacted or amended.

Once a decision is made about the timing of doing something, timing questions continue to play an important role. One might, for example, make smaller changes in legal and regulatory frameworks in order to have an opportunity to evaluate the results and make further adaptive adjustments over time.⁴⁰⁸ This could involve, for example, sunset clauses or regulatory sandboxes.⁴⁰⁹ Alternatively, one might cautiously explore ideas of "future-proofing" new laws.⁴¹⁰

H. International Competitiveness/Security Aspects

International competition and security are key factors in determining access, availability, uptake and applications of emerging technology, especially dual-use technologies. In terms of the governance of emerging technologies, competition arises in research, innovation and commercialization, and is influenced by geopolitical agreements, understandings and arrangements. Emerging technologies are generally regulated for security through international arrangements and national export controls and foreign investment restrictions. Emerging technologies face restrictions in competition across the globe. Rules on who can trade with your country and buy technology impose control on the availability

⁴⁰⁸ ANDREW MURRAY, THE REGULATION OF CYBERSPACE: CONTROL IN THE ONLINE ENVIRONMENT (2007).

⁴⁰⁹ PĂUN, *supra* note **Error! Bookmark not defined.** at 108–132; Antonios Kouroutakis, *Disruptive Innovation and Sunset Clauses: The Case of Uber and Other On-Demand Transportation Networks, in* TIME, LAW, AND CHANGE: AN INTERDISCIPLINARY STUDY 291 (Sofia Ranchordás & Yaniv Roznai eds., 2020).

⁴¹⁰ Sofia Ranchordás & Mattis Van't Schip, *Future-Proofing Legislation for the Digital Age, in* TIME, LAW, AND CHANGE: AN INTERDISCIPLINARY STUDY 291 (Sofia Ranchordás & Yaniv Roznai eds., 2020).

and markets for emerging technology products, platforms and services. Global competitive markets and access to technology are subject to control regimes that control not just the actual goods but also the components and people who work with the technologies in industry or government. The defense and military aspects mean that goods along with components, services and personnel are not freely available. This section briefly describes aspects of international competitiveness and security for quantum technologies.

All technologies go through a period of emerging, and in this period there is immense uncertainty and ambiguity about how the technology will develop, whether consumers will want the product or service, and whether it will ever have a use beyond the lab.⁴¹¹ Many emerging technologies are subject to legal and ethical controls very early in their development lifecycle, especially dual-use technologies, although the extent of control is often dependent on the willingness of countries to comply with and enforce the controls.⁴¹² Some emerging technologies have clear use cases and applications, such as AI, autonomous systems and post-quantum cryptography, making these technologies commercially desirable and in demand in social, economic and defense contexts. Advanced technologies that create paradigm shifts in the way things are done or organized or constituted or constructed, such as biotechnology, nanotechnology and quantum computing, are classified as defense or dual-use goods, services and processes, and included in national export control frameworks.⁴¹³ Once widely commercially available, goods may not be as strictly controlled as defense goods, but they may still be restricted due to their 'dual-use' status.

Strategic competition defines the international economic and security environment.⁴¹⁴ All countries in the world operate in an environment where there is strategic competition for resources, technology, critical minerals and favorable trade relations, and where international

⁴¹¹ Ali Sunyaev, "Emerging Technologies," in *Internet Computing*, by Ali Sunyaev (Cham: Springer International Publishing, 2020), 373–406, https://doi.org/10.1007/978-3-030-34957-8_12.

⁴¹² Antonio Calcara, Raluca Csernatoni, and Chantal Lavallée, eds., *Emerging Security Technologies and EU Governance: Actors, Practices and Processes*, Routledge Studies in Conflict, Security and Technology (London; New York: Routledge/Taylor & Francis Group, 2020). 6.

⁴¹³ Siena Anstis, Niamh Leonard, and Jonathon W. Penney, "Moving from Secrecy to Transparency in the Offensive Cyber Capabilities Sector: The Case of Dual-Use Technologies Exports," *Computer Law & Security Review* 48 (April 2023): 105787, https://doi.org/10.1016/j.clsr.2022.105787.

⁴¹⁴ Tai Ming Cheung and Bates Gill, "Trade Versus Security: How Countries Balance Technology Transfers with China," *Journal of East Asian Studies* 13, no. 3 (December 2013): 443–56, https://doi.org/10.1017/S1598240800008298.

security and stability is negotiated in a range of forums between public and private actors. Emerging technologies, like quantum technology, occupy a special position in the world of international trade, as certain quantum technologies are considered dual-use technologies, and are starting to be regulated throughout the world via import/export controls and foreign investment regimes. It has been well documented that a "quantum arms race" has started and that it involves not state actors, such as China, the United States, the UK and Australia but the private sector too, including Google, Microsoft and IBM.⁴¹⁵

The US is the most advanced nation on the regulation of quantum technologies, passing legislation in 2018 in anticipation of the impending medium to long-term availability of quantum computing, cryptography and communications.⁴¹⁶ US policy reflects national security concerns as well as strategic economic and innovation competition. The 2018 National Quantum Initiative Act authorizes government and non-government organizations to develop and operate programs related to quantum information science, including the establishment of research centers, institutes, and the National Ouantum Initiative Advisory Committee.⁴¹⁷ The US also specifies an annual defense budget, which includes QIS technology development. Furthermore, the CHIPS and Science Act 2022 provides funding for semiconductor chips and makes mention of quantum networking and communications applications of chips. The US reformed its export controls regime in 2018 to capture emerging and "foundational"" dual use technologies, which include quantum technologies.⁴¹⁸ These rules will restrict access and trade in quantum technologies.

The EU has been ambitious in developing and funding innovation in quantum technologies. In 2018, the European Commission launched the Quantum Flagship with a budget of €1 billion and the goal of consolidating and expanding scientific leadership, excellence and competition.⁴¹⁹ The EU uses export controls throughout the EU to control exports, brokering,

⁴¹⁵ See eg, Salahudin Ali, "Quantum Supremacy, Network Security & the Legal Risk Management Framework: Resiliency for National Security Systems," SMU Science and Technology Law Review 23, no. 2 (2020): 103-26.

⁴¹⁶ See supra notes ____ and accompanying text.

⁴¹⁷ See supra note ____ and accompanying text.
⁴¹⁸ See supra notes ____ and accompanying text.
⁴¹⁹ See eg, European Commission, "Quantum Flagship Quantum Principles," Quantum Flagship, 2018, https://qt.eu/quantum-principles/; European Commission, "The Future Is Quantum: EU Countries Plan Ultra-Secure Communication Network | Shaping Europe's Digital Future," June 13, 2019, https://digital-strategy.ec.europa.eu/en/news/futurequantum-eu-countries-plan-ultra-secure-communication-network.

technical assistance, transit and transfer of "dual use" items. ⁴²⁰ In Europe, controlled items include quantum computers and related electronic assemblies and components, qubit devices and qubit circuits containing or supporting arrays of physical qubits, quantum control components and quantum measurement devices; as well as the technology for their development or production.⁴²¹ Other nations have adopted their own quantum programs and technology controls.

Foreign investment controls around the world can inhibit competition but also increase security. These regimes control the countries that are permitted to procure and sell the products and services that are listed or are critical. Recent geostrategic arrangements, such as AUKUS, will restrict global competition, but will enable freer trade between certain countries that will free up trade and skills.⁴²² This arrangement may impact other countries such as India or Japan, members of a geostrategic grouping with the United States and Australia called the QUAD.⁴²³ India is also a member of BRICS, and so potentially supplies its goods and services to those countries, thus expanding the markets where it operates, but also growing other markets in countries where it invests and with whom it trades.⁴²⁴

As previous sections in this paper have demonstrated, trade and competition can be stifled, and onerous control obligations can create false markets or distorted markets for goods and services. Additionally, geostrategic competition often means that any underlying hard rules on the

 ⁴²⁰ Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual-use items (recast) [2021] OJ L 206 11.6.2021/1.
 ⁴²¹ Ibid art 9(4).

⁴²² See Department of Defence, "AUKUS Licence Free environment", Defence Trade Controls Amendment Act 2024 and Defence Trade Legislation Amendment Regulations 2024, Australian Government, <u>https://www.defence.gov.au/about/reviews-</u> inquiries/defence-trade-controls-amendment-act-2024-defence-trade-legislationamendment-regulations-2024, accessed 5 July 2024.

⁴²³ For a comparative discussion of the QUAD and AUKUS in respect of security, see Arzan Tarapore, 'What the Quad could learn from AUKUS', *The Interpreter*, Lowy Institute, 3 April 2023, <u>https://www.lowyinstitute.org/the-interpreter/what-quad-couldlearn-aukus</u>, accessed 4 July 2024. See also William James and David Brunnstrom, 'UK, US, Australia consider Japan's cooperation in AUKUS security pact', 9 April 2024, Reuters, <u>https://www.reuters.com/world/us-uk-australia-considering-cooperation-withjapan-aukus-pact-2024-04-08/</u>, accessed 4 July 2024.

⁴²⁴ Daniel Azevedo et al, 'An evolving BRICS and the Shifting World Order', 29 April 2024, Boston Consulting Group, <u>https://www.bcg.com/publications/2024/brics-</u><u>enlargement-and-shifting-world-order</u>, accessed 5 July 2024; see also John Potter, '4 countries that began funding quantum initiatives in 2022, 16 may 2023, The Quantum Insider, <u>https://thequantuminsider.com/2023/05/16/4-countries-that-began-funding-quantum-initiatives-in-2022/</u>. Accessed 5 July 2024.

emerging technologies means that parts of the world develop technology in one direction (for example, China, Russia and other countries) and other parts of the world go another way (for example, the US, the UK, Australia). Whether the import and export arrangements, and foreign investment restrictions will work for quantum is an open question. Clearly, quantum technologies are important enough to be restricted by 'like-minded' countries to these markets. Non-allied and not aligned countries will not be permitted to have access to the technology. This has not stopped states like China and Russia commencing their own race for quantum supremacy and exchanging technology and personnel and other products and services in their own trading blocks.⁴²⁵

There are lessons to be learned from previous emerging technology and its regulation. Quantum is already regulated in similar ways to previous emerging technologies, through export controls and foreign investment. It faces similar challenges from big technology companies developing the technology alongside smaller operators in the 'quantum ecosystem'. Alongside export control and national security restrictions on foreign investment in certain industries and technologies, there is also innovation policy that seeks to foster markets for advanced and emerging technologies. Significantly, militaries and defense departments continue to fund research and innovation in emerging technologies, dividing research, innovation and markets into geostrategic competition and security lines.

VII. CONCLUSION

Edward Burke cautioned that "you can never plan the future by the past."⁴²⁶ Yet, although scenario analysis, horizon scanning and other techniques may allow us to anticipate and plan for the future, we cannot learn from the future, we can only learn from the past. Thus as H.G. Wells stated, "[w]e live in reference to past experience and not to future events, however inevitable."⁴²⁷

The governance of quantum technologies has much to learn from the history of governance of previous emerging technologies such as

https://www.technologyreview.com/2019/01/03/137969/us-china-quantum-arms-race/.; Gabriel Honrada, "India Aims to Rival China in Quantum Computing," Asia Times, March 4, 2022, https://asiatimes.com/2022/03/india-aims-to-rival-china-in-quantum-computing/. ⁴²⁶ Burke, E., Letter to a Member of the National Assembly, 3rd ed. (Paris, 1791)

⁴²⁵ See eg, "U.S. Bans Export and Re-Export of Quantum Computing Services to Russia from October 15," TASS, September 16, 2022, https://tass.com/world/1508173.; Martin Giles, "The US and China Are in a Quantum Arms Race That Will Transform Warfare," MIT Technology Review, 2019,

⁴²⁷ H.G. Wells, *Mind at the End of Its Tether*, quoted in EHRLICH, E. AND DE BRUHL, M., THE INTERNATIONAL THESAURUS OF QUOTATIONS 493 (2nd rev ed. 1996).

biotechnology, nanotechnology and artificial intelligence. Each of these technological revolutions came with its unique spectrum of benefits, risks, and uncertainties. Yet many of the same tensions and issues are confronted in the governance of each of the technologies and will also certainly apply to quantum technology as well.

In this paper we provide three groupings of recommendations for quantum governance from the history of emerging technology governance, First, we provide 15 lessons from the governance of three individual emerging technologies, including seven lessons from biotechnology,⁴²⁸ four lessons from nanotechnology,⁴²⁹ and four lessons from artificial intelligence.⁴³⁰ Second, we offer seven types of frameworks that other groups and individuals have recommended for governing emerging technologies, including frameworks that emphasize on: (i) anticipatory governance; (2) agile/adaptive governance; (3) equity; (4) sustainability; (5) soft law or new governance; (6) coordination of governance; and (7) international governance.⁴³¹ Third, we identify and discuss eight cross-cutting issues that arise with every emerging technology, which we refer to as governance "pillars" and which collectively provide the foundation for effective technology governance. The eight cross-cutting issues are (A) soft law versus hard law, (B) coordination of governance; (C) protection of small and medium enterprises, (D) stakeholder engagement, (E) transparency, (F) equity, (G) temporal issues, and (H) international completeness/national security.432

To be sure, this is a lot of information and recommendations that must be considered in quantum governance. Yet, goverannce of emerging technologies is a complex endeavor, and is sometimes referred to as a "wicked problem."⁴³³ The difficulty and complexity of emerging technology goverannce is exceeded only by the importance and necessity of emerging technology governance, to which this article seeks to contribute.

⁴²⁸ See supra notes ____ and accompanying text.

⁴²⁹ See supra notes ____ and accompanying text.

⁴³⁰ See supra notes ____ and accompanying text.

⁴³¹ See supra notes _____ and accompanying text.

⁴³² See supra notes ____ and accompanying text.

⁴³³ Gary E. Marchant, *Governance of Emerging Technologies as a Wicked Problem*, 73(6) VANDERBILT L. REV. 1861-1877 (2020).