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Article 1

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NOVA LAW REVIEW

NOVA SOUTHEASTERN UNIVERSITY

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TOUCHING, TAPPING, AND TALKING: THE FORMATION OF CONTRACTS IN CYBERSPACE

MARK E. BUDNITZ*

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I. INTRODUCTION

Technology has transformed the consumer marketplace.¹ It has radically changed the way consumers enter into contracts for goods and

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1. Orrin Broberg, *Eight Ways Technology Is Changing Business*, MODUS: MODUS BLOG (Dec. 5, 2013, 1:35 AM), <http://www.gomodus.com/blog/eight-ways-technology-changing-business>.

services.² Part II of this Article provides the broader context in which online contracting occurs, describing the general electronic environment that technology has made possible, including its costs as well as its benefits.³ The law has failed to keep up with this transformation and Part III points out these gaps in the law.⁴ The major focus of this Article is on issues raised by the new ways in which consumers and businesses enter into online contracts.⁵ Part IV begins this inquiry by providing a brief history of the various media people have used to embody contract terms and to document the parties' intention to enter into a contract.⁶ Part V reviews applicable legislation.⁷ It also analyzes the emerging case law in which courts struggle to determine whether consumers have entered into a contract when they use a mouse to click on a button labeled "I agree" or have the opportunity to click on a hyperlink that leads to an agreement but does not require any explicit indication of their consent.⁸ Part V describes the new environment in which consumers order goods by touching or tapping on small mobile device screens or by talking to virtual personal assistants.⁹ Unique legal issues relating to the formation of contracts arise when agreements are made using these devices.¹⁰ Part VI discusses various approaches policymakers could adopt to develop the law on contracting in cyberspace in an ever-changing consumer e-commerce marketplace.¹¹

II. TECHNOLOGY HAS FOREVER CHANGED THE LIVES OF CONSUMERS FOR GOOD AND BAD

The focus of this article is on the formation of online consumer contracts by consumers when they touch or tap mobile devices and talk to virtual assistants.¹² But in developing legal rules for formation of contracts, courts and policymakers should consider the wider context in which online contracting occurs.¹³ Online contracting using mobile devices and virtual

2. *See id.*

3. *See discussion infra* Part II.

4. *See discussion infra* Parts II–III.

5. *See discussion infra* Part III.

6. *See discussion infra* Part IV.

7. *See discussion infra* Part V.

8. *See discussion infra* Part V.

9. *See discussion infra* Part V.

10. *See discussion infra* Part V.

11. *See discussion infra* Part VI.

12. *See discussion infra* Parts II–IV.

13. *See* KARL N. LEWELLYN, *THE BRAMBLE BUSH: ON OUR LAW AND ITS STUDY* 63–64 (7th ed. 1981); Mark E. Budnitz, *Consumers Surfing for Sales in Cyberspace: What Constitutes Acceptance and What Legal Terms and Conditions Bind the Consumer?*, 16 GA. ST. U. L. REV. 741, 743–45 (2000).

assistants takes place in a world in which technology in general, and electronic devices in particular, are increasingly pervasive.¹⁴ As the following examples illustrate, these developments have brought significant benefits to the consumer who is able to have access to them.¹⁵ They also have introduced costs and risks, have had unintended negative consequences, and have increased the disparity between the haves and the have-nots.¹⁶ For the most part, the law has not responded in a timely or adequate manner, if at all, as described in Part III.¹⁷

Technology has been a *boon* for the disabled.¹⁸ For example, an app enables a blind person to use a smartphone or glasses with a camera to livestream video to a helper, who then assists the blind person to get to the desired destination.¹⁹ But connected health services may collect huge amounts of very personal information.²⁰

Services, such as Florida's SunPass, enable people to drive right through toll booths and receive a monthly bill instead of having to carry cash and face the delay of long lines at the toll booths.²¹ A *botched system*

It is society and not the courts which gives rise to, which shapes in the first instance . . . emerging institution[s]; which kicks the courts into action. It is only from observation of society that the courts can pick their notions of what needs the new institution serves, what needs it baffles.

LLEWELLYN, *supra*, at 63.

14. See Broberg, *supra* note 1.

15. See Christopher G. Bradley, *FinTech's Double Edges*, 93 CHI.-KENT L. REV. 61, 71 (2018). The poor and elderly have limited access to the benefits of technology. *Id.* at 72. Rural areas and minority communities lack adequate access to broadband, presenting "a major constraint on economic opportunity and mobility." K. Sabeel Rahman, *The New Utilities: Private Power, Social Infrastructure, and the Revival of the Public Utility Concept*, 39 CARDOZO L. REV. 1621, 1653 (2018). Financial institutions have not designed websites and apps tailored to meet the needs of the elderly. See Joshua C.P. Reams, Comment, *Twenty-First Century Advertising and the Plight of the Elderly Consumer*, 52 WILLAMETTE L. REV. 325, 333 (2016).

16. Bradley, *supra* note 15, at 71–72; Monica Anderson, *Digital Divide Persists Even as Lower-Income Americans Make Gains in Tech Adoption*, PEW RES. CTR. (Mar. 22, 2017), <http://www.pewresearch.org/fact-tank/2017/03/22/digital-divide-persists-even-as-lower-income-americans-make-gains-in-tech-adoption/>.

17. See discussion *infra* Part III.

18. "Technology, a Boon to Disabled", DECCAN HERALD (Jan. 16, 2010, 11:08 PM), <http://www.deccanherald.com/content/47216/technology-boon-disabled.html>.

19. Joshua Brockman, *Tech Makes Life Easier for Disabled Travelers, Until They Board*, N.Y. TIMES, June 26, 2018, at B5.

20. FED. TRADE COMM'N, INTERNET OF THINGS: PRIVACY & SECURITY IN A CONNECTED WORLD i–ii, vii (2015), <http://www.ftc.gov/system/files/documents/reports/federal-trade-commission-staff-report-november-2013-workshop-entitled-internet-things-privacy/150127iotrpt.pdf>.

21. FLA. TURNPIKE ENTERPRISE, FLORIDA'S TURNPIKE: ALL-ELECTRONIC, NO-CASH TOLLING FREQUENTLY ASKED QUESTIONS 1 (Sept. 2015),

upgrade, however, resulted in drivers receiving erroneous bills for hundreds of dollars.²²

Google dominates internet search with an almost ninety percent market share, and Facebook is the main social network.²³ If they do not deliver the services users want, they would not be so tremendously popular, but they also collect, store, and use huge amounts of information about users.²⁴ As a result, “[t]hey can affect not only our wallets but our privacy, autonomy, democracy, and well-being.”²⁵

Carriers, such as AT&T and T-Mobile, have brought consumers the many revolutionary features of cell phones that have benefitted users in many ways—providing convenient communication with others, email, text messages, navigation tools, and cameras.²⁶ Consumers can increase the phone’s level of service by consenting to share their location to the carrier.²⁷ But it turns out that carriers actually depend on third parties to maintain location information, and some third parties ascertain user locations without obtaining their consent.²⁸

http://www.floridasturnpike.com/documents/aet/All-Electronic%20Tolling%20FAQs%20Sept%202015_print.pdf.

22. Sheri Kotzum, *Botched Upgrade Leaves SunPass Users Facing Huge Fees*, NW. FLA. DAILY NEWS (Aug. 13, 2018, 11:51 AM), <http://www.nwfdailynews.com/news/20180811/botched-upgrade-leaves-sunpass-users-facing-huge-fees>.

23. Greg Ip, *Capital Account: Bail-Bond Ad Bans Spark Web Debate*, WALL ST. J., July 5, 2018, at A2.

24. Maurice E. Stucke, *Here Are All the Reasons It’s a Bad Idea to Let a Few Tech Companies Monopolize Our Data*, HARV. BUS. REV. (Mar. 27, 2018), <http://hbr.org/2018/03/here-are-all-the-reasons-its-a-bad-idea-to-let-a-few-tech-companies-monopolize-our-data>.

25. *Id.*

26. See Drew FitzGerald, *Third Parties Know Exactly Where You Are*, WALL ST. J., July 16, 2018, at B4; *8 Advantages and Disadvantages of Cell Phones*, FUTUREOFWORKING, <http://www.futureofworking.com/8-advantages-and-disadvantages-of-cell-phones> (last visited May 1, 2019).

27. Zack Whittaker, *Verizon, Sprint, AT&T and T-Mobile Stop Sharing Real-Time Cell Phone Location Data*, ZDNET (June 19, 2018, 11:49 AM), <http://www.zdnet.com/article/senator-rebukes-carriers-sharing-real-time-location-data/>; Fred Zahradnik, *Tracking and Other Cell Phone GPS Services*, LIFEWIRE (Oct. 30, 2018), <http://www.lifewire.com/gps-tracking-and-services-on-phone-1683467>.

28. Whittaker, *supra* note 27. “Mapping a cell phone’s location over the course of [one hundred twenty-seven] days provides an all-encompassing record of the holder’s whereabouts. As with GPS information, the time-stamped data provides an intimate window into a person’s life” *Carpenter v. United States*, 138 S. Ct. 2206, 2217 (2018).

Airlines use technology to provide passengers with many conveniences.²⁹ Passengers can relax by watching television programs, movies, or the news on the screen provided on the back of the seat in front of them.³⁰ Or they can connect to the airline's Wi-Fi and use their laptop to catch up on work.³¹ Alaska Airlines gives its flight attendants an app on their mobile devices that they can use to report passengers who create problems, such as sexual harassment, to the company.³² Flight attendants on United Airlines have an app that provides them with information about each frequent flyer passenger.³³

“[T]he Internet of Things (“IoT”) [is] an interconnected environment where all manner of objects have a digital presence and the ability to communicate with other objects and people.”³⁴ IoT has the potential to provide substantial benefits to users.³⁵ There are many obvious risks, however, including security breaches and privacy invasions.³⁶ An unanticipated risk has emerged as well.³⁷ IoT is being used as an instrument of domestic abuse in which the abuser uses IoT “as a means for harassment, monitoring, revenge, and control.”³⁸

29. Marisa Garcia, *6 Innovative In-Flight Technologies Keeping Passengers Distracted*, SKIFT (May 13, 2015, 7:15 AM), <http://www.skift.com/2015/05/13/six-hand-me-down-ife-solutions-which-are-pretty-good-news-for-passengers/>.

30. *Id.*

31. *See id.*

32. Scott McCartney, *The Middle Seat: What the Airline Knows About the Guy in Seat 12A*, WALL ST. J., June 21, 2018, at A11.

33. *Id.* Flight attendants on United Airlines flights have an app that can show them detailed information on each passengers' last five flights. *Id.*

34. FED. TRADE COMM'N, *supra* note 20, at 1. “[T]he [IoT] involves a transformation of everyday physical objects into smart objects able to react to and communicate with the world around them in an efficient and frictionless way.” Jessie Cheng, *Toward the Internet of Value: The Internet of Things and the Future of Payment Systems*, in ELECTRONIC PAYMENT SYSTEMS: LAW AND EMERGING TECHNOLOGIES 287, 287 (1st ed. 2017).

35. *See* FED. TRADE COMM'N, *supra* note 20, at 2. “Connected health devices will allow consumers with serious health conditions to work with their physicians to manage their diseases.” *Id.* “Connected cars will notify first responders in the event of an accident.” *Id.* IoT in the home can provide homeowners with information allowing them to use energy more efficiently and alerting them to water in their basement. *Id.* at 8–9.

36. *Id.* at 10–11.

37. *See* Nellie Bowles, *Thermostats, Locks and Lights: Digital Tools of Domestic Abuse*, N.Y. TIMES: TECH. (June 23, 2018), <http://www.nytimes.com/2018/06/23/technology/smart-home-devices-domestic-abuse.html>.

38. *Id.* Abusers use home IoT to “watch and listen . . . scare or show power. Even after a partner had left the home, the devices often stayed and continued to be used to intimidate and confuse.” *Id.*

Video games have provided children with many hours of entertainment.³⁹ In addition, “[t]hey can help students improve in math and history, plus nurture team-building skills and creativity.”⁴⁰ But experts fear they may also have serious negative effects on behavior.⁴¹ Young children have difficulty telling the difference between what is real and what is fantasy.⁴² This creates behavioral problems when they interact with a virtual personal assistant such as Alexa or Siri.⁴³

Having described some of the features of the current technological revolution and the problems they cause, Part III briefly reviews lawmakers’ failure to take action to provide safeguards or remedies for injury that may occur.⁴⁴

III. LAWMAKERS HAVE NOT RESPONDED TO THE TECHNOLOGICAL REVOLUTION

The technological developments described in Part II have had a profound impact on consumers.⁴⁵ While they have provided consumers with many benefits, they also have inflicted many costs.⁴⁶ To an overwhelming extent, legislatures and government agencies have been silent.⁴⁷

39. See Keith Stuart, *What Every Parent Needs to Know About Video Games: A Crash Course*, GUARDIAN (June 2, 2014, 7:16 PM), <http://www.theguardian.com/technology/2014/jun/02/parents-guide-video-games-playstation-xbox-wii-apps-children>.

40. Sarah E. Needleman, *Game Developers Are Making It Hard for Players to Stop — Availability on Multiple Devices Add to Allure, Long Hours*, WALL ST. J., Aug. 21, 2018, at B4.

41. See *id.* The World Health Organization has added a new disease classification—*gaming disorder*. *Id.*

42. Sue Shellenbarger, *Alexa! Tell My Child to Behave! — Children as Young as 1 Are Using Voice-Activated Technology, but Some Parents Worry They’re Picking Up Rude Habits*, WALL ST. J., July 11, 2018, at A9.

43. See *id.* “Many [young children] see smart speakers as magical, imbue them with human traits and boss them around like a Marine drill sergeant, according to several new studies in the past year.” *Id.* Because adults have difficulty restricting the amount of time they spend on various apps, Apple and Google are developing tools that allow users to limit the time they spend each day on various apps. Joanna Stern, *Willpower Eased iPhone Addiction*, WALL ST. J., Sept. 12, 2018, at B4.

44. See discussion *infra* Part III.

45. See discussion *supra* Part II.

46. See Daniel Callahan, *Health Care Costs and Medical Technology, in FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK FOR JOURNALISTS, POLICYMAKERS, AND CAMPAIGNS* 79, 79–80 (Mary Crowley ed., 2008).

47. See *id.* at 81.

The most important areas in which lawmakers have not acted are data security and consumer privacy.⁴⁸ The technological developments described in Part II have greatly increased the risk that data about personal consumer information will be collected, often secretly stored, sold to others, or stolen.⁴⁹ As a result, there has been a substantial loss of consumer privacy.⁵⁰ The United States, however, has no comprehensive law ensuring consumer privacy.⁵¹ Instead, it has laws covering narrowly-defined situations with limited scope and inadequate consumer remedies.⁵²

There are exceptions, however.⁵³ A few states have enacted statutes or regulations that begin to deal with consumer privacy.⁵⁴ The European Union's General Data Protection Regulation, effective in May 2018, may impact consumers in the United States because some multi-national companies are adopting it as their standard operating practice in every

48. FED. TRADE COMM'N, *supra* note 20, at vii–viii.

49. Cheng, *supra* note 34, at 294; McCartney, *supra* note 32; John D. McKinnon, *Lawmakers to Quiz Tech Giants on Privacy*, WALL ST. J., Sept. 13, 2018, at A6; *see also* discussion *supra* Part II.

50. FED. TRADE COMM'N, *supra* note 20, at 10–11.

51. *See* David Lott, *The GDPR's Impact on U.S. Consumers*, FED. RES. BANK ATLANTA (June 4, 2018), <http://takeonpayments.frbatlanta.org/2018/06/the-gdprs-impact-on-us-consumers.html>. “There have been numerous efforts in the United States to pass uniform privacy legislation, with little or no change.” *Id.*

52. *See* 15 U.S.C. §§ 6501–6506 (2012) (coverage limited to children under thirteen and no private right of action); 15 U.S.C. §§ 6801–6809, 6821–6827 (2012) (limited privacy disclosures to customers of the financial institutions that are covered by the Act; no private right of action); 15 U.S.C. § 7701 (2012); 15 U.S.C. § 7706 (2012) (no private right of action); 47 U.S.C. § 227 (2012) (protections limited to *automat[ed] telephone dialing systems*). Each of these statutes has its own limitations in terms of type of institutions or situations covered as well as no or restricted consumer remedies. Eleanor Lumsden, *Securing Mobile Technology & Financial Transactions in the United States*, 9 BERKELEY BUS. L.J. 139, 172 (2012). Part II explains that cell phone carriers use third parties to obtain location data without users' consent. FitzGerald, *supra* note 26; *see also* discussion *supra* Part II. Some experts believe that does not violate any law. FitzGerald, *supra* note 26.

53. *See* CAL. CIV. CODE §§ 1798.100–1798.199 (West 2019); Ben Kochman, *3 Things You Need to Know About NY's Latest Cyber Regs*, LAW360 (Aug. 30, 2018, 6:23 PM), <http://www.law360.com/articles/1077789/3-things-you-need-to-know-about-ny-s-latest-cyber-regs>.

54. *See* CAL. CIV. CODE §§ 1798.100–1798.199. California Assembly Bill No. 375 deals with the collection, storage, and sale of personal information of California residents. Assemb. B. 375, 2017-2018 Leg., Reg. Sess. (Cal. 2018). It becomes effective on Jan. 1, 2020. *Id.* § 1798.100. New York's Department of Financial Services issued regulations that became effective in September 2018 requiring the destruction of old data, safeguarding sensitive information on company devices or servers, and having the ability to digitally trace the source of a data breach. Press Release, Dep't of Fin. Servs., DFS Superintendent Vullo Reminds Regulated Entities of Approaching Cybersecurity Regulation Compliance Effective Date (Aug. 8, 2018) (on file with author); Kochman, *supra* note 53.

country where they do business—regardless of whether the regulation applies to consumers in those countries.⁵⁵

In addition, there are no laws explicitly dealing with problems consumers might face related to the electronic age in which they now live.⁵⁶ Examples include the IoT;⁵⁷ facial and voice recognition;⁵⁸ surveillance by drones;⁵⁹ electronic monitoring by stores in order to collect, store, and sell customer information,⁶⁰ or charge customer accounts for purchases;⁶¹ and injury to persons and property caused by drones⁶² and self-driving vehicles.⁶³

As discussed in Part II, many technology developments have resulted in products that provide consumers with significant benefits.⁶⁴ But

55. See Tony Romm et al., *Europe, Not the U.S., Is Now the Most Powerful Regulator of Silicon Valley*, WASH. POST (May 25, 2018), http://www.washingtonpost.com/business/technology/europe-not-the-us-is-now-the-most-powerful-regulator-of-silicon-valley/2018/05/25/f7dfb600-604f-11e8-8c93-8cf33c21da8d_story.html.

56. See Daniel Malan, *The Law Can't Keep Up with New Tech. Here's How to Close the Gap*, WORLD ECON. F. (June 21, 2018), <http://www.weforum.org/agenda/2018/06/law-too-slow-for-new-tech-how-keep-up/>.

57. FED. TRADE COMM'N, *supra* note 20, at vii. As described in Part II, IoT is being used as an instrument of domestic abuse. Bowles, *supra* note 37. Victims sometimes request courts to issue restraining orders prohibiting the abuser from having contact with the victim. *Id.* Often, they do not realize they need to ask the judge to specifically prohibit using IoT to abuse the victim. *Id.* If the restraining order merely forbids contact, it may not cover the abuser remotely manipulating devices connected to IoT. *Id.*

58. Natasha Singer, *Tech to Spot Faces Gets It Wrong, Say Lawmakers*, N.Y. TIMES, July 27, 2018, at B4; Oleksandr Pastukhov & Els Kindt, *Voice Recognition: Risks to Our Privacy*, FORBES (Oct. 6, 2016, 5:16 PM), <http://www.forbes.com/sites/realspin/2016/10/06/voice-recognition-every-single-day-every-word-you-say/#2a2f570e786d>.

59. Gail Schontzler, *MSU Moves to Restrict Drones on Campus*, BOZEMAN DAILY CHRON. (Sept. 6, 2018), http://www.bozemandailychronicle.com/news/montana_state_university/msu-moves-to-restrict-drones-on-campus/article_18443f34-51b4-5731-bb4d-b1ad15e353c2.html.

60. JOSEPH TUROW, *THE AISLES HAVE EYES: HOW RETAILERS TRACK YOUR SHOPPING, STRIP YOUR PRIVACY, AND DEFINE YOUR POWER* 3–5 (2017).

61. Dominik Bosnjak, *Amazon's Mission of Making Cashiers Redundant Continues*, ANDROID HEADLINES (Sept. 10, 2018, 7:23 AM), <http://www.androidheadlines.com/2018/09/amazons-mission-of-making-cashiers-redundant-continues.html>.

62. Schontzler, *supra* note 59.

63. Bridget Clerkin, *Are Today's Laws Adequate for Self-Driving Cars?*, DMV.ORG: ARTICLES (May 8, 2018), <http://www.dmv.org/articles/can-current-laws-handle-self-driving-vehicles>; see also Keith Laing, *Few Carmakers Submit Self-driving Car Safety Reports*, DETROIT NEWS (Sept. 10, 2018, 1:51 PM) <http://www.detroitnews.com/story/business/autos/mobility/2018/09/10/few-carmakers-submit-self-driving-safety-assessments/1076691002/>.

64. See discussion *infra* Part II.

only those who can afford those products realize those benefits.⁶⁵ For those who do not have the financial means, the impact of the *digital divide* will only increase.⁶⁶ It is not only the poor who are deprived of this technological revolution.⁶⁷ Regardless of how much money a person has, access also depends on the availability of high-speed internet, cell phone towers, etc.⁶⁸ Many rural areas lack that access.⁶⁹ Legislation to improve affordability and access may be the only way to provide services that are increasingly regarded as essential.⁷⁰ Examples of government programs from the past include rural electrification⁷¹ and universal access to telephone service.⁷²

Social scientists have only begun to assess the psychological impact of this world of pervasive technology.⁷³ But some studies suggest many have become dependent on it and, as a result, may have become socially isolated.⁷⁴ In the future, they may decide legal measures are necessary, at least with regard to young people.⁷⁵ An example of legislation to protect children is the Children's Online Privacy Protection Act.⁷⁶ It prohibits

65. See Anderson, *supra* note 16.

66. See *id.* The models introduced in September 2018 cost an average of \$949—fifteen percent more than a year earlier. Tripp Mickle, *Apple's Phones Get Bigger, Pricier — Latest Models Cost \$949 on Average, 15% More than iPhones Launched a Year Ago*, WALL ST. J., Sept. 13, 2018, at B1.

67. Anderson, *supra* note 16; see also Mark Niese, *Power Co-ops Become Rural Internet Saviors: Utilities Step in to Close Digital Gap in Georgia's Remote Communities*, ATLANTA J.-CONST., Sept. 10, 2018, at A1.

68. See Niese, *supra* note 67.

69. *Id.*

70. See *id.*

71. Jim Galloway, *Rescuing Rural Georgia: A Search for Economic, Political Rationality*, ATLANTA J.-CONST., Sept. 9, 2018, at B1 (quoting Professor Joe Crespino saying there is a *straight-up direct analogy* between the rural electrification program under former President Roosevelt and Congress and the need for government support for rural broadband); see also Niese, *supra* note 67.

72. See Edward Wyatt, *Appeals Court Rules for F.C.C. on Broadband Fund*, N.Y. TIMES, May 24, 2014, at B2. A Federal Communications Commission plan has partially ameliorated the problem of internet access. *Id.* It has converted the universal telephone program to one that would provide a subsidy for high-speed internet service in designated areas of need. *Id.* It has withstood a legal challenge in a case before the Tenth Circuit. See *In re FCC 11-161*, 753 F.3d 1015, 1159 (10th Cir. 2014).

73. See Kaveri Subrahmanyam et al., *The Impact of Computer Use on Children's and Adolescents' Development*, 22 J. APPLIED DEVELOPMENTAL PSYCHOL. 7, 18–19 (2001).

74. *Id.* at 19.

75. See Joanne Orlando, *Banning Kids from Using Technology Is Counter-Productive*, CONVERSATION: SCI. & TECH. (Feb. 10, 2015, 6:44 PM), <http://www.theconversation.com/banning-kids-from-using-technology-is-counter-productive-37173>.

76. 15 U.S.C. §§ 6501–6506 (2012); 16 C.F.R. § 312 (2018).

companies from collecting personal information online from children without parental consent.⁷⁷

Parts II and III have described the larger technological context in which online contracting occurs.⁷⁸ Part IV begins the examination of the formation of contracts in cyberspace by first briefly contrasting how parties entered into contracts over roughly the last two millennia.⁷⁹

IV. A BRIEF HISTORY OF CONTRACT MEDIA AND SIGNATURES

In the ancient Middle East, most people were illiterate⁸⁰ and paper in the form of papyrus was expensive,⁸¹ fragile, not pliable, and subject to deterioration from moisture or cracking if conditions were too dry.⁸² People engaging in business who wanted a tangible manifestation of their transaction used seals.⁸³ A seal could function as a signature.⁸⁴ For example, persons would carve their own unique image on a stone and make an impression of it onto clay.⁸⁵ The center of the object containing the image “was hollowed out and a cord passed through so that it could be worn around the neck. This highly personal object performed the function of a signature in modern society.”⁸⁶ Today, passwords that consumers use online also serve as a way to uniquely identify themselves.⁸⁷

77. 15 U.S.C. § 6502(b)(1)(A)(ii); 16 C.F.R. § 312.3.

78. Budnitz, *supra* note 13, at 743, 745; *see also* discussion *supra* Parts II–III.

79. *See* discussion *infra* Part IV.

80. Dan Falk, *More People Were Literate in Ancient Judah than We Knew*, MENTAL FLOSS (Apr. 11, 2016), <http://www.mentalfloss.com/article/78416/more-people-were-literate-ancient-judah-we-knew>. Christopher Rollston, an expert in Semitic languages and literature at George Washington University, opined that “[l]iteracy in ancient Israel and Judah was probably [fifteen] or [twenty] percent of the population, at most.” *Id.*

81. WILLIAM V. HARRIS, *ANCIENT LITERACY* 194–95 (1991).

82. *Papyrus*, WIKIPEDIA, <http://en.wikipedia.org/wiki/Papyrus> (last updated Mar. 31, 2019, 4:35 PM). In Egypt, in the years before and after the first century A.D., parchment was also available, but its use was limited because it was made from animal skins. *See id.*

83. Joshua J. Mark, *Cylinder Seals in Ancient Mesopotamia — Their History and Significance*, ANCIENT HIST. ENCYCLOPEDIA (Dec. 2, 2015), <http://www.ancient.eu/article/846/cylinder-seals-in-ancient-mesopotamia---their-hist/>.

84. *Id.*

85. *See id.*

86. THE RABBINICAL ASSEMBLY: THE UNITED SYNAGOGUE OF CONSERVATIVE JUDAISM, ETZ HAYIM: TORAH AND COMMENTARY 236 & n.18, (David L. Leiber et al. eds. & trans., Jewish Publ’n. Soc’y 1999) (2001). The Biblical story of Judah and Tamar illustrate the use of the seal as a pledge. *Id.* Judah promises to pay Tamar one goat when he returns to his home. *Id.* To ensure that he will satisfy this obligation, he gives Tamar his seal. *Id.*

87. *See More than Words*, ATLANTIC, <http://www.theatlantic.com/sponsored/ibm-2018/beyond-passwords/1859/> (last visited May 1, 2019).

With increased literacy and the wide availability of inexpensive paper, written agreements became widespread and the parties to a transaction could indicate their consent by affixing their signature to a piece of paper.⁸⁸ Although a forger can produce a *perfect signature*, as a general matter, each signature is different from every other, so it serves as a unique identifier.⁸⁹ Handwriting experts often testify in court as to the authenticity of a signature.⁹⁰ As described in Part V.F, clicking with a mouse on a button labeled “I agree” often has replaced the written signature when parties contract online.⁹¹

The Uniform Commercial Code (“UCC”) illustrates modern American law with regard to the medium on which contracts are written and what constitutes a signature.⁹² UCC Article 2 applies to the sale of goods.⁹³ It has been amended to conform to the federal law validating electronic records—the Electronic Signatures in Global and National Commerce Act (“E-Sign”).⁹⁴ It replaces the former UCC definitions of *writing* and *written* with a new term—a *record*.⁹⁵ A record “means information that is inscribed [in] a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.”⁹⁶

The UCC defines signed as including “any symbol executed or adopted [by a party] with present intention to adopt or accept a writing.”⁹⁷

88. See Hope Restle, *The History of Successful Business Agreements in One Handy Chart*, BUS. INSIDER (June 17, 2015, 12:51 PM), <http://www.businessinsider.com/history-of-the-handshake-2015-6>; *Paper*, WIKIPEDIA, <http://en.wikipedia.org/wiki/Paper> (last updated Mar. 28, 2019, 3:57 AM). Paper was invented in China in the early second century, A.D. *Paper, supra*.

89. See Jacques Mathyer, *The Expert Examination of Signatures*, 52 J. CRIM. L., CRIMINOLOGY & POLICE SCI. 122, 122, 124–25 (1961).

90. See *Yarbrough v. Yarbrough*, No. 107677-RD, 2018 Tenn. App. LEXIS 259, at *1, *16–18 (Tenn. Ct. App. May 11, 2018) (describing in detail qualification of expert forensic document examiner and the three-step process of his examination of wife’s handwriting).

91. Jeff C. Dodd & James A. Hernandez, *Contracting in Cyberspace*, COMPUTER L. REV. & TECH. J., Summer 1998, at 1, 3–4. In a clickwrap agreement, “clicking an ‘I Agree’ button . . . is the digital equivalent of a signature at the bottom of a printed form.” RESTATEMENT OF CONSUMER CONTRACTS, § 2, at 33 (AM. LAW INST., Discussion Draft 2017).

92. U.C.C. § 1-201 (AM. LAW INST. & UNIF. LAW COMM’N 2017).

93. *Id.* § 2-102.

94. Electronic Signatures in Global and National Commerce Act, Pub. L. No. 106-229, § 101, 114 Stat. 464, 464–65 (2000) (codified as amended at 15 U.S.C. § 7001 (2012)).

95. *Id.* § 101(c).

96. 15 U.S.C. § 7006(9) (2012); U.C.C. § 1-201(31).

97. U.C.C. § 1-201(37). The consumer’s signature, or its electronic equivalent, may not always be required. *Zacher v. Comcast Cable Commc’n LLC*, No. 17 CV 7256, 2018 WL 3046955, at *3–*4 (N.D. Ill. June 20, 2018). In *Zacher v. Comcast Cable*

As explained in an Official Comment, “[t]he symbol may be printed, stamped or written; it may be by initials or by thumbprint The question always is whether the symbol was executed or adopted by the party with present intention to adopt or accept the writing.”⁹⁸ Under this definition, a username or password typed onto a website apparently could qualify as a signature.⁹⁹ But neither legislation nor case law has determined whether a click with a mouse would satisfy this provision.¹⁰⁰

Additional guidance is provided from definitions in two statutes specifically tailored to apply to electronic transactions: E-Sign and the Uniform Electronic Transactions Act (“UETA”) that forty-seven states and the District of Columbia have enacted.¹⁰¹ For example, E-Sign requires that in consumer transactions electronic records be perceivable in tangible form.¹⁰² UETA requires, in addition, that the electronic record be *capable of retention* and the sender cannot inhibit the recipient’s ability to print or store the record.¹⁰³ Sellers can satisfy this requirement by posting the agreement in a format in which consumers can produce a paper copy through their printers.¹⁰⁴ It is apparent from this requirement that policymakers recognized

Communications LLC, the court held that the Federal Arbitration Act (“FAA”) requires an arbitration agreement to be in writing but does not require such agreements to be signed. *Id.*

98. U.C.C. § 1-201 cmt. 37.

99. Dodd & Hernandez, *supra* note 91, at 18; *see also* U.C.C. § 1-201 cmt. 37.

100. *See* U.C.C. § 1-201 cmt. 37; Dodd & Hernandez, *supra* note 91, at 18.

101. UETA — *Uniform Electronic Transactions Act*, RIGHTSIGNATURE, <http://www.rightsignature.com/legality/ueta-act> (last visited May 1, 2019); *see also* 15 U.S.C. § 7001; UNIF. ELEC. TRANSACTIONS ACT § 2 (UNIF. LAW COMM’N 1999). E-Sign is codified in 15 U.S.C. § 7001. 15 U.S.C. § 7001(a). *Electronic signature* is defined in 15 U.S.C. § 7006(5). *Id.* § 7006(5). *Record* is defined in 15 U.S.C. § 7006(9). *Id.* § 7006(9). E-Sign and UETA apply to UCC Article 2, the article governing transactions in goods. *Id.*; UNIF. ELEC. TRANSACTIONS ACT § 3(b)(2), cmt. 4. *See* U.C.C. § 1-108 on the relationship between the UCC and E-Sign. U.C.C. § 1-108. “[UETA] is not a general contracting statute, and questions of substantive contract law are governed by the applicable body of contract law, such as the common law of contracts or Article 2 of the [UCC]” Juliet M. Moringiello & William L. Reynolds, *Electronic Contracting Cases 2008 – 2009*, 65 BUS. LAW. 317, 322 (2009). Nevertheless, “for practical purposes the UETA and E-SIGN may be viewed as adjuncts of the UCC.” Donald C. Lampe, *The Uniform Electronic Transactions Act and Federal E-SIGN Law: An Overview*, 55 CONSUMER FIN. L.Q. REP. 255, 256 (2001).

102. 15 U.S.C. § 7006(9); U.C.C. § 1-201(31). E-Sign also includes provisions requiring a business to obtain the consumer’s consent to provide information through electronic records. 15 U.S.C. § 7001(c)(1).

103. UNIF. ELEC. TRANSACTIONS ACT § 8(a).

104. *See id.* § 8(a), (c). The Official Comment to this section explains that the recipient “must have the ability to get back to the information in some way at a later date.” *Id.* § 8, cmt. 3. “The policies underlying laws requiring the provision of information in writing warrant [requiring] the sender to make the information available in a manner which will permit subsequent reference.” *Id.*

the risk of consumers having to rely only on records in electronic form and the continuing reliability of paper documents.¹⁰⁵

In addition, UETA defines *electronic signature* to mean “an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.”¹⁰⁶ Intent is particularly problematic when consumers engage in online transactions and payments because anyone can type any consumer’s name into an online form.¹⁰⁷ The Personal Identification Number (“PIN”) or password is one way for consumers to authenticate who they are.¹⁰⁸ Biometrics such as facial recognition and scanning a person’s fingerprint or iris are other methods being developed.¹⁰⁹

UCC Article 2 applies to *transactions in goods*.¹¹⁰ It is not clear from the text of the UCC whether software qualifies as a good.¹¹¹ Lacking the inclusion of software in the definition of *goods*, courts have not universally held that software qualifies as a good.¹¹² It is clear, however, that

105. See *id.* § 8(a).

106. UNIF. ELEC. TRANSACTIONS ACT § 2(8). E-Sign’s definition of *electronic signature* is almost identical. 15 U.S.C. § 7006(5).

107. See Matthew A. Cordell, *An Introduction to the Law of Electronic Signatures and Electronic Records in North Carolina (Part 2)*, TECH., PRIVACY & DATA SEC. L. BLOG (May 24, 2014, 6:39 PM), <http://www.privacylawnc.blogspot.com/2014/05>.

108. NAT’L TELECOMM. & INFO. ADMIN., U.S. DEP’T OF COMMERCE, ELECTRONIC SIGNATURES: A REVIEW OF THE EXCEPTIONS TO THE ELECTRONIC SIGNATURES IN GLOBAL AND NATIONAL COMMERCE ACT 6 (2003), <http://www.ntia.doc.gov/files/ntia/publications/esignfinal.pdf>. UCC Article 9 replaces the terms *sign* and *signed* with the term *authenticate*. U.C.C. § 9-102(a)(7) (AM. LAW INST. & UNIF. LAW COMM’N 2017). It did this “to . . . authenticat[e] . . . all records, not just writings.” *Id.* § 9-102, cmt 9b; see also UNIFORM COMPUTER INFORMATION TRANSACTIONS ACT § 102(a)(6) (NAT’L CONFERENCE COMM’N UNIF. STATE LAWS 2002). The Uniform Computer Information Transaction Act was enacted in Maryland and Virginia. *What Is the Uniform Computer Information Transaction Act (UCITA)?*, DANIEL W. UHLFELDER P.A., <http://www.dwulaw.com/news/what-is-the-uniform-computer-information-Transaction-Act-UCITA.shtml> (last visited May 1, 2019); see also UNIF. COMP. INFO. TRANSACTIONS ACT § 102.

109. See Bryan Yurcan, *Corporate Customers Want Retail’s Bells and Whistles, Too*, AM. BANKER (July 3, 2018, 11:43 AM), <http://www.americanbanker.com/news/corporate-customers-want-retail-banking-techs-bells-and-whistles-too> (reporting that a Merrill Lynch mobile app includes fingerprint and facial recognition biometric authentication).

110. U.C.C. § 2-102.

111. See U.C.C. § 2-105(1). UCC section 2-105(1) defines goods generally as “all things . . . which are movable.” *Id.*

112. Stacy-Ann Elvy, *Hybrid Transactions and the INTERNET of Things: Goods, Services, or Software?*, 74 WASH. & LEE L. REV. 77, 126–27 (2017). In *Advent System Ltd. v. Unisys Corp.*, the court found a computer program was a good because it could be put in the form of a *floppy disc* or other medium that was tangible and movable. 925 F.2d 670, 674–75 (3d Cir. 1991). But some courts refuse to apply the UCC. See Elvy, *supra*, at 126–

the sale of personal services do not qualify as goods.¹¹³ E-Sign and UETA include definitions that would apply to these transactions.¹¹⁴ State contract law applies to contracts for services.¹¹⁵ In important respects, the UCC differs significantly from the common law of contracts.¹¹⁶

As described above, in ancient times, a party to a transaction could be authenticated by a seal that served as a unique personal identifier, rather than a signature.¹¹⁷ In cyberspace transactions, a party is authenticated by a unique electronic personal identifier, such as a password, instead of a signature.¹¹⁸ It is not clear, however, that electronic identifiers are reliable.¹¹⁹ For example, facial recognition is unreliable because it may incorrectly identify black women.¹²⁰ As a result, some modern methods may even be less reliable than the ancient seal.¹²¹

Throughout history, some agreements have been oral rather than written.¹²² These agreements often are referred to as *gentlemen's agreements*.¹²³ Typically, the parties signify their intention to be bound to

27. For example, some courts determine that the transaction is a license of software, not a sale, and several UCC Article 2 provisions apply only to sales. *Id.* at 126.

113. Bonna Lynn Horovitz, Note, *Computer Software as a Good Under the Uniform Commercial Code: Taking a Byte Out of the Intangibility Myth*, 65 B.U. L. REV. 129, 130 (1985).

114. See 15 U.S.C. § 7006 (2012); UNIF. ELEC. TRANSACTIONS ACT § 2 (UNIF. LAW COMM'N 1999).

115. *Common Law and Uniform Commercial Contracts*, LUMEN, <http://courses.lumenlearning.com/workwithinthelaw/chapter/formation-and-types-of-contracts/> (last visited May 1, 2019); see also Raymond T. Nimmer, *Through the Looking Glass: What Courts and UCITA Say About the Scope of Contract Law in the Information Age*, 38 DUQ. L. REV. 255, 262–63 (2000).

116. Horovitz, *supra* note 113, at 140. The rights and remedies of sellers and buyers vary significantly “in the areas of implied warranties, consequential damages, disclaimers, and limitations on liability and taxes,” as well as regarding procedural issues. *Id.*

117. Mark, *supra* note 83.

118. NAT'L TELECOMM. & INFO. ADMIN., *supra* note 108, at 6.

119. See Cordell, *supra* note 107.

120. Derek Hawkins, *The Cybersecurity 202: Lawmakers Worry Amazon's Facial Recognition Tech Could Reinforce Racial Profiling*, WASH. POST: POWER POST (May 29, 2018), <http://www.washingtonpost.com/news/powerpost/paloma/the-cyber-security-202/2018/05/29/the-cybersecurity-202-lawmakers-worry-amazon-s-facial-recognition-tech-could-reinforce-racial-profiling/5b0c10741b326b492dd07eb8>.

121. See Michael Liebi, *Future Trends and Standards in Authentication*, UNITED SECURITY PROVIDERS: WEB SECURITY (Dec. 6, 2016, 9:24 AM), <http://www.united-security-providers.com/blog/future-trends-and-standards-in-authentication/>; Mark, *supra* note 83.

122. See *Gentleman's Agreement – Definition and Meaning*, MKT. BUS. NEWS, <http://www.marketbusinessnews.com/financial-glossary/gentlemans-agreement/> (last visited May 1, 2019).

123. *Id.* A discussion of the sexist nature of this term, implying that only men enter into business transactions, is beyond the scope of this Article.*

their agreement by shaking hands and courts enforce this method of contracting.¹²⁴ This symbolic act involving two persons, often strangers, touching each other's flesh is in stark contrast to consumers accepting a seller's terms by touching and tapping computer screens where a consumer's consent is acknowledged, if at all, by the seller's electronic agent.¹²⁵ The issue is whether touching and tapping should be treated differently when analyzing the legal validity of online contract formation than other methods of showing agreement.¹²⁶

Cyberspace transactions substitute the tangible piece of paper with an electronic record.¹²⁷ The agreement may be easily accessible, as in a pop-up box that automatically appears, known as a *clickwrap contract*.¹²⁸ The consumer may engage in conduct comparable to signing a piece of paper by clicking on a box accompanied by words such as "I agree" or "accept."¹²⁹ Alternatively, it may be relatively inaccessible, as in a *browsewrap contract* where the website does not require the consumer to do anything affirmative or explicit.¹³⁰ If the consumer denies entering into a binding transaction, the seller may contend that engaging in the transaction by selecting what goods to buy and supplying debit or credit card information clearly indicates intent to adopt or accept the seller's agreement.¹³¹

If the consumer enters into a contract online, two other features are involved that are unique to such contracting: Electronic hardware used by the consumer, such as a desktop computer or a smartphone, and a software program.¹³² In addition, the seller must maintain a site accessible on the

124. See Peter Meijes Tiersma, Comment, *The Language of Offer and Acceptance: Speech Acts and the Question of Intent*, 74 CAL. L. REV. 189, 206 (1986). "A party can accept an offer by . . . shaking hands with the other party . . ." *Id.*

125. See *id.* at 206, 216; Dodd & Hernandez, *supra* note 91, at 10.

126. See Budnitz, *supra* note 13, at 750–51.

127. Dodd & Hernandez, *supra* note 91, at 3.

128. See RESTATEMENT OF CONSUMER CONTRACTS § 2, at 33 (AM. LAW INST., Discussion Draft 2017). "In electronic and web-based transactions, assent is often [manifested] by clicking an 'I agree' button. This . . . is the digital equivalent of a signature at the bottom of a printed form." *Id.* Usually the transaction involves payment as well as purchasing. *Id.* at 18. If the consumer instructs the seller to bill the consumer's credit card account, the Truth in Lending Act and Regulation Z apply. See 15 U.S.C. § 1601 (2012); 12 C.F.R. § 1026.1 (2018). If the consumer instructs the seller to obtain funds from a debit card account, the EFTA and Regulation E apply. 15 U.S.C. § 1693; 12 C.F.R. § 1005.1.

129. See Dodd & Hernandez, *supra* note 91, at 3–4.

130. RESTATEMENT OF CONSUMER CONTRACTS § 2, at 35 (AM. LAW INST., Discussion Draft 2017). In a browsewrap contract, there is no "I agree" button to click on. *Id.* "The website includes a link to another page with the standard terms, and consumers, by proceeding with the purchase or simply by continuing to use the website, are deemed to have adopted the standard terms as part of the contract." *Id.*

131. See *id.* at 18–19.

132. See 15 U.S.C. § 7001(c).

internet.¹³³ The agreement is typically on one of the site's pages.¹³⁴ It is entirely within the power of the seller to remove the agreement that was on the site when the consumer indicated his or her agreement and replace it with a different agreement.¹³⁵ Unless consumers save a copy of the contract at the time they indicate their agreement, it may be impossible—short of discovery in a lawsuit or arbitration—for them to disprove the terms the seller may claim were posted on the site at the time of the transaction.¹³⁶

V. THE LAW HAS NOT CAUGHT UP WITH TECHNOLOGY

There are serious gaps in the law that apply to sellers and buyers entering into a contractual relationship in the new consumer e-commerce environment that technological developments have produced.¹³⁷ Federal and state legislation leave enormous gaps.¹³⁸ Federal agencies have provided scant guidance.¹³⁹ State statutes, such as those modeled after the UCC and UETA, were not designed to deal with the issues raised by the new ways parties enter into contracts.¹⁴⁰ Case law is divided and does not consider the

133. A.J. Zottola & Robert Parr, *Guidelines for Creating Enforceable Contracts Online* — “The New Way Is the Same as the Old Way,” ASS’N CORP. COUNS. (Dec. 20, 2012), <http://m.acc.com/legalresources/quickcounsel/gfcecco.cfm>.

134. *See id.*

135. *See* Deborah R. Eltgroth, Note, *Best Evidence and the Wayback Machine: Toward a Workable Authentication Standard for Archived Internet Evidence*, 78 *FORDHAM L. REV.* 181, 184–85 (2009).

136. *See id.* at 185. Many consumer agreements include mandatory arbitration clauses requiring consumers to use arbitration services. Richard M. Alderman, *Pre-Dispute Mandatory Arbitration in Consumer Contracts: A Call for Reform*, 38 *HOUS. L. REV.* 1237, 1240 (2001). These services typically permit the arbitrator to restrict discovery. *Id.* at 1249–50. A litigant may be able to retrieve a web page from the past through the *Wayback Machine*. *Using the Wayback Machine*, INTERNET ARCHIVE: WAYBACK MACHINE, <http://help.archive.org/hc/en-us/articles/360004651732-Using-The-Wayback-Machine> (last visited May 1, 2019). But not all sites are available either because the Wayback Machine’s *automated crawlers* are not aware of the site when they engaged in their crawl to access sites, because they were password protected or otherwise inaccessible or because the site owner requested that their sites not be included. *Id.*; Holly Andersen, Note, *A Website Owner’s Practical Guide to the Wayback Machine*, 11 *J. ON TELECOMM. & HIGH TECH. L.* 251, 266 (2013). Furthermore, a litigant may encounter evidentiary obstacles to introducing screen shots of past website pages into evidence. *See* Eltgroth, *supra* note 135, at 191.

137. *See* Adine Mitrani et al., *e-Commerce*, GETTING THE DEAL THROUGH (Aug. 2018), <http://gettingthedealthrough.com/area/11/jurisdiction/23/e-commerce-united-states/>.

138. *See id.*

139. *See id.*

140. *See* UNIF. ELEC. TRANSACTIONS ACT § 8 (UNIF. LAW COMM’N 1999); U.C.C. §§ 2-102, 2-103 (AM. LAW INST. & UNIF. LAW COMM’N 2017); Charles W. Mooney,

ever-changing ways in which technology enables consumers and sellers to enter into these relationships.¹⁴¹

A. *E-Sign*

E-Sign does not deal directly with the manner in which parties enter into an agreement when consumers engage in transactions in an electronic environment.¹⁴² Rather, its chief function is to provide that:

- (1) [A] signature, contract, or other record relating to [a transaction in or affecting interstate commerce] may not be denied legal effect, validity, or enforceability solely because it is in an electronic form; and
- (2) [A] contract relating to such transaction may not be denied legal effect, validity, or enforceability solely because an electronic signature or electronic record was used in its formation.¹⁴³

E-Sign does, however, provide consumers limited safeguards that are related to electronic contracting.¹⁴⁴ If a “rule of law requires information relating to a transaction . . . to be . . . in writing,” the seller may not provide the information in an electronic record unless the consumer has *affirmatively consented*.¹⁴⁵ Moreover, an agreement can be in the form of an electronic record, but it must be *retrievable in perceivable form*.¹⁴⁶

B. *EFTA*

Like E-Sign, the Electronic Fund Transfers Act (“EFTA”) does not directly regulate the manner in which consumers and financial institutions

Jr., *Surveys, Introduction to the Uniform Commercial Code Annual Survey: Same Observations on the Past, Present, and Future of the U.C.C.*, 41 BUS. L. 1343, 1346 (1986).

141. See *Cullinane v. Uber Techs., Inc.*, 893 F.3d 53, 64 (1st Cir. 2018).

142. Electronic Signatures in Global and National Commerce Act, Pub. L. No. 106-229, § 101, 114 Stat. 464, 464 (2000) (codified as amended at 15 U.S.C. § 7001 (2012)); Mike Watson, Comment, *E-Commerce and E-Law: Is Everything E-Okay? Analysis of the Electronic Signatures in Global and National Commerce Act*, 53 BAYLOR L. REV. 803, 813–14 (2001).

143. Electronic Signatures in Global and National Commerce Act, § 101, 114 Stat. at 464.

144. See *id.*; Watson, *supra* note 142, at 821.

145. Electronic Signatures in Global and National Commerce Act, § 101, 114 Stat. at 465; Watson, *supra* note 142, at 815.

146. 15 U.S.C. § 7006(9) (2012); see also Watson, *supra* note 142, at 815.

enter into an agreement in an electronic environment.¹⁴⁷ Instead, it requires that financial institutions provide certain protections to consumers who pay via *electronic fund transfers*.¹⁴⁸ The protections cover transfers made using computers, including smartphones.¹⁴⁹ Those protections include an error resolution procedure, if the consumer claims an error occurred.¹⁵⁰

The EFTA requires a financial institution to provide consumers a periodic statement with information about each electronic transfer, fees, balances, and other information.¹⁵¹ A question that arises is whether the EFTA or its accompanying regulations should be amended to clarify what constitutes an adequate statement when the financial institution sends the statement knowing the consumer will be receiving it only on a mobile device with its small screen.¹⁵² Arguably, it may be far more difficult for consumers to identify errors, especially those that are not in substantial amounts, if they are disclosed on such a small screen.¹⁵³

C. *FTC Act*

In determining whether a seller has complied with the requirements for the formation of a contract that appears on the screen of a mobile device, courts often pay particular attention to the design of the website or app.¹⁵⁴ The Federal Trade Commission (“FTC”) has issued a guidance that indirectly provides information that may assist sellers who want to design agreements that appear on mobile devices that will pass muster with courts and consumers attempting to determine how the agreement should be

147. See 15 U.S.C. § 1693; Electronic Signatures in Global and National Commerce Act, § 101, 114 Stat. at 464; Jessie Cheng et al., *Does It Matter How I Pay?*, A.B.A.: BUS. L. TODAY (June 29, 2017), http://www.americanbar.org/groups/business_law/publication/blt/2017/05/08_Cheng/.

148. 15 U.S.C. § 1693a(7); Cheng et al., *supra* note 147. The term is defined in 15 U.S.C. § 1693a(7) to include debiting a consumer’s account at the point-of-sale. 15 U.S.C. § 1693a(7).

149. See 15 U.S.C. § 1693a(7). 15 U.S.C. § 1693a(7) defines an electronic fund transfer to include *transfers initiated by telephone*. *Id.*

150. *Id.* § 1693f(a). The EFTA also provides the protection of limited liability to consumers when there is an unauthorized transfer. *Id.* § 1693g(a).

151. *Id.* § 1693h.

152. See 15 U.S.C. § 1693h; 12 C.F.R. § 1005.1 (2018).

153. See 15 U.S.C. § 1693f; 12 C.F.R. § 1005.1(b); FED. TRADE COMM’N, .COM DISCLOSURES: HOW TO MAKE EFFECTIVE DISCLOSURES IN DIGITAL ADVERTISING 18 (2013), <http://www.ftc.gov/sites/default/files/attachments/press-releases/ftc-staff-revises-online-advertising-disclosure-guidelines/130312dotcomdisclosures.pdf>.

154. Cullinane v. Uber Techs., Inc., 893 F.3d 53, 61 n.10 (1st Cir. 2018); Nicosia v. Amazon.com, Inc., 834 F.3d 220, 233 (2d Cir. 2016); Nguyen v. Barnes & Noble, Inc., 763 F.3d 1171, 1177 (9th Cir. 2014).

disclosed on a small screen such as those on a smartphone and how the screen should be designed to gain the consumer's acceptance.¹⁵⁵

The specific subject matter of the guidance is how sellers should make disclosures in digital advertising that complies with the Federal Trade Commission Act ("FTC Act").¹⁵⁶ The FTC Act prohibits unfair and deceptive acts and practices.¹⁵⁷ The FTC guidance explains that this requires "[c]lear and [c]onspicuous [d]isclosures in [o]nline [a]dvertisements."¹⁵⁸ The guidance addresses disclosure issues that arise because of the small size of the screen on mobile devices, and how that requires considerations that are different from disclosures on the screen of a desktop computer.¹⁵⁹ For example, because of the size of the screen on the mobile device, a consumer would have to engage in "significant vertical and horizontal scrolling" to see disclosures.¹⁶⁰ The guidance includes specific suggestions for how to design the mobile device's website pages to avoid discouraging consumers from scrolling to view disclosures.¹⁶¹ Disclosures on smartphones are more likely to comply with the law "on websites that are optimized for mobile devices or created using responsive design, which automatically detects the kind of device the consumer is using to access the site and arranges the content on the site so it makes sense for that device."¹⁶²

Privacy and security are constant concerns for those participating in e-commerce.¹⁶³ The FTC has brought major enforcement actions, contending that it has the authority under the FTC Act to ensure that sellers safeguard the privacy of consumers shopping online.¹⁶⁴ An Eleventh Circuit Court of Appeals decision, however, may impose major obstacles on the FTC's ability to do so in future cases.¹⁶⁵

155. FED. TRADE COMM'N, *supra* note 153, at 1.

156. *Id.*; *see also* 15 U.S.C. § 45 (2012).

157. 15 U.S.C. § 45(a)(1).

158. FED. TRADE COMM'N, *supra* note 153, at 4.

159. *Id.* at 8.

160. *Id.*

161. *Id.* at 9–10.

162. *Id.* at A-22.

163. Bob Angus, *6 Steps to an Effective Ecommerce Privacy Policy*, PRACTICAL ECOMMERCE: MGMT. & FIN. (Nov. 21, 2014), <http://www.practicalecommerce.com/6-steps-to-an-effective-ecommerce-privacy-policy>.

164. *See* LabMD, Inc. v. FTC, 894 F.3d 1221, 1236 (11th Cir. 2018).

165. *Id.* at 1237. The specific holding in the case is that the FTC's consent order was void because its requirements for LabMD's security program were not sufficiently specific to be enforceable. *Id.* But the court raised more fundamental issues as well. *See id.*

[The consent order] does not enjoin a specific act or practice. Instead, it mandates a complete overhaul of LabMD's data-security program and says precious little about how this is to be accomplished. Moreover, it effectually charges the district court with managing the overhaul. This is a scheme Congress could not have envisioned.

D. UCC

In addition to the definitions discussed above, the UCC includes other definitions and provisions that come into play in determining whether the parties have consented to the terms of the agreement and are bound by those terms.¹⁶⁶ The UCC distinguishes between the parties' *agreement* and the parties' *contract*.¹⁶⁷ An agreement is "the bargain of the parties in fact, as [set forth] in their language or inferred from other circumstances, including course of performance, course of dealing, or usage of trade."¹⁶⁸ Thus, the agreement may be more than the document that appears on a company's website.¹⁶⁹ Importantly, for purposes of determining the legal effect of consumers agreeing by a click, tap, touch, or voice, it is appropriate for courts to look at all the circumstances.¹⁷⁰ Although this definition is useful in that it instructs courts on how to analyze what constitutes the parties' agreement, it does nothing to clarify how courts should determine the parties' agreement under the ever-changing consumer e-commerce environment.¹⁷¹ In contrast to the agreement, the parties' contract is "the total legal obligation that results from the parties' agreement."¹⁷²

Another UCC provision that bears upon the formation of online contracts addresses offer and acceptance.¹⁷³ That section provides that "[u]nless otherwise unambiguously indicated by the language or circumstances . . . an offer to make a contract shall be construed as inviting acceptance in any manner and by any medium reasonable in the circumstances."¹⁷⁴ Therefore, if the online seller is making an offer, it does not matter whether the consumer accepts by signing a piece of paper,

Id. The case raises many questions as to how the FTC can fashion *consent orders* that meet the court's standard. Paige M. Boshell, *The LabMD Case and the Evolving Concept of Reasonable Security*, A.B.A.: BUS. L. TODAY (July 16, 2018), <http://www.businesslawtoday.org/2018/07/labmd-case-evolving-concept-reasonable-security/>.

166. See U.C.C. § 1-201(b) (AM. LAW INST. & UNIF. LAW COMM'N 2017).

167. *Id.* § 1-201(b)(3).

168. *Id.* "[C]ourse of performance, course of dealing, or usage of trade" are defined in UCC section 1-303. *Id.* §§ 1-201(b)(3); 1-303(a)-(c).

169. See *id.* § 1-201(b)(3).

170. See U.C.C. § 1-303.

171. See *id.*

172. *Id.* § 1-201(b)(12). Both in the definition of *agreement* and the definition of *contract*, the UCC notes that the two terms are not the same; instead, they must be distinguished from one another. *Id.* § 1-201(b)(3), (12). The term *contract*, however, "sometimes [is] used as a synonym for [the terms] *agreement* and *bargain*." RESTATEMENT (SECOND) OF CONTRACTS § 1, cmt. a (AM. LAW INST. 1981). The Restatement follows the UCC approach. *Id.* In this Article, *contract* is used as a synonym for *agreement*. See *id.*

173. U.C.C. § 2-206 (AM. LAW INST. & UNIF. LAW COMM'N 2017).

174. *Id.*

clicking on a mouse, or touching or tapping on a screen.¹⁷⁵ In fact, the Official Comment anticipates a changing contracting environment.¹⁷⁶

To form a bilateral contract, one party must make an offer and the other party must accept.¹⁷⁷ On many websites, in order to complete the transaction, the consumer must click on or tap a button labelled “I agree.”¹⁷⁸ On the surface, this would seem to mean the seller is making the offer and the consumer is the party accepting.¹⁷⁹ But this assumes the seller can dictate that it is the party making the offer.¹⁸⁰ In *ProCD v. Zeidenberg*,¹⁸¹ a prominent case involving a business seller and a business buyer entering into a contract online, the court agreed with this assumption, declaring that the seller is the *master of the offer*.¹⁸² In *Klocek v. Gateway, Inc.*,¹⁸³ a case involving a business seller and consumer buyer, the court refused to follow *ProCD*’s conclusion that the seller is the master of the offer and found the consumer made the offer.¹⁸⁴

175. *See id.*

176. *Id.* “This section is intended to remain flexible and its applicability to be enlarged as new media of communication develop or as the more time-saving present-day media come into general use.” *Id.*

177. *Rosin v. First Bank of Oak Park*, 466 N.E.2d 1245, 1249 (Ill. App. Ct. 1984). According to the Restatement (Second) of Contracts, there must be a “[m]anifestation of mutual assent [in which] each party either makes a promise or begins or renders performance.” RESTATEMENT (SECOND) OF CONTRACTS § 18 (AM. LAW INST. 1981). “The manifestation of mutual assent . . . ordinarily takes the form of an offer or proposal by one party followed by an acceptance by the other party or parties.” *Id.* § 22. Section 24 of the Restatement (Second) of Contracts defines *offer*. *Id.* § 24. Under UCC section 2-204, “[a] contract for sale of goods may be made in any manner sufficient to show agreement, including [offer and acceptance], conduct by both parties which recognizes the existence of a contract,” the interaction of electronic agents, and the interaction of an electronic agent and an individual. U.C.C. § 2-204. The Restatement (Second) of Contracts defines *acceptance* in section 50, *acceptance by performance* in section 54, and *acceptance by telephone* in section 64. RESTATEMENT (SECOND) OF CONTRACTS §§ 50, 54, 64.

178. Ed Bayley, *The Clicks That Bind: Ways Users Agree to Online Terms of Service*, EFF (Nov. 16, 2009), <http://www.eff.org/wp/clicks-that-bind-ways-users-agree-online-terms-service>.

179. *Id.*

180. *See id.*

181. 86 F.3d 1447 (7th Cir. 1996).

182. *Id.* at 1452. The court does not explain its blanket statement that the seller, whom the court calls the vendor, is the *master of the offer*, or cite any cases to support this position. *See id.* A comment to the Restatement (Second) of Contracts states: “The offeror is the master of his offer.” RESTATEMENT (SECOND) OF CONTRACTS § 52, cmt. a. But this does not address the question of whether, in a specific transaction, it is the seller or the buyer who is the offeror. *See id.*

183. 104 F. Supp. 2d 1332 (D. Kan. 2000).

184. *Id.* at 1340. The court noted that the court in *ProCD* provided “no explanation for its conclusion that ‘the vendor is the master of the offer.’” *Id.*; *ProCD, Inc.*, 86 F.3d at 1452.

Furthermore, cases have held that “the mere use of the word *accept* does not automatically make a communication an acceptance of an offer.”¹⁸⁵ The seller responsible for a website that does not make clear what the consumer is accepting may be committing a deceptive act or practice that violates the FTC Act.¹⁸⁶ Some sellers specifically provide that the seller is neither making an offer nor accepting an offer from the consumer.¹⁸⁷ These websites stipulate that no contract has been formed until the seller engages in subsequent conduct.¹⁸⁸ Best Buy’s notice states: “At any time after receipt of your order, we may accept, decline or place . . . limits on your order”¹⁸⁹ The notice seems to be assuming the consumer is the party making the offer.¹⁹⁰

Even assuming the online seller is the party making the offer, no law requires online sellers to provide an “I accept” button on their website to bind the consumer.¹⁹¹ Some sellers have used other terms, such as “submit order” and “place order.”¹⁹² The case law has not clarified whether these

185. 17 C.J.S. *Contracts* § 54 (2018) (citing *United States v. Braunstein*, 75 F. Supp. 137, 139 (S.D.N.Y. 1947)).

186. *FTC v. Direct Benefits Grp., LLC*, No. 6:11-cv-1186-Orl-28TBS, 2013 WL 3771322, at *15 (M.D. Fla. July 18, 2013).

187. *See Terms and Conditions*, BEST BUY, <http://www.bestbuy.com/site/help-topics/terms-and-conditions/pcmcat204400050067.c?id=pcmcat204400050067> (last updated May 1, 2019). “Our order confirmation to you does not signify our acceptance of your order, nor does it constitute confirmation of our offer to sell. At any time after receipt of your order, we may accept, decline, or place quantity or other limits on your order for any reason.” *Id.* The first sentence declares that the seller is neither making an offer nor accepting the seller’s offer. *Id.* The second sentence indicates it is the consumer who makes an offer by ordering goods, and the seller has the power to accept the consumer’s terms, modify them by limiting the order, or reject the offer altogether. *Id.* One website provided that after the consumer submitted an order, the seller would send an email confirmation within twenty-four hours. Budnitz, *supra* note 13, at 748. The site’s terms provided: “The receipt of an e-mail . . . confirmation does not constitute the acceptance of an order or a confirmation of an offer to sell.” *Id.* It is unclear who is making the offer and who is accepting. *Id.* at 748–49. Perhaps the seller is making an invitation to the consumer to make an offer and the seller accepts the offer by shipping the goods. *See id.* at 749. Ambiguous offer and acceptance situations are not confined to online transactions. *See* Kenneth K. Ching, *Beauty and Ugliness in Offer and Acceptance*, 60 WAYNE L. REV. 469, 479 (2015). “[I]n some exchanges it will be unclear who technically gave the offer and who gave the acceptance, and to force the facts into the slots of offer and acceptance may be artificial and even unjust.” *Id.*

188. Budnitz, *supra* note 13, at 748–49.

189. *Terms and Conditions*, *supra* note 187.

190. *See id.*

191. *See* Budnitz, *supra* note 13, at 751–52.

192. *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 236–37 (2d Cir. 2016); Budnitz, *supra* note 13, at 744 n.19. Where a website provided a “Place your order” button instead of an “I agree” button and did not present additional terms directly adjacent to the “Place your order” button to indicate the user should continue clicking, user had not accepted additional terms. *Nicosia*, 834 F.3d at 236. The FAA requires an arbitration agreement to be

terms have the same legal effect as an “I accept” button.¹⁹³ In addition, the legal effect of an agreement providing the consumer and/or the seller the option of cancelling within a designated period of time is unclear.¹⁹⁴

Transactions involving virtual personal assistants such as Siri, Alexa, and Echo present several issues in contract formation.¹⁹⁵ There may be more than one agreement.¹⁹⁶ For example, a consumer can order coffee from Starbucks via a virtual personal assistant.¹⁹⁷ But first the consumer must establish an account—the first agreement.¹⁹⁸ Consumers supply Starbucks with their credit card number and other personal information when establishing that account.¹⁹⁹ Next, the consumer tells the virtual assistant to purchase coffee on a particular day.²⁰⁰ For example, the consumer can say, “Alexa, tell Starbucks to place an order.”²⁰¹ Arguably, placing an order is an offer to enter into a second agreement.²⁰² Consequently, no contract is formed unless Starbucks accepts the offer.²⁰³ Presumably, Starbucks accepts the offer by having the order ready when the customer arrives to pick it up.²⁰⁴

in writing but does not require such agreements to be signed. *Zacher v. Comcast Cable Comm’n LLC*, No. CV 7256, 2018 WL 3046955, at *3 (N.D. Ill. June 20, 2018); *see also* 9 U.S.C. § 3 (2012).

193. *Nicosia*, 834 F.3d at 236. “[C]licking ‘Place your order’ does not specifically manifest assent to the additional terms, for the purchaser is not specifically asked whether she agrees or to say ‘I agree.’” *Id.*

194. *See* Ching, *supra* note 187, at 479.

195. *See* Elvy, *supra* note 112, at 81–83

196. *See* Taylor Martin, *Make Alexa Order Your Iced Grande Caramel Macchiato*, CNET (Feb. 6, 2017, 12:35 PM), <http://www.cnet.com/how-to/amazon-echo-how-to-order-starbucks-with-alexa/>.

197. *Id.*

198. Sarah Perez, *Starbucks Unveils a Virtual Assistant That Takes Your Order Via Messaging or Voice*, TECHCRUNCH (Jan. 30, 2017) <http://www.techcrunch.com/2017/01/30/starbucks-unveils-a-virtual-assistant-that-takes-your-order-via-messaging-or-voice>. Customers also must link their Starbucks and Alexa accounts. *Id.* “Before, you could tell Alexa to start brewing your coffee. Now you can tell it to place your favorite Starbucks order.” Martin, *supra* note 196.

199. Martin, *supra* note 196. “If you have an Echo, you’ve already provided Amazon with your credit-card number, address, birthday and the names of all your children.” Matthew Hennessey, *Siri, Why Do I Feel Like I’m Being Watched?*, WALL ST. J., Aug. 11, 2018, at A13.

200. Martin, *supra* note 196.

201. *Id.*

202. *See* Ching, *supra* note 187, at 475–76. The effect of placing an order is not clear in the case law. *See Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 235–36 (2d Cir. 2016).

203. *See* Ching, *supra* note 187, at 476–77; Martin, *supra* note 196.

204. Martin, *supra* note 196. This is an example of acceptance by conduct. U.C.C. § 2-204(1) (AM. LAW INST. & UNIF. LAW COMM’N 2017). The Restatement of Contracts has a comparable provision, called acceptance by performance. RESTATEMENT (SECOND) OF CONTRACTS § 54 (AM. LAW INST. 1981).

But perhaps Starbucks is offering to sell coffee, and the consumer accepts the offer by placing an order by talking to Alexa.²⁰⁵ As Kenneth Ching says, in some transactions it is unclear who is making the offer and who is accepting it.²⁰⁶

Assuming Starbucks is the party making an offer to sell coffee, and the consumer accepts the offer by placing an order by talking to Alexa, what are the legal consequences if Starbucks seeks to impose additional terms to the transaction when the customer goes to Starbucks to pick up the order?²⁰⁷ UCC section 2-207 provides that in a transaction between a merchant and a non-merchant, such as a consumer, when one party accepts the other's offer, but that acceptance "states terms additional to . . . those offered or agreed upon . . . [t]he additional terms are to be construed as proposals for addition to the contract."²⁰⁸ Therefore, in the Starbucks scenario described above, the additional terms are merely proposals that are not binding on consumers unless accepted by them.²⁰⁹

A controversial series of cases may apply in the following scenario.²¹⁰ The consumer establishes an account with Laptops Unlimited, providing information such as a cell phone number and a credit card number.²¹¹ The consumer receives a text message from Laptops Unlimited, informing the consumer it is holding a sale on the Bell Laptop Model X55.²¹² The message contains a few other details such as the price, tax, and estimated delivery time.²¹³ The consumer tells Alexa to purchase that computer from Laptops Unlimited.²¹⁴ When the computer is delivered to the consumer, the box it comes in contains an agreement with additional terms, such as an

205. See Ching, *supra* note 187, at 476–77; Martin, *supra* note 197.

206. Ching, *supra* note 187, at 477, 480.

207. See *id.* at 476–78; Martin, *supra* note 196.

208. U.C.C. § 2-207 (1)–(2).

209. See *id.*; Ching, *supra* note 187, at 486; Martin, *supra* note 196.

210. See *Hill v. Gateway 2000, Inc.*, 105 F.3d 1147, 1148 (7th Cir. 1997); *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1450 (7th Cir. 1996). The scenario is similar to the service Best Buy offers. Bianca Jones, *Best Buy: Voice-Only Deals Now Available on Alexa*, MARKETSCREENER (July 9, 2018, 9:19 AM), <http://www.marketscreener.com/BEST-BUY-COMPANY-11778/news/Best-Buy-Voice-Only-Deals-now-available-on-Alexa-26896696/>.

Consumers establish a Best Buy account. *Id.* They then link to Alexa. *Id.* Among other features, consumers are eligible for *Voice-Only Deals* that are not available on Bestbuy.com or in stores. *Id.*

211. See *id.*

212. See Jones, *supra* note 210.

213. See *id.*

214. See *id.*

arbitration clause and a disclaimer of implied warranties.²¹⁵ The agreement provides that the consumer has fifteen days to return the computer.²¹⁶

Several cases involved the above set of facts, except buyers ordered the product online or over the phone.²¹⁷ Additional terms were delivered with the product and the consumer had a specified number of days to return the product.²¹⁸ The courts held that no contract is formed until the buyer accepts the goods by not returning them within that time.²¹⁹ In *Hill v. Gateway 2000*,²²⁰ the consumer ordered a computer by phone and the additional terms came in the carton with the computer.²²¹ That case followed *ProCD, Inc. v. Zeidenberg*, where the buyer being sued purchased the software in person but then posted the information online, thereby breaching the software use agreement.²²² The *ProCD* court noted that software can be ordered over the internet and arrives *by wire*.²²³ Courts deciding cases where the consumer orders a product by talking to a virtual assistant instead of talking to a person over a phone may find this line of cases applicable.²²⁴ Other courts and legal scholars contend *ProCD* and its progeny were wrongly decided because the courts incorrectly applied the UCC.²²⁵ The critics contend buyers are not bound by the additional terms unless they agree to the additional terms.²²⁶

215. See *Hill*, 105 F.3d at 1148; *ProCD, Inc.*, 86 F.3d at 1450, 1453.

216. See *Hill*, 105 F.3d at 1148.

217. See *id.*; *ProCD, Inc.*, 86 F.3d at 1450.

218. *Hill*, 105 F.3d at 1148.

219. *Id.* “A buyer may accept by performing the acts the vendor proposes to treat as acceptance.” *ProCD, Inc.*, 86 F.3d at 1452. Here, the buyer accepted by using the software “after having an opportunity to read the license at leisure.” *Id.*

220. 105 F.3d 1147 (7th Cir. 1997).

221. *Id.* at 1148.

222. 86 F.3d at 1450.

223. *Id.* at 1451.

224. See *Hill*, 105 F.3d at 1148–50; *ProCD, Inc.*, 86 F.3d at 1451–52.

225. *Klocek v. Gateway, Inc.*, 104 F. Supp. 2d 1332, 1339 (D. Kan. 2000); Roger C. Bern, *Terms Later Contracting: Bad Economics, Bad Morals, and a Bad Idea for Uniform Law*, *Judge Easterbrook Notwithstanding*, 12 J.L. & POL’Y 641, 642–43 (2004); Robert A. Hillman, *Rolling Contracts*, 71 *FORDHAM L. REV.* 743, 753 (2002); John E. Murray Jr., *The Dubious Status of the Rolling Contract Formation Theory*, 50 *DUQ. L. REV.* 35, 46 (2012). Bern contends that in the *ProCD* case Judge Easterbrook “defly discarded clear statutory language and foundational common law principles and created in their place, virtually out of whole cloth, a new doctrine of contract formation.” Bern, *supra*. Bern states that despite Easterbrook’s citing the Restatement (Second) of Contracts to support his position, that restatement offers no support. See *id.* at 654.

226. *Id.* at 654–55.

But even assuming the cases applied the UCC properly, they leave many crucial questions unanswered.²²⁷ For example, in *Hill*, the seller gave the consumer thirty days to read the contract terms that came in the box and return the computer.²²⁸ In another case involving the same seller, the consumer had only five days to return the computer.²²⁹ While it is reasonable to assume courts would require sellers to provide consumers a reasonable period of time in order to avoid a finding of unconscionability, the cases provide no guidance on how much time is reasonable.²³⁰

Another issue is who must pay the cost of returning the goods?²³¹ The *Hill* court found the question interesting but refused to provide any guidance.²³² Those costs could be considerable if the goods are fragile and must be carefully packed.²³³ Consumers may have to purchase a new carton and packing materials if the originals were damaged when the product was

227. See *Hill*, 105 F.3d at 1150; *ProCD, Inc.*, 86 F.3d at 1452–53; *Klocek*, 104 F. Supp. 2d at 1337–41.

228. *Hill*, 105 F.3d at 1148.

229. *Klocek*, 104 F. Supp. 2d at 1335.

230. *Id.* at 1341; *Hill*, 105 F.3d at 1150. The Reporters' Notes to the Draft Restatement of Consumer Contracts states that the consumer must be granted sufficient time to exercise the right to terminate. RESTATEMENT OF CONSUMER CONTRACTS § 2, at 27 (AM. LAW INST., Discussion Draft 2017). Cf. *Lima v. Gateway, Inc.*, 886 F. Supp. 2d 1170, 1182, 1186 (C.D. Cal. 2012) (determining that a fifteen-day window and fifteen percent restocking fee made the affirmative duty to reject so oppressive as to contribute to procedural unconscionability). UCC section 2-302 provides that a court may refuse to enforce an unconscionable contract or any clause it finds unconscionable. U.C.C. § 2-302 (AM. LAW INST. & UNIF. LAW COMM'N 2017). The unconscionability doctrine has not provided adequate relief for consumers. Stephen E. Friedman, *Giving Unconscionability More Muscle: Attorney's Fees as a Remedy for Contractual Overreaching*, 44 GA. L. REV. 317, 319 (2010). In addition, UCC Article 2 applies only to the sale of goods, not the sale of services. U.C.C. § 2-102. Some courts find software transactions involve a license, not a sale. *Elvy*, *supra* note 112 at 126–27; see also *SAS Inst., Inc. v. World Programming Ltd.*, No. 5:10-25, 2016 WL 3435196, at *10 (E.D.N.C. June 17, 2016). Consequently, Article 2 does not apply. U.C.C. § 2-102. UCC section 2-105(1) defines *goods* as “all things . . . which are movable at the time of identification to the contract for sale.” U.C.C. § 2-105(1). Courts have struggled over the question of whether software is included within the meaning of *goods*. *SAS Inst., Inc.*, 2016 WL 3435196, at *10.

231. See *Hill*, 105 F.3d at 1150.

232. *Id.* The court said it need not deal with that issue because the consumers knew the carton in which the computer was sent would contain important contract terms but didn't bother to find out what the terms were. *Id.* A Comment to the Restatement of Consumer Contracts states: “[T]he consumer's opportunity to terminate the transaction after receiving the terms must not place unreasonable cost, personal burden, or risk of loss on the consumer.” RESTATEMENT OF CONSUMER CONTRACTS § 2 (AM. LAW INST., Discussion Draft 2017). The reporters' notes state that the cost of terminating the transaction “must not be so large that it deters the exercise of the right.” *Id.*

233. See *Behind the Box: How to Safely Ship Fragile Items*, PACKLANE (Oct. 18, 2017), <http://www.packlane.com/blog/how-to-safely-ship-fragile-items>.

unpacked or if consumers threw them away, not realizing they would later decide to return the merchandise.²³⁴ If the item is expensive, consumers may feel they need to purchase shipping insurance.²³⁵

Yet another question is whether consumers may use the goods before returning them.²³⁶ In *Brower v. Gateway 2000, Inc.*,²³⁷ the court opined that consumers may use the product and not lose the right to return it as long as it was done within the time the seller gave the consumer to return the goods.²³⁸

The *ProCD* court talked about the contractual return period giving buyers time to review the terms of the agreement and decide whether to accept its provisions.²³⁹ But consumers also can take advantage of that time to decide whether to return the product because they discover they can get a better price elsewhere or they do not like the way the product performs, even if they have no objection to the terms of the contract.²⁴⁰ That is a logical conclusion since under the *ProCD* analysis, no contract is formed until the return period has passed.²⁴¹ This can be a significant benefit for consumers.²⁴² In the case of a product such as a computer, consumers may not be able to reasonably decide whether to return the product unless they use it or compare the price with those of other sellers.²⁴³

The *ProCD* court says the buyer must be given the opportunity to read the contract terms and decide whether to return the goods.²⁴⁴ In cases

234. See *id.*; *Hill*, 105 F.3d at 1148, 1150.

235. See *Hill*, 105 F.3d at 1149.

236. See *Brower v. Gateway 2000, Inc.*, 676 N.Y.S.2d 569, 573 (N.Y. App. Div. 1998).

237. 676 N.Y.S.2d 569 (N.Y. App. Div. 1998).

238. *Id.* at 573. In *ProCD, Inc.*, the court noted that the buyer “tried out the software, learned of the license, and did not reject the goods.” *ProCD, Inc. v. Zeidenberg*, 86 F.3d 1447, 1453 (7th Cir. 1996).

239. *ProCD, Inc.*, 86 F.3d at 1453 (stating that the UCC permits the parties to structure their relations so the buyer has the opportunity to decide whether to accept the seller’s terms *after a detailed review*). In upholding the agreement, the court noted approvingly that the buyer had the “opportunity to read the license at leisure.” *Id.* at 1452.

240. See *Hill*, 105 F.3d at 1148; *Brower*, 676 N.Y.S.2d at 573. The consumers in *Hill* complained about the computer’s *components and performance*. *Hill*, 105 F.3d at 1148. The UCC grants buyers the right to reject or revoke acceptance. U.C.C. § 2-601 (AM. LAW INST. & UNIF. LAW COMM’N 2017). But both rights have substantial barriers the buyer must overcome. *Id.* § 2-602. The buyer can reject only if the goods or the tender of delivery fail in any respect to conform to the contract.” *Id.* § 2-601. Furthermore, rejection “must be within a reasonable time after their delivery or tender.” *Id.* § 2-602. In order to revoke acceptance, the goods must not conform to the contract and that nonconformity must be one that *substantially impairs* the value of the goods to the buyer. *Id.* § 2-608.

241. See *ProCD, Inc.*, 86 F.3d at 1452.

242. See *id.*

243. See *id.*

244. *Id.* at 1452–53.

like *Hill*, the additional terms are in the box delivered with the good.²⁴⁵ What if instead of a contract in the box, the box merely contained a notice instructing the consumer to read the contract on the seller's website?²⁴⁶ Would that provide the consumer with the opportunity to read the contract and decide whether to return the product, as the courts require?²⁴⁷ If a contract provides that the consumer must return the goods within thirty days, does that mean the seller must receive the goods within thirty days, or has the consumer complied with the requirement as long as the return package is postmarked by the thirtieth day?²⁴⁸

In *Nicosia v. Amazon.com, Inc.*,²⁴⁹ the court analyzed a website on Amazon that provided the consumer with the opportunity to click on a button labelled "Place your order."²⁵⁰ The court pointed out that "the purchaser is not specifically asked whether she agrees or to say 'I agree.'"²⁵¹ According to the court, "[n]othing about the 'Place your order' button alone suggests that additional terms apply."²⁵²

UCC section 2-207 provides that in transactions involving a merchant and a non-merchant, such as a consumer, "[t]he additional terms are to be construed as proposals for addition to the contract."²⁵³ If the additional terms are proposals, does Starbucks accept the consumer's proposals when the customer takes possession of the product?²⁵⁴ The issue in the case law is whether the agreements subsequent to the original is a counteroffer that has to be separately accepted by the buyer.²⁵⁵ The cases conflict.²⁵⁶

245. *Hill*, 105 F.3d at 1148.

246. *See id.* at 1148, 1150.

247. *See id.*

248. *See id.* at 1148, 1150.

249. 834 F.3d 220 (2d Cir. 2016).

250. *Id.* at 234.

251. *Id.* at 236.

252. *Id.* It is not apparent why the court mentions that consumers are not asked to say they agree in the context of a transaction on Amazon's website since the decision does not indicate consumers are given the opportunity to enter into the transaction speaking into their computer's microphone or any other type of device. *See id.* But the court's reasoning would seem to apply to consumers speaking into their virtual assistant and ordering goods. *Nicosia*, 834 F.3d at 236; Martin, *supra* note 196; Perez, *supra* note 198.

253. U.C.C. § 2-207(2) (AM. LAW INST. & UNIF. LAW COMM'N 2017). Merchant is defined in UCC section 2-104(1). *Id.* § 2-104(1). Section 2-207 contains a different rule for transactions that occur between merchants. *Id.* § 2-207(2). In sharp contrast to the provision that applies to merchant-non-merchant contracts, the presumption is that the additional terms "become part of the contract unless" specific circumstances are present. *Id.*

254. *See id.*

255. *See* Ching, *supra* note 187, at 478–79.

256. *Compare* Hill v. Gateway 2000, Inc., 105 F.3d 1147, 1150 (7th Cir. 1997) (finding that U.C.C. § 2-207 does not apply because there was only one contract, formed when

Being able to determine whether and when a contract is formed becomes crucial when a dispute arises.²⁵⁷ When a consumer uses a phone to order goods and talks to the store's employees, there is always the possibility of a misunderstanding.²⁵⁸ The risk of miscommunication is even greater when the consumer orders through a virtual assistant.²⁵⁹ This is illustrated by situations in which virtual assistants have received orders that consumers never authorized.²⁶⁰ For example, a consumer's parrot ordered gift boxes without the consumer's knowledge.²⁶¹ Unauthorized purchases have been made by children.²⁶² Orders have been placed based on words the virtual assistant heard when consumers' televisions broadcasted commercials advertising products.²⁶³ On the other hand, consumers trying to order products using Alexa were unable to do so when the service stopped working due to "technolog[ical] outages and service interruptions."²⁶⁴

In addition, researchers have been able to hack not only into smartphones, but also smart speakers.²⁶⁵ They were able to open consumers' websites.²⁶⁶ They claim hackers would be able to purchase goods.²⁶⁷

the customer had the opportunity to inspect the goods and the terms, and did not return the goods), *with Klocek v. Gateway, Inc.*, 104 F. Supp. 2d 1332, 1339 (D. Kan. 2000) (finding that even if there was only one contract, UCC section 2-207 applies and consumer, as party making the offer, was not bound by seller's terms); *see also* Hillman, *supra* note 225, at 753 (stating that Judge Easterbrook was *plainly wrong* in finding that UCC section 2-207 did not apply).

257. *See* Ching, *supra* note 187, at 477.

258. *See id.*

259. *See* Gia Liu, *Hey, I Didn't Order This Dollhouse! 6 Hilarious Alexa Mishaps*, DIGITAL TRENDS (Mar. 5, 2018 4:30 PM), <http://www.digitaltrends.com/home/funny-accidental-amazon-alexa-ordering-stories/>.

260. *See id.*

261. *Polly Want A-lexa? Clever Parrot Orders Amazon's Virtual Assistant to Turn Off the Lights — and the Robot Obeys*, DAILY MAIL (May 15, 2018, 7:26 AM), <http://www.dailymail.co.uk/news/article-5729837/Polly-want-lexa-clever-parrot-talks-virtual-assistant-orders-turn-lights.html>.

262. Liu, *supra* note 259.

263. *Id.*; *see also* Lisa Marie Segarra, *It's Not Just You: Amazon Admitted That Alexa Has Been Laughing at People*, TIME (Mar. 7, 2018), <http://www.time.com/5190044/amazon-alexa-echo-laughing> (reporting that users were hearing Alexa having random laughing fits without being prompted).

264. Sarah Gray, *Amazon Alexa Lost Its Voice, Forcing Users to Use Light Switches and Check Weather Themselves*, TIME (Mar. 2, 2018), <http://www.time.com/5183713/amazon-alexa-down-outage/>.

265. Craig S. Smith, *Alexa and Siri Can Hear This Hidden Command. You Can't.*, N.Y. TIMES (May 10, 2018), <http://www.nytimes.com/2018/05/10/technology/alexa-siri-hidden-command-audio-attacks.html>.

266. *Id.*

267. *See id.*

E. UETA

The UETA has been enacted in the District of Columbia and forty-seven states.²⁶⁸ Like E-Sign, UETA validates electronic records and signatures.²⁶⁹ UETA, however, also includes provisions that are absent from E-Sign.²⁷⁰ Most pertinent to the formation of contracts online is the section providing that if there is an error when a consumer buys a product on a website, the consumer can prevent being held liable.²⁷¹ An example of the type of error covered by this provision occurs when a consumer makes an error by typing a number one to indicate an order for one computer, but then accidentally also types a zero, resulting in an order for ten computers.²⁷²

If the seller provides the consumer with the opportunity to correct the error, however, the consumer must take advantage of that opportunity in order to escape liability.²⁷³ In the typical online consumer transaction, the seller provides that opportunity by taking the consumer to a confirmation screen before the sale is finalized.²⁷⁴ That screen describes the product the consumer ordered, as well as other essential information such as the price and quantity.²⁷⁵ The consumer who does not want to be bound by the transaction can refuse to confirm the order and thereby avoid liability.²⁷⁶ If the consumer does not refuse and continues the transaction, the consumer

268. Dan DeNiculo, *The Future of Electronic Wills*, A.B.A. (Oct. 15, 2018) http://www.americanbar.org/groups/law_aging/publications/bifocal/vol_38/issue-5--june-2017/the-future-of-electronic-wills/.

269. UNIF. ELEC. TRANSACTIONS ACT § 7 (UNIF. LAW COMM'N 1999).

270. *See id.*

271. *Id.* § 10.

In an automated transaction involving an individual, the individual may avoid the effect of an electronic record that resulted from an error made by the individual in dealing with an electronic agent of another person if the electronic agent did not provide an opportunity for the prevention or correction of the error and, at the time the individual learns of the error, the individual promptly notifies the other person of the error . . . that the individual [does] not intend to be bound, . . . takes reasonable steps . . . to return, [or] destroy [any] consideration received . . . and has not used or received any benefit or value from the consideration.

Id.

272. *See id.* The Official Comment to section 10 explains that the section covers two types of mistakes. UNIF. ELEC. TRANSACTIONS ACT § 10, cmt. 1. One occurs when the consumer makes a typing error, such as typing an order for 1,000 widgets when 100 is intended. *Id.* The other occurs when the buyer's *information processing system* changes the buyer's order of 100 widgets to an order for 1,000. *Id.* Another provision in UETA, but not in E-Sign, is a provision governing attribution. *Id.* § 9.

273. *Id.* § 10.

274. UNIF. ELEC. TRANSACTIONS ACT § 10. Comment 5 describes the confirmation screen scenario. *Id.* § 10, cmt. 5.

275. *Id.* § 10.

276. *Id.*

cannot rely on UETA to avoid liability.²⁷⁷ Because sellers provide consumers the confirmation screen, consumers will not be able to avoid liability for errors.²⁷⁸ With consumers increasingly engaging in transactions on their mobile devices, questions may arise as to the adequacy of the format used for the confirmation screen because of the small size of the screen on a mobile device.²⁷⁹

Transactions that consumers engage in through their virtual assistants pose new challenges.²⁸⁰ The UETA does not require the seller to provide a confirmation screen.²⁸¹ Rather, it provides that the seller must give the consumer an opportunity to prevent or correct an error.²⁸² The issue for sellers is how they can provide the consumer with the equivalent of a confirmation screen so consumers cannot later avoid liability on the contract by claiming there was an error and they did not have any such opportunity.²⁸³

F. *Case Law*

Case law has attempted to apply traditional contract law to the cyberspace environment.²⁸⁴ The cases, however, involve clickwrap and browsewrap agreements; they do not deal with issues that arise when parties form contracts by touching or tapping on smartphones or talking to virtual personal assistants.²⁸⁵

As described above, the online environment is very different in important respects than when the sellers and consumers deal with each other, typically face-to-face, in the physical world.²⁸⁶ Previously, in consumer transactions there was an agreement written on paper and the consumer usually had possession of the original or a copy.²⁸⁷ There might be disagreements about the meaning and legal effect of the terms, but ordinarily

277. *See id.*

278. *See* UNIF. ELEC. TRANSACTIONS ACT § 10, cmt. 5.

279. *See* FED. TRADE COMM'N, *supra* note 153, at i.

280. *See* Penny Crosman, *Is Amazon's Alexa Ready for Person-to-Person Payments?*, AM. BANKER (Mar. 19, 2018, 12:17 PM), <http://www.americanbanker.com/news/is-amazons-alexa-ready-for-p2p-payments>.

281. UNIF. ELEC. TRANSACTIONS ACT § 10.

282. *Id.*

283. *See* Cullinane v. Uber Techs, Inc., 893 F.3d 53, 64 (1st Cir. 2018); Crosman, *supra* note 280.

284. *Cullinane*, 893 F.3d at 64; *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 231–32, 235 (2d Cir. 2016). Karl Llewellyn refers to this as putting “new wine into old bottles.” Llewellyn, *supra* note 13, at 64.

285. *See Cullinane*, 893 F.3d at 61 n.10; *Nicosia*, 834 F.3d at 235.

286. *See* Budnitz, *supra* note 13, at 745.

287. Restle, *supra* note 88.

there is no dispute about what the written agreement says.²⁸⁸ In cyberspace, the terms of the agreement may be difficult or impossible to ascertain.²⁸⁹ The seller may have replaced the agreement that was posted when the consumer entered into the transaction with one or even many modifications.²⁹⁰ The seller may not have saved a copy of the agreement it posted on its website at the time of the consumer's transaction, and therefore, cannot retrieve it.²⁹¹

Courts have struggled to apply traditional contract law to consumer disputes.²⁹² They have examined the design and format of websites, including the placement and color of hyperlinks to agreements.²⁹³ They have applied different rules depending on whether the method to obtain the consumer's consent was in a clickwrap or a browsewrap format.²⁹⁴ To make matters more complex, at least one court thought the site it reviewed was a hybrid—combining elements of both clickwrap and browsewrap.²⁹⁵

In websites that obtain the consumer's consent by means of a typical clickwrap agreement, the consumer agrees to the online terms by clicking with a mouse or touching a mobile device on a button that says "I agree."²⁹⁶ Often the "I agree" button is at the bottom of a scroll-down window that contains the standard terms.²⁹⁷ Courts have held that, in general, clickwrap agreements are valid and consumers are bound by their terms.²⁹⁸ They have not ruled that these agreements are automatically valid, however.²⁹⁹ Many courts reached that conclusion only after careful examination of the website's format and the manner in which consumer consent was obtained on the website.³⁰⁰ Clickwrap agreements may be invalid if not carefully

288. See *Contracts Basics*, FINDLAW, <http://smallbusiness.findlaw.com/business-contracts-forms/contracts-basics.html> (last visited May 1, 2019).

289. See Sterling Miller, *Ten Things: Website User Agreements*, TEN THINGS YOU NEED TO KNOW AS IN-HOUSE COUNS. (June 9, 2015), <http://www.sterlingmiller2014.wordpress.com/2015/06/07/ten-things-website-user-agreements/>.

290. See *id.*

291. See *id.*

292. *Cullinane v. Uber Techs, Inc.*, 893 F.3d 53, 61 n.10 (1st Cir. 2018).

293. *Id.* at 63; *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 236 (2d Cir. 2016).

294. *Cullinane*, 893 F.3d at 61 n.10. One judge identified four different types of wrap agreements: Clickwrap, browsewrap, scrollwrap, and sign-in wrap. *Berkson v. Gogo LLC*, 97 F. Supp. 3d 359, 395–402 (E.D.N.Y. 2015).

295. *Nicosia*, 834 F.3d at 236.

296. *Berkson*, 97 F. Supp. 3d at 397.

297. *Id.*

298. *Id.*

299. See *id.*

300. *Caspi v. Microsoft Network, L.L.C.*, 732 A.2d 528, 532 (N.J. Super. Ct. App. Div. 1999). The court examined the size and placement of the challenged forum

presented, and specific terms of the agreements have been successfully challenged.³⁰¹

Moreover, some courts insist they are not applying new legal requirements when determining the validity of clickwrap agreements.³⁰² Rather, these courts interpret and apply the same common law rules that courts have applied for hundreds of years to oral and written agreements and signatures on paper.³⁰³

Some companies choose to obtain the consumer's consent by designing browsewrap agreements rather than clickwrap agreements.³⁰⁴ A website containing a browsewrap agreement does not include an "I agree" button.³⁰⁵ Indeed, consumers are never asked and have no opportunity to indicate their consent in any affirmative way.³⁰⁶ But, at least one page on the website contains a hyperlink to another page that includes the agreement.³⁰⁷ As a result, consumers have the opportunity to read the agreement if the link is clearly identified as a way to access the agreement.³⁰⁸ "The defining feature of browsewrap agreements is that the user can continue to use the website or its services without visiting the page hosting the browsewrap agreement or even knowing that such a webpage exists."³⁰⁹

In face-to-face transactions, consumers write their unique signatures on a piece of paper that includes contract terms.³¹⁰ In the absence of proof that the seller engaged in fraudulent conduct, courts assume the consumer's signature indicates the intention to adopt or accept a record.³¹¹ In clickwrap

selection clause and "the style [and] mode of presentation." *Id.* The court satisfied itself that there was no basis for concluding that the clause was presented in such a way as to "conceal or de-emphasize it[]." *Id.*; see also *Berkson*, 97 F. Supp. 3d at 397.

301. *Berkson*, 97 F. Supp. 3d at 397–98; see also *Sgouros v. TransUnion Corp.*, 2015 WL 507584, at *5–6 (N.D. Ill. 2015).

302. *Cullinane v. Uber Techs., Inc.*, 893 F.3d 53, 61 n.10 (1st Cir. 2018).

303. See *Register.com, Inc. v. Verio, Inc.*, 356 F.3d 393, 403 (2d Cir. 2004) (stating that although Internet Commerce "has exposed courts to . . . new situations, it has not fundamentally changed the principles of contract.").

304. Jay Spillane, *Passive Browsewrap Agreements Are Losing Enforceability*, PRIORI (Oct. 12, 2016), <http://www.priorilegal.com/blog/passive-browsewrap-agreements-are-losing-enforceability>.

305. RESTATEMENT OF CONSUMER CONTRACTS § 2, at 35 (AM. LAW INST., Discussion Draft 2017).

306. *Id.*

307. *Id.*

308. *Id.*

309. *Be In, Inc. v. Google Inc.*, No. 12-CV-03373-LHK, 2013 WL 5568706, at *6 (N.D. Cal. Oct. 9, 2013).

310. See *Signature Law: What Signing a Contract Means*, ROCKET LAW., <http://www.rocketlawyer.com/article/signature-law-cb.rl> (last visited May 1, 2019).

311. U.C.C. § 2-103(p) (AM. LAW INST. & UNIF. LAW COMM'N 2017) (defining *sign*).

agreements, courts—in effect—substitute clicking the “I agree” button for writing a signature.³¹² A browsewrap agreement removes both the signature and any signature substitute.³¹³

Courts have been less willing to validate browsewrap agreements than clickwrap contracts.³¹⁴ Some courts apply traditional principles on the formation of contracts.³¹⁵ One of these requires the “mutual manifestation of assent, whether by written or spoken word or by conduct.”³¹⁶ Courts applying that principle require evidence that the consumer had actual or constructive knowledge of the seller’s terms and conditions.³¹⁷ To satisfy the constructive notice requirement, the seller must put the consumer on inquiry notice.³¹⁸ Courts examine both the design and content of the website, and the webpage containing the agreement, to determine whether the requisite notice was given.³¹⁹

Courts have held that the inquiry notice requirement has not been satisfied when the link to the agreement “is buried at the bottom of the page or tucked away in obscure corners of the website where users are unlikely to see it.”³²⁰ Courts have invalidated agreements where links are not obvious or the agreement is not easily accessible because it requires several steps.³²¹ A court found that even a conspicuous link on every page of the website—including a link close to buttons the user has to click on to complete a

312. RESTATEMENT OF CONSUMER CONTRACTS § 2, at 33 (AM. LAW INST., Discussion Draft 2017).

313. *See id.* at 35.

314. *Website Agreements: Browse-wrap vs. Clickwrap Agreements*, DASH FARROW LLP: BLOG (July 19, 2012), <http://www.dashfarrow.com/blog/2012/July/website-agreements-browse-wrap-vs-clickwrap-agre/>.

315. Hilary Smith, Note, *The Federal Trade Commission and Online Consumer Contracts*, 2016 COLUM. BUS. L. REV. 512, 524.

316. *Nguyen v. Barnes & Noble Inc.*, 763 F.3d 1171, 1175 (9th Cir. 2014) (quoting *Specht v. Netscape Comm’ns Corp.*, 306 F.3d 17, 29 (2d Cir. 2002)).

317. *Id.* at 1176–77. Constructive knowledge is defined as “[k]nowledge that one using reasonable care or diligence should have, and . . . that is attributed by law to a given person.” *Constructive Knowledge*, BLACK’S LAW DICTIONARY (10th ed. 2014).

318. *Nguyen*, 763 F.3d at 1177.

319. *Id.*; *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 233 (2d Cir. 2016); *Be In, Inc. v. Google Inc.*, No. 12-CV-03373-LHK, 2013 WL 5568706, at *6 (N.D. Cal. Oct. 9, 2013); *see also Zaltz v. JDATE*, 952 F. Supp. 2d 439, 451–52 (E.D.N.Y. 2013); *Fteja v. Facebook, Inc.*, 841 F. Supp. 2d 829, 835–37, 841 (S.D.N.Y. 2012).

320. *Nguyen*, 763 F.3d at 1175, 1177.

321. *Van Tassell v. United Mktg. Grp., LLC*, 795 F. Supp. 2d 770, 792 (N.D. Ill. 2011); *Hines v. Overstock.com, Inc.*, 668 F. Supp. 2d 362, 367 (E.D.N.Y. 2009). User could not see the link without scrolling to the bottom of the screen. *Id.* Textual notice was in small gray print against a gray background. *Pollstar v. Gigmania LTD.*, 170 F. Supp. 2d 974, 981 (E.D. Cal. 2000).

purchase—was insufficient.³²² Users are not bound by contract terms that are hidden or difficult to reach.³²³

Courts consider the sufficiency of a website’s inquiry notice according to a *reasonably prudent user* standard.³²⁴ It can be difficult to apply that standard, however, because—as courts have acknowledged—the level of online experience and sophistication varies greatly among different consumers.³²⁵ As a result, consumers’ familiarity with how websites notify and provide access to browsewrap contracts is not uniform.³²⁶ For example, the design and format of a website targeted at millennials likely would not meet the inquiry notice requirements for a website targeting the elderly.³²⁷ The Ninth Circuit Court of Appeals took a narrow approach to consideration of a user’s familiarity with websites.³²⁸ The court refused to consider the fact that the user, in the past, had experience with websites.³²⁹ It would consider only the website involved in the case before it.³³⁰

Adding to the confusion, it may not be clear to a court whether an agreement is a clickwrap, a browsewrap, or some other type of online agreement.³³¹ In *Nicosia*, the consumer argued that Amazon’s website contained a browsewrap agreement.³³² Amazon contended that this agreement was *something in between*.³³³ For purposes of the appeal of the district court’s grant of Amazon’s motion to dismiss, the court assumed the agreement was a hybrid between the two types of agreements.³³⁴ The court asked “whether a reasonably prudent offeree would know that the . . . [c]onditions of [u]se governed, such that her purchase manifested implied assent to the additional terms.”³³⁵ After a detailed examination and analysis

322. *Nguyen*, 763 F.3d at 1178–79.

323. *Specht v. Netscape Commc’ns Corp.*, 306 F.3d 17, 35 (2d Cir. 2002). Terms visible only by scrolling down to next screen. *Id.* at 20.

324. *Resorb Networks, Inc. v. YouNow.com*, 30 N.Y.S.3d 506, 511 (N.Y. Sup. Ct. 2016); *see also* Nancy S. Kim, *Online Contracting*, 72 BUS. LAW. 243, 248 (2017).

325. *See Nguyen*, 763 F.3d at 1179. The Ninth Circuit noted “the breadth of the range of technological savvy of online purchasers.” *Id.*

326. *Id.* “Negligence is defined as the doing of some act that a reasonably prudent person would not do or the failure to do some act that a reasonably prudent person would do under the same or similar circumstances.” *Benton v. Diamond Servs., Inc.*, No. 92-3544, 1994 WL 57352, at *2 (5th Cir. Feb. 11, 1994) (per curiam).

327. *See Resorb Networks, Inc.*, 30 N.Y.S.3d at 511.

328. *Nguyen*, 763 F.3d at 1179.

329. *Id.*

330. *Id.*

331. *See Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 235 (2d Cir. 2016).

332. *Id.*

333. *Id.*

334. *Id.* at 236. The court cautioned that it did “not mean to suggest that a *hybrid* agreement is a type of agreement that Washington law would recognize as such.” *Id.*

335. *Nicosia*, 834 F.3d at 236.

of the design and content of Amazon's website, the court held that "reasonable minds could disagree on the reasonableness of notice."³³⁶ Consequently, the court vacated the district court's motion to dismiss.³³⁷

These cases involving both clickwrap and browsewrap agreements are fact-specific.³³⁸ Since the format and design of every website which includes browsewrap agreements differs from one another, courts have been unable to provide clear guidance on how sellers can offer browsewrap agreements that courts will enforce.³³⁹ Consequently, it is difficult for both businesses and consumers to determine if a court would hold consumers bound by the agreement's terms in a disputed case based on prior published cases.³⁴⁰ It is highly unlikely that the website used by the seller in the disputed case is so similar to those in earlier cases that the parties can confidently predict how a court or arbitrator would rule in their case.³⁴¹

Arbitration is another reason for the lack of satisfactory case law development.³⁴² Disputes increasingly are decided in private arbitration forums.³⁴³ The arbitrator's decision is not public.³⁴⁴ As a result, there is less case law than if arbitration was not so widespread.³⁴⁵ The lack of case law hinders sound development of the law.³⁴⁶ This makes it even less likely the case law will provide guidance as more contracts are formed in cyberspace.³⁴⁷

If a court decides an online contract has been formed, consumers and sellers are contractually bound and incur significant responsibilities and liabilities.³⁴⁸ Consequently, it is important that online communications are

336. *Id.* at 238.

337. *Id.* at 240.

338. *See id.* at 231–33; *Nguyen v. Barnes & Noble Inc.*, 763 F.3d 1171, 1177 (9th Cir. 2014).

339. *See Nguyen*, 763 F.3d at 1177.

340. *See id.* at 1178.

341. *See id.* Moreover, arbitrators are not required to base their decisions on judicial opinions. Amy J. Schmitz, *Untangling the Privacy Paradox in Arbitration*, 54 U. KAN. L. REV. 1211, 1216 (2006).

342. Schmitz, *supra* note 341, at 1211.

343. *Id.* at 1211.

344. *Id.* "[Arbitrations] do not produce published opinions that courts infuse into public law." *Id.* "[A]rbitrations are, by their very nature, private and not public." Bert K. Robinson, *Arbitration: The Quest for Confidentiality*, 58 LA. B.J. 180, 181 (2010).

345. *See Schmitz, supra* note 341, at 1211.

346. *Id.* at 1212.

347. *See id.*

348. *See Challenges of E Commerce to Traditional Contracts*, LAWTEACHER (Feb. 2, 2018), <http://www.lawteacher.net/free-law-essays/contract-law/challenges-of-e-commerce-to-traditional-contracts-contract-law-essay.php>.

secure and the consumer's privacy is protected.³⁴⁹ That is important, not only to protect consumers, but also to benefit sellers.³⁵⁰ Consumers who trust sellers' measures to protect privacy and security are more likely to engage in e-commerce.³⁵¹ There is no federal law, however, ensuring the security of online communications or the privacy of online transactions.³⁵² Consequently, there is no law to ensure the security and privacy of consumers entering into contracts using cellphones and virtual personal assistants.³⁵³

Finally, there is no case law development dealing with issues that arise when consumers enter into contracts by touching or tapping on the small screen of a smartphone or talk to a virtual personal assistant.³⁵⁴ As the number of consumers contracting in these new ways increases, and new environments are introduced, the lack of applicable legal rules may make it more difficult for businesses to feel confident that the sites they design for online contracting will withstand legal challenges.³⁵⁵

VI. WHERE SHOULD WE GO FROM HERE?

Increasingly, consumers enter into contracts by touching or tapping on the small screens of cellphones and talking to virtual personal assistants.³⁵⁶ Legislation and case law have failed to adequately address contract formation questions that arise in the traditional online environment of websites and mouse clicks.³⁵⁷ Statutes and cases have not even begun to consider the unique issues raised by contracting using cellphones and virtual personal assistants.³⁵⁸ New methods of entering into consumer contracts will surely be developed.³⁵⁹

Policymakers should decide what action to take in response to this situation.³⁶⁰ They could decide to enact new statutes.³⁶¹ Alternatively, they

349. FED. TRADE COMM'N, *supra* note 20, at iii; Budnitz, *supra* note 13, at 772; Ken Blackwell, *Protecting Online Privacy is a Nonpartisan No-Brainer*, HILL (Oct. 1, 2018, 5:15 PM), <http://www.thehill.com/opinion/cybersecurity/409348-protecting-online-privacy-is-a-nonpartisan-no-brainer>.

350. *See* Angus, *supra* note 163.

351. *See id.*

352. *See* Blackwell, *supra* note 349.

353. *See* Stacy-Ann Elvy, *Contracting in the Age of the Internet of Things: Article 2 of the UCC and Beyond*, 44 HOFSTRA L. REV. 839, 842 (2016).

354. *Id.* at 77, 79.

355. *See* Blackwell, *supra* note 352.

356. *See* Elvy, *supra* note 353, at 863.

357. *Id.* at 842.

358. *See id.*

359. *See id.* at 840.

360. *See id.* at 842–43.

could continue the current approach, which is to do nothing and rely on courts to develop case law based on the transactions brought before them.³⁶² Whichever course they choose, non-governmental organizations could provide valuable assistance to legislators and courts by developing model laws, statements of principles, or standards.³⁶³ Each of these alternatives is explored below.³⁶⁴

A. *Legislation*

Legislation could be enacted on either the federal or state level.³⁶⁵ The advantage of the state-by-state approach is the opportunity it gives each state to determine what approach best suits the needs of their communities.³⁶⁶ States may adopt different approaches.³⁶⁷ Over time, a consensus hopefully will emerge as to which is the best approach, as it did with adoption of the UCC.³⁶⁸ The problem, however, is that this would result in a patchwork of statutes, at least in the short term.³⁶⁹ That would make it difficult both for businesses and consumers to know what law applies to their transactions.³⁷⁰ This is particularly acute for online transactions where it may not be apparent where the seller is located and what law applies.³⁷¹

The advantage of a federal law is the assurance of national uniformity.³⁷² Cyber-contracting is subject to significant and frequent changes as new technology is developed and applied to e-commerce.³⁷³ Consequently, Congress might prefer a statute that sets general standards.³⁷⁴ An agency such as the FTC could be given authority to issue more specific

361. See Elvy, *supra* note 353, at 843.

362. See Richard A. Mann & Barry S. Roberts, *CyberLaw: A Brave New World*, 106 DICKINSON L. REV. 305, 330–31 (2001).

363. See *id.* at 335–36, 338.

364. See discussion *infra* Part VI.A & B.

365. See *Legal Issues in Contracting on the Internet*, FINDLAW, <http://www.corporate.findlaw.com/business-operations/legal-issues-in-contracting-on-the-internet.html> (last visited May 1, 2019).

366. See *id.*

367. See *id.*

368. See U.C.C. § 2-102 (AM. LAW INST. & UNIF. LAW COMM'N 2017); Mann & Roberts, *supra* note 362, at 329.

369. See Mann & Roberts, *supra* note 362, at 338.

370. See *id.*

371. *Id.* at 344 (pointing out that in cyberspace “it is difficult to define . . . where a transaction is *located* or formed”); see also *South Dakota v. Wayfair, Inc.*, 138 S. Ct. 2080, 2101, 2104 (2018) (Roberts, J. dissenting) (describing how e-commerce enables a company to easily do business nationally without needing a physical presence in each state).

372. Mann & Roberts, *supra* note 362, at 338.

373. See *id.*

374. See *id.*

regulations as the agency gains experience and expertise.³⁷⁵ Furthermore, it is much easier to revise regulations than legislation when changed circumstances require adjustments.³⁷⁶

Another approach is to enact both federal and state legislation.³⁷⁷ This results in uniform rules nation-wide, pre-empting state law in certain ways.³⁷⁸ As with other federal consumer laws, states could be permitted limited authority to devise their own requirements.³⁷⁹

Policymakers would face important issues regardless of whether legislation is federal or state-by-state.³⁸⁰ For example, should the law rely principally on disclosure to consumers or impose substantive requirements on sellers?³⁸¹ Should the law establish general standards such as commercial reasonableness, reasonable consumer expectations, state of the art technology, etc.?³⁸² Or should it include specific prohibitions or requirements?³⁸³ Should the law primarily adopt common law and UCC legal concepts or develop a new conceptual framework that takes into account the very different context of small screens, touching, tapping, authentication, and passwords?³⁸⁴ Is a tap or a touch on a cellphone screen equivalent to a click with a mouse?³⁸⁵ Under what circumstances, if any, should browsewrap agreements, which require no affirmative consent, be permitted?³⁸⁶ Should rules on contracting through apps be treated differently than contracting through websites?³⁸⁷

375. See Mariam Baksh, *Internet Society: FTC Should Craft Rules, Spell Out Liability to Help Secure Internet of Things*, INSIDE CYBERSECURITY: DAILY NEWS (Aug. 28, 2018), <http://insidecybersecurity.com/daily-news/intranet-society-ftc-should-craft-rules-spell-out-liability-help-secure-internet-things>.

376. See *id.*

377. See Mann & Roberts, *supra* note 362, at 338.

378. *Id.*

379. *Legal Issues in Contracting on the Internet*, *supra* note 365.

380. See *id.*

381. See *id.*

382. See *id.*

383. See *id.*

384. See Elvy, *supra* note 353, at 846, 863.

385. Timothy Murray, *Contract Drafting Concerns: Beware Browsewrap*, LEXIS PRACTICE ADVISOR JOURNAL (June 7, 2017), <http://www.lexisnexis.com/lexis-practice-advisor/the-journal/b/ipn/archive/2017/06/07/contract-drafting-concerns-beware-browsewrap.aspx>.

386. See *id.*; *Browsewrap vs. Clickwrap*, TERMSFEED: BLOG (Aug. 21, 2018), <http://www.termsfeed.com/blog/browsewrap-clickwrap/>.

387. *Browsewrap vs. Clickwrap*, *supra* note 386. Federal regulators have issued guidelines addressed to the threats and risks consumer face when they use mobile financial services apps, distinguishing those from accessing services on browser access from a PC. See Penny Crosman, *Should All Banks Have Mobile Apps?*, AM. BANKER (June 16, 2016, 2:10 PM), <http://www.americanbanker.com/news/should-all-banks-have-mobile-apps>. Bank

A major obstacle to reaching a broad consensus on legislation is the likely strong disagreement between businesses and consumers over mandatory pre-dispute arbitration and class action waivers.³⁸⁸ If the seller can require the consumer to bring any and all claims in arbitration forums and only as individual actions, then the impact of any legislation will be questionable.³⁸⁹ While some arbitrators may follow the requirements of that statute, arbitrators are not required to follow the law.³⁹⁰ Arbitrators are not required to make written findings of fact or conclusions of law.³⁹¹ Decisions are not public.³⁹² Supreme Court opinions have established the general rule that under the FAA arbitration provisions in valid contracts are enforceable and generally preempt state law.³⁹³ The Consumer Financial Protection Bureau (“CFPB”) issued a rule prohibiting class action waivers in consumer arbitration agreements but Congress overruled it.³⁹⁴ Consequently, in light of the probability that most online consumer contracts will include arbitration clauses, the only way to ensure any cyber-contracting legislation is enforced is to pass legislation that would exempt consumer transactions

websites have features that are different from those of bank apps. Andy Peters, *Bank Websites Said to Suffer from Attention Shift to Mobile*, AM. BANKER (Feb. 10, 2015, 11:15 AM), <http://www.americanbanker.com/news/bank-websites-said-to-suffer-from-attention-shift-to-mobile>.

388. See Jennifer M. Keas & Jay N. Varon, *Shouldn't You Be Using Arbitration Agreements to Reduce the Costs of Litigation and the Risk of Class Action Claims?*, FOLEY & LARDNER LLP (May 10, 2017), <http://www.foley.com/shouldnt-you-be-using-arbitration-agreements-to-reduce-the-costs-of-litigation-and-the-risk-of-class-action-claims-05-10-2017/>.

389. See *id.*

390. Schmitz, *supra* note 341, at 1216; see also *Bowles Fin. Group, Inc. v. Stifel, Nicolaus & Co.*, 22 F.3d 1010, 1011 (10th Cir. 1994) (finding that “[a]rbitration provides neither the procedural protections nor the assurance of the proper application of substantive law . . .”); *Sprinzen v. Nomberg*, 389 N.E.2d 456, 458 (N.Y. 1979) (pointing out that “the arbitrator is not bound to abide by . . . those principles of substantive law . . . which govern the traditional litigation process”); *Lentine v. Fundaro*, 278 N.E.2d 633, 635 (N.Y. 1972) (stating that “[a]bsent provision to the contrary in the arbitration agreement, arbitrators are not bound by principles of substantive law . . .”).

391. See Daniel S. Kleinberger, *The Consensual Special Magistrate: Minnesota’s Appealable Alternative to Arbitration*, BENCH & B. MINN., Jan. 2016, at 24, 25 (stating that under Minnesota law no record, findings of fact, conclusions of law, or opinions supporting the arbitrator’s decision are required). Even if the arbitrator issues findings of fact or conclusions of law, they are not reviewable by a court. Stephen Wills Murphy, *Judicial Review of Arbitration Awards Under State Law*, 96 VA. L. REV. 887, 890 (2010).

392. Keas & Varon, *supra* note 388.

393. *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 343 (2011).

394. Rebecca D. Floyd, *Populist Conundrum: Big Banks or Plaintiffs’ Bar? Banks Win as Congress Overrides the CFPB Rule Banning Class Action Waivers in Arbitration Agreements*, 22 N.C. BANKING INST. 165, 170–71, 182–83 (2018).

from the FAA.³⁹⁵ Legislation to invalidate class action waivers would also ensure that consumers could bring lawsuits to enforce cyber-contracting legislation.³⁹⁶ In light of Congress' overturning of the CFPB's limited rule restricting consumer arbitration and opposition from the business community, it is doubtful legislation to prohibit pre-dispute arbitration and class action waivers would be enacted in the near future.³⁹⁷

Even assuming consumers could benefit from legislation despite arbitration clauses and class action waivers, legislators face difficult choices in drafting such legislation.³⁹⁸ The statute could be based on rules and standards developed by the courts, or the legislature could attempt to write a law based on an entirely novel approach.³⁹⁹

Assuming legislatures decide to base a statute on law already developed by the courts, they would nevertheless face formidable obstacles.⁴⁰⁰ This is illustrated by the American Law Institute's ("ALI") project to write a Restatement of the Law of Consumer Contracts.⁴⁰¹ As of the time this Article was written, the proposed restatement had been through nine drafts since the project began in 2012.⁴⁰² A crucial decision was made at the outset: The restatement would set forth one set of provisions that cover both traditional contracts and online contracts.⁴⁰³ This was a reasonable approach for a project that purports to be a restatement of present

395. See CHRISTOPHER BORAN ET AL., THE USE AND ENFORCEABILITY OF CLASS ACTION WAIVERS IN ARBITRATION AGREEMENTS IN THE UNITED STATES, Westlaw W-006-8537.

396. See *id.*

397. See Christopher G. Ward, *Supreme Court Ends the Debate and Upholds Class Action Waivers*, FOLEY & LARDNER LLP (May 21, 2018), <http://www.laboremploymentperspectives.com/2018/05/21/supreme-court-ends-the-debate-and-upholds-class-action-waivers/>.

398. See *id.*; BORAN ET AL., *supra* note 395.

399. See Ward, *supra* note 397.

400. See *id.*; BORAN ET AL., *supra* note 395.

401. RESTATEMENT OF CONSUMER CONTRACTS § 2 (AM. LAW INST., Discussion Draft, 2017).

402. See *id.*; A GUIDE TO THE AMERICAN LAW INSTITUTE PUBLICATIONS 28 (2018 Recompiled ed. 2018); Letter from Advocates for Basic Legal Equal., Inc., et al., to Council Members of the Am. Law Inst. (Oct. 12, 2018) (on file with author); *Project Meeting: Restatement of the Law, Consumer Contracts*, A.L.I., <http://www.ali.org/meetings/show/restatement-law-consumer-contracts-oct-2017/> (last visited May 1, 2019). There has been one Discussion Draft, three Preliminary Drafts, and five Council Drafts. RESTATEMENT OF CONSUMER CONTRACTS xvii (AM. LAW INST., Discussion Draft 2017); A GUIDE TO THE AMERICAN LAW INSTITUTE PUBLICATIONS, *supra*; Letter from Advocates for Basic Legal Equal., Inc., et al., to Council Members of the Am. Law Inst., *supra*; *Project Meeting: Restatement of the Law, Consumer Contracts*, *supra*.

403. RESTATEMENT OF CONSUMER CONTRACTS § 2 (AM. LAW INST., Discussion Draft 2017).

law.⁴⁰⁴ The courts have not tried to develop separate rules or concepts for online contracting.⁴⁰⁵ Indeed, some courts explicitly declare they are applying common law contract rules.⁴⁰⁶

But there is a fundamental problem in trying to draft a restatement of the law of consumer contracts that includes online contracting.⁴⁰⁷ There are few cases in few jurisdictions that have dealt with issues of online contract formation; there is little uniformity of analysis and very few appellate-level cases.⁴⁰⁸ It is premature to issue a restatement of the law when there is no consensus among the courts on what the law is.⁴⁰⁹ Moreover, in the current draft, the Reporters discuss only online cases that involve clickwrap, browsewrap, or “Pay Now Terms Later” contracts.⁴¹⁰ They do not examine cases involving online contracts in which the consumer signifies agreement with a touch, a tap, or a voice because apparently none existed.⁴¹¹ For that reason as well, a restatement at this time is premature.⁴¹² Consequently, the

404. *Id.* at x.

405. *See id.* at 5.

406. *See Cullinane v. Uber Techs., Inc.*, 893 F.3d 53, 61 n.10 (1st Cir. 2018).

407. Nicholas Malfitano, *Criticism Follows Powerful Law Group to Next Project — A Troubling Take on Consumer Contracts*, FORBES (June 25, 2018, 5:15AM), <http://www.forbes.com/sites/legalnewsline/2018/06/25/criticism-follows-powerful-law-group-to-next-project-a-troubling-take-on-consumer-contracts/#6304ad9d2f60>.

408. RESTATEMENT OF CONSUMER CONTRACTS § 2 (AM. LAW INST., Discussion Draft 2017). The Reporters found only four appellate cases involving browsewrap contracts. *Id.* The Reporters discovered only eleven appellate decisions in which clickwrap contracts were used. *Id.* at 34. Serious questions have been raised about the reliability of the collection of cases the Reporters cite to justify the rules in the Restatement. Gregory Klass, *Empiricism and Privacy Policies in the Restatement of Consumer Contract Law*, 36 YALE J. ON REG. 45, 67 (2018). The Reporters for the Principles of the Law of Software Contracts explained why the ALI decided to issue *principles* instead of a restatement. PRINCIPLES OF THE LAW OF SOFTWARE CONTRACTS 2 (AM. LAW INST., Discussion Draft 2007). Their explanation applies equally well to why a statement of principles concerning formation of online contracts would be appropriate. *See id.* “In light of the many percolating legal issues that pertain to the formation and enforcement of software agreements, an attempt to *restate* this law would be premature. Reinforcing this view, software technology continues to develop, which influences methods of doing business and changes or creates new legal issues.” *Id.*

409. *See id.*

410. RESTATEMENT OF CONSUMER CONTRACTS § 2 (AM. LAW INST., Discussion Draft 2017).

411. *See id.* *Cullinane v. Uber Techs., Inc.* was published after the December 2017 Council Draft was issued. *Cullinane v. Uber Techs., Inc.*, 893 F.3d 53, 53 (1st Cir. 2018). The case involved consumers who downloaded an app on their iPhones and used the app to create accounts. *Id.* at 55. Applying the principles of Massachusetts law — as stated in a Massachusetts Court of Appeals case — the court held the arbitration clause was not enforceable because the consumers “were not reasonably notified of the terms of the Agreement.” *Id.* at 62. Therefore, “they did not provide their unambiguous assent to those terms.” *Id.* at 64.

412. PRINCIPLES OF THE LAW OF SOFTWARE CONTRACTS at 2.

restatement—if approved by the ALI—will be seriously deficient as a restatement if it purports to cover case law in which consumers agree to be bound in these new ways.⁴¹³

Even if there were more than a few appellate-level cases, it is questionable whether they could provide helpful guidance for legislators.⁴¹⁴ Courts decide issues concerning contract formation based on a detailed examination of the content and format of the specific screens presented to the consumer in the case before the court.⁴¹⁵ They apply general and vague standards such as the *reasonably prudent user*.⁴¹⁶ It is doubtful the conclusions reached in these cases could provide guidance to a business trying to ascertain whether a court would approve of the content and format of the unique website used by that company.⁴¹⁷

On the other hand, if legislatures enact laws that are too specific, they may unduly restrict format and design options, and stifle innovation and experimentation.⁴¹⁸ A creative business, for example, might want to test a variety of types of websites with focus groups in order to determine which best display the seller's product, which are most user-friendly and which are more likely to result in completed sales.⁴¹⁹ It may be difficult to draft legislation that imposes specific requirements for formation of a binding agreement that does not interfere with legitimate business objectives.⁴²⁰

Congress could enact legislation that establishes general standards, and delegate to the FTC authority to issue regulations.⁴²¹ As an interim measure, the FTC might want to issue guidance as it did regarding how sellers should make representations about products that are displayed on

413. Malfitano, *supra* note 407.

414. See RESTATEMENT OF CONSUMER CONTRACTS § 2 (AM. LAW INST., Discussion Draft 2017); *Cullinane*, 893 F.3d at 63–64.

415. *Cullinane*, 893 F.3d at 63–64.

416. *Resorb Networks, Inc. v. YouNow.com*, 30 N.Y.S.3d 506, 511 (N.Y. Sup. Ct. 2016); see also *Kim*, *supra* note 324, at 248.

417. See *Cullinane*, 893 F.3d at 62–64; *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 226 (2d Cir. 2016); *Nguyen v. Barnes & Noble Inc.*, 763 F.3d 1171, 1177–80 (9th Cir. 2014); *Zaltz v. JDATE*, 952 F. Supp. 2d 439, 454 (E.D.N.Y. 2013); *Fteja v. Facebook Inc.*, 841 F. Supp. 2d 829, 840–41 (S.D.N.Y. 2012).

418. See PRINCIPLES OF THE LAW OF SOFTWARE CONTRACTS 2 (AM. LAW INST. Discussion Draft 2007); *Malan*, *supra* note 56.

419. See *Web Site Focus Groups 101*, BEACON: BLOG (Dec. 14, 2010), <http://www.beacontechnologies.com/blog/2010/12/web-site-focus-groups-101/>.

420. See Felix Hilgert, *EU Legislation Watch: New Rules for Consumer Contracts Under the Digital Content Directive*, OSBORNE CLARKE (Aug. 21, 2017), <http://www.osborneclarke.com/insights/eu-legislation-watch-new-rules-for-consumer-contracts-under-the-digital-content-directive/>.

421. See *Baksh*, *supra* note 375.

small smartphone screens.⁴²² That FTC guidance suggests certain features that the seller's website should contain.⁴²³

Most businesses likely would prefer to faithfully follow the FTC's guidance and avoid the Commission's scrutiny.⁴²⁴ Some businesses, however, might figure out how to design a website that lacks some of the features recommended by the FTC, but nevertheless, does not violate the legislation's required general standards.⁴²⁵ As the FTC becomes more familiar with the various ways in which businesses enter into online contracts, and it develops greater expertise, it may find it advisable to issue somewhat specific regulations.⁴²⁶ The FTC may find it appropriate to first regulate contract formation that takes place on desktops and laptops where the consumer has the advantage of a larger screen.⁴²⁷ At the same time, it may be appropriate to publish guidance on contract formation on smartphones that is adapted from its current guidance regarding product representations.⁴²⁸ Over time, it could refine this into a regulation, while issuing guidance on new forms of electronic commerce such as ordering a product by talking to a virtual assistant.⁴²⁹

Unfortunately, legislation probably can never be sufficient because it can neither anticipate future radical changes nor respond to them rapidly enough.⁴³⁰ Recent examples of such changes include the IoT, virtual personal assistants, drones, and self-driving vehicles.⁴³¹ Therefore, even if a

422. See FED. TRADE COMM'N, *supra* note 153, at 10.

423. See *id.* at 8–10. A bill introduced in Congress in 2017 includes requirements for government websites that suggest some of the provisions the FTC might consider. H.R. 3088, 115th Cong. § 2 (2017). The bill requires the Secretary of Labor to “establish and maintain standards and best practices for the provision of [employment] services through electronic means, including . . . internet websites.” *Id.* The bill includes specific standards for these websites: They must be friendly, up-to-date, and accessible by mobile devices. *Id.* The bill also requires the Secretary to issue “best practices for assuring a secure network and the protection of any personal information.” *Id.* Although the FTC is an independent agency, it may be influenced by the Trump administration's policy to limit agency guidance. See Cheryl Bolen, *Trump Administration Offers Relief from Agency Guidance*, BNA: NEWS (Mar. 2, 2018), <https://www.bna.com/trump-administration-offers-n57982089503/>; *What We Do*, FTC, <http://www.ftc.gov/about-ftc/what-we-do>.

424. 15 U.S.C. § 45 (2012); Jessica Rich, *How the FTC Works for Your Community – and Your Business*, FTC (July 1, 2015, 1:11 PM), <http://www.ftc.gov/news-events/blogs/business-blog/2015/07/how-ftc-works-your-community-your-business>.

425. See Malan, *supra* note 56.

426. See Baksh, *supra* note 375.

427. See FED. TRADE COMM'N, *supra* note 153, at 8–9.

428. See *id.* at 6, 8–9.

429. Martin, *supra* note 196; see also Smith, *supra* note 315, at 534.

430. Malan, *supra* note 56.

431. See Elvy, *supra* note 353, at 840; Elvy, *supra* note 112 at 82–83, 88; Malan, *supra* note 56.

suitable form of legislation could be developed and enacted, future development of the law would need to combine legislation with other initiatives, such as those considered below.⁴³²

B. *Case Law*

An alternative to enacting legislation would be to continue the current situation, which is to allow the courts to develop the law of online contracting case-by-case.⁴³³ Undoubtedly, for some period of time there would be a variety of approaches.⁴³⁴ Some courts may follow previous cases in their jurisdiction where the court confronted a comparable situation.⁴³⁵ Others may decide to use cases in other jurisdictions as a guide.⁴³⁶ It is likely that most courts would continue to purport to follow the contract law of their state, applying it to the new context of an online environment.⁴³⁷ Some courts, however, may determine that new environments call for new approaches.⁴³⁸ For example, a court may decide that ordering goods by talking to a virtual assistant is so different from traditional contracting that it calls for new concepts.⁴³⁹

Unfortunately, leaving the development of this body of law to the courts has several disadvantages for both businesses and consumers.⁴⁴⁰ For a number of years, there would continue to be a lack of uniformity.⁴⁴¹ Perhaps there would never be a consensus among all the courts across the country.⁴⁴² This would pose a great burden for online companies that do business in several states.⁴⁴³

Case law develops incrementally at a slow pace.⁴⁴⁴ Therefore, it is highly unlikely it will reflect the application of rapidly changing technology

432. See Malan, *supra* note 56.

433. Smith, *supra* note 315, at 524.

434. See *id.*

435. N. ILL. U: BASIC LEGAL RES., <http://www.libguides.niu.edu/c.php?g=425200&p=2904391> (last updated Jan. 3, 2019, 11:34 AM); see also *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 231–32 (2d Cir. 2016).

436. N. ILL. U.: BASIC LEGAL RES., *supra* note 435.

437. See Smith, *supra* note 315, at 524.

438. See Elvy, *supra* note 112, at 79–80.

439. See *id.*

440. *Id.* at 82.

441. See *id.* at 80, 82.

442. See *id.* at 80.

443. See Elvy, *supra* note 112, at 79–80.

444. See Rodrigo, *Discuss the Role and Importance of Judicial Precedent in English Legal System. What Are the Advantages and Disadvantages of the Doctrine?*, WRITEPASS J. (Jan. 23, 2017), <http://www.writepass.com/journal/2017/01/discuss-the-role->

to the online formation of contracts.⁴⁴⁵ The situation today reflects this.⁴⁴⁶ Current case law addresses websites and mouse clicks; it does not include apps and consumers touching and tapping on small smartphone screens and talking to virtual personal assistants.⁴⁴⁷

New ways for consumers to pay for goods illustrate some of the changes now occurring and those in the near future.⁴⁴⁸ When problems arise, courts will have to determine how to apply legal rules to these novel transactions.⁴⁴⁹ IoT and artificial intelligence have resulted in the widespread use of virtual assistants.⁴⁵⁰ These devices are used to purchase goods as well as pay for them.⁴⁵¹ In the near future, virtual assistants likely will be used to perform many types of financial transactions.⁴⁵² Consumers' television remote controls may add some of the same e-commerce features as virtual assistants.⁴⁵³ Already, consumers can order movie tickets by talking to their television remote controls.⁴⁵⁴ Consumers can engage in financial transactions with their smartwatches.⁴⁵⁵ The Amazon Go stores employ an example of *invisible payments* in which no device is used by the consumer or

and-importance-of-the-doctrine-of-judicial-precedent-in-english-legal-system-what-are-the-advantages-and-disadvantages-of-the-doctrine/.

445. See *id.*

446. See Leah Hamilton, *3 Key Legal Cases on Clickwrap*, TERMSFEED (Dec. 12, 2018), <http://termsfeed.com/blog/3-key-legal-cases-clickwrap/>.

447. See *id.*

448. See Martin, *supra* note 196.

449. See Rodrigo, *supra* note 444.

450. See FED. TRADE COMM'N, *supra* note 20, at 1; Matthew Finnegan, *A.I. and Speech Advances Bring Virtual Assistants to Work*, COMPUTERWORLD (Mar. 20, 2018, 4:43 AM), <http://www.computerworld.com/article/3264433/digital-assistants/ai-and-speech-advances-bring-virtual-assistants-to-work.html>.

451. Crosman, *supra* note 280. Customers of U.S. Bank can use Alexa to pay their credit card bills. *Id.* In regard to using virtual assistants for financial transactions, one bank official said, "This technology is moving very fast." *Id.* Customers of Capital One Bank can pay credit card bills using Amazon Echo's Alexa. *Limitless Potential*, BANKER: MIDDLE EAST, Apr. 30, 2018, at 73.

452. Crosman, *supra* note 387.

453. See *Comcast and Fandango Launch Voice-Activated Movie Ticketing Experience on the Television*, COMCAST (May 30, 2018), <http://corporate.comcast.com/press/releases/comcast-and-fandango-launch-voice-activated-movie-ticketing-experience-on-the-television>.

454. *Id.*

455. Mark Real, *Michael Kors Unveils Runway Smartwatches with Wear OS*, ANDROID HEADLINES (Aug. 13, 2018, 12:33 PM), <http://www.androidheadlines.com/2018/08/michael-kors-unveils-runway-smartwatches-with-wear-os.html>. Smartwatches can also aid the elderly by monitoring their hearts and detecting when they fall. Peter Loftus & Tripp Mickle, *Smartwatch Adds Heart Monitoring and Fall Detection*, WALL ST. J., Sept. 13, 2018, at B2.

the merchant.⁴⁵⁶ New technologies such as enhanced reality and virtual reality may present e-commerce opportunities as well.⁴⁵⁷

The legal rules courts try to apply to online contracting were developed when parties agreed with a handshake or a signature on paper.⁴⁵⁸ New types of hardware and new software programs require consumers to enter into contracts in radically different ways.⁴⁵⁹ Courts have not considered whether those changes require a different analysis and different legal rules.⁴⁶⁰ They cannot even agree on who is the offeror and who is the offeree.⁴⁶¹ But an ever-increasing number of people who have grown up living in constant daily contact with various online environments will become judges.⁴⁶² They may have an entirely different conceptual approach to the formation of online contracts.⁴⁶³

456. Elan Fin. Servs., *Mobile Apps, Wearables, & Invisible Payments: The Journey Toward Frictionless Payments*, CREDITUNIONS.COM (Nov. 5, 2018), <http://www.creditunions.com/articles/mobile-apps-wearables--invisible-payments-the-journey-toward-frictionless-payments/>. In addition to Amazon Go, Standard Market in San Francisco and stores in China are eliminating cashiers using a variety of apps, cameras, sensors, scanners, and artificial intelligence. Nellie Bowles, *Stealing from a Cashierless Store (Without You, or the Cameras, Knowing It)*, N.Y. TIMES (Sept. 13, 2018), <http://www.nytimes.com/2018/09/13/technology/standard-market-retail-automation-behavioral-data.html>.

457. See Joanna Stern, *A Peek into Augmented Reality's Future*, WALL ST. J., Aug. 9, 2018, at B4. The implementation of 5G service will provide greater opportunities for new and faster services. Stu Woo, *5G Technology (A Special Report) — Why Being First in 5G Matters: The U.S., China, South Korea and Japan All See a Big Payoff from Winning the Battle for the Wireless Future*, WALL ST. J., Sept. 13, 2018, at R1.

458. See Restle, *supra* note 88; *Electronic Signatures and Online Contracts*, NOLO, <http://www.nolo.com/legal-encyclopedia/electronic-signatures-online-contracts-29495.html> (last visited May 1, 2019).

459. See R3 & NORTON ROSE FULBRIGHT, CAN SMART CONTRACTS BE LEGALLY BINDING CONTRACTS? 7–8 (2016), <https://www.ilsa.org/ILW/2018/CLE/Panel%20%2311%20-%20norton-rose-fulbright--r3-smart-contracts-white-paper-key-findings-nov-2...pdf>.

460. See *Cullinane v. Uber Techs., Inc.*, 893 F.3d 53, 61 n.10 (1st Cir. 2018).

461. See *All About Business Law*, PBS: STANDARD DEVIATION, http://www.pbs.org/standarddeviantstv/transcript_business.html (last visited May 1, 2019).

462. See Laura Pappano, *The iGen Shift*, N.Y. TIMES, Aug. 5, 2018, at F6 (describing how colleges have learned to adapt to a generation of students who are *digital natives*). Mobile devices are not really technology to them. *Id.* Banks are developing electronic services tailored to meet the preferences of millennials for apps and websites. Brian Patrick Eha, *Big Banks Are Winning the Battle for Millennials*, AM. BANKER (May 5, 2016, 4:39 PM), <http://www.americanbanker.com/news/big-banks-are-winning-the-battle-for-millennials>.

463. See Pappano, *supra* note 462.

One way courts may be able to develop sensible rules is by testing possible analogies.⁴⁶⁴ For example, is a consumer entering into a contract using a desktop or laptop and clicking on a button labeled “I agree” with a mouse analogous to touching or tapping on a much smaller button on the much smaller screen of a smartphone?⁴⁶⁵ Social scientists with expertise in perception and cognition may be able to provide information to inform a court’s answer to that question.⁴⁶⁶ If it is not analogous, how are tapping and touching different, and do those differences require a different legal rule?⁴⁶⁷

Consumers have very different levels of skill when using computers, as some courts have recognized.⁴⁶⁸ Courts should consider whether legal standards should vary depending on the type of consumer the product is aimed at.⁴⁶⁹ For example, products specifically targeting the elderly may call for stricter rules or standards.⁴⁷⁰ While this is the sort of distinction that would be suitable for an agency such as the FTC, courts also have experience making these determinations.⁴⁷¹

In addition, courts need to keep struggling with basic questions related to online contract formation.⁴⁷² One example is: Who is “the master of the offer?”⁴⁷³ And who is the offeror?⁴⁷⁴ Maybe the courts can resolve

464. See Richard A. Posner, *Reasoning by Analogy*, 91 CORNELL L. REV. 761, 764–65 (2006).

465. See Juliet M. Moringiello & William L. Reynolds, *From Lord Coke to Internet Privacy: The Past, Present, and Future of the Law of Electronic Contracting*, 72 MD. L. REV. 452, 480 (2013); RESTATEMENT OF CONTRACTS § 2 (AM. LAW INST., Discussion Draft 2017).

466. See Shmuel I. Becher, *Behavioral Science and Consumer Standard Form Contracts*, 68 LA. L. REV. 117, 119 (2007).

467. See *id.*; *Designing for Touch: The Science of Tap vs. Click*, ORTHOGONAL, <http://www.orthogonal.io/user-experience-design/designing-touch-science-tap-click/> (last visited May 1, 2019).

468. *Nguyen v. Barnes and Noble Inc.*, 763 F.3d 1171, 1179 (9th Cir. 2014).

469. See Joshua C. P. Reams, Comment, *Twenty-First Century Advertising and the Plight of the Elderly Consumer*, 52 WILLAMETTE L. REV. 325, 349 (2016).

470. See *id.*

471. *Nguyen*, 763 F.3d at 1179. For example, courts deciding cases under the Fair Debt Collection Practices Act have developed the *least sophisticated consumer standard*. *Ellis v. Solomon & Solomon, P.C.*, 591 F.3d 130, 135 (2d Cir. 2010); see also 15 U.S.C. § 1692 (2012); *Russell v. Equifax A.R.S.*, 74 F.3d 30, 34 (2d Cir. 1996). For an example of an agency establishing rules tailored to a specific transactional environment, see the FTC’s door-to-door sales rule. 16 C.F.R. § 429.1 (2018).

472. See Smith, *supra* note 315, at 524.

473. Stephen Y. Chow, *Contracting in Cyberspace: The Triumph of Forms?*, BOS. B.J., May–June 1997, at 16, 26.

474. See *id.*

their disagreement on that issue, or perhaps it all depends on the circumstances.⁴⁷⁵

Another issue arises in transactions, like those of the Starbucks and Best Buy customer, where there is an underlying account agreement as well as each individual sales transaction.⁴⁷⁶ Is every sale a separate contract, or does every sale constitute additional terms to the original contract establishing the underlying account agreement?⁴⁷⁷

A major impediment to timely and fruitful development of case law on these questions is the ubiquity of mandatory pre-dispute arbitration clauses in consumer contracts.⁴⁷⁸ Arbitration agreements result in far fewer opportunities for courts to grapple with these issues.⁴⁷⁹ This is a serious problem, given the wide variety of hardware and software, resulting in many different online contracting environments.⁴⁸⁰ For the optimal development of the law, courts need to be exposed to as many different online environments as possible.⁴⁸¹ Case law development is incremental, with each case serving as potential precedent or guidance for future cases.⁴⁸² Arbitration removes many cases from that source of precedent.⁴⁸³ Sound case law development will be difficult to achieve if the majority of consumer transactions never reach the courts.⁴⁸⁴

475. See *id.* at 26–27.

476. RESTATEMENT OF CONSUMER CONTRACTS § 2, at 35 (AM. LAW INST., Discussion Draft 2017); Kristin B. Cornelius, *Standard Form Contracts and a Smart Contract Feature*, INTERNET POL'Y REV. May 2018, <http://www.policyreview.info/node/790/pdf>.

477. See RESTATEMENT OF CONSUMER CONTRACTS § 2, at 35 (AM. LAW INST., Discussion Draft 2017).

478. Mindy R. Hollander, Note, *Overcoming the Achilles' Heel of Consumer Protection: Limiting Mandatory Arbitration Clauses in Consumer Contracts*, 46 HOFSTRA L. REV. 363, 363 (2017).

479. See *id.*; Jessica Silver-Greenberg & Robert Gebeloff, *Arbitration Everywhere, Stacking the Deck of Justice*, N.Y. TIMES, Nov. 1, 2015, at A1.

480. See Cornelius, *supra* note 476.

481. See Register.com, Inc., 356 F.3d at 403.

482. *Precedent and the Doctrine of Stare Decisis* (Let the Decision Stand), IND. JUD. BRANCH, <http://www.in.gov/judiciary/2675.htm> (last visited May 1, 2019).

483. Jean R. Sternlight, *Creeping Mandatory Arbitration: Is It Just?*, 57 STAN. L. REV. 1631, 1661–62 (2005) (opining that arbitration “eliminates the development of public precedent . . . we hope that our public litigation system will ensure predictable, fair, and consistent interpretation of the society’s laws”); see also LLEWELLYN, *supra* note 13, at 63–64 (describing how courts respond to new business practices by following precedent or depart[ing] from earlier molds).

484. See Hollander, *supra* note 478, at 363; Silver-Greenberg & Gebeloff, *supra* note 479.

C. *Independent Development of Principles, Standards, Model Acts, and Best Practices*

Independent organizations could provide a useful role by drafting principles, standards, model statutes, and best practices that could serve as guides for legislatures and courts developing the law of consumer cyber-contracting.⁴⁸⁵ For example, the ALI has issued model acts and principles for software contracts.⁴⁸⁶ Industry associations have published best practices policies.⁴⁸⁷ Consumer organizations have recommended model acts.⁴⁸⁸

Assuming organizations will develop guides that specifically address cyber-contracting, the challenge for legislatures and courts will be to determine which guides to follow.⁴⁸⁹ Those suggested by the industry likely will not be consistent with or supported by consumer groups, and vice versa.⁴⁹⁰ In addition, because the marketplace changes so significantly and rapidly, guides may quickly become obsolete.⁴⁹¹ Furthermore, policymakers will have to decide among a variety of approaches, including required disclosures, substantive rules, dispute and error resolution mechanisms, and burdens and presumptions.⁴⁹² Despite the difficulties, independent organizations should be encouraged to consider making this contribution to the future evolution of the law of online contracting.⁴⁹³

485. See PRINCIPLES OF THE LAW OF SOFTWARE CONTRACTS, at 2.

486. See *id.* The principles are “intended to guide the drafting of software contracts and assist in judicial resolution of disputes involving software [contracts].” *Principles of the Law, Software Contracts*, A.L.I., <http://www.ali.org/publications/show/software-contracts/> (last visited May 1, 2019). The Uniform Commercial Code is an example of a model act that has been adopted by every state and the District of Columbia, but with many jurisdictions making limited modifications. Mooney, Jr., *supra* note 140, at 1346–47.

487. SPARK INST., INC., *INDUSTRY BEST PRACTICE DATA SECURITY REPORTING* 2 (2017), <http://www.sparkinstitute.org/pdf/SPARK%20Data%20Security%20Industry%20Best%20Practice%20Standards%209-2017.pdf>.

488. See *Model State Laws*, NAT’L CONSUMER L. CTR., <http://www.nclc.org/legislation-regulation/model-state-laws.html> (last visited May 1, 2019). The National Consumer Law Center, along with other consumer organizations, has drafted many model acts. *Id.*; *Uniform Laws*, CORNELL L. SCH.: LEGAL INFO. INST., <http://www.law.cornell.edu/uniform> (last visited May 1, 2019).

489. See *Uniform Laws*, *supra* note 488.

490. Compare SPARK INST., INC., *supra* note 487, at 1, with *Model State Laws*, *supra* note 488.

491. See Maria Matarelli, *How Can Businesses Adapt to a Rapidly Changing World?*, FORBES (Jan 5, 2018, 6:01 PM), <http://www.forbes.com/sites/quora/2018/01/05/how-can-businesses-adapt-to-a-rapidly-changing-world/#3aecac955930>.

492. See *Uniform Laws*, *supra* note 488.

493. See Christopher Tay, *Contracts, Technology, and Electronic Commerce: The Evolution Continues*, 9 J.L. & INFO. SCI. 177, 177–78 (1998).

In order to gain consumer trust and comfort, entering into contracts online needs to be done in an environment that is secure.⁴⁹⁴ Independent organizations have developed standards for certifying a company's data security and privacy protection.⁴⁹⁵ Policymakers should encourage the development of programs for monitoring and evaluating consumer websites for their security, privacy protection, clarity, transparency, and ease in the contract formation process.⁴⁹⁶

VII. CONCLUSION

Legal rules related to the formation of contracts are crucial to every transaction.⁴⁹⁷ They are necessary when disputes arise about when parties entered into a contract, and even whether they entered into a contract at all.⁴⁹⁸ Considering how they went about agreeing is a vital component in evaluating whether there is a valid contract and what the terms of that contract are.⁴⁹⁹

The legal rules that apply to each of these issues have been thrown into doubt when companies and consumers form contracts online.⁵⁰⁰ Courts and legislatures have failed to respond in a timely and adequate manner.⁵⁰¹ Meanwhile, new online e-commerce environments are constantly introduced into the marketplace, causing the law to fall further behind.⁵⁰²

In order to flourish, e-commerce needs legal rules for online contract formation that provide clarity and certainty for businesses while permitting

494. See Sue Pelletier, *3 Ways to Make Your Contracts More Cyber-Secure*, MEETINGSNET (Jan. 23, 2018), <http://www.meetingsnet.com/negotiating-contracts/3-ways-make-your-contracts-more-cyber-secure>.

495. See *Resilinc Awarded Two of the World's Most Stringent Data Security and Privacy Certifications*, CISION PRWEB (Aug. 28, 2018), http://www.prweb.com/releases/resilinc_awarded_two_of_the_worlds_most_stringent_data_security_and_privacy_certifications/prweb15717147.htm. Cision PRWeb reported that the company complied with requirements for "the ISO/IEC 27001 standard for information security; the US-EU Privacy Shield Framework; and the EU's Global Data Protection Regulation." *Id.*

496. See *Task Force on Cybersecurity*, NAT'L CONFERENCE OF STATE LEGIS. (Jan. 23, 2019), <http://www.ncsl.org/ncsl-in-dc/task-forces/task-force-on-cybersecurity.aspx>.

497. See Dodd & Hernandez, *supra* note 91, at 3; Nimmer, *supra* note 115, at 260.

498. Nimmer, *supra* note 115, at 260.

499. See *id.*; Dodd & Hernandez, *supra* note 91, at 3-4.

500. See Budnitz, *supra* note 13, at 742; *Challenges of E Commerce to Traditional Contracts*, *supra* note 348.

501. See *A Primer on the Basic Law of E-Commerce*, LAW OFFICES STIMMEL, STIMMEL & SMITH, <http://www.stimmel-law.com/en/articles/primer-basic-law-e-commerce> (last visited May 1, 2019).

502. See Malan, *supra* note 56.

them to innovate and experiment.⁵⁰³ Consumers need laws that ensure they know what they are agreeing to and to do so in a setting that is secure.⁵⁰⁴

503. See *Challenges of E Commerce to Traditional Contracts*, *supra* note 348.

504. See Armel Nkuzimana, *E-Commerce and Consumer Protection*, *SERV. MAG.* (Jan. 29, 2017), <http://www.theservicemag.com/e-commerce-and-consumer-protection/>.

DATA-CENTRIC TECHNOLOGIES: PATENT AND COPYRIGHT DOCTRINAL DISRUPTIONS

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I. INTRODUCTION

Research, development, and investment in data-centric technologies¹ has skyrocketed in recent years.² Market adoption and customer use of data-centric technologies have followed a similar trend.³ Data-centric technologies are proliferating at a faster pace than previous innovations.⁴ While data-centric applications have spread, intellectual property law regimes have been slow to react.⁵ Critical questions about intellectual property protection have been understudied and the scope, standards, and relationships between actors involved with data-centric technologies is

1. *Data-centric technologies* is the term used throughout this Article to refer to both 3D printing and artificial intelligence. See discussion *infra* Parts II–V. While data-centric technologies utilize and are controlled by software, data-centric technologies are more closely linked to the physical world than software. Tabrez Y. Ebrahim, *3D Printing: Digital Infringement & Digital Regulation*, 14 NW. J. TECH. & INTELL. PROP. 37, 66 (2016) [hereinafter Ebrahim, *Digital Infringement & Digital Regulation*]. This Article is focused on the digital foundations that drive industrial applications in the physical world. See discussion *infra* Parts II–V. Data-centric technologies are defined as technology capabilities that create information content that directly controls, modifies, or responds to the physical world. Tabrez Y. Ebrahim, *Trademarks & Brands in 3D Printing*, 17 WAKE FOREST J. BUS. & INTELL. PROP. L. 1, 7 (2016) [hereinafter Ebrahim, *Trademarks & Brands*]. Data-centric technologies' information content resides in the digital world, yet its impact is in the physical world of industrial applications. *Id.* at 7, 15.

2. See Navin Shenoy, *Innovating for the Data-Centric Era*, INTEL: NEWSROOM (Aug. 8, 2018), <http://newsroom.intel.com/editorials/data-centric-innovation-summit/>; Neil Tyler, *The Future Is Datacentric, According to Intel*, NEW ELECTRONICS (Mar. 13, 2018), <http://www.newelectronics.co.uk/electronics-interviews/the-future-is-datacentric-according-to-intel/170703/>.

3. Shenoy, *supra* note 2.

4. See Tyler, *supra* note 2.

5. See MICHAEL WEINBERG, IT WILL BE AWESOME IF THEY DON'T SCREW IT UP: 3D PRINTING, INTELLECTUAL PROPERTY, AND THE FIGHT OVER THE NEXT GREAT DISRUPTIVE TECHNOLOGY 12 (2010), <http://www.publicknowledge.org/files/docs/3DPrintingPaperPublicKnowledge.pdf>.

unclear.⁶ A number of doctrinal disruptions have arisen with 3D printing and artificial intelligence, particularly with patent law and copyright law.⁷

While trade secrecy has been an alternative intellectual property protection mechanism proposed for the data-centric world, trade secrecy has some downsides.⁸ Trade secrecy of data-centric technologies reduces incentives for creators and inventors, requires corporations to spend resources on policies and reasonable steps to maintain trade secrecy, and produces socially harmful results with innovations that do not enter the public domain.⁹ Unlike trade secret law, patent law and copyright law are based on the notion that inventorship and authorship will be rewarded by governmental incentives.¹⁰ Therefore, data-centric technologies that could attain copyright or patent protection incentivize an author or inventor to recoup costs of research and development.¹¹

There remain doctrinal quandaries concerning patentability and copyrightability of two data-centric technologies: 3D printing and artificial intelligence.¹² Data-centric technologies are defined to be information flows more closely connected to the physical world than historical definitions of software and computer code.¹³ For example, 3D printing is considered a data-centric technology because its use of Computer Aided Design (“CAD”) files provide digital data for eventual printing of physical goods and

6. *See id.*

7. *See* Lucas S. Osborn, *Trademark Boundaries and 3D Printing*, 50 AKRON L. REV. 865, 868–70 (2017); Andres Guadamuz, *Artificial Intelligence and Copyright*, WIPO MAG., Oct. 2017, at 14, 17.

8. David S. Levine & Ted Sichelman, *Why Do Startups Use Trade Secrets?*, 94 NOTRE DAME L. REV. 751, 758–60 (2019) (suggesting that innovators of data-centric technologies, such as software and business methods, tend to focus away from patents and towards trade secrecy); Brenda M. Simon & Ted Sichelman, *Data-Generating Patents*, 111 NW. U. L. REV. 377, 379 (2017) (contending that inventions that generate data that is distinct from the operation and use of the invention can be maintained as a trade secret).

9. RONALD T. COLEMAN, JR. ET AL., TRADE SECRETS — THE BASIC PRINCIPLES AND ISSUES 4 (2014) http://www.americanbar.org/content/dam/aba/publications/litigation_committees/intellectual/trade-secrets-the-basic-principles-and-issues.authcheckdam.pdf; Simon & Sichelman, *supra* note 8, at 432–33.

10. Michael Risch, *Why Do We Have Trade Secrets?*, 11 MARQ. INTELL. PROP. L. REV. 1, 11 (2007).

11. *See id.*

12. *See* Lucas Osborn, *3D Printing and Intellectual Property*, in RESEARCH HANDBOOK ON DIGITAL TRANSFORMATIONS 254, 254 (F. Xavier Olleros & Majlinda Zhegu eds., 2016); Sean Semmler & Zeeve Rose, *Artificial Intelligence: Application Today and Implications Tomorrow*, 16 DUKE L. & TECH. REV. 85, 86 (2018).

13. Marco Conti & Andrea Passarella, *The Internet of People: A Human and Data-Centric Paradigm for the Next Generation Internet*, COMPUTER COMM., Oct. 2018, at 51, 51.

objects.¹⁴ Additionally, for example, artificial intelligence is considered a data-centric technology because its information flows can be mathematically trained from unique data sets for use in physical systems.¹⁵ Unlike historical definitions of software and computer code, such as source code and object code, data-centric technologies directly connect with or control the physical world through the laws of probability theory and information science.¹⁶

This Article focuses on the patent law and copyright law doctrinal disruptions of data-centric technologies.¹⁷ Part II is descriptive and provides the technological foundations and commonalities of data-centric technologies, 3D printing, and artificial intelligence.¹⁸ It describes the similarities of information representation of the physical world, blurring of the digital and physical divide, ease of transmission, and ability to dramatically improve the physical world through modifications in the digital realm.¹⁹ Part III describes the doctrinal foundations of inventorship in patent law and authorship in copyright law as a few of a growing number of doctrinal concerns, and introduces the ramifications posed by 3D printing and artificial intelligence technologies.²⁰ Part IV.A describes litigation that has resulted from the unclear doctrinal boundaries of copyright and patent protection of data-centric technologies.²¹ It identifies recent litigation and summarizes the doctrinal issues underlying the disputes.²² Part IV.B provides a conceptual foundation and normative justifications for a new spectrum-based view on legal standards.²³ It formulates a two-by-two matrix as a conceptual framework of data-centric technologies encompassing axes of human to non-human and physical to digital.²⁴ It proposes that standards relevant to patent

14. Timothy R. Holbrook & Lucas S. Osborn, *Digital Patent Infringement in an Era of 3D Printing*, 48 U.C. DAVIS L. REV. 1319, 1321 (2015); *see also* Osborn, *supra* note 12, at 257–58.

15. *See* Semmler & Rose, *supra* note 12, at 86–87 (defining artificial intelligence as “the process of simulating human intelligence through machine processes,” specifying that machine learning, as a subset of artificial intelligence, learns from user-fed data to respond to new data); Phillipe Aghion et al., *Artificial Intelligence and Economic Growth 2* (Nat’l Bureau of Econ. Research, Working Paper No. 23928, 2017) (defining artificial intelligence as “the capability of a machine to imitate intelligent human behavior or an agent’s ability to achieve goals in a wide range of environments.”).

16. Stan Schneider, *The Data-Centric Future*, EMBEDDED SYSTEMS EUROPE, Nov.–Dec. 2006, at 30, 30; *see also* Semmler & Rose, *supra* note 12, at 87.

17. *See* discussion *infra* Part II.

18. *See* discussion *infra* Part II.

19. *See* discussion *infra* Part II.

20. *See* discussion *infra* Part III.

21. *See* discussion *infra* Part IV.A.

22. *See* discussion *infra* Part IV.A.

23. *See* discussion *infra* Part IV.B.

24. *See* discussion *infra* Part IV.B.1.

law and copyright law have not been static, but instead have been and continue to be dynamic.²⁵ It suggests that the doctrinal origins of patent law and copyright law were grounded in the human/physical conceptualization, but data-centric technologies have now introduced human-digital, non-human/physical, and non-human/digital considerations.²⁶ The conceptualization matrix will be reformulated with time progression to become dominated with non-human/digital considerations and inconsequential human/physical considerations.²⁷ This analysis suggests that authorship and inventorship should not be evaluated within the human and physical realms, but should also consider non-human and digital realms, which would have prevented the recent litigation identified in Part IV.A.²⁸ The implication for innovation is that unclear doctrinal boundaries will lessen incentives for copyright and patent protection in a data-centric world and increase trade secrecy considerations.²⁹ Part V concludes that data-centric technologies' doctrinal disruptions necessitate reevaluation of copyright and patent doctrines.³⁰

II. FOUNDATIONS OF DATA-CENTRIC TECHNOLOGIES

The concept of data-centric technologies refers to technologies that transmit, represent, modify, and/or control physical objects through digital operation or use.³¹ For instance, 3D printing technology can scan, modify, and transmit a physical object for eventual production of the object at a 3D printer located elsewhere.³² Additionally, artificial intelligence technology can generate statistical information about physical objects and interpret, modify, and transmit that statistical information for control of physical objects.³³ Specifically, these technologies operate mostly in the digital world yet their beneficial use is in the physical world.³⁴ While information content

25. See discussion *infra* Part IV.B.1.

26. See discussion *infra* Part IV.B.2.

27. See discussion *infra* Part IV.B.3.

28. See W. Keith Robinson & Joshua T. Smith, *Emerging Technologies Challenging Current Legal Paradigms*, 19 MINN. J.L., SCI. & TECH. 355, 357, 372 (2018); discussion *infra* Part IV.A.

29. Levine & Sichelman, *supra* note 8, at 758–60.

30. See discussion *infra* Part V.

31. See Tan Wee Kwang, *The Future of Production: IoT, AI, Robotics, Wearables and 3D Printing*, ENTERPRISE INNOVATION: EGOV (Apr. 26, 2017), <http://www.enterpriseinnovation.net/article/future-production-iot-ai-robotics-wearables-and-3d-printing-51643031>.

32. Stefan Bechtold, *3D Printing and the Intellectual Property System 3* (World Intellectual Prop. Org., Working Paper No. 28, 2015).

33. See Semmler & Rose, *supra* note 12, at 86–87.

34. See Holbrook & Osborn, *supra* note 14, at 1321–22.

technologies have generated data about physical objects,³⁵ data-centric technologies are not limited to simply monitoring and estimating performance of physical objects.³⁶ Instead, data-centric technologies offer unique capabilities of controlling and transmitting a massive amount of information about the physical objects.³⁷ When data-centric technologies are utilized, information concerning physical objects and their control and creation can be transmitted across national borders.³⁸

Some common traits of data-centric technologies are that they depend on digital foundations,³⁹ blur the digital and physical divide,⁴⁰ and dramatically improve physical goods in some way.⁴¹ Both 3D printing and artificial intelligence have underlying information content that is governed by the law of mathematics and probability; yet, their resulting output is applicable in the physical world of goods, objects, products, and systems.⁴² Data-centric technologies' information content produces information

35. See K. J. Bathe et al., *Some Recent Advances for Practical Finite Element Analysis*, 47 COMPUTERS & STRUCTURES 511, 511, 513–14 (1993) (illustrating finite element procedures using iterative methods for analysis and structures with the use of computers); Sergey P. Zotkin et al., *About Development and Verification of Software for Finite Element Analysis of Beam Systems*, 111 PROEDIA ENGINEERING 902, 902–03 (2015) (describing structural analysis using the finite element method).

36. See Betchold, *supra* note 32, at 3–5; Semmler & Rose, *supra* note 12, at 86–87.

37. See Kwang, *supra* note 31.

38. Graeme B. Dinwoodie, *Developing a Private International Intellectual Property Law: The Demise of Territoriality?*, 51 WM. & MARY L. REV. 711, 713 (2009).

39. See Holbrook & Osborn, *supra* note 14, at 1321–22. Data-centric technologies are digital in nature, but unlike pure software, which refers to data instructions and executable code consisting of machine language instructions, data-centric technologies refer to embodying and directly influencing the physical domain through software. *Id.*

40. *Id.* at 1321. 3D printing's use of CAD files blurs the divide between digital representation of physical objects as blueprint instruction files. *Id.*; Lucas Osborn, *Regulating Three-Dimensional Printing: The Converging Worlds of Bits and Atoms*, 51 SAN DIEGO L. REV. 553, 555 (2014) [hereinafter Osborn, *Regulating Three-Dimensional Printing*]; Lucas Osborn, *Of PhDs, Pirates, and the Public: Three-Dimensional Printing Technology and the Arts*, 1 TEX. A&M L. REV. 811, 812 (2014) [hereinafter Osborn, *Of PhDs, Pirates, and the Public*]. Artificial intelligence blurs the divide between statistical methods that learn from data sets to make predictions of future input data in a physical system or a manufacturing process. See Semmler & Rose, *supra* note 12, at 86–87.

41. See Holbrook & Osborn, *supra* note 14, at 1321. 3D printing improves development time through the use of prototyping to develop test products, which can quickly be modified for production. Kwang, *supra* note 31. Artificial intelligence improves product design, yield, and efficiency of physical goods and systems, such as manufacturing systems and autonomous vehicle systems. See *id.*

42. Ebrahim, *Trademarks & Brands*, *supra* note 1, at 7–9; Semmler & Rose, *supra* note 12, at 86–87.

goods.⁴³ The digital foundations of data-centric technologies have enabled cross-border transmission or control of information goods without being hindered by slow-to-respond copyright and patent laws.⁴⁴ However, unclear scope of protection, legal standards, and legal relationships between actors of copyright and patent protection of data-centric technologies have created doctrinal disruptions that necessitate greater discussion.⁴⁵

A. 3D Printing

3D printing is a technology that enables creation, replication, modification, and transmission of three-dimensional objects via instructions from a digital file—a CAD file.⁴⁶ The process of 3D printing starts with the creation of a digital representation in a CAD file of a physical object for eventual 3D printing.⁴⁷ CAD files serve as templates and blueprint instructions of the physical object that is 3D printed.⁴⁸ The creation of a CAD file is either from scanning an existing three-dimensional object or from creating a digital representation of a physical object in a computer program.⁴⁹ The CAD file, which is the brain of the 3D printing operation, is utilized to print the physical object by slicing the digital object into electronic 2D layers that are sent to the 3D printer *layer-by-layer* to produce the object *layer-by-layer*.⁵⁰ In effect, 3D printing technology enables users to turn digital blueprints and digital models into physical objects with the press of a button.⁵¹ 3D printing challenges intellectual property laws through its digital approach to production and its customization.⁵² The information content of physical objects is embedded in CAD files, which can be

43. See Jacqueline Lipton, *Information Property: Rights and Responsibilities*, 56 FLA. L. REV. 135, 140–41 (2004) (describing that information goods, while unlike tangible goods, still may entail the use of the bundle of rights analogy in balancing relevant competing interests); Osborn, *Regulating Three-Dimensional Printing*, *supra* note 40, at 572.

44. See Dinwoodie, *supra* note 38, at 713; Lipton, *supra* note 43, at 164.

45. See Holbrook & Osborn, *supra* note 14, at 1325–27.

46. Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 41; see also Timothy R. Holbrook, *Extraterritoriality and Digital Patent Infringement*, in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND DIGITAL TECHNOLOGIES (T. Aplin, ed. forthcoming 2019) (manuscript at 2) (on file with author).

47. Holbrook & Osborn, *supra* note 14, at 1329.

48. Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 41.

49. Osborn, *Of PhDs, Pirates, and the Public*, *supra* note 40, at 814.

50. *Id.* at 812, 814.

51. Weinberg, *supra* note 5, at 2.

52. See Michael Henry, *How 3D Printing Challenges Existing Intellectual Property Law*, HENRY PATENT LAW FIRM (Aug. 13, 2018), <http://www.henrypatentfirm.com/blog/3d-printing-challenges-patent-law>.

modified, replicated, and shared digitally as information content and digital data, away from control from centralized actors in a democratized fashion.⁵³

B. *Artificial Intelligence*

There is no single definition of *artificial intelligence*,⁵⁴ which is a term that was first introduced in 1956 at an academic research conference.⁵⁵ The connotation of artificial intelligence has changed over time and with rapid technological development.⁵⁶ The lack of a precise or commonly

53. John Hornick, *3D Printing and IP Rights: The Elephant in the Room*, 55 SANTA CLARA L. REV. 801, 804–05 (2015) (defining *away from control* to mean making objects without anyone knowing or without being able to control it).

54. KAY FIRTH-BUTTERFIELD & YOON CHAE, *ARTIFICIAL INTELLIGENCE COLLIDES WITH PATENT LAW* 5 (2018), http://www3.weforum.org/docs/WEF_48540_WP_End_of_Innovation_Protecting_Patent_Law.pdf (defining artificial intelligence as “a computerized system exhibiting behavior commonly thought of as requiring intelligence” or “a system capable of rationally solving complex problems or taking appropriate action to achieve its goals in real-world circumstances”); Aghion et al., *supra* note 15, at 2 (defining artificial intelligence as “the capability of a machine to imitate intelligent human behavior” or “an agent’s ability to achieve goals in a wide range of environments”); Semmler & Rose, *supra* note 12, at 86 (defining artificial intelligence as “the process of simulating human intelligence through machine processes”); W. Nicholson Price II, *Artificial Intelligence in Health Care: Applications and Legal Issues*, SCITECH. LAW., Fall 2017, at 10, 10 (defining artificial intelligence as relying on “[s]uch algorithms . . . best described as *black-box*”); Chris Smith, *Introduction, in THE HISTORY OF ARTIFICIAL INTELLIGENCE* 4, 4 (2006) (defining artificial intelligence as “a system which amplified people’s own knowledge and understanding”); Roger Parloff, *Why Deep Learning is Suddenly Changing Your Life*, FORTUNE, (Sept. 28, 2016, 5:00 PM), <http://www.fortune.com/ai-artificial-intelligence-deep-machine-learning/> (defining modern *artificial intelligence* as “a vast range of technologies—like traditional and rules-based systems—that enable computers and robots to solve problems in ways that at least superficially resemble thinking”).

55. NILS J. NILSSON, *THE QUEST FOR ARTIFICIAL INTELLIGENCE: A HISTORY OF IDEAS AND ACHIEVEMENTS* 77 (2009) (ebook). The term *artificial intelligence* came from a proposal titled “Summer Research Project on Artificial Intelligence” that was submitted to the Rockefeller Foundation in August 1955. *Id.* The proposal specified:

We propose that a [two] month, [ten] man study of artificial intelligence be carried out during the summer of 1956 at Dartmouth College The study is to proceed on the basis of the conjecture that every aspect of learning or any other feature of intelligence can in principle be so precisely described that a machine can be made to simulate it For the present purpose the artificial intelligence problem is taken to be that of making a machine behave in ways that would be called intelligent if a human were so behaving.

Id.

56. Joost N. Kok et al., *Artificial Intelligence: Definitions, Trends, Techniques, and Cases, in ARTIFICIAL INTELLIGENCE* 1, 1–2 (2009). The following definitions of artificial intelligence are based on The New International Webster’s Comprehensive Dictionary of the English Language, Encyclopedic Edition:

accepted definition has made artificial intelligence seem like a *black-box*.⁵⁷ The breadth of each word, *artificial* and *intelligence*, conflates the definitional problem of the nebulous and interdisciplinary phrase *artificial intelligence*.⁵⁸ Artificial intelligence has been broadly defined as a program running on a computer system that is able to learn and adapt itself in a dynamic environment.⁵⁹ This Article utilizes machine learning, a sub-field of artificial intelligence that applies algorithms to parse data and learns from it to make a prediction about the physical world, when referring to artificial intelligence.⁶⁰ Artificial intelligence technology, specifically machine learning,⁶¹ utilizes algorithms to change its output based on experiences, and such learning can either be supervised learning or unsupervised learning.⁶²

An area of study in the field of computer science. Artificial intelligence is concerned with the development of computers able to engage in human-like thought processes such as learning, reasoning, and self-correction.

The concept that machines can be improved to assume some capabilities normally thought to be like human intelligence such as learning, adapting, self-correction, etc.

The extension of human intelligence through the use of computers, as in times past physical power was extended through the use of mechanical tools.

In a restricted sense, the study of techniques to use computers more effectively by improved programming techniques.

Id. at 2.

57. See Price II, *supra* note 54, at 10.

58. Kok et al., *supra* note 56, at 1–2.

59. Nicolas Mialhe & Cyrus Hodes, *The Third Age of Artificial Intelligence*, 17 FIELD ACTIONS SCI. REPS. (Special Issue) 6, 6 (2017).

60. *Id.* at 7; Harry Surden, *Machine Learning and Law*, 89 WASH. L. REV. 87, 89 (2014); see also MARIETTE AWAD & RAHUL KHANNA, EFFICIENT LEARNING MACHINES: THEORIES, CONCEPTS, AND APPLICATIONS FOR ENGINEERS AND SYSTEM DESIGNERS 1 (2015) (describing machine learning as being able to predict future events or scenarios unknown to computers; quoting Arthur Samuel as describing machine learning to be the “field of study that gives computers the ability to learn without being explicitly programmed;” quoting Tom Mitchell as describing machine learning in the context of “[a] computer program is said to learn from experience *E* with respect to some class of tasks *T* and performance measure *P*, if its performance at tasks in *T*, as measured by *P*, improves with experience *E*”).

61. Surden, *supra* note 60, at 88–89 (defining machine learning techniques as algorithms that have the ability to improve in performance over time on some task, by detecting patterns in data in order to automate complex tasks and make predictions).

62. INFO. COMM’RS OFFICE, BIG DATA, ARTIFICIAL INTELLIGENCE, MACHINE LEARNING AND DATA PROTECTION 7 (2017), <http://www.ico.org.uk/media/for-organisations/documents/2013559/big-data-ai-ml-and-data-protection.pdf> (defining machine learning generally as being “the set of techniques and tools that allow computers to ‘think’ by creating mathematical algorithms based on accumulated data” specifying that supervised learning involves algorithms based on labelled datasets, such that the algorithms are trained how to map form input to output with the provision of correct values assigned to them, and where the initial training phase creates models of the world on which predictions can be made in a subsequent prediction phrase; and specifying that unsupervised learning involves algorithms that are not trained, but are left to find regularities in input data without what to look for).

Machine learning has gained prominence in a variety of applications since its computational techniques and tools can automatically design models from large amounts of observed data without relying on rule-based programming.⁶³ The ability to train existing data sets allows for the production of *data-generating patents*, or inventions that result from generating valuable data by design or use.⁶⁴

C. *Digitization Commonalities: Digital Control and Digital Transmission*

3D printing and artificial intelligence are different technologies yet they share common traits of digitization and the sheer volume of data creation.⁶⁵ These data-centric technologies have been enabled by increased computing power that allow for easier data modification, storage, and transmission.⁶⁶ For example, advancements in graphics processing units have allowed for quicker and easier digital slicing of 3D printing CAD files comprising complex objects.⁶⁷ As another example, advancements in hardware resources and new computer architectures for high performance computing allow for analysis of massive data sets based on specified workflows.⁶⁸

63. ALEX SMOLA & S. V. N. VISHWANATHAN, INTRODUCTION TO MACHINE LEARNING 3–7 (2008) (describing a variety of machine learning applications, where there exists a nontrivial dependence between some observations for which a simple set of deterministic rules is not known, such as: (1) *web page ranking*, which is a process of submitting a query to a search engine to find webpages relevant to the query and returning them in an order of relevance; (2) *collaborative filtering*, where Internet bookstores utilize users' past purchase and viewing decisions information to predict future viewing and purchase habits of similar users; (3) *speech recognition*, where an audio sequence is annotated with text or where handwriting is annotated with a sequence of strokes; and (4) *classification*, where spam filtering programs can identify whether an email contains relevant information or not, such as a frequent traveler email, based on the type of user); see also GIANLUCA BONTEMPI, HANDBOOK: STATISTICAL FOUNDATIONS OF MACHINE LEARNING 9 (2017) http://di.ulb.ac.be/map/gbonte/mod_stoch/syl.pdf.

64. See Simon & Sichelman, *supra* note 8, at 378–79.

65. See DAVID REINSEL ET AL., THE DIGITALIZATION OF THE WORLD: FROM EDGE TO CORE 2–3 (2018), <http://www.seagate.com/files/www-content/our-story/trends/files/idc-seagate-dataage-whitepaper.pdf>.

66. Zulfiqar A. Memon et al., *CPU-GPU Processing*, INT'L J. COMPUTER SCI. & NETWORK SECURITY, Sept. 2017, at 188, 188.

67. Xipeng Zhang et al., *A GPU-based Parallel Slicer for 3D Printing*, in 13TH IEEE INT'L CONF. AUTOMATION SCI. & ENGINEERING, 55–56 (2017); Tony Kontzer, *How GPUs Can Kick 3D Printing Industry into High Gear*, NVIDIA: NVIDIA BLOG (June 6, 2017), <http://blogs.nvidia.com/blog/2017/06/06/3d-printing/>; *NVIDIA GVDB Voxels*, NVIDIA, <http://developer.nvidia.com/gvdb> (last visited Mar. 24, 2019).

68. Mauro Garofalo, GPU Computing for Machine Learning Algorithms, 60 (2011) (unpublished thesis, Universita' degli Studi di Napoli Federico II),

These data-centric technologies enable information-based product development from digital transmission and digital control.⁶⁹ In both technologies of 3D printing and artificial intelligence, control over the physical good, object, product, or system is not entirely by an originator-human, who was the creator or inventor.⁷⁰ Instead, data-centric technologies enable for non-human, digital control.⁷¹ In the case of 3D printing, democratization of manufacturing leads to making goods and parting away from control by bypassing the traditional supply chain.⁷² The ability to easily modify, share, and transmit 3D printing CAD files has created new interactions between creators, distributors, and end-users of physical objects and products.⁷³ In the case of artificial intelligence—specifically machine learning—computer programs make predictions and take action based on a training set drawn from hypotheses.⁷⁴ In both cases, digital control is not directed by the creator-inventor human, but instead by someone or something else—another person or entity in 3D printing, and a learning algorithm in artificial intelligence.⁷⁵ The issue of digital control of data-centric technologies creates new patent law and copyright law doctrinal quandaries concerning the scope of protection.⁷⁶

http://dame.dsf.unina.it/documents/TESI_GAROFALO_FINALE.pdf; Tulasi Bomatpulli et al., *High Performance Computing and Big Data Analytics — Paradigms and Challenges*, 116 INTL. J. COMPUTER APPLICATIONS 28, 28 (Apr. 2015).

69. See Memon et al., *supra* note 66, at 188; Ulf Koester, *Product Development: The Digital Thread in Industry 4.0*, ORACLE (June 7, 2018), <http://blogs.oracle.com/today/product-development-the-digital-thread-in-industry-40>.

70. See REINSEL ET AL., *supra* note 65, at 2–3.

71. See Azita Martin, *The Difference Between Knowledge-Centric and Data-Centric Approaches*, MAANA (Sept. 9, 2016), <http://www.maana.io/2016/09/knowledge-power-not-data/>.

72. See Hornick, *supra* note 53, at 804–05 (suggesting that *away from control* with 3D printing includes, “3D printing at home from blueprints obtained [from] peer-to-peer [networks], . . . scanning and [3D] printing anything, . . . buying 3D printed products on the black market,” obtaining other’s CAD files from the Internet; therefore, with self-manufacturing, traditional supply chains will be disturbed, such that traditional manufacturers will be forced to sell blueprint CAD files and retail outlets will face challenges in selling products).

73. See REINSEL ET AL., *supra* note 65, at 2–3; Kontzer, *supra* note 67.

74. KE-LIN DU & M. N. S. SWAMY, NEURAL NETWORKS AND STATISTICAL LEARNING 39, 39 (2014).

75. See Osborn, *Regulating Three-Dimensional Printing*, *supra* note 40, at 559; Semmler & Rose, *supra* note 12, at 86–87.

76. See discussion *infra* Part III.

The result of digital control not residing in the creator-inventor is digital transmission.⁷⁷ Data-centric technologies allow for the transmission of information content concerning physical goods, objects, products, or systems.⁷⁸ In the case of 3D printing, CAD files, which represent the physical object that can be printed with *de minimis* effort, can be transmitted from computer-to-computer or from one CAD file-sharing website to another.⁷⁹ In the case of artificial intelligence—specifically predictive analytics—which allows for the prediction of future outcomes and trends based on large scale datasets, artificial intelligence can find and transmit potentially valuable information about the physical world.⁸⁰ Artificial intelligence “can increase the efficiency of industrial operations,” monitor damage to equipment, and enable repairing actions.⁸¹ The valuable information from predictive analytics can take a variety of forms, which can affect the value of a commercial good, object product, or system.⁸² In both cases, digital transmission disrupts traditional supply chains and traditional relationships between commercial actors—between the manufacturer and distributor in 3D printing and between the manufacturer and marketer in artificial intelligence.⁸³ The issue of digital transmission of data-centric technologies creates new patent law and copyright law doctrinal quandaries which require evaluating statutes.⁸⁴

77. See Kholid Rafsanjani, *Data Transmission — Digital Data Transmission*, CCM (Feb. 6, 2018, 5:42 AM), <http://www.ccm.net/contents/703-data-transmission-digital-data-transmission>.

78. See Holbrook & Osborn, *supra* note 14, at 1321–22, 1332.

79. See *id.* at 1319, 1332.

80. ERIC SIEGEL, PREDICTIVE ANALYTICS: THE POWER TO PREDICT WHO WILL CLICK, BUY, LIE, OR DIE 15–16 (2016).

81. IAN WALDEN & THEODORA A. CHRISTOU, LEGAL AND REGULATORY IMPLICATIONS OF DISRUPTIVE TECHNOLOGIES IN EMERGING MARKET ECONOMIES 5 (June 2018), http://www.researchgate.net/publication/327013729_Legal_and_Regulatory_Implications_of_Disruptive_Technologies_in_emerging_market_economics.

82. See Thomas H. Davenport, *A Predictive Analytics Primer*, HARV. BUS. REV. (Sept. 2, 2014), <http://www.hbr.org/2014/09/a-predictive-analytics-primer> (providing as examples customer lifetime value, next best offer, most likely to buy next, forecasts, and determination of best ads as examples of forms of predictive analytics).

83. See *id.*; Osborn, *Regulating Three-Dimensional Printing*, *supra* note 40, at 562; WALDEN & CHRISTOU, *supra* note 81, at 5.

84. See Osborn, *Regulating Three-Dimensional Printing*, *supra* note 40, at 586, 589.

D. *Information Property Commonalities*

Data-centric technologies comprise information flows and information ownership.⁸⁵ Intellectual property protection has existed for “information products [such as] computer software and Internet business [models].”⁸⁶ However, data-centric technologies, which share digital characteristics of other information products, are different because their information content has direct applicability in the physical world.⁸⁷ For example, 3D printing CAD files are digital blueprint representations of physical objects that can be produced with the simple click of a button.⁸⁸ As another example, artificial intelligence—specifically machine learning—contains algorithms that provide valuable predictive information about the physical world.⁸⁹

The mixing of digital and physical with data-centric technologies challenges how we think about intellectual property protection.⁹⁰ Moreover, such digital-physical mixed objects force reevaluation of whether intellectual property protection even applies.⁹¹ Data-centric technologies may contain information property⁹² that is not necessarily protected by a specific intellectual property right or may thrive even without intellectual property protection akin to the theory of the *IP negative space*.⁹³ Some aspects of data-centric technologies fit comfortably well within traditional intellectual property protection, such as printer equipment and ink with 3D printing and computer readable media and methods with artificial intelligence.⁹⁴ However, intellectual property law encounters quandaries with the digital-physical mixed aspects, where the absence of or lack of clarity in information property protection causes doctrinal disruptions.⁹⁵ This makes protecting data-centric technologies more difficult for intellectual property owners.⁹⁶

85. See Conti & Passarella, *supra* note 13, at 51–52.

86. Lipton, *supra* note 43, at 143.

87. See Ebrahim, *Trademark & Brands*, *supra* note 1, at 7.

88. *Id.*

89. INFO. COMM’RS OFFICE, *supra* note 62, at 9; Davenport, *supra* note 82.

90. See Robinson & Smith, *supra* note 28, at 356.

91. See *id.* at 356–57.

92. See Lipton, *supra* note 43, at 140 (suggesting that information property refers to private rights in information containing some degree of control over the relevant information).

93. Elizabeth L. Rosenblatt, *A Theory of IP’s Negative Space*, 34 COLUM. J.L. & ARTS 317, 319 (2011) (defining *IP negative space* as “a series of nooks, crannies, and . . . oceans . . . where creation and innovation thrive in the absence of intellectual property protection”).

94. See Robinson & Smith, *supra* note 28, at 364–65.

95. See *id.* at 357, 364.

96. See *id.*

III. DOCTRINAL QUANDARIES

Data-centric technology is a type of emerging, disruptive technology for which the law has struggled to keep pace with its development and adoption.⁹⁷ One reason is that data-centric technologies have challenged the precise meanings of intellectual property doctrines, which did not envision such technological advancements.⁹⁸ Another reason is that data-centric technologies challenge the scope of intellectual property doctrines, which may overlap or possibly have voids in coverage.⁹⁹ Additionally, data-centric technologies create new interactions among actors that challenge the scope of protection intended for each actor in a marketplace.¹⁰⁰ In sum, intellectual property laws—particularly patent law and copyright law—are either ill-defined or ill-suited for data-centric technologies, which have outpaced intellectual property law’s response and adaptation.¹⁰¹

There are numerous motivations for clarifying doctrinal patent law and copyright law quandaries with data-centric technologies, or for any emerging technology.¹⁰² First, intellectual property law can enable innovation and normatively steer technological development.¹⁰³ Second, decisions about the scope of intellectual property coverage shapes society, social futures, and sources of power.¹⁰⁴ Third, intellectual property law can affect the diffusion of new technologies, the demand takeoff, and the creation of complementary infrastructure.¹⁰⁵ These reasons motivate identification, herein in Part III, of the doctrinal quandaries in each of patent law and copyright law based on the foundations of 3D printing and artificial intelligence identified in Part II.¹⁰⁶

97. *Id.* at 356; WALDEN & CHRISTOU, *supra* note 81, at 3.

98. *See* Robinson & Smith, *supra* note 28, at 356.

99. Daniel Harris Breaun, *Patenting Physibles: A Fresh Perspective for Claiming 3D-Printable Products*, 55 SANTA CLARA L. REV. 837, 841 (2015); *see also* Rosenblatt, *supra* note 93, at 319.

100. *See* WALDEN & CHRISTOU, *supra* note 81, at 4; Lucie Gaget, *Artificial Intelligence and 3D Printing: Meet the Future of Manufacturing*, SCULPTEO: BLOG (Oct. 24, 2018), <http://www.sculpteo.com/blog/2018/10/24/artificial-intelligence-and-3d-printing-meet-the-future-of-manufacturing>.

101. Robinson & Smith, *supra* note 28, at 356.

102. *Id.*; Rosenblatt, *supra* note 93, at 318.

103. *See* WALDEN & CHRISTOU, *supra* note 81, at 3.

104. Stephen Hilgartner, *Intellectual Property and the Politics of Emerging Technology: Inventors, Citizens, and Powers to Shape the Future*, 84 CHI. KENT L. REV. 197, 198–99 (2009).

105. *See* Shenoy, *supra* note 2; Tyler, *supra* note 2.

106. *See* discussion *infra* Parts II, III.

A. 3D Printing

3D printing is an emerging technology that challenges how we think about tangible and digital objects.¹⁰⁷ Intellectual property law scholars have identified numerous doctrinal challenges with 3D printing CAD files under patent law and copyright law, as well as trademark law.¹⁰⁸ The uncertainty among the scope of protection afforded by intellectual property laws for 3D printing CAD files has necessitated reevaluating the relationships between actors in a traditional manufacturing value chain, since a producer can also be a consumer.¹⁰⁹ Some scholars have developed proposals for reforming intellectual property laws and proposed new regulations in response to the emergence of 3D printing.¹¹⁰

1. Patent Law Disruptions

3D printing technology disrupts the patent system due to digitization and decentralized production.¹¹¹ The heart of the doctrinal patent law disruption created by 3D printing is “the CAD file, [which is] the digital representation of a physical object [and] . . . a crucial component of the 3D printing process.”¹¹² The digital-physical blur of 3D printing CAD files presents challenges with patentable subject matter,¹¹³ digital patent

107. Lucas S. Osborn, *Doctrinal Quandaries with 3D Printing and Intellectual Property*, A.B.A. SEC. LITIG. INTELL. PROP. LITIG., Summer 2016, at 18, 18.

108. Osborn, *supra* note 7, at 868–69; *see also* Digital Millennium Copyright Act, Pub. L. No. 105-304, § 102, 112 Stat. 2860, 2861 (1998) (codified as amended at 17 U.S.C. §§ 101–1401 (2012)).

109. *See* Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 48.

110. Brean, *supra* note 99, at 838, 842 (proposing the creation of new *Beauregard*-like patent claim format to protect CAD files *per se*); Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 67–70 (proposing the creation of a Digital Millennium Copyright & Patent Act (“DMCPA”) and reformation of the repair-and-reconstruction doctrine); Digital Millennium Copyright Act § 103, 112 Stat. at 2863.

111. Geertrui Van Overwalle & Reinout Leys, *3D Printing and Patent Law: A Disruptive Technology Disrupting Patent Law?*, 48 INT’L REV. INTELL. PROP. & COMPETITION L. 504, 506 (2017).

112. *Id.* at 512.

113. *Id.* at 511–12 (suggesting that CAD files may face considerable patentable subject matter challenges similar to traditional software application claims, and instead proposing copyright as an alternative means of protection or suggesting focusing on the physical aspect of CAD file if considering patent protection); Tabrez Y. Ebrahim, *3D Bioprinting Patentable Subject Matter Boundaries*, 41 SEATTLE U.L. REV. 1, 44 (2017) (suggesting that post-processing and integration of 3D bioprinted materials may challenge patentable subject matter doctrine when they are indistinguishable from natural tissues and organs); Phoebe H. Li, *3D Bioprinting Technologies: Patents, Innovation, and Access*, 6 L.

infringement,¹¹⁴ and the International Trade Commission's ("ITC") jurisdiction over importation of a patented article entering the United States,¹¹⁵ as well as civil procedure challenges.¹¹⁶

First, 3D printing disrupts patentability because a CAD file, which is essentially a mix of software instructions and program code that digitally represents a three-dimensional object, may be too abstract to satisfy 35 U.S.C. § 101 or too challenging to claim in traditional patent claim format.¹¹⁷ One patent law scholar has proposed using *Beauregard* patent claims for 3D printing CAD files, but has also acknowledged limitations.¹¹⁸ Additionally, there has been debate on whether 3D printing of nature-based substances, in 3D bioprinting, would qualify as patentable subject matter.¹¹⁹ This debate has centered on whether 3D bioprinting technology has advanced to the point of creating tissues and organs that are exact replicas of nature and on the unsettled law of genetic replication.¹²⁰

Second, 3D printing disrupts patent infringement doctrine because it challenges the reach of the infringement statute.¹²¹ A doctrinal assessment of 3D printing patent infringement focuses on what constitutes infringement related to digital CAD files and whether laypeople qualify as indirect infringers.¹²²

INNOVATION & TECH. 282, 288 (2014) (suggesting that certain cloning and human embryo related inventions produced by 3D bioprinting may not be patentable because they violate the morality exception in European patent law); Timo Minssen & Marc Mimler, *Patenting Bioprinting-Technologies in the US and Europe: The Fifth Element in the Third Dimension*, in 3D PRINTING, INTELLECTUAL PROPERTY AND INNOVATION: INSIGHTS FROM LAW AND TECHNOLOGY 13 (Rosa M. Ballardini et al. eds., 2017) (suggesting that perfect replication of human organs via 3D bioprinting could blur the distinction between patentable and unpatentable subject matter).

114. Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 49; *see also* Holbrook & Osborn, *supra* note 14, at 1323–24.

115. *See* Sapna Kumar, *Regulating Digital Trade*, 67 FLA. L. REV. 1909, 1917–20 (2015).

116. Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 49; *see also* Holbrook & Osborn, *supra* note 14, at 1332–33.

117. *See* 35 U.S.C. § 101 (2012); Brean, *supra* note 99, at 852; Van Overwalle & Leys, *supra* note 111, at 512.

118. *See* Brean, *supra* note 99, at 842–845.

119. *See* Ebrahim, *supra* note 113, at 3.

120. *Id.* at 10; *In re* Roselin Inst., 750 F.3d 1333, 1339 (Fed. Cir. 2014) (holding that patent claims directed to the famed Dolly the Sheep were not patent eligible since a cloned animal would be an exact genetic replica).

121. *See* 35 U.S.C. § 271(b) (2012).

122. *See id.*; Holbrook & Osborn, *supra* note 14, at 1327.

A statutory interpretation of 35 U.S.C. § 271(a) concerning direct infringement¹²³ and applied to 3D printing raises a number of questions, such as: (i) is the CAD file itself considered an *object*, if someone uses a 3D printer to print a patented object when the object is made without authorization or without a license from the patent owner?; (ii) is the *making* of a CAD file considered to be the making of a patented item under the statute?; and (iii) is an *offer to sell* considered a true offer, since the sale of a CAD file involves potentially selling many items—due to the CAD file’s potential ability to make many items?¹²⁴

A statutory interpretation of 35 U.S.C. § 271(b) concerning indirect infringement could be interpreted to find anyone who posts a CAD file on a file-sharing networking to be an indirect infringer.¹²⁵ Thus, 3D printing intermediaries, 3D printing service companies, and anyone posting or transferring CAD files on websites or peer-to-peer networks could be accused of indirect patent infringement.¹²⁶ However, since direct infringement is a necessary element of indirect infringement and it may be difficult to ascertain the occurrence of the 3D printing infringing step, then indirect patent infringement may not be clear cut.¹²⁷ Additionally, since indirect infringement requires active inducement and it may be difficult to find anyone who provided printing instructions, then indirect patent infringement may be an even more challenging determination.¹²⁸

A statutory interpretation of 35 U.S.C. § 271(c) concerning contributory infringement¹²⁹ and applied to 3D printing also raises doctrinal interpretation questions, such as: Is a CAD file considered a component of a

123. 35 U.S.C. § 271(a) (specifying that “whoever without authority makes, uses, offers to sell, or sells any patented invention . . . infringes the patent.”).

124. See Holbrook & Osborn, *supra* note 14, at 1327–28, 1332–36.

125. See 35 U.S.C. § 271(b) (stating “[w]hoever actively induces [the] infringement of a patent shall be liable as an infringer”); Ebrahim, *Trademark & Brands*, *supra* note 1, at 50–51.

126. See Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 51–52; Holbrook & Osbourne, *supra* note 14, at 1332, 1334.

127. See 35 U.S.C. § 271(c); Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341 (1961); Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 49.

128. See *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 760, 766 (2011); Holbrook & Osborn, *supra* note 14, at 1335–36.

129. 35 U.S.C. § 271(c) (specifying that patent owners may have a claim against actors who while not directly infringing, aid and abet the direct infringer, by, for example, supplying an individual component of a patented invention, more specifically, requiring: (i) somebody offering to sell, selling, or importing into the U.S.; (ii) components of a patented device; (iii) knowing the components are adapted for use in infringement of a patent without substantial non-infringing use; and (iv) which result in an act of direct infringement).

patented device or does a digital representation of a physical object suffice to be considered a component?¹³⁰ The uncertainty in the scope of contributory patent infringement could be problematic for patent owners who may raise claims in litigation against CAD file creators and CAD file distributors.¹³¹

The patent infringement disruptions of 3D printing also encounter territoriality issues, since 3D printing CAD files can be transmitted across borders.¹³² The digital-physical blur of CAD files arises in doctrinal issues of jurisdiction, such as whether the ITC's breadth of statutory authority of importation of *articles* encompasses the regulation of CAD files.¹³³ The scope of whether the word *articles* includes electronic transmission of digital data representing articles has not been considered by Congress and has only recently been addressed by the Federal Circuit.¹³⁴

Each of these doctrinal disruptions stems from patent law lacking a meaningful patent protection for the CAD file.¹³⁵ Quite simply, patent law struggles with protecting digital representations of patentable physical objects.¹³⁶ In doing so, the patent regime is challenged by 3D printing in patentability and infringement.¹³⁷

2. Copyright Law Disruptions

3D printing technology disrupts copyright law since it challenges the notions of copyright requirements and derivative works.¹³⁸ First, 3D printing technologies face challenges with copyright protection due to the conceptual separation between creative and functional features and the status of a derivative work.¹³⁹ Second, 3D printing technologies are prone to *Napsteriz[ation]*, or similar peer-to-peer infringement issues faced by digital music files.¹⁴⁰ The peer-to-peer reproduction and distribution issues raise

130. See Holbrook & Osborn, *supra* note 14, at 1345–48.

131. See *id.* at 1353.

132. See Daniel Harris Brean, *Patent Enforcement in Cyberterritories*, 40 CARDOZO L. REV. (forthcoming 2019) (manuscript at i–ii).

133. See Kumar, *supra* note 115, at 1911–12.

134. See *id.* at 1912–13.

135. See Brean, *supra* note 99, at 840.

136. See *id.*

137. See *id.*

138. See MICHAEL WEINBERG, WHAT'S THE DEAL WITH COPYRIGHT AND 3D PRINTING? 4 (2013), http://www.publicknowledge.org/files/What%27s%20the%20Deal%20with%20Copyright_%20Final%20version2.pdf.

139. See WEINBERG, *supra* note 5, at 5–6.

140. Brean, *supra* note 99, at 857; see also Holbrook & Osborn, *supra* note 14, at 1332–33.

enforcement and civil procedure challenges in copyright law similar to that of patent law.¹⁴¹

Copyright protection over CAD files may be problematic in cases where the 3D printed objects are not purely aesthetic.¹⁴² The doctrine of severability in copyright law prevents an object with both artistic and useful features to attain copyright protection.¹⁴³ There is no straightforward severability test and, therefore, a fact-finding inquiry into copyright protection creates uncertainty as to the scope of copyright protection.¹⁴⁴

The possibility of copyright protection in 3D printing is further complicated with the notion of derivative works.¹⁴⁵ This doctrinal issue is based on the doctrinal assessment of CAD files in a digital environment, which complicates whether copyright protects the design of the eventual 3D printed object.¹⁴⁶ While unsettled, one viewpoint considers that a CAD file that is protected by copyright would require permission from the copyright holder to 3D print the object, since the physical object would be a derivative work of the design in the CAD file.¹⁴⁷ This problem is further complicated by whether the change in the 3D printed physical object is so minor and too trivial to be entitled as a derivative work.¹⁴⁸

B. *Artificial Intelligence*

Artificial intelligence technologies challenge the way we think about patent law and copyright law doctrines.¹⁴⁹ Artificial intelligence applications minimize the separation between human-generated content and machine-

141. See Brean, *supra* note 99, at 857; Kumar, *supra* note 115, at 1912.

142. WEINBERG, *supra* note 138, at 9.

143. *Id.* (stating that if the aesthetic and functional features cannot be separated, then copyright law errs on the side of keeping useful objects available to the entire public and prevents attachment of copyright protection).

144. ANGELA DALY, SOCIO-LEGAL ASPECTS OF THE 3D PRINTING REVOLUTION 26 (2016).

145. 17 U.S.C. § 101 (2012) (defining *derivative work* as “a work based upon one or more preexisting works, such as a translation, musical arrangement, dramatization, fictionalization, motion picture version, sound recording, art reproduction, abridgement, condensation, or any other form in which a work may be recast, transformed, or adapted”); WEINBERG, *supra* note 138, at 19.

146. WEINBERG, *supra* note 138, at 14.

147. See *id.* at 19 (describing that copying and/or distributing the object into 3D-printed physical form would require permission from the copyright holder, but this distinction can vary depending on whether the digital object in the CAD file was created by scanning an object or was created digital in the CAD file itself); DALY, *supra* note 144, at 26.

148. See 17 U.S.C. § 101; WEINBERG, *supra* note 138, at 19.

149. Robinson & Smith, *supra* note 28, at 356–57; Guadamuz, *supra* note 7, at 17.

generated content.¹⁵⁰ However, much of patent law and copyright law focuses on either purely human control or human-machine interactions but has yet to counter machine generated content.¹⁵¹ As artificial intelligence applications proliferate, patent law and copyright law will increasingly need to respond to a world in which human, human-machine interactions, and machine generations move closer together.¹⁵²

Some aspects of artificial intelligence technologies fit well within traditional intellectual property law doctrines.¹⁵³ For example, inventors have obtained patents on equipment, processes, and chemicals controlled by artificial intelligence technologies.¹⁵⁴ Even some underlying business methods of artificial intelligence technologies have successfully resulted in issued U.S. patent claims.¹⁵⁵ As another example, musicians could conceivably obtain copyright protection on artistic and musical works with the help of artificial intelligence technologies.¹⁵⁶

However, intellectual property laws encounter difficulties when algorithms can learn and make predictions on data.¹⁵⁷ These techniques are different from the use of computational statistics, mathematical optimization, or finite element analysis as computational research tools, which have been utilized to solve equations concerning the physical world for many years.¹⁵⁸ Recent advances in computing power, algorithms, and sensor technology, and the proliferation of data as a strategic asset, have enabled computers to make data-driven decisions that affect the physical world.¹⁵⁹ For example, machine learning is being utilized for autonomous vehicles,¹⁶⁰ medical imaging interpretation and diagnosis,¹⁶¹ oil and gas exploration,¹⁶² and

150. See Guadamuz, *supra* note 7, at 17; JJ Charlesworth, *AI Can Produce Pictures, but Can It Create Art for Itself?*, CNN: STYLE (Sept. 10, 2018), <http://www.cnn.com/style/article/artificial-intelligence-ai-art/index.html>.

151. See Bechtold, *supra* note 32, at 19; WEINBERG, *supra* note 138, at 2.

152. See Robinson & Smith, *supra* note 28, at 364–65; Neil Ballinger, *The Proliferation of Artificial Intelligence in 2019 Could Lead to a New Talent Gap*, DRUM: NEWS (Jan. 29, 2019, 4:35PM), <http://www.thedrum.com/news/2019/01/29/the-proliferation-artificial-intelligence-2019-could-lead-new-talent-gap>.

153. See Robinson & Smith, *supra* note 28, at 364–65.

154. See *id.* at 365; FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 5, 8.

155. See Levine & Sichelman, *supra* note 8, at 754, 758.

156. Guadamuz, *supra* note 7, at 17.

157. FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 6, 8.

158. See *id.* at 5; DU & SWAMY, *supra* note 74, at 39.

159. See FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 5–6; REINSEL ET AL., *supra* note 65, at 2.

160. LEX FRIDMAN ET AL., MIT AUTONOMOUS VEHICLE TECHNOLOGY STUDY: LARGE-SCALE DEEP LEARNING BASED ANALYSIS OF DRIVER BEHAVIOR AND INTERACTION WITH AUTOMATION 3, <http://www.arxiv.org/abs/1711.06976>.

161. Maryellen L. Giger, *Machine Learning in Medical Imaging*, 15 J. AM. C. RADIOLOGY 512, 512 (2018).

predictive maintenance of manufacturing systems.¹⁶³ The ability to determine anomalies and predict solutions in behavior profiles of physical phenomena makes protection of machine-controlled physical phenomena difficult for intellectual property owners.¹⁶⁴

1. Patent Law Disruptions

Artificial intelligence technologies infuse the role of a machine in the invention process.¹⁶⁵ The algorithms at the heart of artificial intelligence are arguably playing a role in *conception* and *reduction to practice* of inventions.¹⁶⁶ Some algorithms substitute the human in the inventive process, and other algorithms augment the human in the inventive process.¹⁶⁷ While conceptually, such algorithms do not think in the cognitive sense of humans, the line between what is attributable to a human and what is attributable to a human-machine interaction becomes blurred.¹⁶⁸

The involvement of artificial intelligence technologies in the invention process raises doctrinal patent law issues concerning inventorship,¹⁶⁹ non-obviousness,¹⁷⁰ and enablement.¹⁷¹ These doctrines

162. Hossein Hassani & Emmanuel Sirimal Silva, *Big Data: A Big Opportunity for the Petroleum and Petrochemical Industry*, 42 OPEC ENERGY REV. 74, 74, 78 (2018).

163. Gian Antonio Susto et al., *Machine Learning for Predictive Maintenance: A Multiple Classifier Approach*, 11 IEEE TRANSACTIONS ON INDUS. INFORMATICS 812, 812–13 (2015); SUMEET KAUL ET AL., PREDICTIVE MAINTENANCE AND THE SMART FACTORY: PREDICTIVE MAINTENANCE CONNECTS MACHINES TO RELIABILITY PROFESSIONALS THROUGH THE POWER OF THE SMART FACTORY 3 (2017).

164. See FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 6.

165. See Robinson & Smith, *supra* note 28, at 357.

166. MPEP § 2138.04 (9th ed. Rev 8, Jan. 2018) (quoting *Townsend v. Smith*, 36 F.2d 292, 295 (C.C.P.A. 1929) (defining *conception* as “the complete performance of the mental part of the inventive act and it is the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice”); *Id.* § 2138.05 (stating that reduction practice, which “may be an actual reduction or a constructive reduction to practice,” requires recognition and appreciation of the invention); Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV. 1171, 1177 (2016) (emphasis in original) (explaining that “conception of an invention does *not* require that the inventor know that the invention will work for its intended purpose,” and that *conception* does not require “reduction to practice [nor] experimentation”).

167. Liza Vertinsky, *Thinking Machines and Patent Law*, in RESEARCH HANDBOOK ON THE LAW OF ARTIFICIAL INTELLIGENCE 489, 490 (2018).

168. See *id.* at 490–93; Surden, *supra* note 60, at 89 (suggesting that the idea that computers are *learning* is a metaphor and does not mean that machines are replicating the cognitive abilities of humans in human learning).

169. MPEP § 2137.01.

170. 35 U.S.C. § 103 (2012).

171. *Id.* § 112(a).

assume a human being as the inventor for inventorship, as a standard for comparison of non-obviousness, and as providing some act of ingenuity to be eligible patentable subject matter.¹⁷² The specific meanings of these doctrines have profound implications for ownership and control of the invention, as well as for management of innovation and competition.¹⁷³

First, artificial intelligence technologies seem to challenge patent law's inventorship doctrine, which is based on conception.¹⁷⁴ U.S. patent law defines an inventor as being a human being, as evidenced in the statement: "The threshold question in determining inventorship is who conceived [of] the invention. Unless a person contributes to the conception of the invention, he is not an inventor."¹⁷⁵ Inventorship in U.S. patent law is attributed to conception, which is defined as "the complete performance of the mental part of the inventive act," presumably achieved by a human being.¹⁷⁶ The doctrinal issue is whether artificial intelligence technologies qualify under the inventorship requirement of U.S. patent law.¹⁷⁷ Additionally, the creation and use of artificial intelligence technologies raises the doctrinal issue of whether the human beings that assist artificial intelligence technologies also qualify as inventors.¹⁷⁸ The doctrinal problem with either the artificial intelligence technology or the human assisting the artificial intelligence technology stems from patent law's restrictive definition of *inventor* and imprecise definition of *conception*.¹⁷⁹ Is the term *inventor* in U.S. patent law limited to only a *person*, or does *person* have a more expansive meaning?¹⁸⁰ Is conception in U.S. patent law restricted to a mental act by a human being only?¹⁸¹ U.S. patent law has not addressed these questions.¹⁸²

Second, artificial intelligence technologies also challenge the non-obviousness doctrine, which is a threshold requirement for patentability in

172. See FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 9–10.

173. See Vertinsky, *supra* note 167, at 493; Iain M. Cockburn et al., *The Impact of Artificial Intelligence on Innovation* 26 (Nat'l Bureau of Econ. Research Working Paper No. W24449).

174. See MPEP § 2138.04; Lemley, *supra* note 166, at 1172.

175. MPEP § 2137.01 (quoting *In re Hardee*, 233 U.S.P.Q. (BNA) 1122, 1123 (Comm'r Pat. & Trademarks 1984)).

176. MPEP § 2138.04.

177. FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 9–10.

178. *Id.* at 10.

179. See MPEP §§ 2137.01, 2138.04.

180. See *id.*; Patrick G. Gattari, *Determining Inventorship for US Patent Applications*, INTELL. PROP. & TECH L.J., May 2005, at 16, 16.

181. See MPEP § 2138.04; Gattari, *supra* note 180, at 16.

182. See MPEP § 2138.04.

U.S. patent law.¹⁸³ The finding of obviousness is based on ascertaining the difference between the claimed invention and the prior art based on the “person of ordinary skill in the art,” or a PHOSITA, which is also known as POSITA.¹⁸⁴ The POSITA is defined as “a hypothetical person who is presumed to have known the relevant art at the time of the invention,”¹⁸⁵ and is also a “person of ordinary . . . creativity, not an automation.”¹⁸⁶ Thus, U.S. patent law’s standard for obviousness involves a comparison with a hypothetical person with knowledge of the relevant art or similar technologies.¹⁸⁷ A doctrinal problem arises because inventions generated by artificial intelligence technologies may not be comparable to the capabilities of a POSITA.¹⁸⁸ Artificial intelligence technologies may develop inventions based on learning from data representations—capabilities and computational horsepower that is lacking in human beings.¹⁸⁹ In the rare case of an extraordinary human being who possessed computational-like pattern detection capabilities, they would be unable to develop the invention generated by the artificial intelligence technology that learns from data representations.¹⁹⁰ Another doctrinal problem arises from the phrase *relevant art*, which may be problematic with inventions generated by machine learning techniques that rely on training of unique data sets, since machine learning algorithms are capable of changing their behavior to enhance their performance; hence, the *relevant art* would conceptually change.¹⁹¹ Since *relevant art* is not static in a machine learning context, then this aspect of the obviousness comparison standard is inapplicable for comparison purposes.¹⁹² Thus, the obviousness doctrine is problematic with inventions generated by artificial intelligence technologies due to limitations with the phrase *person*, unclear implications with the phrase *not an automation*, and dynamic interpretation with the phrase *relevant art*.¹⁹³

183. 35 U.S.C. § 103 (2012); FIRTH-BUTTERFIELD & CHAE, *supra* note 154, at 10.

184. MPEP § 2141.03.

185. *Id.*

186. KSR Int’l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007).

187. *See id.* at 419–20.

188. *See* FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 5.

189. *See* Lance Whitney, *Are Computers Already Smarter Than Humans?*, TIME (Sept. 29, 2017), <http://www.time.com/4960778/computers-smarter-than-humans/>.

190. *Id.*

191. MPEP § 2141.03 (9th ed. Rev. 8, Jan. 2018); *see also* Surden, *supra* note 60, at 89–90.

192. MPEP § 2141.03; *see also* Surden, *supra* note 60, at 89–90.

193. MPEP § 2141.03; *see also* Apple Inc. v. Samsung Elecs. Co., 839 F.3d 1034, 1076 (Fed. Cir. 2016).

Third, inventions generated by artificial intelligence technologies may not satisfy the enablement requirement of U.S. patent law.¹⁹⁴ Enablement requires that “one skilled in the art must be [able] to make and use . . . that defined by the claim(s) of the particular application or patent.”¹⁹⁵ Similar to the issues with the obviousness standard requiring a POSITA, the enablement requirement also faces challenges with the phrase “one skilled in the art.”¹⁹⁶ In order for an invention created by a machine learning algorithm to meet enablement, “one skilled in the art”—whether a person or machine learning technique—would need access to the same data set utilized by the machine learning algorithm that created the invention.¹⁹⁷ Since inventions created by machine learning are based on detecting patterns in data and making predictions based on training, one would not be able to make and use the invention without data and without sophistication in knowing the same machine learning technique.¹⁹⁸ The enablement standard is problematic with artificial intelligence technologies due to the inapplicability of the phrase “one skilled in the art.”¹⁹⁹

Each of these doctrinal disruptions stems from patent law lacking meaningful patentability standards and terms applicable to artificial intelligence technologies.²⁰⁰ Quite simply, patent law struggles with its focus on a human being in its patentability requirements.²⁰¹

2. Copyright Law

The conceptual difficulties with copyright law for artificial intelligence technologies concern the doctrines of authorship,²⁰² originality,²⁰³ and work made for hire.²⁰⁴ Copyright law protects original

194. FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 4; *see also* 35 U.S.C. § 112 (2012).

195. MPEP § 2164.

196. *Id.* §§ 2141, 2164.01; Frank A. DeCosta & Aliza George Carrano, *Intellectual Property Protection for Artificial Intelligence*, WESTLAW J. INTELL. PROP., Aug. 30, 2017, at 3.

197. MPEP § 2141; DeCosta & Carrano, *supra* note 196, at 3.

198. DeCosta & Carrano, *supra* note 196, at 3.

199. *Id.*; *see also* 35 U.S.C. § 112(a).

200. FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 4.

201. *Id.* at 8–9.

202. 17 U.S.C. § 102(a) (2012) (stating that “[c]opyright protection subsists, in accordance with this title, in original works of authorship . . .”).

203. H.R. REP. NO. 94-1476, at 51 (1976); *see also* 17 U.S.C. § 102(a) (which codifies developments in case law that require some independent creation by the author and modest quantum of creativity); 17 U.S.C. § 102(b) (which codifies developments in case law that copyright protects an author’s expression of an idea, but not the idea itself).

works created by authors, and the doctrinal issues concern whether copyright protection can be attained for computer generated works.²⁰⁵ Similar to artificial intelligence technologies that develop functional patentable inventions embodying utility, artificial intelligence technologies can develop potentially copyrightable works embodying creativity.²⁰⁶ Thus, similar to—although distinct from—ingenuity and inventorship issues with artificial intelligence patents, creativity and authorship issues arise with copyrightable works from artificial intelligence technologies.²⁰⁷

First, copyright law is a form of protection for anyone who creates *original work[s] of authorship*.²⁰⁸ The problem with works generated by artificial intelligence technologies—or computer-generated works—is that they do not fit “the *standard model* of copyright law, [for] which a person” is the author who creates the work.²⁰⁹ Artificial intelligence can output what appears to be a *work* created by its underlying technology, “but there [is] no person whose actions resemble those of a traditional *author*.”²¹⁰ In such a case, the meaning given by copyright law’s existing construction of authorship does not qualify works generated by artificial intelligence technologies.²¹¹ The lack of a *spark of human brilliance* and the lack of human creativity showing *some creative spark* would suggest that copyright law would not qualify computer generated works for authorship.²¹² In fact, the U.S. Copyright Office has indicated that a work must be created by a human being to qualify as a work of authorship.²¹³ The unresolved question

204. 17 U.S.C. § 101; Pamela Samuelson, *Allocating Ownership Rights in Computer-Generated Works*, 47 U. PITT. L. REV. 1185, 1190 (1986).

205. Samuelson, *supra* note 204, at 1185 (defining computer generated work as “software [that] automatically generates output that is not identical to its own text, some of which is potentially copyrightable and some of which is not.”).

206. *See id.* at 1197; 17 U.S.C. § 102(a)–(b), FIFTH-BUTTERFIELD & CHAE, *supra* note 54, at 4.

207. *See* FIFTH-BUTTERFIELD & CHAE, *supra* note 54, at 4; Samuelson, *supra* note 204, at 1192, 1195–97.

208. 17 U.S.C. § 102(b).

209. Bruce E. Boyden, *Emergent Works*, 39 COLUM. J.L. & ARTS 377, 378 (2016).

210. *Id.*

211. *See* FIFTH-BUTTERFIELD & CHAE, *supra* note 54, at 8.

212. Feist Publ’ns, Inc. v. Rural Tel. Serv. Co., 499 U.S. 340, 345 (1991); Margot E. Kaminski, *Authorship, Disrupted: AI Authors in Copyright and First Amendment Law*, 51 U.C. DAVIS L. REV. 589, 592 (2017); *see also* Annemarie Bridy, *The Evolution of Authorship: Work Made by Code*, 39 COLUM. J.L. & ARTS 395, 398 (2016) (providing as reasoning, that how creativity defined as quintessentially human faculty would prohibit computers, or artificial intelligence technology utilized by computers, from being authors).

213. U.S. COPYRIGHT OFFICE, COMPENDIUM OF U.S. COPYRIGHT OFFICE PRACTICES 313.2 (3d ed. 2014) (stating that “the Office will not register works produced by a

on this doctrinal issue is whether the artificial intelligence technology is an assisting mechanism to a human being, or whether the authorship was not truly fully executed by a human being.²¹⁴

Second, depending on how the invention is developed by the artificial intelligence technology, it may or may not contain the requisite originality.²¹⁵ In *Feist Publications, Inc. v. Rural Telephone Service Co.*,²¹⁶ the Supreme Court ruled that the Copyright Clause requires originality, which means that “(1) the work must be independently created (2) with a modicum of creativity.”²¹⁷ However, copyright law has not defined the precise boundaries and scope of creativity.²¹⁸ While the lack of clarity concerning creativity has not caused much litigation concerning creativity since *Feist*, copyright law is facing a doctrinal disruption with creations from artificial intelligence technologies.²¹⁹ The notions of *independent creation* and *modicum of creativity* are being strained by human-machine interactions or machine-generated works of artificial intelligence technologies.²²⁰

Third, the work made for hire doctrine of copyright law could either help to complicate or to resolve doctrinal copyright disruptions of artificial intelligence technologies.²²¹ The work made for hire doctrine, which is found in “Section 201(b) of the Copyright Act, states: ‘In the case of a work-made-for-hire, the employer or other person for whom the work was prepared is considered the author for purposes of this title.’”²²² Thus, a person who is an employer and one who has played no role in the creation of the work could be treated as the author and owner of the work.²²³ The doctrinal problem stems from “a broad, utilitarian interpretation of [the] *author*[],” and hence, for the work made for hire doctrine.²²⁴ A person who is a *motivating factor in producing* can be considered to qualify as the author for the work made for hire, and in doing so, would treat the employer as the

machine or mere mechanical process that operates randomly or automatically without any creative input or intervention from a human author.”).

214. Samuelson, *supra* note 204, at 1192.

215. See 17 U.S.C. § 102(a)–(b) (2012); Edward Lee, *Digital Originality*, 14 VAND. J. ENT. & TECH. L. 919, 920 (2012).

216. 499 U.S. 340 (1991).

217. Lee, *supra* note 215, at 920.

218. *Id.* at 920–21.

219. *Id.*; see also *Feist Publ’ns, Inc.*, 499 U.S. at 345.

220. Lee, *supra* note 215, at 920–21.

221. See 17 U.S.C. § 201(b) (2012); Bridy, *supra* note 212, at 400–01.

222. Robert C. Denicola, *Ex Machina: Copyright Protection for Computer-Generated Works*, 69 RUTGERS U. L. REV. 251, 275 (2016) (quoting 17 U.S.C. § 201(b)).

223. *Id.* at 276.

224. *Id.* at 277; see also *Goldstein v. California*, 412 U.S. 546, 561 (1973).

author.²²⁵ The treatment of a work generated by artificial intelligence technology as a work made for hire would provide a solution to the aforementioned doctrinal copyright problems of vesting legal rights in a machine for a computer-generated work.²²⁶ However, the level of human interaction with an artificial intelligence technology would weigh on the assessment of the work made for hire doctrine.²²⁷ For example, a small degree of human interaction with an artificial intelligence technology could prevent attributing authorship to the employer.²²⁸ Thus, similar to the unresolved question of authorship with artificial intelligence technology, the applicability of the work made for hire doctrine depends on whether the authorship was not truly fully executed by a human being.²²⁹

IV. INITIAL DATA-CENTRIC LITIGATION & A CONCEPTUAL PROPOSAL

The law's struggle "to keep pace with technological developments" has always raised questions about intellectual property protections in emerging areas.²³⁰ Data-centric technologies are not an exception.²³¹ Some of the aforementioned doctrinal quandaries have created unclear boundaries concerning patent law and copyright law protections, which has resulted in initial litigation.²³²

A. Doctrinal Problems in Recent Litigation

There is a mismatch between traditional intellectual property law doctrinal frameworks and new innovation with data-centric technologies, which has resulted in recent litigation.²³³ These cases have centered over tensions in the scope of protection.²³⁴

225. Denicola, *supra* note 222, at 277 (quoting *Picture Music, Inc. v. Bourne, Inc.*, 457 F.2d 1213, 1216 (2d Cir. 1972)).

226. Bridy, *supra* note 212, at 400.

227. *See id.* at 399–400.

228. *See id.*

229. *See id.* at 400.

230. Robinson & Smith, *supra* note 28, at 356.

231. *See id.* at 356–57.

232. *See supra* Section III.B.

233. *See ClearCorrect Operating, LLC v. Int'l Trade Comm'n*, 810 F.3d 1283, 1286–88 (Fed. Cir. 2015); *Naruto v. Slater*, 888 F.3d 418, 420 (9th Cir. 2018); *Purepredictive, Inc. v. H2O.AI, Inc.*, No. 17-cv-03049-WHO, 2017 U.S. Dist. LEXIS 139056, at *1 (N.D. Cal. Aug. 29, 2017).

234. *See ClearCorrect Operating, LLC*, 810 F.3d at 1286–87; *Naruto*, 888 F.3d at 420; *Purepredictive, Inc.*, 2017 U.S. Dist. LEXIS 139056, at *7–21.

1. 3D Printing Patent Law Dispute Over *Articles*

In *ClearCorrect Operating, LLC v. International Trade Commission*,²³⁵ the dispute centered on the interpretation of the term *articles*, which the ITC has the power to regulate under section 337 of the Tariff Act.²³⁶ The doctrinal issue concerned whether the production of digital data sets of infringing digital patient data files was considered to be unfair importation into the United States.²³⁷ In evaluating whether a patent owner could assert whether another entity was importing infringing articles, the ITC interpreted *articles* broadly to include all intangible digital information and asserted jurisdiction over digital information, resulting in an appeal to the U.S. Court of Appeals for the Federal Circuit.²³⁸ After a challenge of the ITC's decision, the Federal Circuit challenged the ITC's decision that its jurisdiction included digital files and held that Congress had never intended the ITC to have authority over the Internet.²³⁹ While the Federal Circuit determined that Congress had directly spoken on this issue concerning *articles*, it also brought to light the imprecise and vague meaning of *articles*—which Congress may still want to clarify further.²⁴⁰ This case highlighted the mismatch between a definition intended by Congress and the patent law's inability to keep with digitization and digital transmission of 3D

235. 810 F.3d 1283 (Fed. Cir. 2015).

236. *Id.* at 1286–87; *see also* 19 U.S.C. § 1337 (2012).

237. *ClearCorrect Operating, LLC*, 810 F.3d at 1286–88; Barclay Oudersluys, *Following ClearCorrect: A Guideline for Regulating Digital Trade*, 32 BERKELEY TECH. L.J. 653, 659–60 (2017).

238. *ClearCorrect Operating, LLC*, 810 F.3d at 1286; Oudersluys, *supra* note 237, at 659–60; *see also* Kumar, *supra* note 115, at 1912, 1924–25 (summarizing that the litigation involved plastic, invisible braces for repositioning teeth and a series of custom-made aligners for successively straightening a patient's teeth, wherein the sequence of events included: (1) uploading digital scans of patients' teeth to a server in Houston; (2) digital modification by creating digital models of patients' teeth in Pakistan; and (3) retransmission back to Houston for downloading and eventual 3D printing of physical models of the patient's teeth to create aligners; noting that none of the patent claims were directed to a tangible object, but instead were directed to methods of creating dental appliances, digital data sets, and digital treatment plans; stating that the ITC interpreted the term *articles* broadly to include all intangible digital information).

239. *ClearCorrect Operating, LLC*, 810 F.3d at 1294, 1302; *see also* Oudersluys, *supra* note 237, at 661–62.

240. *ClearCorrect Operating, LLC*, 810 F.3d at 1291–92, 94; Oudersluys, *supra* note 237, at 661–62.

printing.²⁴¹ It provided motivation for how the law should evolve in light of a proliferating data-centric technology.²⁴²

2. Artificial Intelligence Patent Law Dispute Over *Predictive Analytics*

In *Purepredictive, Inc. v. H2O.AI, Inc.*,²⁴³ the dispute centered on patent eligibility of *predictive analytics* and whether the mere running of data through a machine goes to the “general abstract concept of predictive analytics rather than a specific application.”²⁴⁴ The case, which is being appealed to the Federal Circuit, centers around whether an artificial intelligence technology—specifically machine learning ensembling in the form of predictive analytics that “could be performed by humans”—qualifies as patentable subject matter or is an abstract idea.²⁴⁵ This case highlights the mismatch between patent law’s origination on human-based considerations in the physical world and emerging artificial intelligence technologies that focus on non-human considerations in a digital world.²⁴⁶

3. Artificial Intelligence Copyright Law Dispute Over *Monkey Selfie*

In *Naruto v. Slater*,²⁴⁷ the dispute centered on whether animals could sue for copyright infringement and on who had rights to a photograph taken by a macaque.²⁴⁸ The case concerned the doctrinal issue of whether animals had the statutory standing to sue for copyright infringement under the Copyright Act.²⁴⁹ While the case did not concern data-centric technology, but instead a monkey, the underlying issue of the lack of specificity of

241. See *ClearCorrect Operating, LLC*, 810 F.3d at 1291–92, 1295; Kumar, *supra* note 115, at 1912, 1924–25; Oudersluys, *supra* note 237, at 661.

242. See *ClearCorrect Operating, LLC*, 810 F.3d at 1291–92; Oudersluys, *supra* note 237, at 658, 664.

243. No. 17-cv-03049-WHO, 2017 U.S. Dist. LEXIS 139056, at *2 (N.D. Cal. Aug. 29, 2017).

244. *Id.* at *15.

245. *Id.* at *4, 6, 13–15.

246. See *id.* at *7.

247. 888 F.3d 418 (9th Cir. 2018). This *monkey selfie* litigation is being classified under artificial intelligence for the purposes of this Part IV and for the purposes of this Article, even though it does not fit the prior definition of artificial intelligence technology. Paulina Julia Perkal, *Monkey Business Finally Settled: The Monkey Selfie Disputes*, KLUWER COPYRIGHT BLOG (Feb. 5, 2018), <http://copyrightblog.kluweriplaw.com/2018/02/05/monkey-business-finally-settled-monkey-selfie-disputes/>; see also *Naruto*, 888 F.3d at 431. The reason for introducing this *monkey selfie* case here is to provide an analogy of a non-human consideration, which has similar consideration as artificial intelligence technology with respect to copyright law. Perkal, *supra*; *Naruto*, 888 F.3d at 420.

248. *Naruto*, 888 F.3d at 420.

249. *Id.*

copyright law for animals—and arguably other non-humans, such as artificial intelligence technology—is similar.²⁵⁰ This case highlights the mismatch between copyright law’s coverage to certain entities, touching on the similar consideration of authorship with artificial intelligence technology.²⁵¹

B. *Conceptual Data-Centric Matrix to Address Doctrinal Disruptions*

Data-centric doctrinal disruptions of an initial litigation is a result of intellectual property law’s traditional assumptions that do not keep pace with emerging technologies.²⁵² While there may not be “a single model legal framework to govern” emerging technologies, intellectual property law should still evolve and clarify its scope of protection in order to avoid litigation.²⁵³ This Part introduces a broad, over-arching conceptual framework for intellectual property law’s treatment of scope of protection in present day, in the past, and in the likely future.²⁵⁴

1. Introducing the Conceptual Data-Centric Doctrinal Matrix

The doctrinal disruptions brought by data-centric technologies and the recent litigation concerning data-centric technologies can be conceptualized as levels of interpreting domains of human, non-human, physical, and digital.²⁵⁵ This Part has conceptualized patent law and copyright law statutes not as a static and narrow interpretation, but instead as a dynamic and broad interpretation.²⁵⁶ First, key patent law and copyright law terms have varying meanings that are being brought to the forefront due to unimagined, yet now feasible, data-centric technological developments.²⁵⁷ Second, the scope of protection provided by patent law and copyright law will continue to change as data-centric technology continues to advance at a much faster pace than regulations.²⁵⁸ These considerations are

250. *Id.* at 425–26.

251. *Id.* at 420.

252. *See* Robinson & Smith, *supra* note 28, at 356.

253. WALDEN & CHRISTOU, *supra* note 81, at 3.

254. *See infra* Part IV.B.3.

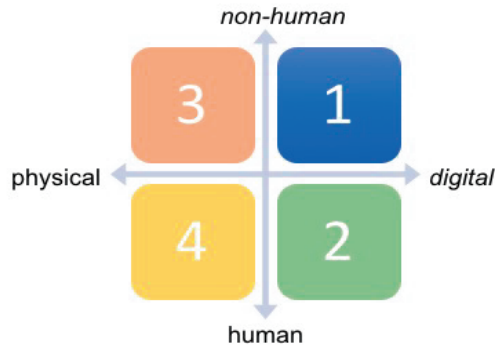
255. *Naruto*, 888 F.3d at 420; *ClearCorrect Operating, LLC v. Int’l Trade Comm’n*, 810 F.3d 1283, 1286–87 (Fed. Cir. 2015); *Purepredictive Inc. v. H2O.AI, Inc.*, No. 17-cv-03049-WHO, 2017 U.S. Dist. LEXIS 139056, at *1 (N.D. Cal. Aug. 29, 2017).

256. Kalin Hristov, *Artificial Intelligence and the Copyright Dilemma*, 57 IDEA: J. FRANKLIN PIERCE CTR. FOR INTELL. PROP. 431, 453 (2017); *see also* discussion *supra* Part IV.B.1

257. Hristov, *supra* note 256, at 437–38, 453.

258. *See* Robinson & Smith, *supra* note 28, at 364–65.

conceptualized in the forthcoming figures, starting with the present-day pictorial representation of scope of coverage not as a dot or circle, but instead as two-by-two matrix encompassing these multiple domains:



This conceptual data-centric doctrinal matrix demonstrates that patent law and copyright law definitions, scope, and standards should be evaluated in multiple domains, such as: (1) non-human in digital domain; (2) human in digital domain; (3) non-human in physical domain; and (4) human in physical domain.²⁵⁹ This conceptual framework demonstrates that patent law and copyright law is multi-faceted and more complex than what may have been intended in their originations.²⁶⁰

2. From the Past to the Current Time

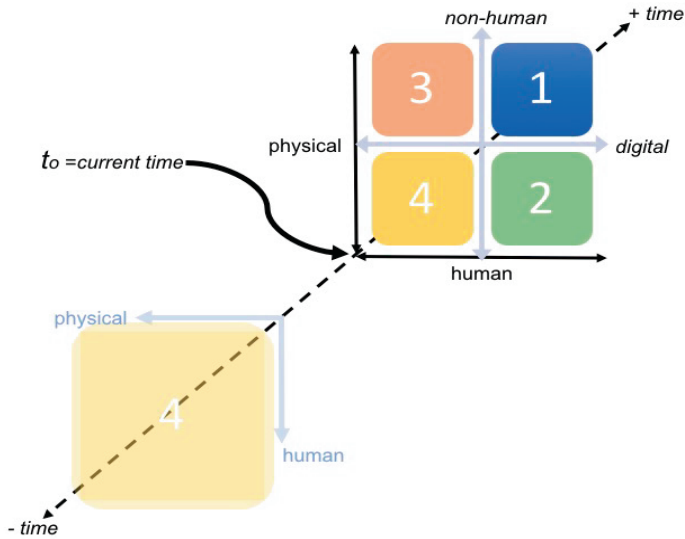
The aforementioned conceptual data-centric doctrinal matrix can better be understood by evaluation from a time standpoint.²⁶¹ As shown here, in the past, during the origination of patent law and copyright law statutes, the definitions, scope, and standards were based on only physical and human considerations—shown as region four, prior to the current time and closer to time, below.²⁶²

259. See *id.* at 372.

260. See Kumar, *supra* note 115, at 1911; Robinson & Smith, *supra* note 28, at 364–65.

261. See Robinson & Smith, *supra* note 28, at 364–65.

262. See 17 U.S.C. §§ 101–102 (2012); 35 U.S.C. § 101 (2012); U.S. COPYRIGHT OFFICE, *supra* note 213, at 313.2 (stating that “To qualify as a work of *authorship* a work must be created by a human . . . [T]he Office will not register works produced by a machine or mere mechanical process that operates randomly or automatically without any creative input or intervention from a human author.”); Robinson & Smith, *supra* note 28, at 364–65.



Thus, the origination of patent law and copyright law in this conceptual framework is based on the past—without digital and without non-human aspects.²⁶³ However, present-day time has required patent law and copyright law to evaluate data-centric technologies with considerations of digital and non-human interpretations.²⁶⁴ Thus, at the current time, the definitions, scope, and standards of patent law and copyright law doctrines are not limited to only human in physical domain, but instead, also encompass non-human in digital domain, human in digital domain and non-human in physical domain.²⁶⁵ The cause of recent litigation of data-centric technologies is that data-centric technologies, in the current time, are being evaluated by the origins of patent law and copyright law from a prior time that based principles only on human and physical principles.²⁶⁶

3. From the Current Time to a Future Time

In order to prevent future litigation, patent law and copyright law will need to evolve not only from their past framework to apply to a data-centric current framework, but also anticipate and prepare for a future

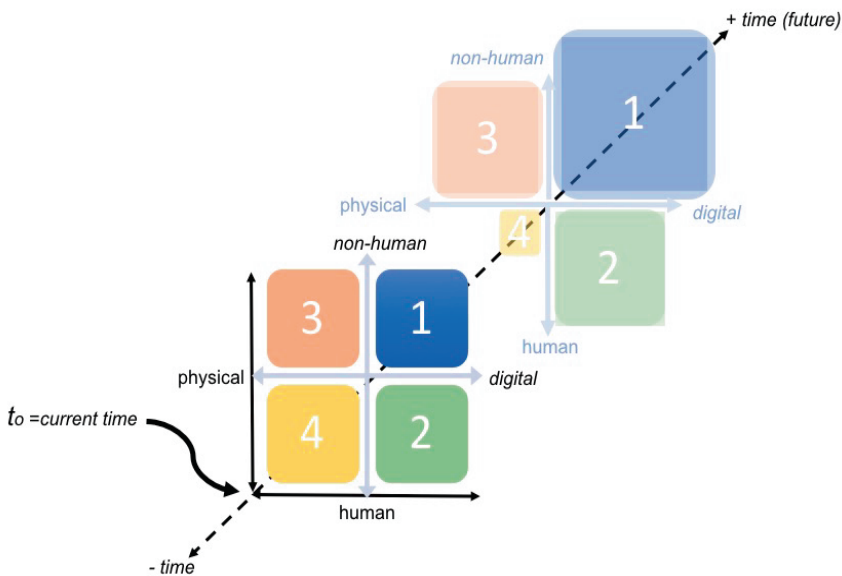
263. See FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 9; Hristov, *supra* note 256, at 440.

264. Hristov, *supra* note 256, at 433; Robinson & Smith, *supra* note 28, at 356–57.

265. See Robinson & Smith, *supra* note 28, at 364–66.

266. See Perkal, *supra* note 247.

framework.²⁶⁷ Conceptually speaking, patent law and copyright law will need to prepare for a future where data-centric technologies will need more clarity and precision of non-human/digital considerations that will be prevalent and dominating—shown in the future matrix closer to +time for region 1, as shown below.²⁶⁸ The future of data-centric technologies will also need more clarity and precision of human/digital considerations—shown in the future matrix closer to +time for region 2, as shown below—and non-human/physical considerations—shown in the future matrix closer to +time for region 3, as shown below.²⁶⁹ However, the human/physical considerations will be less relevant in the future of data-centric technologies—shown in the future matrix closer to +time for region 4, as shown below.²⁷⁰



Thus, this conceptualization has implications for how patent law and copyright law should evolve in light of rapidly developing and proliferating

267. FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 4; Hristov, *supra* note 256, at 453; Robinson & Smith, *supra* note 28, at 372.

268. See FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 4; Robinson & Smith, *supra* note 28, at 372.

269. See FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 14; Robinson & Smith, *supra* note 28, at 372.

270. See FIRTH-BUTTERFIELD & CHAE, *supra* note 54, at 14; Robinson & Smith, *supra* note 28, at 365–67.

data-centric technologies.²⁷¹ First, patent law and copyright law should not remain static, but should anticipate the need to evolve.²⁷² Second, patent law and copyright law should focus on non-human and digital considerations.²⁷³ Third, they should also anticipate an increase in unique, future doctrinal disruptions not only in the non-human/digital domain, but also in the human/digital domain and in the non-human/physical domain.²⁷⁴ These considerations will impact incentives for inventors and creative authors, and in doing so, impact the breadth, pace, and scope of innovation and advancement of data-centric technologies.²⁷⁵

V. CONCLUSION

Data-centric technologies such as 3D printing and artificial intelligence are rapidly proliferating and gaining adoption.²⁷⁶ Digitization of the physical world into digital operation or use has enabled transmission or control of information goods.²⁷⁷ However, the information content view of the physical world has caused doctrinal disruptions with patent law and copyright law.²⁷⁸ Imprecise and unclear definition, scope, and standards has challenged doctrines and resulted in initial litigation.²⁷⁹ Data-centric technology disputes will continue unless patent law and copyright law embrace and better define the non-human and digital worlds, rather than remaining tied to doctrinal concepts only in the human and physical worlds.²⁸⁰

271. Kumar, *supra* note 115, at 1911; *see also* Hristov, *supra* note 256, at 437–38.

272. *See* Hristov, *supra* note 256, at 453; Robinson & Smith, *supra* note 28, at 365.

273. *See* *Naruto v. Slater*, 888 F.3d 418, 420 (9th Cir. 2018); Guadamuz, *supra* note 7, at 19; Hristov, *supra* note 256, at 453; Robinson & Smith, *supra* note 28, at 365.

274. Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 41; Hristov, *supra* note 256, at 453; Robinson & Smith, *supra* note 28, at 365; Van Overwalle & Leys, *supra* note 111, at 507–08.

275. Hristov, *supra* note 256, at 453; *see also* Guadamuz, *supra* note 7, at 17.

276. Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 41; Robinson & Smith, *supra* note 28, at 358.

277. *See* Lipton, *supra* note 43, at 141, 143.

278. *See id.* at 157, 164; Ebrahim, *Digital Infringement & Digital Regulation*, *supra* note 1, at 42; Hristov, *supra* note 256, at 453; Robinson & Smith, *supra* note 28, at 365, 372.

279. *See* *ClearCorrect Operating, LLC v. Int’l Trade Comm’n*, 810 F.3d 1283, 1291–92 (Fed. Cir. 2015); Perkal, *supra* note 247.

280. *See* *Naruto v. Slater*, 888 F.3d 418, 420 (9th Cir. 2018); Hristov, *supra* note 256, at 453; Robinson & Smith, *supra* note 28, at 365, 372.

TELEHEALTH, CHILDREN, AND PEDIATRICS: SHOULD THE DOCTOR MAKE HOUSE CALLS AGAIN, DIGITALLY?

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“Children represent one of our most vulnerable populations, and as such, require special considerations when participating in telehealth encounters.”¹

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1. AM. TELEMEDICINE ASS’N, OPERATING PROCEDURES FOR PEDIATRIC TELEHEALTH 3 (2017).

I. INTRODUCTION

Although telehealth was initially developed primarily for those in rural areas who have difficulty accessing traditional health care services due to distance, the use of telehealth has significantly expanded in the past decade across various groups, including children and adolescents, through pediatrics.² “Pediatricians can use telemedicine for a broad range of applications. Telemedicine can be used for tele-education, teleconsultation, telepractice, and teleresearch.”³ The growth of the acceptance of telehealth in pediatrics is also evidenced by the American Academy of Pediatrics’ (“AAP”) agreement for utilization of SnapMD.⁴ Additionally, with a rising shortage of medical professionals in pediatrics unable to sustain the growing need for pediatric care, the potential benefits of telehealth cannot be overlooked.⁵ As the use of telehealth becomes more prevalent in pediatrics, the opportunities for entrepreneurs to impact this area have increased to create greater access to health care for this vulnerable population that is not only more efficient, but also cost effective.⁶

A number of recent entrepreneurial endeavors have demonstrated a growing interest in pediatrics.⁷ In 2016, Tyto Care began marketing an at-home medical kit to enable parents to obtain medical information of their children that can be delivered to their pediatricians who also have the Tyto Care technology.⁸ While reserved for non-urgent care, the kit is designed to provide efficiency by avoiding the necessity of an in-person doctor’s office

2. See John Commins, *Pediatric Telemedicine Poised for Growth Spurt*, HEALTHLEADERS (Apr. 24, 2017), <http://www.healthleadersmedia.com/innovation/pediatric-telemedicine-poised-growth-spurt>; *Telehealth Use in Rural Healthcare*, RURAL HEALTH INFO. HUB, <http://www.ruralhealthinfo.org/topics/telehealth> (last updated Mar. 26, 2019).

3. Bryan L. Burke Jr. et al., *Telemedicine: Pediatric Applications*, 136 AM. ACAD. PEDIATRICS e293, e294 (2015).

4. Cara Livernois, *American Academy of Pediatrics Selects SnapMD as Telehealth Provider*, AI IN HEALTHCARE: CONNECTED CARE, (May 24, 2018), <http://www.aiin.healthcare/topics/connected-care/american-academy-pediatrics-selects-snapmd-telehealth-provider>.

5. *Id.*

6. See *id.*; Brit Morse, *This Startup Has a Small Army of Therapists with Laptops, Ready to Help People Anywhere*, INC. (May 7, 2018), <http://www.inc.com/brit-morse/dotcom-therapy-30-under-30-2018.html>; Josh Wilson, *Majority of Parents Plan to Use Telemedicine for Pediatric Care*, NEMOURS (Apr. 23, 2017), <http://www.nemours.org/about/mediaroom/press/dv/majority-of-parents-plan-to-use-telemedicine.html>.

7. See Morse, *supra* note 6; Rina Raphael, *Can This Home Medical Kit Save You from Constant Doctor Visits?*, FAST COMPANY (May 10, 2018), <http://www.fastcompany.com/40565776/can-this-home-medical-kit-save-you-from-constant-doctor-visits>.

8. Raphael, *supra* note 7.

visit and significantly assisting parents who are employed and/or have otherwise complicated daily schedules.⁹ Started in 2015, DotCom Therapy is a telehealth therapy startup that has partnered with schools to provide children with a variety of therapy services including “speech therapy, occupational therapy, mental health, and teleaudiology services.”¹⁰ Other examples have shown a growing market for telehealth with options available at retailers.¹¹

This Article explores the different challenges that arise in incorporating telehealth into pediatrics, especially for entrepreneurs.¹² First, this Article explains how telehealth has been applied, specifically in pediatrics.¹³ Next, the Article explores the various legal barriers involving telehealth with particular attention to these issues as they relate to pediatric care, including: Physician-patient relationship, standard of care, informed consent, liability/liability insurance, equipment, and security.¹⁴ This Article then examines the benefits and disadvantages that have been raised in the use of telehealth in relation to pediatric care.¹⁵ Finally, this Article concludes by offering recommendations to those entrepreneurs who hope to have an influence on the future development of telehealth in pediatrics.¹⁶

II. DEFINING TELEHEALTH AND ITS APPROPRIATE USE IN PEDIATRICS

As the focus of this Article is the use of telehealth, specifically as it relates to pediatric care, it is imperative to have a working knowledge of how certain terms are defined within this specialty.¹⁷ In 2015, the AAP released its own technical report on the use of telemedicine in pediatrics.¹⁸ In defining telemedicine, the AAP deferred to the definition used by the American Telemedicine Association (“ATA”).¹⁹ The ATA defined telemedicine as: “[T]he use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical

9. *Id.*

10. Morse, *supra* note 6.

11. Burke Jr. et al., *supra* note 3, at e296.

12. *See* discussion *infra* Part III–IV.

13. *See* discussion *infra* Part II.

14. *See* discussion *infra* Part III.

15. *See* discussion *infra* Part IV.

16. *See* discussion *infra* Part V.

17. *See* discussion *infra* Part III.

18. Burke Jr. et al., *supra* note 3, at e293. It should be noted that, according to this technical guidance document: “All technical reports from the [AAP] automatically expire [five] years after publication unless reaffirmed, revised, or retired at or before that time.” *Id.*

19. *Id.* at e293, e304 n.1.

health status.”²⁰ The AAP recognized that the term telehealth has a more expansive definition than telemedicine.²¹ “Telehealth has historically had a broader definition, encompassing telemedicine’s clinical care for patients and tele-education, teleresearch, and disaster response.”²² Despite this, the AAP acknowledged the interchangeability of telemedicine and telehealth, describing the common use of these terms as synonymous.²³ For purposes of this Article, the term telehealth will be used generally to describe all telemedicine services unless reference is made to a specific document’s use of a particular term.²⁴

A primary consideration for pediatric care is whether there is an appropriate age for which a child may have medical care and treatment using telehealth.²⁵ The ATA’s April 2017 Operating Procedures for Pediatric Health—approved by the AAP—specifically advises against the use of telehealth with a child under the age of two unless there has been a prior in-person relationship developed and referral is made for telehealth services based on a chronic or medically complex condition.²⁶

III. LEGAL BARRIERS TO THE USE OF TELEHEALTH

The AAP guidance summed it up quite simply when it stated, “[l]egal barriers can be substantial” with regard to the use of telehealth.²⁷ “Liability in the context of telemedicine means the exposure of a physician to a claim for damages for alleged medical malpractice or negligence while providing telemedicine services.”²⁸ The AAP identified several issues that should be examined with regard to legal liability, including: The physician-patient relationship, roles and communications responsibilities, patient abandonment, technological failures, liability insurance, site of malpractice action, standard of care, informed consent, security, and unknown legal risks associated with telemedicine.²⁹ The following sections will explore a number of these issues.³⁰

20. *Telemedicine or Telehealth – Definitions*, TELEHEALTH ALLIANCE OF OR., <http://www.ortelehealth.org/content/telemedicine-or-telehealth-definitions> (last visited May 1, 2019).

21. Burke Jr. et al., *supra* note 3, at e293.

22. *Id.*

23. *Id.*

24. See discussion *infra* Part III.

25. See AM. TELEMEDICINE ASS’N, *supra* note 1, at 2–3.

26. *Id.* at 3.

27. Burke Jr. et. al., *supra* note 3, at e300.

28. *Id.*

29. *Id.*

30. See discussion *infra* Parts III.A, III.B, III.C, III.D.

A. *Practicing Telehealth*

1. Physician-Patient Relationship

Physicians who engage in the practice of telehealth will be subject to liability for medical malpractice.³¹ Drawn from the traditional elements of tort law, the prima facie case for a malpractice liability claim is relatively uniform across jurisdictions.³² Indeed, as noted in *Rolon-Alvarado v. Municipality of San Juan*,³³ the elements of medical malpractice liability are fairly comparable among varying jurisdictions.³⁴ In order to prevail, the patient-plaintiff must prove each of the following elements: (1) the physician had a duty to act according to accepted professional standards; (2) the physician breached that duty by deviating from the applicable standard of care; (3) the patient suffered injury; and (4) a causal connection exists between the breach of duty and the patient's injury.³⁵ "For telemedicine physicians, the most significant issues will be: (1) [d]oes the telemedicine physician owe the patient a duty of care, [i.e.,] has a physician-patient relationship been established? (2) [w]hat is the applicable standard of telemedical care or, more accurately, what are the applicable standards of care?"³⁶

To be successful in a claim for medical malpractice, a plaintiff-patient must, among other things, prove the existence of a physician-patient relationship as it is from this relationship that a duty is created of the physician to the patient.³⁷ "In the context of telemedicine, several factors need to be considered in determining when, or if, a physician-patient

31. See Christopher J. Caryl, *Malpractice and Other Legal Issues Preventing the Development of Telemedicine*, 12 J.L. & HEALTH 173, 192–93 (1997–1998).

32. *Id.* at 193; see also *Hollis v. United States*, 323 F.3d 330, 336 (5th Cir. 2003); *Arkin v. Gittleson*, 32 F.3d 658, 664 (2d Cir. 1994); *Rolon-Alvarado v. Municipality of San Juan*, 1 F.3d 74, 77 (1st Cir. 1993); *MacGuineas v. United States*, 738 F. Supp. 566, 569 (D.D.C. 1990).

33. 1 F.3d 74 (1st Cir. 1993).

34. *Id.* at 77 n.2; see also *Hollis*, 323 F.3d at 336 (applying Texas law); *Arkin*, 32 F.3d at 664 (applying New York law); *Fletscher v. United States*, No. C-92-20151, 1993 WL 151223, at *1 (N.D. Cal. May 5, 1993) (applying California law); *MacDonald v. United States*, 767 F. Supp. 1295, 1307 (M.D. Pa. 1991) (applying Pennsylvania law); *MacGuineas*, 738 F. Supp. at 569 (applying Maryland law); *Powers v. United States*, 589 F. Supp. 1084, 1099 (D. Conn. 1984) (applying Connecticut law).

35. *Hollis*, 323 F.3d at 336; *Rolon-Alvarado*, 1 F.3d at 77 n.2; Caryl, *supra* note 31, at 193.

36. LYNN D. FLEISHER & JAMES C. DECHENE, TELEMEDICINE AND E-HEALTH LAW § 1.04(3), LexisNexis (last visited May 1, 2019).

37. *Id.* § 1.04(3)(a).

relationship exists.”³⁸ Among one of the chief considerations that arises is distinguishing whether a website is simply providing general information to a patient or is in an interactive format that is being utilized by licensed physicians and patients.³⁹ When a website is distinguishable as an interactive site, it will be deemed a practice location.⁴⁰

In a court’s determination of whether a physician-patient relationship exists in the context of telehealth, the following considerations will be made:

A physician-patient relationship likely will be found where: (1) the telemedicine physician and the patient see each other during the telemedicine visit; (2) where an actual exam takes place; (3) where the physician provides diagnosis, treatment or other care on which the patient relies; (4) where the physician has access to the patient’s medical records; and (5) where the physician accepts a fee for the telemedicine consultation.⁴¹

A number of cases have found that a physician-patient relationship has been established without a physician actually physically seeing a patient.⁴² The AAP guidance further indicates that as telehealth medical malpractice will likely be similarly aligned to telephone medical malpractice, the physician-patient relationship may attach to both the on-site physician as well as the remote consultant.⁴³ “Extrapolating from case law on telephone use, it is reasonable to conclude that a physician-patient relationship has been established with both the on-site treating physician and the remote consultant

38. *Id.*

39. *Id.*

40. *Id.*

41. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(a)(i); P. Greg Gulick, *E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs*, 12 ALB. L.J. SCI. & TECH. 351, 393–94 (2002). But lack of payment may not immunize the physician from liability, except when the physician’s services fall under a state’s Good Samaritan laws. *Compare* Blanchard v. Murray, 771 N.E.2d 1122, 1131–32 (Ill. App. Ct. 2002) (finding that even though an obstetrician did not charge for services related to the performance of a caesarean section, it was still a question of fact as to whether the obstetrician was liable for negligence because she was given prior notice of the patient’s condition), *with* 745 ILL. COMP. STAT. 49/25 (2018) (Illinois Good Samaritan law conferring civil immunity to physicians under certain circumstances, including not charging the patient any fee for the service). *See also* Henslee v. Provena Hosps., 373 F. Supp. 2d 802, 809–15 (N.D. Ill. 2005) (discussing good faith requirement for *without fee* element of the Illinois statute).

42. Diggs v. Arizona Cardiologists, Ltd., 8 P.3d 386, 388–89; 391 (Ariz. Ct. App. 2000); McKinney v. Schlatter, 692 N.E.2d 1045, 1050 (Ohio Ct. App. 1997), *overruled in part by* Lownsbury v. VanBuren, 762 N.E.2d 354 (2002); Bienz v. Central Suffolk Hosp., 557 N.Y.S.2d 139, 139–40 (N.Y. App. Div. 1990); *see also* Caryl, *supra* note 31, at 195–96.

43. Burke Jr. et al., *supra* note 3, at e300.

during a telemedicine encounter if the remote consultant participates in the history, examination, diagnosis, and development of the treatment plan.”⁴⁴

Case law has developed in the area of telephone communications establishing a physician-patient relationship.⁴⁵ Several cases have been illuminating.⁴⁶ For example, the Supreme Court Appellate Division of New York held that a telephone call was sufficient to create a doctor-patient relationship.⁴⁷ Courts have even found a past relationship between a physician and patient sufficient to create the requisite physician-patient relationship and, thus, to establish a duty.⁴⁸ This has specifically occurred within the area of pediatrics.⁴⁹

Indeed, courts have found physician-patient relationships in the most casual of circumstances.⁵⁰ For example, in *Wilson v. Teng*,⁵¹ a pediatrician who had a previous relationship with a patient may have had a duty to the patient when she encountered her in the emergency room while she was seeing another patient and simply exchanged a few words with her.⁵² The Alabama Supreme Court held that there was a genuine issue of fact as to whether Dr. Teng breached the standard of care by not admitting the patient to the hospital despite the fact that, at the time Dr. Teng encountered the patient, she was neither an emergency physician nor was she even in the emergency room to see that particular patient.⁵³

“Thus, in the telemedicine context, it is unlikely that courts will allow a physician to avoid responsibility for a missed diagnosis or other negligent act on the basis of never having met or directly examined the patient.”⁵⁴

44. *Id.*

45. *Bienz*, 557 N.Y.S.2d at 139–40.

46. *See id.* at 140; *Diggs*, 8 P.3d at 389, 391; *McKinney*, 692 N.E.2d at 1050.

47. *Bienz*, 557 N.Y.S.2d at 140; *see also Diggs*, 8 P.3d at 389 (finding that the test to be applied is “whether a sufficient relationship existed between [the doctor and patient] such that, as a matter of policy, [the doctor] owed [the patient] a duty of reasonable care”). Even though the advice was communicated over a telephone wire rather than in person, the existence of a doctor-patient relationship was an issue of fact for the jury. *Bienz*, 557 N.Y.S.2d at 140.

48. *See Wilson v. Teng*, 786 So. 2d 485, 499 (Ala. 2000).

49. *Id.* at 487.

50. *See id.* at 499.

51. 786 So. 2d 485 (Ala. 2000).

52. *Id.* at 487–88.

53. *Id.* at 499.

54. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(a)(i).

2. Standard of Care

Another legal barrier that occurs in telehealth can occur with regard to the standard of care.⁵⁵ As the AAP points out, there is the potential for a variety of standards for telehealth practice, which substantially complicates this area.⁵⁶ “The standard of care for telemedicine may vary depending on technological sophistication, available options, and patient expectations.”⁵⁷ In order to succeed in a medical malpractice case, a plaintiff-patient, after establishing the physician-patient relationship, will need to substantiate the standard of care.⁵⁸ The standard of care in medical malpractice must be established as follows:

The standard of care element of a malpractice case is a two-part inquiry. First, the applicable standard of care must be established. Second, a determination must be made as to whether the physician-defendant breached that standard. Historically, the accepted standard of care for malpractice cases was defined as the degree of care exercised by clinicians, in good standing, in the same or similar locality as the defendant physician.⁵⁹

One development that has occurred with regard to standard of care has been the courts’ adoption of recognized national standards, in particular, with regard to specialties.⁶⁰ While it was believed that the traditional standard of care would be applicable to physicians, standards of care have evolved due to the technological nature of the medical care being provided to patients in these instances.⁶¹

Telehealth creates a host of additional issues in the delivery of health care.⁶² Of particular concern, in the area of standard of care for a medical malpractice claim, a plaintiff may be challenging “whether the use of telemedicine was appropriate.”⁶³ The appropriateness or suitability of a physician opting to use telehealth to deliver medical care can arise in a number of circumstances.⁶⁴

55. Burke Jr. et al., *supra* note 3, at e300.

56. *See id.*

57. *Id.*

58. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b).

59. *Id.* at § 1.04(3)(b); Caryl, *supra* note 31, at 197.

60. *See* Caryl, *supra* note 31, at 197–98. “In recent years, however, national standards of care, particularly specialty care, have been recognized and accepted by most courts.” FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b).

61. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b).

62. Caryl, *supra* note 31, at 192–93.

63. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(i).

64. *See id.*

Among the myriad *tele*-specific issues that may arise in a telemedicine malpractice suit are questions relating to: (1) whether the use of telemedicine was appropriate in the specific circumstances of the patient's care; (2) whether the best available technology, e.g., store and forward vs. dynamic imaging, was used; and (3) whether it was sufficient, for example, to have a pathology assistant rather than a physician select and transmit patient images. Few standards currently exist to address these issues.⁶⁵

As new technologies emerge, physicians may be hesitant to use such technologies for fear of creating a greater potential to face liability.⁶⁶ At the other end, there may be a legal argument by a plaintiff-patient that telehealth should have been used in the course of care in the case of misdiagnosis—i.e., a test should have been read by a remote expert/specialist that would have made a different diagnosis.⁶⁷

Another issue that arises as to standard of care is whether or not a difference exists in the clinical standards required of a physician with the introduction of the use of telehealth in the delivery of medical care.⁶⁸ “With respect to some medical procedures and services, there will be little distinction between the way a physically-present physician and a telemedicine physician should perform. In such circumstances, the standard of care in both cases should be similar.”⁶⁹ However, this does not mean it will always be the case that standards will be the same when a patient's care involves a technological component.⁷⁰ In some specialties, the nature of the specialty has already incorporated telehealth's use to such a degree that it has become virtually a regular part of that specialty.⁷¹ However, there are instances of medical care in which the use of telehealth presents a new dynamic that demands an adjustment in the standard of care.⁷² “In many other cases, however, the customary standard of care for a particular

65. *Id.*

66. *Id.*

67. *Id.*

68. *See* FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

69. *Id.*

70. *See id.*

71. *Id.*

In other instances, certain uses of telemedicine, such as the transmission of digitized pathology images, already have become part of the customary practice of care for that specialty. In these cases, standard practice is fairly well-established and both physicians and patients are comfortable with the use of telemedicine in the provision of care.

Id.

72. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

procedure may have to be modified significantly to accommodate, inter alia, the fact that the physician will not be able to touch the patient.”⁷³ Several states have regulated the standard of care for the use of telehealth that, unsurprisingly, differ by state.⁷⁴ Despite these attempts to provide consistency for telehealth practice in terms of a standard of care, the establishment of standards in this area have been described as a *moving target*.⁷⁵ A pertinent example of how a state’s standard of care can impact a telehealth startup business is demonstrated by an Illinois order which prohibited a company from treating and prescribing for online patients due to the lack of previous physician-patient relationship and physical exam.⁷⁶ More will be discussed in a later section regarding the licensure barriers that have already existed for physicians to practice medicine across state lines but presents an even greater challenge to the various startup businesses that want to pursue a purely telehealth medical practice.⁷⁷ States still have an enormous ability to regulate and essentially dictate the boundaries of the

73. *Id.*; Caryl, *supra* note 31, at 199.

74. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

Some states already have promulgated regulations that attempt to specify applicable standards of care for telemedicine practice. And, as expected, they vary from state to state. Colorado’s regulation requires the standard of care for telemedicine treatment to be the same as the standard of care for in-person treatment. Florida’s regulation states that prescribing medicine based solely on an electronic medical questionnaire fails to meet the required standard of care. Texas has a rule similar to Florida’s, which states that the standard of care is not met merely by an online or telephonic evaluation of the patient. The regulations state that “[t]reatment and consultation recommendations made in an online setting, including issuing a prescription via electronic means, will be held to the same standards of appropriate practice as those in traditional in person settings.” The Texas regulation requires the physician to diagnose the patient using acceptable medical practices, discuss treatment options with the patient, and be available for follow up care, if necessary. At least two states require that a physician treating a patient via telemedicine keep that patient’s records confidential.

Id.; see also TEX. OCC. CODE ANN. § 111.003 (West 2017); ALA. ADMIN. CODE r. 540-x-9-.11 (2018); ALA. ADMIN. CODE r. 540-x-15-.01 (repealed 2015); 10 COLO. CODE REGS. § 2505-10, 8.200.3.B (LexisNexis 2018); FLA. ADMIN. CODE ANN. r 64B8-9.0141 (2018); FLA. ADMIN. CODE ANN. r 64B15-14.0081 (2018); FLA. ADMIN. CODE ANN. r 64B8-9.014 (repealed and reenacted as 64B8.9.0141 (2018)); GA. COMP. R. & REGS. 360-3-.07 (2018); MONT. ADMIN. R. 24.156.810 (repealed 2018); 22 TEX. ADMIN. CODE § 174.4 (2018); 22 TEX. ADMIN. CODE § 174.8 (2018).

75. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(ii).

76. *Id.*

In November 2002, the Illinois Department of Professional Regulation ordered MyDoc.com, an Indiana-based medical consultation company, to stop treating and prescribing to online patients ‘without the benefit of prior physician-patient relationship or physical exam.’ The order also alleges that the company violated the Illinois Medical Practice Act by practicing medicine without a license.

Id. (citation omitted) (quoting Tyler Chin, *Firm Treating Strangers by Web Shut Out by Illinois Directive*, AM. MED. NEWS, Nov. 4, 2002, at 21).

77. See discussion *infra* Part III.B.2.

practice of medicine within its borders.⁷⁸ It should also be noted that a number of voluntary telehealth standards have been developed by various associations.⁷⁹

3. Informed Consent

“Informed consent refers to a process of communication between a patient and physician that results in the patient’s authorization or agreement to undergo a specific medical intervention.”⁸⁰ The AAP has identified the importance of informed consent in the use of telehealth; “[s]pecial consent may be necessary regarding the risks associated with the use of telemedicine, including involvement of nonmedical staff, recording of the interaction, and the vulnerability of the equipment to failure.”⁸¹ The failure of a physician to obtain proper consent can result in legal consequences.⁸² “In most states, a physician who fails to obtain informed consent from a patient may face liability for assault, battery, fraud, and/or negligence.”⁸³ The first case credited for the doctrine of informed consent is *Schloendorff v. Society of New York Hospital*.⁸⁴ States have developed different standards for evaluating the doctrine of informed consent, including the professional standard and the reasonable patient standard.⁸⁵ “Additionally, some states require the disclosure of specific factors including diagnosis, nature and purpose of treatment, potential risks and outcomes, skill or status risks, alternatives, prognosis without intervention, prognosis with intervention, and potential conflicts of interest as part of the informed consent process.”⁸⁶ While much more can be said, generally, about informed consent, the importance here is that the duty of a physician to obtain informed consent still applies in the telehealth context.⁸⁷ Several states have laws mandating

78. See FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(b)(iii).

79. *Id.*

80. *Id.* § 1.04(3)(c)(i).

81. Burke Jr. et al., *supra* note 3, at e300.

82. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(c)(i).

83. *Id.*

84. 105 N.E. 92, 93 (N.Y. 1914), *overruled by* Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957).

In the case at hand, the wrong complained of is not merely negligence. It is trespass. Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without his patient’s consent commits an assault, for which he is liable in damages.

Id. at 93.

85. FLEISHER & DECHENE, *supra* note 36, § 1.04 (3)(c)(i).

86. *Id.*

87. See *id.* § 1.04(3)(c)(ii)(A).

physicians practicing telehealth obtain informed consent.⁸⁸ While physicians may traditionally obtain informed consent orally, much more emphasis is made on getting written consent when medical care is delivered by means of telehealth, even to the extent that some states require consent to medical care be in written format when delivery involves telehealth.⁸⁹ Additionally, telehealth necessitates the possibility of having to obtain informed consent in more than one instance.⁹⁰ The introduction of technology into traditional health care delivery amplifies the significance of acquiring multiple informed consents.⁹¹

Moreover, the practice of telemedicine raises novel informed consent issues and more than one type of consent may be necessary. A practitioner should consider documenting consent for the general risks of a treatment or procedure, as well as special consent for the specific risks associated with the use of telemedicine for that treatment or procedure. Additionally, in the context of the interstate practice of telemedicine, both the teleconsulting physician's home state and the patient's home state may impose other specific informed consent duties on the physician.⁹²

It has also been stressed that as the use of technology in medical care is likely to be novel for a patient, it is critical that a physician is careful in explaining a number of things to the patient for consent.⁹³

Because the use of telemedicine will be a new experience for most patients, the treating physician is well advised to . . . explain to the patient the risks and benefits associated with receiving medical care from a telemedicine physician and/or through the use of telemedical technology. At a minimum, the patient should know that a telemedicine consult: (1) necessitates that the treating physician and the telemedicine physician discuss the patient's health information via telecommunication technology; (2) may require that non-medical staff be involved in the consult for the purposes of operating the technology, both at the treatment site and at the teleconsult physician's site; and (3) may be recorded by audio, video, or some other medium. . . . The patient also should be informed that, as with any technology,

88. *Id.*

89. *Id.*

90. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(c)(ii)(A).

91. *Id.*

92. *Id.*

93. *Id.*

telemedicine systems are vulnerable to failure and unauthorized access. . . . In addition, the patient should be advised of his or her rights to privacy and informed consent. Finally, the patient should be informed regarding the state(s) in which the telemedicine physician is licensed and should be advised of the procedure for follow-up. . . . Patients should be told up front which physician—the referring physician or the teleconsult physician—should be contacted if the patient has any follow-up questions.⁹⁴

The AAP also emphasized the importance of informed consent regarding possible technology failure in its 2015 technical assistance: “When any electronic device is used, plans should be in place to deal with problems such as system failure, loss of power, or loss of connectivity. Telemedical informed consent should include this potential problem.”⁹⁵ It is critical to know that, similar to licensure, informed consent will vary by state in terms of requirements and will often require an obtained oral consent to be captured in writing.⁹⁶

A number of special considerations come up in the area of informed consent involving pediatrics that were addressed by the ATA in its April 2017 Operating Procedures for Pediatric Health.⁹⁷ The ATA gives general guidance regarding informed consent as follows:

Prior to the initiation of a telemedicine encounter, except in the case of emergency, the provider or designee shall inform and educate the patient and/or legal representative about the nature of telemedicine service compared with in-person care, billing arrangements, and the relevant credentials of the distant site provider. The provider or designee should also include information about the timing of service, record keeping, scheduling, privacy and security, potential risks, mandatory reporting, and billing arrangements. Providers should consider whether consent for care is based on a specific condition, episode of care or a period of time. The information shall be provided in simple language that can be easily understood by the patient and/or legal representative. The provider shall follow state-specific requirements for the use of translation services for consent, and the provider may utilize translation services as necessary for consent in the absence of such state-specific requirements. These considerations are particularly important when discussing technical issues like encryption or the potential for technical

94. *Id.* (citations omitted).

95. Burke Jr. et al., *supra* note 3, at e299.

96. FLEISHER & DECHENE, *supra* note 36, at § 1.04(3)(c)(i).

97. AM. TELEMEDICINE ASS’N, *supra* note 1, at 3.

failure. As with in-person care, providers should also make an effort to obtain the assent of pediatric patients participating in telehealth services in a manner appropriate to their understanding.⁹⁸

Additionally, the ATA provides guidance on the age of consent for telehealth practice involving pediatric care.⁹⁹ While this becomes more of an issue concerning adolescence, it is something important to be mindful of with regard to informed consent in the context of telehealth as well as the applicable state laws.¹⁰⁰ Finally, the ATA provided guidance regarding emergency scenarios that may arise.¹⁰¹ The ATA articulated the following guidance for informed consent in emergency care in pediatrics using telehealth:

In certain limited emergency situations, as with in person care, the informed consent requirement may be waived. A health care professional's decision to treat combined with parental consent and patient assent, when appropriate, is the preferred scenario for the provider working in a medical emergency. When any one of those factors is absent or unclear, the health care provider shall be (1) knowledgeable of state and federal laws related to a minor's right, or lack thereof, to consent for testing and treatment and (2) prepared to confront the ethical challenges surrounding those same issues.¹⁰²

98. *Id.* at 4–5.

99. *Id.* at 5.

100. *See id.* at 4–5.

Age of Consent: The age at which a person may lawfully consent to care can vary with the health condition at issue, the person's state of residence, or the state where the patient is at the time of the telemedical visit. Minors in all states have the right to consent to testing and treatment for a sexually transmitted disease ("STD"). In many states, minors also have the right to consent to: (1) outpatient treatment for mental health issues; (2) prenatal care; (3) contraceptive services; and/or (4) alcohol and substance abuse. The age of consent for these various conditions can vary not only among states, but also within a given state. For example, in one state the age of consent is [twelve] years for treatment for an STD and [fourteen] years for substance abuse. The provider shall be aware of each state's rules in which the patient is physically located for that visit. In certain environments additional elements of consent may need to be considered.

Id. at 5.

101. AM. TELEMEDICINE ASS'N, *supra* note 1, at 5.

102. *Id.*

B. *Telehealth Practice Crossing State Lines*

1. Liability and Liability Insurance

Another issue that comes up in medical malpractice cases involves the issue of liability.¹⁰³ In the telehealth context, multiple providers have the potential to be involved, which leads to the question of who will ultimately be liable in the event that something goes wrong.¹⁰⁴ Although it is not groundbreaking for there to be multiple providers of medical care involved in a patient's treatment, the introduction of telehealth practice does create another wrinkle in the liability determination and one that apparently has not been addressed.¹⁰⁵

Although relevant cases have not yet arisen in the telemedicine context, general principles of joint and several liability should apply when apportioning liability between, for example, the local treating physician and the remote telemedicine specialist. However, as with many legal issues arising from telemedicine practice, apportionment of liability will be a matter of state law, and thus will vary from state to state.¹⁰⁶

Additionally, the AAP recognized the potential legal barrier—in terms of the insurance coverage—that someone practicing telehealth has when the telehealth physician's practice of medicine crosses state lines: "If a physician crosses a state line to practice telemedicine, he or she must determine whether malpractice insurance covers out-of-state telemedicine encounters and whether the coverage is sufficient for the distant state."¹⁰⁷ The issue of liability insurance will be important to companies that have developed specifically to be able to provide telehealth coverage across state lines.¹⁰⁸ Regardless, the issue of liability insurance may be even more complex generally for physicians practicing telehealth.¹⁰⁹

"Exacerbating concerns over potential telemedicine malpractice liability is the fact that medical malpractice liability insurance policies may not cover allegations of *telemedicine malpractice*. Yet, physicians who are

103. FLEISHER & DECHENE, *supra* note 36, § 1.04(2).

104. *See id.* at § 1.04(3)(d).

105. *See id.*

106. *Id.* § 1.04(3)(d).

107. Burke Jr. et al., *supra* note 3, at e300.

108. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(d)–(e).

109. *See id.* § 1.04(3)(e); Alicia Gallegos, *Telemedicine Poses Novel Legal Risks for Doctors*, *CARDIOLOGY NEWS* (Oct. 6, 2015), <http://www.mdedge.com/chestphysician/article/103362/health-policy/telemedicine-poses-novel-legal-risks-doctors>.

involved in the practice of telemedicine may be in particular need of such coverage.”¹¹⁰

Liability insurance may not cover telehealth practitioners in a number of other ways.¹¹¹ “For one thing, malpractice liability insurance policies may not cover telemedicine activities that cross state lines, or where the physician is found to be practicing telemedicine *without a license*.”¹¹² Another distinction that may be made in liability insurance coverage with regards to telehealth is whether the coverage pertains to actual medical care and/or technical error that may occur as a result of the use of technology.¹¹³ It is important that a physician consider this in ensuring proper liability coverage for telehealth practice.¹¹⁴

“A liability insurer also may not provide telemedicine coverage where the alleged malpractice arises from actions or omissions relating to the telecommunications rather than the medical aspects of the service. Accordingly, physicians should ensure that their malpractice liability insurance policy covers such telemedicine-related telecommunications errors.”¹¹⁵

It has been recommended that the physician practicing telehealth should be mindful of the extent of liability coverage and have the following items included in liability coverage.¹¹⁶

Specifically, a telemedicine physician’s medical malpractice liability insurance policy should contain an endorsement specifying that the policy covers medical malpractice and related claims arising from medical diagnosis, treatment, consultation and/or referral, including claims arising in connection with the use of telecommunications technology, and that such coverage is provided for every state the telemedicine physician *enters*.¹¹⁷

It is also likely that the telehealth practitioner will face increased costs associated with liability coverage.¹¹⁸ Another issue that is of significance in consideration of liability insurance for telehealth is technology failures.¹¹⁹ It is advised that the telehealth physician pursue

110. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(e).

111. *Id.*

112. *Id.*

113. *Id.*

114. Gallegos, *supra* note 109.

115. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(e).

116. *Id.*

117. *Id.*

118. *Id.*

119. *Id.*

coverage for equipment failure, if at all possible, and consider other options for coverage if that is unavailable.¹²⁰

Further, telemedicine adds the additional risk of equipment failures and transmission errors. Because of these unresolved issues, telemedicine practitioners are likely to find that, if in fact they can obtain comprehensive telemedicine coverage, it is likely to come at a significantly higher price. If a malpractice insurer is unwilling to cover failures of telecommunications problems, telemedicine equipment failure or similar *non-medical* claims, a telemedicine practitioner may wish to seek a general negligence insurance policy to cover such failures.¹²¹

Thus, issues of liability and liability coverage are extremely important for the physician practicing telehealth—in particular, due to the fact that practitioners may practice across state lines and that the introduction of technology into medical care requires extra layers of protection to account for the possibilities of technological, as well as equipment, malfunctions.¹²²

2. Licensure Limitations and State Telehealth Laws

One of the biggest issues for startup businesses that endeavor to provide telehealth services is that state laws will often limit the ability to cross state lines due to licensure.¹²³ Because of differing telehealth laws, a telehealth startup may need to have physicians licensed in multiple states.¹²⁴ The complexity that exists due to the lack of a national telehealth law is explained by the AAP as follows:

However, the use of interstate telemedicine often requires participants to be licensed in both states, which can be a formidable barrier, particularly for telemedicine providers who work in multiple states. Many states have recognized the value of allowing out-of-state physicians to share their knowledge and expertise and have therefore granted specific exceptions to their licensing rules. Nevertheless, all states still have the authority to license and regulate the practice of medicine within their borders, and physicians who practice telemedicine must carefully follow

120. FLEISHER & DECHENE, *supra* note 36, § 1.04(3)(e).

121. *Id.*

122. *Id.*

123. Burke Jr. et. al., *supra* note 3, at e300–01.

124. *Id.*

the rules in each state that they *enter* electronically to provide medical care.¹²⁵

The AAP has pointed to several cases that have been litigated that emphasize the significance of state control and regulation over the ability to practice medicine within its state's borders, although it is done by a physician remotely.¹²⁶

C. *Equipment*

1. Standards of Practice

In addition to the state laws regulating telehealth practice as described above and case law that has developed on these issues, a number of standards or guidelines have been developed with regard to the oversight of equipment and technologies being used in the practice of telehealth—"in an effort to assure the clarity, reliability, interoperability, and interconnectivity of telemedicine equipment."¹²⁷ An example of such standards are those used for digital imaging and the equipment that stores this information.¹²⁸ The ATA's 2017 Operating Practices for Pediatric Health has a number of provisions for guidance specific to equipment.¹²⁹ An important first provision acknowledges that the equipment used for telehealth in pediatrics has to be such that it is appropriate for the child based on a number of factors: "Equipment used for provision of pediatric telehealth services should be appropriate to the age, size, and developmental stage of the child, including size, comfort, accuracy, and validity of measurements."¹³⁰ Another notable provision by the ATA is the need for someone to be present who can properly operate the equipment and that the telehealth practitioner appropriately evaluates whether the images provided by the technology are adequate for diagnosis purposes.¹³¹

For any telehealth encounter, there shall be at least one party to the encounter who is capable of operating all involved equipment in accordance with the specifications for the use of that equipment. Providers should be aware that the use of some equipment in children may pose unique challenges relating to

125. *Id.*

126. *Id.* at 301.

127. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(a).

128. *Id.*

129. AM. TELEMEDICINE ASS'N, *supra* note 1, at 10.

130. *Id.*

131. *Id.*

patient cooperation, size, comfort, and technique, and should be comfortable with the use of all involved equipment in children. Providers shall determine whether the quality of the device output and displayed images are sufficient for the diagnosis and/or management of the patient's condition.¹³²

Further, the ATA advises planning due to any technological or equipment failure: "Telehealth providers shall have a technical support plan and contingency plan in place in the event of technology or equipment failure during an encounter."¹³³

Of particular interest regarding equipment are the latest technological developments for telehealth involving children, such as the Tyto Care home kit described at the beginning of this Article; however, the ATA has refrained from providing any direct guidance on these technologies, finding them too novel to adequately assess them.¹³⁴ This is according to the ATA's 2017 Operating Procedures for Pediatric Health.¹³⁵

"Peripheral examination devices designed for home use by parents or other nonclinical caregivers are an emerging technology. However, further study of the accuracy and effectiveness of these devices is required before any recommendations can be made regarding their use."¹³⁶ With the growing use of such technologies, the ATA will likely develop guidelines regarding these items, as well.¹³⁷

2. Who is Liable?

Besides the standards for use of equipment, it has already been mentioned that a physician practicing telehealth may be subject to liability for malfunctioning equipment as it has been advised that telehealth physicians get liability insurance to cover the possibility of equipment failure.¹³⁸ The AAP pointed out in its guidance regarding pediatrics: "The liability for technology failures may be shared by all involved parties. A supervising physician may be at risk for equipment failure, although the [ATA] has no record of any such lawsuit."¹³⁹ A physician using telehealth to deliver medical care may be subject to liability in a number of instances

132. *Id.*

133. *Id.*

134. *See* AM. TELEMEDICINE ASS'N, *supra* note 1, at 3; Raphael, *supra* note 7.

135. AM. TELEMEDICINE ASS'N, *supra* note 1, at 3.

136. *Id.*

137. *See id.*

138. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(b); Burke Jr. et al., *supra* note 3, at e300.

139. Burke Jr. et al., *supra* note 3, at e300.

including: “[A] physician’s negligent selection of telemedicine equipment, misuse of the equipment, or misdiagnosis or mistreatment based on faulty data received from the equipment.”¹⁴⁰ However, if the particular defect of the equipment is latent, the telehealth physician will not be liable.¹⁴¹

While physicians and health care entities may be held liable for negligence in the care, maintenance, or use of telemedicine equipment, providers will not likely be liable for latent defects. However, plaintiffs who are injured by telemedicine equipment that is defective and unreasonably dangerous may sue the manufacturers and distributors of the equipment under a theory of strict liability.¹⁴²

The rationale behind this is that the manufacturer or seller is in the best position to bear financial responsibility based on its relationship to the public.¹⁴³ A strict liability claim involving a latent defect may take the following forms:

A strict liability claim against a manufacturer could arise from a misdiagnosis based upon defective machinery that produced, for example, defective image resolution, sound quality, speed of encoding, or delivery of data. Under a theory of strict liability, manufacturers and distributors of defective and unreasonably dangerous telemedicine products may be jointly and severally liable for injuries to the patient caused by such products unless one defendant party can prove that its co-defendant was solely at fault. One hundred and sixty [h]ospitals and practitioners, in general, are not subject to strict liability claims, since they are not engaged in the business of selling or supplying products but instead provide professional services.¹⁴⁴

Understanding the potential liability that a telehealth practitioner may be subjected to by the use of equipment is an important consideration in entering into this area of practice.¹⁴⁵

140. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(b).

141. *Id.*

142. *Id.* at § 1.04(4)(c).

143. *Id.*

144. *Id.*

145. *See* FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(c).

3. FDA Regulation and Telehealth

In addition to the issues already discussed regarding equipment, a substantial portion of regulation may occur involving the Food and Drug Administration (“FDA”), which can be implicated in the area of telehealth due to the use of both equipment and technology.¹⁴⁶ Specifically, the FDA is implicated in the oversight of medical devices which are those “intended for use in the diagnosis . . . treatment, or prevention of disease.”¹⁴⁷ Device is defined under the Federal Food, Drug, and Cosmetic Act as:

[A]n instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.¹⁴⁸

Overall, there have been specific barriers to approval of medical devices in pediatrics.¹⁴⁹ The FDA has specified regulatory authority over telehealth services in a number of categories.¹⁵⁰ The following is the guidance provided with regard to technologies as they relate to telehealth for FDA regulation.¹⁵¹

Given the breadth of that definition, it is not surprising that telemedicine systems—and many of their components—fall within the regulatory purview of the FDA. The FDA Working Group on Telemedicine has defined *clinical telemedicine* as the “delivery and provision of health care and consultative services to individual

146. *Id.* at § 1.04(4)(c)–(d).

147. *Medical Device Overview*, FDA, <http://www.fda.gov/forindustry/importprogram/importbasics/regulatedproducts/ucm510630.htm> (last updated Sept. 14, 2018).

148. 21 U.S.C. § 321(h)(1)–(3) (2012).

149. Melissa Jenco, *AAP Brings Need for Pediatric Medical Devices to Forefront*, AAP NEWS (Aug. 17, 2018), <http://www.aapublications.org/news/2018/08/17/fdadevices081718>.

150. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d).

151. *Id.*

patients and the transmission of information related to care, over distance, using telecommunications technologies,” including the following activities: (1) [d]irect clinical, preventive, diagnostic, and therapeutic services and treatments impacting the clinical care of a specific patient; (2) consultative and follow-up services; (3) remote monitoring, including the remote reading and interpretation of patient’s procedures; (4) rehabilitation services; and (5) patient education delivered in the context of delivering health care to individuals. The FDA has determined that devices used in activities [one] through [four] are subject to [Center for Devices and Radiological Health] (“CDRH”) regulatory authority, and those related to activity [five] are integral to that authority when the *education* delivered is medical device labeling information.¹⁵²

The FDA’s CDRH plays a major role in the approval of medical devices that are used in the delivery of medical services using telehealth.¹⁵³

A 1996 Report of the FDA noted CDRH’s responsibility for ensuring the safety and efficacy of the medical devices used in telemedicine systems, and described its telemedicine-related activities, including pre-market review of telemedicine devices, post-market surveillance, quality systems regulations (good manufacturing practices), control, and standards development. The FDA is likely to have the greatest impact on the development and future use of telemedicine technology through its premarket review activities. Many of the telemedicine devices cleared for marketing by the FDA in recent years have been classified into Class II. Manufacturers of Class II medical devices must meet performance standards and/or comply with the requirements of [s]ection 510(k) of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360(k) and the regulations promulgated thereunder. Once a medical device has been cleared for marketing, any modification to the device made by the manufacturer that “could significantly affect the safety [and] effectiveness of a device,” such as an alteration in the device’s indications for use, may trigger further review by the FDA.¹⁵⁴

152. *Id.* (citations omitted).

153. *Id.*; *Telemedicine Related Activities*, FDA: CTR. FOR DEVICES & RADIOLOGICAL HEALTH (July 11, 1996), [<http://web.archive.org/web/19961019084/http://www.fda.gov/cdrh/telemed.html>].

154. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d) (citation omitted) (quoting 21 C.F.R. § 807.81 (2018)); *see also* Federal Food, Drug, and Cosmetic Act, Pub. L. No. 75-717, § 1, 52 Stat. 1040, 1040 (1938); 21 U.S.C. § 360k (2012); *Telemedicine Related Activities*, *supra* note 153.

There are a variety of other ways the FDA is involved in regulation concerning telehealth, which in and of itself could likely be more fully explored in a complete article of its own.¹⁵⁵ Other areas of regulation include: “radiology devices related to medical image communication, storage, processing, and display,” medical devices used by patients that involve monitoring including implanted pacemakers that allow monitoring of the patient’s cardiac data by transmission of the data directly from the device to the physician’s office, robotic devices, and mobile medical applications used with smartphones and tablets.¹⁵⁶ It should be noted that medical applications can also be subjected to regulation by the Federal Trade Commission (“FTC”).¹⁵⁷

Another twist in the area of regulation by the FDA is an understanding that there are differences between regulation of the manufacturer of a medical device as opposed to regulation of a physician who chooses to use a medical device to deliver medical services using telehealth.¹⁵⁸ In fact, there has been recognition of this distinction to the extent of indicating that the physician’s actual use of a device is not at issue when it comes to FDA regulation.¹⁵⁹

While FDA’s regulatory interest in telemedicine technology has obvious implications for telemedicine equipment manufacturers, its impact on physicians, hospitals and other *users* of the equipment is less than clear. The issue of whether a manufacturer may distribute a medical device is a separate matter from the issue of whether a physician who receives the device—or manufactures it himself—may use it. More specifically, physicians’ decisions to use a particular telemedicine device within the scope of their medical practice may be implicitly exempt from regulation under the federal Food, Drug, and Cosmetic Act. Although there is no express provision in the Act, both the courts and the FDA have recognized that the Act was never intended to limit a physician’s ability to treat patients. In September 1996, FDA officials testified before Congress that “once a product is approved for marketing for a specific use, FDA generally does not regulate how, and for what uses, physicians prescribe that [product].”¹⁶⁰

155. FLEISHER & DECHENE, *supra* note 36, §1.04(4)(d).

156. *Id.*

157. *Id.*

158. *Id.*

159. *See id.*

160. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d) (citations omitted) (quoting *Off-Label Drug Use and FDA Review of Supplemental Drug Applications: Hearing Before the Subcomm. on Human Res. & Intergovernmental Relations of the Comm. on Gov’t*

Additionally, modifications of devices by physicians have also been typically free of FDA regulation.¹⁶¹ “As a general rule, unless the physician is involved in active marketing or commercialization of the modified device, particularly in interstate commerce, the practice-of-medicine doctrine should effectively immunize the physician from regulation by the FDA.”¹⁶²

Finally, it is important to point out that there are possible consequences of using unapproved devices for telehealth.¹⁶³ Of critical consideration, “even if a physician’s use of an unapproved—or a modified—telemedicine device does not run afoul of the Food, Drug, and Cosmetic Act, it would no doubt greatly increase the risk of medical malpractice liability should a patient be injured in connection with the use of the device.”¹⁶⁴ Additionally, there are potential fraud concerns that arise when reimbursement is being sought for telehealth services and an unapproved device is used.¹⁶⁵

D. *Security*

Another potential legal issue that undoubtedly comes into play with the introduction of technology into health care is a patient’s personal information and how this information is protected.¹⁶⁶ In 2015, the AAP recognized this as one of the potential legal barriers in the practice of telehealth in pediatrics: “Security policies and procedures for telemedicine systems must be designed and operated in compliance with the final [Health Insurance Portability and Accountability Act] directive on the subject, titled ‘Standards for Privacy of Individually Identified Health Information’—published in 2002, and applicable state laws governing patient confidentiality.”¹⁶⁷ Similarly, the ATA has advised of the importance of

Reform & Oversight House of Representatives, 104th Cong. 61 (1996) (statement of Michael Friedman, Deputy Comm’r for Operations, FDA).

161. *Id.*

162. *Id.* (citing John J. Smith, *Physician Modification of Legally Marketed Medical Devices: Regulatory Implications Under the Federal Food, Drug, and Cosmetic Act*, 55 FOOD & DRUG L.J. 245, 254 (2000)).

163. *Id.*

164. *Id.*

165. FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(d). “Moreover, a physician or hospital’s requests for reimbursement for telemedicine services involving the use of an unapproved medical device may raise false claims or fraud and abuse concerns.” *Id.*

166. *See* Burke Jr. et al., *supra* note 3, at e300.

167. *Id.*; *see also* Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53182 (Aug. 14, 2002) (codified at 45 C.F.R. pts. 160, 164).

adherence to state and federal laws regulating the security of this information in its 2017 Operating Procedures.¹⁶⁸

Providers shall comply with all federal and individual state laws and regulations regarding child privacy, including but not limited to [the Children’s Online Privacy Protection Act], [the Health Insurance Portability and Accountability Act], [the Health Information Technology for Economic and Clinical Health Act] and [the Family Educational Rights and Privacy Act]. All existing laws and regulations regarding patient privacy and confidentiality, including laws pertaining to protection of privacy when minors consent for their own health care, apply to telehealth encounters just as they do for traditional encounters; however, there may be additional language specifically for security of patient privacy and confidentiality when care is delivered via telehealth.¹⁶⁹

Further, the ATA advises that the provider should always ensure that a secure connection is maintained throughout the duration of the telehealth encounter.¹⁷⁰ In the event the provider becomes aware that there is a security concern which may leave private information susceptible to being compromised, the ATA advises termination of the encounter immediately.¹⁷¹ Recording of a telehealth encounter creates additional special considerations.¹⁷² If a telehealth encounter is recorded, the telehealth practitioner must be aware of applicable state laws for recording these encounters and is required to notify the patient—or in the case of a child, the child’s guardian or legal representative—that the encounter is being recorded, as well as to obtain consent prior to recording the encounter.¹⁷³ If a telehealth encounter is recorded, a copy is also to be timely made available to the patient, if requested, and in accordance with any other applicable policy determinations regarding recordings.¹⁷⁴

Another area of importance in security involves the transfer of digital images taken in the course of the patient’s care to ensure that such images are properly maintained and transmitted safely by means of a secure connection.¹⁷⁵ The ATA cautions particular care with regard to children in this area: “The transmission of pediatric patient images, in particular,

168. AM. TELEMEDICINE ASS’N, *supra* note 1, at 4.

169. *Id.*

170. *Id.*

171. *Id.*

172. *Id.*

173. AM. TELEMEDICINE ASS’N, *supra* note 1, at 4.

174. *Id.*

175. *Id.*

represents a special situation which is subject to numerous state and federal regulations regarding both private health information and child privacy.”¹⁷⁶

Thus, it is critical that a telehealth practitioner is mindful of both state and federal laws regarding these issues of security.¹⁷⁷

IV. THE PROS AND CONS OF TELEHEALTH USE FOR PEDIATRIC CARE

Like any new advancement in a particular field, the pros and cons of the use of telehealth for pediatric care are being scrutinized as a means of providing access to traditional health care services.¹⁷⁸

A. *Benefits of Telehealth in Pediatrics*

One of the major benefits of the use of telehealth in pediatrics is the access to care that is created for children who would otherwise be disadvantaged by distance/location or specialized health care needs.¹⁷⁹

There is significant disparity in the geographic distribution of pediatric physicians across the country, resulting in many underserved regions. Underserved communities are most commonly found in rural regions but can include suburban and urban settings. This maldistribution of workforce results in differential access and is at least partly to blame for differential health outcomes between rural and nonrural populations, particularly for those children with special health care needs. The literature shows that access barriers related to distance can be partly addressed with the use of telemedicine technologies, which can also minimize burdens of parents and other caregivers missing work, children missing school, and costs and risks associated with travel.¹⁸⁰

The availability of these services to children who would otherwise not have them also leads to a greater quality of care.¹⁸¹

Another benefit of the use of telehealth in pediatrics is that it can increase the expertise of pediatricians which, in turn, can increase the amount of time pediatricians have for treating additional children resulting in greater

176. *Id.*

177. *Id.*

178. See James P. Marcin et al., Comm. on Pediatric Workforce, *The Use of Telemedicine to Address Access and Physician Workforce Shortages*, 136 PEDIATRICS 202, 203–06 (2015).

179. *Id.* at 203, 205.

180. *Id.* at 203.

181. *Id.* at 204.

efficiency of pediatric care.¹⁸² As has been acknowledged, there is a shortage of pediatricians, and the ability of the current pediatricians to be able to care for more children is of vital importance to this specialty.¹⁸³

Additionally, it has been suggested that the use of telehealth in pediatrics can improve quality of care.¹⁸⁴ The AAP has cited multiple reasons why this is the case.¹⁸⁵

First, by increasing health care access for children, particularly for children living in rural communities, the use of telemedicine technologies can help reduce missed appointment rates, increase adherence to recommended therapies, and help ensure the appropriate frequency of recommended physician visits. Second, studies have shown that telemedicine can enhance both comfort and facility in managing specific medical subspecialty issues.¹⁸⁶

Further, the use of telehealth can not only improve communications between the pediatrician and patient/family but can also lead to ensuring more comprehensive care than the patient would have experienced otherwise.¹⁸⁷

B. *Disadvantages of Telehealth in Pediatrics*

Perhaps the biggest challenge facing telehealth practice involving pediatrics is that choosing to develop a startup—and what becomes a stand-alone practice—is not seen as being compatible to the current best practices for pediatrics, especially if it is truly divorced from in-person care.¹⁸⁸ Specifically, the AAP has cautioned that the model embraced by these types of telehealth service providers is contrary to the prevailing model for providing pediatric services.¹⁸⁹

The use of telemedicine care by virtual health care providers, such as those linked to retail-based clinics, entrepreneurs, or insurers whose business model is to provide health care services to patients via smart phone, laptop, or video-consult kiosk without a previous physician-patient relationship, previous medical history, or hands-on physical examination, other than what can be accessed via the

182. *Id.* at 203.

183. *See* Marcin et al., *supra* note 178, at 203.

184. *Id.* at 204.

185. *See id.*

186. *Id.*

187. *Id.* at 203.

188. Marcin et al., *supra* note 178, at 205.

189. *Id.* at 205–06.

technology, can undermine the basic principles of the [Patient-Centered Medical Home] model.¹⁹⁰

According to the AAP, “[i]n isolation, the use of virtual telemedicine care represents the antithesis of the medical home model of quality pediatric care: [C]are that is patient-centered, comprehensive, team-based, coordinated, accessible, and focused on quality and safety.”¹⁹¹ Additionally, the AAP raises a number of issues with regard to providing pediatric care in this way.¹⁹²

Virtual health care services are provided episodically and are lacking the essentials of the patient’s medical record. Increasing fragmentation of care is the result, which leads to incomplete or redundant services and wastes health care dollars. More importantly, virtual telemedicine care in isolation does not provide timely and comprehensive follow-up with the patient and the medical home.¹⁹³

The AAP cautions parents against relying on a telehealth model of care, arguing that while it may sound appealing for a variety of reasons, the model does not promote the best interests of the child’s health care.¹⁹⁴

A major disadvantage of having a telehealth practice are the significant costs associated with such a practice.¹⁹⁵ The AAP has described the extent of these costs as follows:

The implementation of telemedicine requires an initial financial investment in equipment, software, and telecommunications. There are often ongoing costs associated with maintenance of technology and personnel costs associated with training and technical support. These costs can represent a significant barrier for pediatric physicians and other clinicians who care for children. The underserved practices and locations most likely to benefit from telemedicine are probably those least likely to afford the initial financial investment or ongoing maintenance.¹⁹⁶

190. *Id.* at 205.

191. *Id.*

192. *Id.* at 206.

193. Marcin et al., *supra* note 178, at 206.

194. *Id.* at 206. “Although such novelty care appeals to parents because it can be faster, more convenient, and more affordable than an office visit, the loss of continuity of care, quality of care, and patient safety shows why this telemedicine care model should not be embraced.” *Id.*

195. *Id.*

196. *Id.*

This will be particularly burdensome to a telehealth startup which does not have the luxury of any connection to a hospital or medical facility to potentially assist in this type of financial investment.¹⁹⁷

Another challenge facing telehealth practitioners which has already been substantially addressed by the various legal issues is the fact that telehealth practice laws vary by state.¹⁹⁸ “All physicians practicing intra- and interstate telemedicine must comply with state licensing and other practice rules in every state in which they practice, in person and via telemedicine.”¹⁹⁹

An additional cost that must be inevitably born by the telehealth practitioner is to cover the cost of medical malpractice insurance, as previously discussed.²⁰⁰

Another potential barrier with additional costs associated with care delivery with the use of telemedicine is related to malpractice insurance. Malpractice insurance most often covers in-person care and should cover care delivered to patients in remote health care facilities and possibly in other states. Physicians should review their current malpractice policy to be certain that the appropriate malpractice coverage that includes the treatment of patients using telemedicine is included.²⁰¹

This type of medical malpractice coverage will be extremely important for a telehealth practitioner that decides to practice telehealth in multiple states.²⁰² As the telehealth practitioner engages in practice in multiple states, the practitioner will be subjected to the applicable telehealth laws in all of those states, thereby creating a greater chance for malpractice to occur as well as the liability that can attach for technology malfunctions or errors.²⁰³

V. CONCLUSION

With the continued shortage of pediatricians and the ability of technology to allow parents to access health care services for their children in a variety of situations—from those who are living in rural areas to those

197. See Marcin et al., *supra* note 178, at 206.

198. *Id.*

199. *Id.*

200. *Id.*

201. *Id.*

202. See Burke Jr. et al., *supra* note 3, at e300.

203. *Id.*; see also FLEISHER & DECHENE, *supra* note 36 § 1.04(4)(c).

children who have special needs which makes a doctor's house call virtually a less stressful scenario—telehealth offers a variety of benefits to ensure children have access to and receive necessary health care.²⁰⁴ However, it is also clear that for any pediatrician or physician to decide to engage in telehealth services to provide pediatric care, it is critical that he or she is aware of the possible legal issues, consequences, and role that state laws, in particular, will play in impacting any sort of telehealth practice.²⁰⁵ Further, specific guidelines, such as those provided by the AAP and ATA, are essential for the specialized nature of pediatrics in treating and serving children as a population.²⁰⁶

Additionally, the development of technologies for use by parents in the home to assess their children are still in their infancy, making it difficult for entities like the ATA to take a position on their use and effectiveness in providing access to health care for children, or providing guidance otherwise on the use of such technologies.²⁰⁷ Overall, technologies for use in pediatrics have been slow to develop and gain approval with the FDA, generally.²⁰⁸ It is expected that guidance on these newer in-home technologies will develop over time, as the evidence of their use becomes more prevalent.²⁰⁹ However, those who manufacture and sell these products need to be aware of the regulations they will be subjected to, including approval by the FDA for medical devices, liability for latent defects, and other security regulations.²¹⁰

For entrepreneurs in telehealth to be successful in pediatrics, they are going to need to develop innovative ways of ensuring that this vulnerable population does not inevitably experience a greater hindrance to receiving adequate health care by splintering the care, which creates gaps between the telehealth services they provide and health care provided by the child's primary pediatrician—assuming the child has an established pediatrician.²¹¹ A disruption of care of this nature is discouraged by the AAP guidance for pediatric care.²¹² An independent telehealth provider of pediatric care can and should be done through coordination with the child's primary pediatrician—if the child has one—and immediate follow-up to ensure medical records are not only consulted, but updated to reflect the telehealth

204. Marcin et al., *supra* note 178, at 203.

205. See Burke Jr. et al., *supra* note 3, at e300.

206. See AM. TELEMEDICINE ASS'N, *supra* note 1, at 1–3.

207. *Id.* at 3.

208. Jenco, *supra* note 149.

209. See *id.*

210. See FLEISHER & DECHENE, *supra* note 36, § 1.04(4)(c); Burke Jr. et al., *supra* note 3, at e299; *Medical Device Overview*, *supra* note 147.

211. See Burke Jr. et al., *supra* note 3, at e296.

212. See *id.*

appointment and treatment.²¹³ In the alternative, if a stand-alone telehealth practitioner is going to engage in pediatric service, it will need to make fundamental operational changes by having a face-to-face with the child from the beginning and as a regular part of continued care, so as to discourage reliance on episodic telehealth visits which is currently discouraged by best practice standards in pediatrics, as detailed by the AAP.²¹⁴ If the doctor makes house calls again—now virtually—it must be in a way that ultimately benefits the long-term care and well-being of the child, rather than simply providing episodic care that disrupts the continuity of care for the child.²¹⁵

213. See Marcin et al., *supra* note 178, at 204, 206.

214. See Burke Jr. et al., *supra* note 3, at e296, e300; Marcin et al., *supra* note 178, at 206.

215. See Burke Jr. et al., *supra* note 3, at e296.

FLORIDA LAW, MOBILE RESEARCH APPLICATIONS, AND THE RIGHT TO PRIVACY

STACEY A. TOVINO*

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I. INTRODUCTION

This Article builds on the Author’s prior work investigating the privacy and security implications of mobile application (“mobile app”) mediated health research¹ conducted by “independent scientists,² citizen

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1. See Sarah Moore et al., *Consent Processes for Mobile App Mediated Research: Systematic Review*, J. MED. INTERNET RES. MHEALTH & UHEALTH, Aug. 2017 at 3, 4 (discussing Apple’s ResearchKit and Android’s ResearchStack, two open source frameworks that any scientist can use to create a mobile research app); Vincent Tourraine, *List of All ResearchKit Apps*, SHAZINO: SCI. (Feb. 1, 2016), <http://blog.shazino.com/articles/science/researchkit-list-apps/> (listing more than a dozen mobile research apps designed using ResearchKit); *About the Study*, MPOWER, <http://parkinsonmpower.org/about> (last visited May 1, 2019) (describing a mobile app mediated research study that monitors the symptoms and progression of Parkinson’s disease).

2. See Amber Dance, *Solo Scientist*, 543 NATURE 747, 747 (2017) (reporting the story of Jeffrey Rose, an independent scientist who conducts research without the benefits of a traditional *bricks-and-mortar employer*); Carrie Arnold, *Going Rogue*, SCI. (May 17, 2013, 8:15 PM), <http://www.sciencemag.org/careers/2013/05/going-rogue> (reporting the story of Ethan Perlstein, an independent scientist who engages in scientific research without

scientists,³ and patient researchers⁴ (collectively, independent scientists)⁵ as well as [the] mobile app developers and data storage companies that support them.”⁶ As background, mobile “apps are a fast-growing category of software typically installed on personal smartphones and wearable devices.”⁷ Used for a wide range of health-related activities, including fitness, health education, health predictions, diagnosis, health care delivery, treatment support, chronic disease management, disease surveillance, epidemic outbreak tracking, and health research, mobile apps have tremendous versatility and promise.⁸

university, pharmaceutical company, research institute, or government agency affiliation, and without public funding).

3. See Mark A. Rothstein et al., *Citizen Science on Your Smartphone: An ELSI Research Agenda*, 43 J.L. MED. & ETHICS 897, 897 (2015) (explaining that the term citizen scientist originally referred to “nonprofessionals who assist[ed] professional scientists by contributing observations and measurements to ongoing research enterprises;” also explaining that the term “now includes nonprofessionals who conduct scientific experiments of their own design independent from professional scientists;” clarifying that citizen science has been made possible by “online crowdsourcing, big data capture strategies, and computational analytics,” among other technological developments); Todd Sherer, *Parkinson’s Disease at 200*, SCI. AM.: BLOGS (Apr. 12, 2017), <http://blogs.scientificamerican.com/guest-blog/parkinsons-disease-at-200/> (referencing technology that citizens use to participate in research investigating Parkinson’s disease).

4. See Jenny Leese et al., *Evolving Patient-Researcher Collaboration: An Illustrative Case Study of a Patient-Led Knowledge Translation Event*, J. PARTICIPATORY MED., no. 1, 2017, at 3, 3 (discussing patient engagement in research).

5. Paul Wicks et al., *Accelerated Clinical Discovery Using Self-Reported Patient Data Collected Online and a Patient-Matching Algorithm*, 29 NATURE BIOTECHNOLOGY 411, 411–12 (2011) (analyzing data reported on a website by patient researchers with Amyotrophic Lateral Sclerosis (“ALS”) who experimented with lithium carbonate).

6. Stacey A. Tovino, *Going Rogue: Mobile Research Applications and the Right to Privacy*, 95 NOTRE DAME L. REV. (forthcoming 2019) (manuscript at 4) (on file with author).

7. See Nicolas P. Terry & Tracy D. Gunter, *Regulating Mobile Mental Health Apps*, 36 BEHAV. SCI. & L. 136, 137 (2018) (providing background information regarding mobile health apps).

8. See Valerie Gay & Peter Leijdekkers, *Bringing Health and Fitness Data Together for Connected Health Care: Mobile Apps as Enablers of Interoperability*, J. MED. INTERNET RES., Nov. 2015, at 37, 37–38 (2015) (discussing fitness and health uses of mobile apps as well as the aggregation of such uses); Deborah Lupton & Annemarie Jutel, “*It’s Like Having a Physician in Your Pocket!*” *A Critical Analysis of Self-Diagnosis Smartphone Apps*, 133 SOC. SCI. & MED. 128, 128–30 (2015) (analyzing diagnostic uses of mobile apps, including the effects such apps have on the physician-patient relationship and medical authority in relation to diagnosis); Elaine O. Nsoesie et al., *New Digital Technologies for the Surveillance of Infectious Diseases at Mass Gathering Events*, 21 CLINICAL MICROBIOLOGY & INFECTION 134, 134–35 (2015) (focusing on disease surveillance uses of mobile apps and other digital technologies); Ben Underwood et al., *The Use of a Mobile App to Motivate Evidence-Based Oral Hygiene Behaviour*, 219 BRIT. DENTAL J. 166, 166 (2015) (reporting the

This Article focuses on independent scientists, citizen scientists, and patient researchers who use mobile apps to conduct or participate in health research.⁹ As background, an independent scientist—also known as a rogue or lone scientist—is an individual who engages in scientific research without university, pharmaceutical company, research institute, government agency, or other third-party affiliation.¹⁰ A citizen scientist—also known as a community scientist, crowd scientist, or amateur scientist—is a member of the general public who engages in scientific work, often in collaboration with or under the direction of a professional, affiliated scientist and the scientist’s academic or other institution.¹¹ Citizen scientists also include non-professionally trained scientists who independently conduct their own experiments, frequently with the assistance of mobile apps, online crowdsourcing, computational analytics, and other technologies made possible by big data.¹² A patient researcher is a current or former patient who initiates or assists research at any stage of the research process, including establishing the research agenda, designing the research protocol, collecting data, and disseminating research results.¹³ Mobile apps have been tremendously helpful to independent scientists, citizen scientists, and patient researchers, as well as conventional scientists who fall outside traditional

results of a study assessing user perceptions of an oral health app that provides oral health education and oral health behavioral support); Sharon Parmet, *App Developed at UIC to Track Mood, Predict Bipolar Disorder Episodes*, UIC TODAY (Jan. 15, 2019, 2:32 PM), <http://www.today.uic.edu/app-developed-at-uic-to-track-mood-predict-bipolar-disorder-episodes> (explaining that the mobile app BiAffect “unobtrusively monitors keyboard dynamics metadata, such as typing speed and rhythm, mistakes in texts, and the use of backspace and auto-correct” and that such data is then “analyzed using an artificial intelligence-based machine learning approach to identify digital biomarkers of manic and depressive episodes in people with bipolar disorder”); Sarah Peddicord, *FDA in Brief: FDA Launches New Digital Tool to Help Capture Real World Data from Patients to Help Inform Regulatory Decision-Making*, FDA (Nov. 6, 2018), <http://www.fda.gov/newsEvents/newsroom/FDAInBrief/ucm625228.htm> (“announcing the MyStudies app, . . . a new mobile technology designed to foster the collection of real world evidence via patients’ mobile devices” for health research and other purposes).

9. See discussion *infra* Parts II–IX.

10. See James Lovelock, *James Lovelock: We Need Lone Scientists*, INDEPENDENT: INDY/LIFE (Mar. 26, 2014, 1:00 PM), <http://www.independant.co.uk/life-style/health-and-families/features/james-lovelock-we-need-lone-scientists-9215280.html> (comparing affiliated scientists, who work in large corporations or for the government, with lone, or independent, scientists who work alone in their own laboratories).

11. See Rothstein et al., *supra* note 3, at 897; *Citizen Science*, OXFORD DICTIONARY, http://en.oxforddictionaries.com/definition/us/citizen_science (last visited May 1, 2019) (defining citizen scientist).

12. Rothstein et al., *supra* note 3, at 897 (explaining the development of the term citizen scientist).

13. See Leese et al., *supra* note 4, at 3 (discussing patient engagement in research).

regulation—collectively, independent scientists—in the conduct of a wide range of health research projects.¹⁴

As explained in the Author's other work, independent scientists who use mobile apps to conduct health research collect a wide variety of data regarding their research participants' health including, but not limited to, data regarding sexual health,¹⁵ occupational health,¹⁶ neurological health,¹⁷ and cardiovascular health.¹⁸ As one might imagine, this voluminous and diverse health data may be at risk of privacy and security breaches, leading to dignitary, psychological, and economic harms for which the mobile research participants have few legally enforceable rights or remedies due to a lack of regulation and applicable standards.¹⁹

In a forthcoming publication, the Author analyzes existing federal statutes and regulations designed to protect the privacy and/or security of health data, including data generated in the research context.²⁰ In that article, the Author shows that a variety of federal authorities, including the Health Insurance Portability and Accountability Act ("HIPAA") Administrative Simplification Rules,²¹ the Common Rule,²² and the Federal Trade

14. See Elizabeth Klemick, *Mobile Apps for Citizen Science*, SMITHSONIAN SCI. EDUC. CTR. (July 15, 2018), <http://www.ssec.si.edu/stemvisions-blog/mobile-apps-citizen-science>. "An abundance of mobile apps makes participation in citizen science projects easier than ever and allows data entry in the field." *Id.*

15. See Tovino, *supra* note 6, at 9 (discussing Kinsey Reporter, a mobile research app that collects sexual health data from research participants).

16. See *id.* at 10–11 (discussing Active Day and Fall Safety Pro, two mobile apps that collect fall data from workers, such as painters and roofers, who experience falls from height).

17. See *id.* at 11–12 (discussing Patients Like Me, a mobile app that collects all types of health data, including Parkinson's symptoms and other neurological health data, and discloses that data for research purposes).

18. See *id.* at 13 (discussing MyFitnessPal, a mobile app that collects health and fitness data and discloses that data for research purposes).

19. See *Opperman v. Path, Inc.*, 205 F. Supp. 3d 1064, 1073 (N.D. Cal. 2016) (explaining that the mobile app Yelp exceeded the scope of its users' consent when it uploaded its users' contacts data without explicit permission); Mark A. Rothstein, *Ethical Issues in Big Data Health Research*, 43 J.L. MED. & ETHICS 425, 426–27 (2015) (discussing physical and dignitary harms associated with the loss of privacy in the context of big data health research); Zeynep Tufekci, *The Latest Data Privacy Debacle*, N.Y. TIMES (Jan. 30, 2018), <http://www.nytimes.com/2018/01/30/opinion/strava-privacy.html> (reporting the mobile exercise app Strava, which inadvertently revealed the secret locations of American military bases and service members).

20. See Tovino, *supra* note 6, at 16–17 (analyzing existing federal statutes and regulations designed to protect the privacy and/or security of health data).

21. See *id.* at 2–3, 16–17; Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 1, 110 Stat. 1936, 1936 (codified as amended at 42 U.S.C. § 201 (2012)); Health Information Technology for Economic and Clinical Health Act, Pub. L. No. 111-5, § 13001, 123 Stat. 226, 226 (2009) (codified as amended in scattered sections of

Commission Act,²³ either: (1) do not apply to mobile app mediated health research conducted by independent scientists; or (2) fail to establish comprehensive data privacy and security standards that will drive the implementation of privacy and security best practices by independent scientists.²⁴

In response to these lapses in federal regulation, many academics and practitioners have suggested new federal laws or amendments to existing federal laws in an attempt to create comprehensive privacy and security standards that, once implemented, may help protect otherwise unprotected data.²⁵ It is not clear, however, whether the federal government has the

42 U.S.C.). HHS's privacy regulations, which implement section 264(c) of HIPAA, are codified at 45 C.F.R. §§ 164.500–534 (2018). 45 C.F.R. §§ 164.500–534 (2018). HHS's security regulations, which implement section 262(a) of HIPAA [42 U.S.C. § 1320d–2(d)(1)], are codified at 45 C.F.R. §§ 164.302–318. *Id.* §§ 164.302–318. HHS's breach notification regulations, which implement section 13402 of HITECH [42 U.S.C. § 17932], are codified at 45 C.F.R. §§ 164.400–414. *Id.* §§ 164.400–414. Collectively, the HIPAA Privacy Rule, the HIPAA Security Rule, and the HIPAA Breach Notification Rules are known as the HIPAA Administrative Simplification Rules. *See id.* §§ 164.302–534.

22. *See* 45 C.F.R. 46.101–409 (2018); Federal Policy for the Protection of Human Subjects, 83 Fed. Reg. 28,497, 28,518 (June 19, 2018) (to be codified at 49 C.F.R. pt. 11) (showing changes to HHS's Common Rule with which compliance is required by July 21, 2019); Mark A. Rothstein, *Currents in Contemporary Ethics: Research Privacy Under HIPAA and the Common Rule*, 33 J.L. MED. & ETHICS 154, 155 (2005) (explaining the application of the Common Rule).

23. *See* 15 U.S.C. § 45(a)(1) (2012). “Unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce, are hereby declared unlawful.” *Id.*

The FTC has brought legal actions against organizations that have violated consumers' privacy rights, or misled them by failing to maintain security for sensitive consumer information . . . [i]n many of these cases, the FTC has charged the defendants with violating Section 5 of the FTC Act, which bars unfair and deceptive acts and practices in or affecting commerce.

Privacy and Security Enforcement, FTC, <http://www.ftc.gov/news-events/media-resources/protecting-consumer-privacy/privacy-security-enforcement> (last visited May 1, 2019).

24. *See* FLA. STAT. § 501.171(1)(b) (2018); Sharona Hoffman, *Citizen Science: The Law and Ethics of Public Access to Medical Big Data*, 30 BERKELEY TECH. L.J. 1741, 1746 (2015); Tovino, *supra* note 6, at 15 (discussing the application of these federal authorities in detail and noting which apply and which contain privacy and security standards).

25. *See* David W. Bates et al., *Health Apps and Health Policy: What Is Needed?*, 320 JAMA 1975, 1975 (2018). “The FDA also needs to review apps specifically with respect to safety, protection of privacy, and false claims.” *Id.* “[I am] sure there will be some major breaches that just might push the drive for national legislation over the top.” James Swann, *That Apple Watch May Show Hackers Your Heart's Health*, BLOOMBERG L.: HEALTH L. & BUS. (Oct. 18, 2018, 6:15 AM), <http://www.bloomberglaw.com/health-law-and-business/that-apple-watch-may-show-hackers-your-hearts-health> [hereinafter *Apple Watch*] (quoting a prominent health care attorney); James Swann, *Video: Your Fitbit Steps May Not*

desire or capacity to enforce expanded or new laws in this area.²⁶ In an earlier publication, the Author found that a consumer complaint involving a violation of the HIPAA Administrative Simplification Rules has a 0.1% chance of triggering a government-imposed settlement or civil money penalty.²⁷ In that same article, the Author showed that in those few cases that go to settlement or penalty, the federal government takes a significant amount of time—more than seven years in some cases—to execute the settlement agreement or to impose the civil money penalty.²⁸ The Author concluded that the federal desire and/or capacity to enforce the HIPAA Administrative Simplification Rules is low, resulting in a lack of timely attention to the privacy and security rights of individuals.²⁹

This Article furthers the line of research by investigating whether state law contains comprehensive privacy, security, and breach notification standards that could apply to independent scientists who conduct mobile app mediated health research.³⁰ Focusing only on Florida law, this Article assesses potentially relevant and applicable sources of privacy, security, and breach notification standards for health data of the type obtained during mobile app mediated health research studies.³¹ This Article concludes that, with one exception, Florida law tends to fall into one of two categories: (1) the law contains at least one data privacy, security, or breach notification standard, but the standard is limited in application to certain actors, certain professions, or certain institutions and the law does not apply to independent scientists,³² or (2) the law is not necessarily limited in application, but the law fails to establish comprehensive privacy, security, and breach

Be Protected by Federal Law, BLOOMBERG L.: NEWS (May 30, 2018), www.bna.com/video-fitbit-steps-n57982093031/ [hereinafter *Fitbit*]. “[It is] almost certain that the federal government will look to regulate health information [that is] not subject to HIPAA” *Fitbit, supra*.

26. See Sarah Fellay, *Changing the Rules of Health Care: Mobile Health and Challenges for Regulation*, AM. ENTERPRISE INST.: TECH & INNOVATION (Aug. 4, 2014), <http://www.aei.org/publication/changing-the-rules-of-health-care-mobile-health-and-challenges-for-regulation/>.

27. Stacey A. Tovino, *A Timely Right to Privacy*, 104 IOWA L. REV. (forthcoming 2019).

28. *Id.*

29. *See id.*

30. *See* discussion *infra* Part X.

31. *See* discussion *infra* Part X; Tovino, *supra* note 6, at 9–10, 12–13 (providing several examples of health data collected by mobile research apps).

32. FLA. STAT. §§ 282.318, 381.026, 395.001, 408.051, 456.003 (2018); *see also* FLA. CONST. art I, § 23.

notification standards that will drive the implementation of privacy and security best practices by independent scientists.³³

As discussed in more detail below, Florida laws that fall into the first category include the Florida Constitution,³⁴ Florida's health institution licensing laws,³⁵ Florida's health professional licensing laws,³⁶ the Florida Electronic Health Records Exchange Act ("Health Records Act"),³⁷ the Florida Information Technology Security Act ("Florida ITS Act"),³⁸ and the Florida Patient's Bill of Rights and Responsibilities ("Patient Bill of Rights").³⁹ Florida laws that fall into the second category include the Florida Information Protection Act ("FIPA")⁴⁰ and Florida common law.⁴¹ This Article concludes that FIPA, which contains data security and breach notification standards that will apply to some—but not all—dependent scientists who conduct mobile app mediated research, is the best option for protecting mobile app mediated research data going forward.⁴² This Article proposes amendments to FIPA that are designed to protect the privacy and security of all big data subjects, including mobile app mediated health research participants.⁴³

II. THE FLORIDA CONSTITUTION

Article I, Section 23 of the Florida Constitution provides: "Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein."⁴⁴ Although the Florida Supreme Court has stated that the phrase *natural person* includes all Floridians, even minors and individuals who are incompetent, the phrase *governmental intrusion* makes clear that the Florida Constitution only protects individuals against governmental—not private—intrusions.⁴⁵ Although mobile app mediated research certainly can be

33. See FLA. STAT. § 501.171; *Florida Common Law*, WITHOUT MY CONSENT, <http://www.withoutmyconsent.org/50state/state-guides/florida/common-law#> (last visited May 1, 2019).

34. See FLA. CONST. art. I, § 23.

35. See FLA. STAT. § 395.001.

36. See *id.* § 456.003.

37. See *id.* § 408.051.

38. See *id.* § 282.318.

39. See *id.* § 381.026.

40. See FLA. STAT. § 501.171.

41. See *Florida Common Law*, *supra* note 33.

42. Discussion *infra* Part X; see also FLA. STAT. § 501.171.

43. Discussion *infra* Part X; see also FLA. STAT. § 501.171.

44. FLA. CONST. art. I, § 23.

45. *Id.*; *In re Guardianship of Browning*, 568 So. 2d 4, 12 (Fla. 1990) (in the context of a request for the discontinuation of medical treatment with respect to individuals

conducted by an agent of the Florida—or any other—government,⁴⁶ this Article focuses on private health research conducted or facilitated by mobile apps such as: Kinsey Reporter;⁴⁷ Active Day;⁴⁸ Patients Like Me;⁴⁹ and My Fitness Pal.⁵⁰ Described in detail in the Author’s prior work,⁵¹ these apps are neither sponsored, supported, nor affiliated with any governmental agency or agent thereof.⁵² As a result, the Florida Constitution is inapplicable to the issue on which this Article focuses.⁵³

Assuming for the moment that the Florida Constitution did apply to mobile app mediated research conducted by private, independent scientists, Floridians do have a constitutionally protected interest in their health-related data.⁵⁴ However, neither the Florida Constitution nor its interpretive case law sets forth particular privacy, security, and breach notification standards that could help protect that data, or that could minimize the risk of an

who are incompetent); *In re T.W.*, 551 So. 2d 1186, 1193 (Fla. 1989) (in the context of abortion with respect to minors); Ben F. Overton & Katherine E. Giddings, *The Right of Privacy in Florida in the Age of Technology and the Twenty-First Century: A Need for Protection from Private and Commercial Intrusion*, 25 FLA. ST. U. L. REV. 25, 26 (1997). “[I]t is critical to recognize that this [constitutional] provision protects only against intrusions by the government. It does nothing to protect citizens from intrusions by private or commercial entities. . . . [T]he provision provides no protection from private or commercial intrusion because the present provision is limited to governmental intrusions.” Overton & Giddings, *supra* at 26, 41.

46. See Peddicord, *supra* note 8 (“announcing the MyStudies app, a new mobile technology [designed] to foster the collection of real-world evidence via patients’ mobile devices” for health research and other purposes).

47. See Clayton A. Davis et al., *Kinsey Reporter: Citizen Science for Sex Research*, ARXIV, <http://arxiv.org/pdf/1602.04878.pdf> (last visited May 1, 2019) (using Kinsey Reporter, “[c]itizen sex scientists submit reports, each consisting of one or more surveys, after participating in or observing sexual activity. Surveys cover topics such as flirting, sexual activity, unwanted experience, consumption of pornography, and hormonal birth control side effects”); *Kinsey Reporter*, APP STORE, <http://itunes.apple.com/us/app/kinsey-reporter/id533205458?mt=8> (last visited May 1, 2019) [hereinafter *Kinsey Reporter: Apple Store*]; *Kinsey Reporter*, GOOGLE PLAY, http://play.google.com/store/apps/details?id=com.kinsey.android&hl=en_us (last visited May 1, 2019) [hereinafter *Kinsey Reporter: Google Play*].

48. *ActiveDay — Activity Study*, APP STORE, <http://itunes.apple.com/us/app/activeday-activity-study/id1183046259?mt=8> (last visited May 1, 2019).

49. *PatientsLikeMe*, APP STORE, <http://itunes.apple.com/us/app/patientslikeme/id955272281?mt=8> (last visited May 1, 2019).

50. *MyFitnessPal*, APP STORE, <http://itunes.apple.com/us/app/myfitnesspal/id341232718?mt=8> (last visited May 1, 2019).

51. Tovino, *supra* note 6, at 9–14.

52. See *id.* at 9–14.

53. See *id.*; FLA. CONST. art. I, § 23.

54. See *State v. Tamulonis*, 39 So. 3d 524, 528 (Fla. 2d Dist. Ct. App. 2010). “An individual has a privacy interest in his or her prescription records.” *Id.*

unconstitutional intrusion.⁵⁵ Florida case law simply makes clear that, in assessing a claim for an unconstitutional privacy intrusion, a court shall:

[D]etermine whether the individual possesses a legitimate expectation of privacy in the information or subject at issue . . . [i]f so, the burden shifts to the State to show that . . . there is a compelling state interest warranting the intrusion into the individual's privacy, and . . . that the intrusion is accomplished by the least intrusive means.⁵⁶

The keys to a constitutional inquiry, thus, are a legitimate expectation of privacy, a compelling state interest, and the means of the intrusion—not adherence to particular privacy, security, and breach notification standards.⁵⁷

III. FLORIDA HEALTH INSTITUTION LICENSING LAWS

Although the Florida Constitution does not contain particular privacy, security, or breach notification standards, a number of other Florida laws do contain privacy standards applicable to physical and mental health data of the type collected by mobile health apps and mobile research apps.⁵⁸ That said, many of these additional laws only apply to licensed health care institutions, not independent scientists who, by definition, do not work for or within any type of institution.⁵⁹ For example, Florida's hospital licensing law, codified at Chapter 395 of the Florida Statutes, contains privacy standards applicable to patient records.⁶⁰ In particular, Chapter 395 defines a patient record as a system that includes the following elements: “[B]asic client data collection; a listing of the patient's problems; the initial plan with diagnostic and therapeutic orders as appropriate for each problem identified; and progress notes, including a discharge summary.”⁶¹ Chapter 395 then establishes individual rights requirements as well as use and disclosure requirements—similar to those set forth in the HIPAA Privacy Rule—

55. See *id.*; compare FLA. CONST. art. I, § 23, with Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 1, 110 Stat. 1936, 1936 (codified as amended at 42 U.S.C. § 201 (2012)) (setting forth particular privacy, security, and breach notification standards).

56. *Tamulonis*, 39 So. 3d at 528.

57. See *id.*

58. FLA. STAT. §§ 395.3015, .3025(4)–(11) (2018); see also FLA. CONST. art. I, § 23.

59. FLA. STAT. §§ 395.3015, 395.3025(1).

60. *Id.* §§ 395.3015, 395.3025(1).

61. *Id.* § 395.3015.

relating to these records.⁶² For example, Chapter 395 gives Florida hospital patients the right to obtain a copy of their patient records.⁶³ By further example, Chapter 395 establishes that hospital patients' records are confidential and may not be disclosed without the prior consent of the patient.⁶⁴ However, Chapter 395 also establishes several exceptions to this prior consent requirement, including when the patient records are needed for treatment, risk management and quality assurance activities, trauma registry purposes, organ procurement activities, and epidemiological investigations.⁶⁵ Although the data collected and maintained by Florida hospitals in patient records are similar in type and kind to the data obtained by some independent scientists through some mobile health and mobile research apps, hospitals are heavily regulated by the privacy standards referenced in this paragraph but independent scientists—who, by definition, work independent of an institution—are not.⁶⁶

By further illustrative example, Florida's nursing home licensing law, codified within Chapter 400 of the Florida Statutes, establishes certain nursing home patient rights, including the right of nursing home patients to privacy in treatment and to confidentiality of personal and medical records.⁶⁷ Although the information collected by nursing homes about their residents is similar in type and kind to that obtained by some independent scientists using some mobile health research apps,⁶⁸ nursing homes are required to comply with a variety of privacy standards set forth in the Florida nursing

62. Compare FLA. STAT. § 395.3015, and FLA. STAT. § 395.3025(1), with 45 C.F.R. § 164.520 (2018) (establishing the HIPAA Privacy Rule's individual rights requirements), and 45 C.F.R. § 164.502 (2018) (establishing the HIPAA Privacy Rule's use and disclosure requirements).

63. FLA. STAT. § 395.3025(1).

64. *Id.* § 395.3025(4).

65. *Id.* § 395.3025(4)(a), (4)(b), (4)(f), (4)(i), (5).

66. Compare FLA. STAT. § 395.3015 (defining the content of a patient record for purposes of the Florida hospital licensing law), with *PatientsLikeMe*, *supra* note 49 (collecting information regarding app users' diagnoses, symptoms, and treatments; charting users' daily and monthly symptom progress; disclosing such information to partners of PatientsLikeMe for research purposes).

67. FLA. STAT. §§ 400.011, 400.022(1)(m), 400.20.

68. See *Elderly Hip Fracture: Prevention and Treatment*, PLACE FOR MOM, <http://www.aplaceformom.com/planning-and-advice/articles/hip-fractures-in-the-elderly> (last visited May 1, 2019) (noting that individuals who are elderly may fall, sustain a hip fracture, and receive care for that fracture in a nursing home); *ActiveDay — Activity Study*, *supra* note 48 (a mobile research app that collects, among other information, information regarding whether an app user has fallen); *FallSafety Pro — Safety Alerts*, APP STORE, <http://itunes.apple.com/us/app/fallsafety-pro-safety-alerts/id870864283?mt=8> (last visited May 1, 2019) (a mobile occupational safety and health app that collects information regarding whether a user has fallen, the number of time the user has fallen, and whether a first responder was called to assist the fallen user).

home licensing law, whereas independent scientists do not have the same obligations.⁶⁹

As a final illustrative example, Florida's hospice licensing law, also codified within Chapter 400 of the Florida Statutes, defines and establishes uses and disclosure requirements relating to interdisciplinary records of hospice patients.⁷⁰ In particular, the hospice licensing law requires hospices to maintain an "up-to-date, interdisciplinary record of care being given and patient and family status. Records shall contain pertinent past and current medical, nursing, social, and other therapeutic information and such other information that is necessary for the safe and adequate care of the patient."⁷¹ The hospice licensing law further provides that the interdisciplinary record as well as related billing records are confidential and may not be disclosed, although exceptions exist for certain situations, including those involving an authorization executed by the patient or an order by a court of competent jurisdiction ordering the release of the interdisciplinary record.⁷² Although the information collected by hospices about their terminally ill patients is similar in type and kind to that obtained by some independent scientists through some mobile health research apps, hospices are required to comply with the privacy requirements set forth in Florida's hospice licensing law, whereas independent scientists are not.⁷³

IV. FLORIDA HEALTH PROFESSIONAL LICENSING LAWS

In addition to health institution licensing laws, a number of additional Florida laws contain privacy standards applicable to physical and mental health data of the type collected by mobile health apps and mobile research apps.⁷⁴ However, many of these laws only apply to certain licensed health care professionals, not non-provider independent scientists whose

69. See Rothstein et al., *supra* note 3, at 897, 899; *Nursing Home Regulations — State Laws and Nursing Homes*, NURSING HOME ABUSE GUIDE, <http://nursinghomeabuseguide.com/legal-action/nursing-home-regulations/> (last visited May 1, 2019).

70. FLA. STAT. § 400.611.

71. *Id.* § 400.611(1).

72. *Id.* § 400.611(3)–(4).

73. See *id.* § 400.611(1) (requiring hospice records to "contain pertinent past and current medical, nursing, social, and other therapeutic information . . . necessary for the safe and adequate care of [hospice] patient[s]," who, by definition, have a terminal illness); *ALS Mobilizer Analyzer*, GOOGLE PLAY, http://play.google.com/store/apps/details?id=com.prizeforlife.healthcare&hl=en_US (last visited May 1, 2019) (a mobile research app used to investigate disease progression in ALS, a progressive and terminal disease); *Nursing Home Regulations — State Laws and Nursing Homes*, *supra* note 69.

74. FLA. STAT. §§ 395.3015, 395.3025, 400.011, 400.611, 456.013, 456.059.

training is in software engineering, information systems, marketing, and communications.⁷⁵ For example, Chapter 456 of the Florida Statutes establishes general licensing requirements for physicians and other health care practitioners who practice a health profession in Florida.⁷⁶ With respect to practitioners who are psychiatrists, Chapter 456 specifically states that “[c]ommunications between a patient and a psychiatrist . . . shall be held confidential and shall not be disclosed except upon the request of the patient or the patient’s legal representative.”⁷⁷ Chapter 456 further explains, however, that a psychiatrist may disclose patient communications to the extent necessary to warn a potential victim or to communicate a threat to a law enforcement agency when:

(1) A patient is engaged in a treatment relationship with a psychiatrist; (2) [the] patient has made an actual threat to physically harm an identifiable victim or victims; and (3) [t]he treating psychiatrist makes a clinical judgment that the patient has the apparent capability to commit such an act and that it is more likely than not that in the near future the patient will carry out that threat.⁷⁸

The general rule requiring psychiatrist confidentiality is designed to encourage patients with mental health conditions to fully disclose their past diagnoses and treatments as well as their current “[m]ood, level of anxiety, thought content, . . . and perception and cognition” to enable the psychiatrist to accurately diagnose and treat the patient.⁷⁹ The general rule, combined with the three exceptions, is also designed to remind the psychiatrist that each patient’s history, physical, and other information must be maintained in confidence and is not to be disclosed except in discrete situations in which

75. *See About Us*, FALLSAFETY, <http://www.fallsafetyapp.com/about-us> (last visited May 1, 2019) (noting that the FallSafety employees responsible for developing several occupational safety and health mobile apps, including the FallSafety Pro, Lone Worker Pro, and Worker Safety Pro apps, include “safety-oriented engineers, keen-eyed designers, disciplined quality assurance people, passionate marketers and business development professionals, advanced researchers and technology innovators,” but not licensed health care professionals).

76. FLA. STAT. § 456.013.

77. *Id.* § 456.059.

78. *Id.*

79. *See* AM. PSYCHIATRIC ASS’N, PRACTICE GUIDELINES FOR THE PSYCHIATRIC EVALUATION OF ADULTS 6, 9 (3d ed. 2015) (stating as a guideline that a psychiatrist should obtain this information during an initial psychiatric evaluation of a patient; further stating, “[t]he goal of this guideline is to improve the quality of the doctor-patient relationship, the accuracy of psychiatric diagnoses, and the appropriateness of treatment selection.”).

the public interest outweighs the patient's right to confidentiality.⁸⁰ Interestingly, the information obtained by psychiatrists—including information regarding past diagnoses and treatments as well as current mood, level of anxiety, and thought content—is very similar to the information obtained by a number of mobile health apps and mobile research apps.⁸¹ Although Florida psychiatrists are heavily regulated by privacy standards set forth in Chapter 456 of the Florida Statutes, non-provider independent scientists who conduct mobile app mediated research are not.⁸²

By further illustrative example, Chapter 490 of the Florida Statutes establishes licensure requirements for clinical psychologists who practice in Florida.⁸³ In the legislative intent section of Chapter 490, the Florida Legislature explains that:

[A]s society becomes increasingly complex, emotional survival is equal in importance to physical survival. Therefore, in order to preserve the health, safety, and welfare of the public, the Legislature must provide privileged communication for members of the public or those acting on their behalf to encourage needed or desired psychological services to be sought out.⁸⁴

To this end, Chapter 490 establishes a general rule that, “[a]ny communication[s] between [a psychologist] and her or his patient or client

80. See FLA. STAT. § 456.059.

81. See AM. PSYCHIATRIC ASS'N, *supra* note 79, at 5, 6; compare Parmet, *supra* note 8 (explaining that the mobile research app BiAffect “unobtrusively monitors keyboard dynamics metadata, such as typing speed and rhythm, mistakes in texts, and the use of backspace and auto-correct [and that such data is then] analyzed using an artificial intelligence-based machine learning approach to identify digital biomarkers of manic and depressive episodes in people with bipolar disorder”), with Olwen Glynn Owen, *Bipolar Disorder: Psychiatrists Are Taking a New Approach that Aims to Treat Not Just Symptoms but the Whole Person*, MED. NEWS TODAY (July 18, 2007), <http://www.medicalnewstoday.com/articles/77227.php> (discussing the traditional treatment of patients with bipolar disorder by psychiatrists); compare *Featured Conditions at PatientsLikeMe*, PATIENTSLIKEME: CONDITIONS, <http://www.patientslikeme.com/conditions> (last visited May 1, 2019) (noting that the PatientsLikeMe mobile app collects symptom data from patients who have a number of mental and behavioral health conditions, including drug addiction and alcohol addiction), with PSYCHOL. TODAY: YAHYA SAEED (Feb. 15, 2019), http://www.psychologytoday.com/us/psychiatrists/yahya-saeed-houston-tx/391190?sid=1545765952.5073_17507&city=San+Antonio&state=TX&spec=248&ref=1&tr=ResultsName (profiling a traditional psychiatrist who treats patients and collects information regarding patients with alcohol and drug addiction).

82. See FLA. STAT. § 456.059; *Who Regulates All These Health-Related Apps?*, HEALTHLINE, <http://www.healthline.com/health-news/who-regulates-all-these-health-related-apps#1> (last visited May 1, 2019).

83. FLA. STAT. §§ 490.005–.006.

84. *Id.* § 490.002.

shall be confidential.”⁸⁵ Chapter 490 allows the privilege to be waived in only three situations:

(1) When the [psychologist] is a . . . defendant [in a legal] action arising from a complaint filed by the patient, . . . in which case the waiver [is] limited to that [legal] action; (2) [w]hen the patient . . . agrees to the waiver, in writing, or when more than one person in a family is receiving therapy, when each family member agrees to the waiver, in writing; [or] (3) [w]hen there is a clear and immediate probability of physical harm to the patient or client, to other individuals, or to society and the [psychologist] communicates the information only to the potential victim, appropriate family member, or law enforcement or other appropriate authorities.⁸⁶

Although psychologists may obtain information that is similar in type and kind to that obtained by non-psychologist independent scientists through a mobile health or health research app, psychologists are heavily regulated by the privacy standards referenced in this section whereas independent scientists are not.⁸⁷

Similarly, Chapter 490 and 491 of the Florida Statutes establishes licensure requirements for psychotherapists, clinical social workers, marriage and family therapists, and mental health counselors.⁸⁸ In the legislative intent section of Chapter 491, the Florida Legislature explains that:

[A]s society becomes increasingly complex, emotional survival is equal in importance to physical survival. Therefore, in order to preserve the health, safety, and welfare of the public, the Legislature must provide privileged communication for members of the public or those acting on their behalf to encourage needed or desired counseling, clinical and psychotherapy services, or certain other services of a psychological nature to be sought out.⁸⁹

85. *Id.* § 490.0147.

86. *Id.*

87. *See id.*; compare *Parmet*, *supra* note 8 (explaining that the mobile research app BiAffect “unobtrusively monitors keyboard dynamics metadata, such as typing speed and rhythm, mistakes in texts, and the use of backspace and auto-correct [and that such data is then] analyzed using an artificial intelligence-based machine learning approach to identify digital biomarkers of manic and depressive episodes in people with bipolar disorder”), with *Culbertson v. Culbertson*, 455 S.W.3d 107, 113 (Tenn. Ct. App. 2014) (discussing a child custody case involving a father with bipolar disorder and legal questions relating to waiver of the psychologist-patient privilege).

88. FLA. STAT. §§ 490.0051, 491.0046.

89. *Id.* § 491.002.

To this end, Chapter 491 provides that, “[a]ny communication between [a mental health counselor] and her or his patient or client shall be confidential.”⁹⁰ Chapter 491 permits waiver of this secrecy only:

(1) When the [mental health counselor] is a party defendant to a [legal] action arising from a complaint filed by the patient . . . in which case the waiver [is] limited to that [legal] action; (2) [w]hen the patient . . . agrees to the waiver in writing; or . . . (3) [w]hen, in the clinical judgment of the [mental health counselor], there is a clear and immediate probability of physical harm to the patient or client, to other individuals, or to society and the [mental health counselor] communicates the information only to the potential victim, appropriate family member, or law enforcement or other appropriate authorities.⁹¹

Although Florida’s mental health counselors may obtain information that is similar in type and kind to that obtained by non-counselor independent scientists through a mobile health or mobile research app, mental health counselors are heavily regulated by the privacy standards set forth in this section whereas independent scientists are not.⁹²

The examples above involve psychiatrists, psychologists, and mental health counselors.⁹³ As background for this initial focus, many mobile health apps are specifically designed to help individuals with their mental health.⁹⁴ However, non-mental health practitioners also are required to adhere to privacy standards set forth in Florida law.⁹⁵ Again, however, these standards apply only to health care practitioners, not non-practitioner independent scientists.⁹⁶ For example, one provision within Chapter 456 of the Florida Statutes regulates a *records owner*, defined as:

90. *Id.* § 491.0147.

91. *Id.*

92. *See id.* §§ 491.0147, 491.002; *Independent Scientists: Young Researchers Producing Remarkable Research*, MANA, <http://www.nims.go.jp/mana/about/independent.html> (last visited May 1, 2019); compare Pooja Chandrashekar, *Do Mental Health Mobile Apps Work: Evidence and Recommendations for Designing High-Efficacy Mental Health Mobile Apps*, MHEALTH, Mar. 23, 2018, at 1, 3 (noting that mobile mental health apps “enable users to self-monitor their mood by periodically reporting their thoughts, behaviors, and actions”), with *Gracey v. Eaker*, 837 So. 2d 348, 357 (Fla. 2002) (noting that the defendant psychotherapist obtained—and then shared without consent—confidential mental health information).

93. FLA. STAT. §§ 456.059, 490.0051, 490.0147, 491.0046.

94. Terry & Gunter, *supra* note 7, at 136 (discussing mobile mental health apps).

95. FLA. STAT. § 456.057.

96. *Id.* § 456.057(1).

[A]ny health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; [and] any health care practitioner's employer, including, but not limited to, group practices and staff-model health maintenance organizations, provided the employment contract or agreement between the employer and the health care practitioner designates the employer as the records owner.⁹⁷

This provision then requires health care practitioners and records owners to give “copies of all reports and records relating to [their] examination [and] treatment” to patients upon request.⁹⁸ This provision also prohibits the furnishing of such records, or the discussion of a patient's medical condition, with any person other than the patient, without patient authorization, unless an exception applies.⁹⁹ To the extent an individual conducting mobile app mediated health research is a non-practitioner scientist, software engineer, or other businessperson, the provisions discussed in this paragraph will not apply.¹⁰⁰ Again, these privacy standards are limited in application to health care practitioners.¹⁰¹

V. THE HEALTH RECORDS ACT

In addition to Florida laws that impose privacy requirements on health care institutions and health care professionals as a condition of licensure, additional Florida laws seek to regulate the electronic exchange of health records.¹⁰² However, these laws also only apply to licensed health care professionals, not to non-provider independent scientists.¹⁰³ For example, the Health Records Act, codified in Chapter 408 of the Florida Statutes, required the Florida Agency for Health Care Administration to develop, by the year 2010, a universal patient authorization form that “may be used by a health care provider to document patient authorization for the use or [disclosure] of an identifiable health record.”¹⁰⁴ As background, the Health Records Act defines *health record* as “any information, recorded in any form or medium, which relates to the past, present, or future health of an

97. *Id.*

98. *Id.* § 456.057(6).

99. *Id.* § 456.057(7)(a).

100. *See* FLA. STAT. § 456.057(7)(a).

101. *Id.*

102. *See id.* § 408.051.

103. *Id.*

104. *Id.* § 408.051(4)(a).

individual for the primary purpose of providing health care and health-related services.”¹⁰⁵ The Health Records Act further defines *identifiable health record* as “any health record that identifies the patient or with respect to which there is a reasonable basis to believe the information can be used to identify the patient.”¹⁰⁶

Pursuant to the terms of the Health Records Act, “[a] health care provider receiving [a universal] authorization form containing a request for the release of an identifiable health record [is required to] accept the form as a valid authorization to release an identifiable health record.”¹⁰⁷ In addition, “[t]he exchange by a health care provider of an identifiable health record upon receipt of an authorization form completed and submitted in accordance with [the Health Records Act] creates a rebuttable presumption that the release of the identifiable health record was appropriate.”¹⁰⁸ Moreover, “[a] health care provider that exchanges an identifiable health record upon receipt of an authorization form [is] deemed to have [not] violated or waived any privilege protected under [Florida law].”¹⁰⁹ Finally, the Health Records Act specifies that the release of an identifiable health record of a patient without the patient’s authorization is permitted for “the treatment of the patient for an emergency medical condition.”¹¹⁰

Although the health data collected by a mobile research app could easily fit within the definition of a *health record*, the privacy standards set forth within the Health Records Act only apply to health care providers, not non-provider scientists.¹¹¹ Stated another way, the Health Records Act’s universal authorization form provisions have no application to the context of mobile app mediated health research conducted by independent scientists.¹¹²

VI. FLORIDA ITS ACT

Although many of the laws discussed above are limited in application to health industry participants, Florida has a number of additional laws that establish security standards that, in theory, could help protect physical and mental health data of the type collected by independent scientists who use mobile health apps and mobile research apps.¹¹³ For

105. FLA. STAT. § 408.051(2)(d).

106. *Id.* § 408.051(2)(e).

107. *Id.* § 408.051(4)(c).

108. *Id.* § 408.051(4)(e).

109. *Id.* § 408.051(4)(f).

110. FLA. STAT. § 408.051(3).

111. *See id.* § 408.051(2)(d), (4).

112. *See id.* § 408.051(4).

113. *See id.* § 282.318(3)(b) (2018).

example, the Florida ITS Act requires the Florida Agency for State Technology (“Agency”) to establish “standards and processes consistent with generally accepted best practices for information technology security, to include cybersecurity, and [to] adopt[] rules that safeguard an agency’s data, information, and information technology resources to ensure availability, confidentiality, and integrity and to mitigate risks.”¹¹⁴

In particular, the Florida ITS Act requires the Agency to:

(a) Develop, and annually update . . . a statewide information technology security strategic plan that includes security goals and objectives for the strategic issues of information technology security policy, risk management, training, incident management, and disaster recovery planning.

(b) Develop, and publish for use . . . an information technology security framework that, at a minimum, includes guidelines and processes for:

(1) Establishing asset management procedures to ensure that an agency’s information technology resources are identified and managed consistent with their relative importance to the agency’s business objectives.

(2) Using a standard risk assessment methodology that includes the identification of an agency’s priorities, constraints, risk tolerances, and assumptions necessary to support operational risk decisions.

(3) Completing comprehensive risk assessments and information technology security audits

(4) Identifying protection procedures to manage the protection of an agency’s information, data, and information technology resources.

(5) Establishing procedures for accessing information and data to ensure the confidentiality, integrity, and availability of such information and data.

(6) Detecting threats through proactive monitoring of events, continuous security monitoring, and defined detection processes.

(7) Establishing agency computer security incident response teams and describing their responsibilities for responding to information technology security incidents, including breaches of personal information containing confidential or exempt data.

(8) Recovering information and data in response to an information technology security incident

(9) Establishing an information technology security incident reporting process

114. *Id.* § 282.318(1), (3).

(10) Incorporating information obtained through detection and response activities into the agency's information technology security incident response plans.

(11) Developing agency strategic and operational information technology security plans

(12) Establishing the managerial, operational, and technical safeguards for protecting state government data and information technology resources¹¹⁵

The Florida ITS Act thus establishes comprehensive security standards similar to those set forth in the HIPAA Security Rule.¹¹⁶ The catch is that only state agencies, defined as any “official, officer, commission, board, authority, council, committee, or department of the executive branch of [Florida] state government; the Justice Administrative Commission; and the Public Service Commission” are required to comply with these security standards.¹¹⁷ By definition, independent scientists do not work for a state agency.¹¹⁸ As a result, the Florida ITS Act has no application to the instant issue.¹¹⁹

VII. FIPA

Florida still has other laws that contain security standards, as well as breach notification standards that could, in theory, help protect physical and mental health data of the type collected by mobile health apps and mobile research apps.¹²⁰ For example, FIPA—codified within Chapter 501 of the Florida Statutes—applies to a *covered entity*, defined to include “a sole proprietorship, partnership, corporation, trust, estate, cooperative, association, . . . commercial entity, [or governmental entity] that acquires, maintains, stores, or uses personal information;” as well as a *third-party agent*, defined as “an entity that has been contracted to maintain, store, or process personal information on behalf of a covered entity or governmental entity.”¹²¹ Because an independent scientist could be a sole proprietor, or an independent scientist could form a commercial entity with other business, marketing, and communication professionals, FIPA has potential application

115. FLA. STAT. § 282.318(3)(a), (b)(1)–(12).

116. *Id.*; see also 45 C.F.R. §§ 164.302–.308 (2018).

117. FLA. STAT. § 282.0041(23).

118. See Lovelock, *supra* note 10.

119. See FLA. STAT. § 282.318(2)–(3).

120. See *id.* § 501.171.

121. *Id.* § 501.171(1)(b), (h).

to independent scientists, and/or their commercial entities, that develop and/or use mobile apps to conduct health research.¹²²

The application of FIPA hinges, however, on whether the covered entity “acquires, maintains, stores, or uses personal information.”¹²³ FIPA defines *personal information* as:

(1) An individual’s first name or first initial and last name in combination with any one or more of the following data elements for that individual: [a] social security number; [b] . . . driver[’s] license or identification card number, passport number, military identification number, or other similar number issued on a government document used to verify identity; [c] . . . financial account number or credit or debit card number, in combination with any required security code, access code, or password that is necessary to permit access to an individual’s financial account; [d] . . . information regarding an individual’s medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional; or [e] [a]n individual’s health insurance policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual; or (2) [a] user name or e-mail address, in combination with a password or security question and answer that would permit access to an online account.¹²⁴

Some mobile research apps require the user to enter: (1) the user’s first and last name; and (2) a user name or email address combined with a password or security question.¹²⁵ To the extent the user also provides the app with “information regarding [the] individual’s medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional,” FIPA’s security and breach notification standards, discussed below, would apply.¹²⁶ However, other mobile research apps allow research participants to supply health information without providing: (1) a first and last name; or (2) a user name or email address combined with a password or

122. See *id.*; Tovino, *supra* note 6, at 40; *About Us*, *supra* note 75 (referencing the commercial entity Fall Safety, which employs software engineers as well as marketing and communications professionals to develop occupational safety and health apps as well as occupational safety and health research apps).

123. FLA. STAT. § 501.171(1)(b).

124. *Id.* § 501.171(1)(g)(1).

125. See *Privacy Policy*, PATIENTSLIKEME, <http://www.patientslikeme.com/about/privacy> (last visited May 1, 2019). PatientsLikeMe is a mobile health app that requires the user to enter an email address, a user name, and a password before the user may enter health information. *Id.*; *PatientsLikeMe*, *supra* note 49.

126. FLA. STAT. § 501.171(1)(g)(IV); *What Is PII?*, U. MASS. MED. SCH., <http://www.umassmed.edu/it/security/compliance/what-is-pii/> (last visited May 1, 2019).

security question.¹²⁷ In the case of these latter mobile research apps, FIPA's security and breach notification standards would not apply.¹²⁸

To the extent FIPA applies, the law requires “[e]ach covered entity, governmental entity, or third-party agent [to] take reasonable measures to protect and secure data in electronic form containing personal information.”¹²⁹ This provision may be referred to as a modest reasonable security standard.¹³⁰ FIPA also requires “[e]ach covered entity [and] third-party agent [to] take all reasonable measures to dispose, or arrange for the disposal, of customer records containing personal information within [their] custody or control when the records are no longer to be retained.”¹³¹ “Such disposal shall involve shredding, erasing, or otherwise modifying the personal information in the records to make it unreadable or undecipherable through any means.”¹³² These latter two provisions may be referred to as modest secure disposal standards.¹³³ These provisions are modest because they pale in comparison to the comprehensive security standards set forth in the HIPAA Security Rule,¹³⁴ as well as other state laws, including the Florida ITS Act.¹³⁵

127. FLA. STAT. § 501.171(1)(g)(1); see also *Frequently Asked Questions*, KINSEY REP., <http://www.kinseyreporter.org/#/faq> (last updated May 1, 2019). Kinsey Reporter is a mobile sexual health research app that allows users to donate sexual health data, such as female hormonal birth control effects, for research purposes without the users identifying themselves or providing a user name or email address. *Frequently Asked Questions, supra*.

128. See FLA. STAT. § 501.171.

129. *Id.* § 501.171 (2).

130. *Id.*; Kevin L. Miller, *What We Talk About When We Talk About Reasonable Cybersecurity: A Proactive and Adaptive Approach*, FLA. B.J., Sept./Oct. 2016, at 23, 26.

131. FLA. STAT. § 501.171(8). Florida Statute § 501.171(1)(c) defines a *customer record* as:

[A]ny material, regardless of the physical form, on which personal information is recorded or preserved by any means, including, but not limited to, written or spoken words, graphically depicted, printed, or electromagnetically transmitted that are provided by an individual in [Florida] to a covered entity for the purpose of purchasing or leasing a product or obtaining a service.

Id. § 501.171(1)(c).

132. *Id.* § 501.171(8).

133. See Charles H. Kennedy, *Secure Records Disposal: Is Not Shredding Ever a Good Idea?*, IRON MOUNTAIN, <http://www.ironmountain.com/resources/whitepapers/s/secure-records-disposal-is-not-shredding-ever-a-good-idea> (last visited May 1, 2019).

134. See Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191 § 201, 110 Stat. 1936, 1992 (codified as amended at 42 U.S.C. § 201 (2012)); FLA. STAT. §§ 282.318(3), 501.171(2), (4), (8).

135. See FLA. STAT. § 282.318.

In addition to these modest security standards, FIPA contains comprehensive breach notification provisions.¹³⁶ In particular, FIPA requires a covered entity to give notice to each individual in the state of Florida whose personal information was, or the covered entity reasonably believes to have been, accessed as a result of a breach of security, defined as “unauthorized access of data in electronic form containing personal information.”¹³⁷ FIPA requires the notice to be made “as expeditiously as practicable and without unreasonable delay, taking into account the time necessary to allow the covered entity to determine the scope of the breach of security, to identify individuals affected by the breach, and to restore the reasonable integrity of the data system that was breached;” however, the notice may not be made later than thirty days after the determination of a breach or reason to believe a breach occurred.¹³⁸ When required, notice to an individual shall include, at a minimum:

- (1) [t]he date, estimated date, or estimated date range of the breach of security;
- (2) [a] description of the personal information that was accessed or reasonably believed to have been accessed as a part of the breach of security;
- (3) [i]nformation that the individual can use to contact the covered entity to inquire about the breach of security and the personal information that the covered entity maintained about the individual.¹³⁹

In addition to notifying the individual who was the subject of the information breach, FIPA also requires the covered entity to provide notice to the Florida Department of Legal Affairs (“Department”) of any breach of security affecting five hundred or more individuals in the state of Florida.¹⁴⁰ The covered entity must provide this notice to the Department *as expeditiously as practicable*, but not later than thirty days after the determination of the breach or reason to believe a breach has occurred.¹⁴¹ A covered entity may, however, receive fifteen additional days if the covered entity provides the Department, in writing, *good cause for delay* within thirty days after determination of the breach or reason to believe a breach has occurred.¹⁴² FIPA requires written notice to the Department to include:

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136. *Id.* § 501.171(4).
 137. *Id.* § 501.171(1)(a), (4)(a).
 138. *Id.* § 501.171(4)(a).
 139. *Id.* § 501.171(4)(e).
 140. FLA. STAT. § 501.171(3)(a).
 141. *Id.* § 501.171(3)(a).
 142. *Id.*

(1) [a] synopsis of the events surrounding the breach at the time notice is provided; (2) [t]he number of individuals in [Florida] who were, or potentially have been affected by the breach; (3) [a]ny services related to the breach being offered or scheduled to be offered, without charge, by the covered entity to individuals, and instructions as to how to use such services; (4) [a] copy of the notice . . . ; (5) [t]he name, address, telephone number, and e-mail address of the employee or agent of the covered entity from whom additional information may be obtained about the breach.¹⁴³

“If a covered entity discovers circumstances requiring notice . . . of more than [one thousand] individuals at a single time,” FIPA also requires the covered entity to “notify, without unreasonable delay, all consumer reporting agencies that compile and maintain files on consumers on a nationwide basis, . . . of the timing, distribution, and content of the notices.”¹⁴⁴

Interestingly, FIPA provides that:

Notice provided pursuant to rules, regulations, procedures, or guidelines established by the covered entity’s primary or functional federal regulator is deemed to be in compliance with [FIPA’s] notice requirement . . . if the covered entity notifies affected individuals in accordance with the rules, regulations, procedures, or guidelines established by the primary or functional federal regulator in the event of a breach of security.¹⁴⁵

As discussed in the Author’s prior work and above in this Article, most independent scientists do not have a primary or functional federal regulator.¹⁴⁶ Thus, FIPA, to the extent applicable, may be the primary—or actually only—form of regulation.¹⁴⁷

FIPA provides that a violation of its reasonable security, secure disposal, or breach notification provisions “shall be treated as an unfair or deceptive trade practice” for which the Department may bring a legal action.¹⁴⁸ A covered entity that fails to notify affected individuals and the

143. *Id.* § 501.171(3)(b).

144. *Id.* § 501.171(5).

145. FLA. STAT. § 501.171(4)(g).

146. Stacey A. Tovino, *Incidental Findings: A Common Law Approach*, 15 ACCOUNTABILITY RES. 242, 242 (2008); *see also* discussion *supra* Parts I–VI (discussing the lack of application of many Florida laws to independent scientists who conduct mobile app mediated research).

147. *See* FLA. STAT. § 501.171.

148. *Id.* § 501.171(9)(a).

Department in accordance with FIPA's breach notification requirements shall also be liable for: (1) during the first thirty days following the violation, a civil penalty of \$1,000 per day; (2) for each subsequent thirty-day period or portion thereof through the 180th day following the violation, a civil penalty of \$50,000; and (3) after the 180th day following the violation, a civil penalty up to \$500,000.¹⁴⁹ FIPA clarifies that these civil penalties apply *per breach*, not "per individual affected by the breach."¹⁵⁰ Notably, FIPA "does not establish a private cause of action."¹⁵¹

VIII. PATIENT BILL OF RIGHTS

None of the Florida laws discussed above have specific or express application to researchers.¹⁵² However, the Patient Bill of Rights, codified in Chapter 381 of the Florida Statutes, provides that "a patient has the right to know if medical treatment is for purposes of experimental research and to consent prior to participation in such experimental research."¹⁵³ The Patient Bill of Rights further provides that, "[f]or any patient, regardless of ability to pay or source of payment for his or her care, participation must be a voluntary matter; and a patient has the right to refuse to participate. The patient's consent or refusal must be documented in the patient's care record."¹⁵⁴ If applicable to mobile app mediated research, these provisions create some privacy protections for research participants; that is, they prohibit the collection of an individual's information by an app for research purposes without the individual's prior consent.¹⁵⁵ Nothing in the quoted language set forth in this paragraph limits the application of this privacy prohibition to just health care providers or health care facilities.¹⁵⁶ That said, the stated intent of the Patient Bill of Rights is to protect "patients of health care providers and health care facilities."¹⁵⁷ In addition, the prefatory statement in the beginning of the Patient Bill of Rights suggests that the enumerated obligations only apply to health care providers and health care

149. *Id.* § 501.171(9)(b).

150. *Id.* § 501.171(9)(b)(2).

151. *Id.* § 501.171(10).

152. *See* discussion *supra* Parts I–VII.

153. FLA. STAT. § 381.026(4)(e).

154. *Id.*

155. *See id.*

156. *See id.*

157. *Id.* at § 381.026(3). "It is the purpose of this section to promote the interests and well-being of the patients of health care providers and health care facilities and to promote better communication between the patient and the health care provider." FLA. STAT. § 381.026(3).

facilities.¹⁵⁸ As such, these privacy protections probably would not apply to a non-provider independent scientist, who does not work within or for a Florida-licensed health care facility.¹⁵⁹

IX. FLORIDA COMMON LAW

Florida recognizes a number of common law causes of action that involve duties relevant to confidentiality and privacy.¹⁶⁰ For example, Florida recognizes a cause of action for breach of fiduciary duty when a fiduciary impermissibly discloses a confidence.¹⁶¹ Under Florida law, the elements of the cause of action for breach of fiduciary duty include: (1) the existence of a fiduciary duty; (2) a breach of such duty; (3) proximate causation; and (4) damages.¹⁶² The first element, which is the crucial element for the issue at hand, requires an actor to have a fiduciary relationship with the person who is claiming damages.¹⁶³ Fiduciary duties have been recognized in cases involving an attorney/client, executor/heir, guardian/ward, agent/principal, trustee/beneficiary, corporate officer/shareholder, psychiatrist/patient, psychotherapist/patient, mental health counselor/patient, and other similar relationships where great trust is imposed on one person for the benefit of another.¹⁶⁴ Some courts, however, have imposed fiduciary duties on other, less-classic actors, including lenders, clerics, and wives.¹⁶⁵ The question in the instant case is whether a court would impose a fiduciary duty on an independent scientist who conducts mobile app mediated research and, to a lesser extent, whether that scientist could breach that duty in a case involving a privacy or security breach of confidential research data.¹⁶⁶

158. *Id.* § 381.026(4). “Each health care facility or provider shall . . .” *Id.*

159. *See id.*

160. *See Florida Common Law, supra* note 33.

161. *Gracey v. Eaker*, 837 So. 2d 348, 353 (Fla. 2002).

162. *Id.*

163. *Id.*

164. John F. Mariani et al., *Understanding Fiduciary Duty*, FLA. B.J., March 2010, at 21, 21; *see also Gracey*, 837 So. 2d at 353; *DeVaughn v. DeVaughn*, 840 So. 2d 1128, 1132 (Fla. 5th Dist. Ct. App. 2003); *Barnett Bank of Marion Cty. v. Shirey*, 655 So. 2d 1156, 1158 (Fla. 5th Dist. Ct. App. 1995); *Cohen v. Hattaway*, 595 So. 2d 105, 107 (Fla. 5th Dist. Ct. App. 1992); *Hoopas v. Hammargren*, 725 P.2d 238, 242 (Nev. 1986); *Eckhardt v. Charter Hosp. of Albuquerque, Inc.*, 953 P.2d 722, 727–28 (N.M. Ct. App. 1997).

165. Mariani et al., *supra* note 164, at 21 (providing an outstanding overview of Florida law governing the fiduciary relationship and fiduciary duties).

166. *See Suthers v. Amgen Inc.*, 372 F. Supp. 2d 416, 429 (S.D.N.Y. 2005); *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003); *Tovino, supra* note 6, at 25 (discussing the application of fiduciary duties in the

As the Author explained in a prior work, “fiduciary relationships may be expressly or impliedly created.”¹⁶⁷ Because it is unlikely that an independent scientist who conducts mobile app mediated research would expressly identify as a fiduciary in any electronic or other policies related to the mobile app, the concept of an implied fiduciary relationship is discussed.¹⁶⁸ “Implied fiduciary relationships are premised on the specific facts and circumstances surrounding the transaction and the relationship of the parties. These relationships have been found when confidence is reposed by one individual, the principal, and trust is accepted by the other individual, the fiduciary.”¹⁶⁹ Although research participants have sought to impose fiduciary duties on researchers, these attempts are usually unsuccessful.¹⁷⁰ As the Author explained elsewhere:

In *Moore v. Regents of the University of California*,¹⁷¹ a patient, Moore, who underwent treatment for hairy-cell leukemia, and whose treating physician used the patient’s cells to establish and patent a new cell line without his permission, sued the physician, Dr. Golde, the Regents of the University of California (“Regents”), a researcher employed by the Regents, Quan, and other parties for breach of fiduciary duty and twelve additional causes of action . . . The California Supreme Court applied the fiduciary duty to Dr. Golde, but summarily dismissed the breach of fiduciary cause of action with respect to the other defendants: “The Regents, Quan [and others] are not physicians. In contrast to [Dr.] Golde, none of these defendants stood in a fiduciary relationship with Moore or had the duty to obtain Moore’s informed consent to medical procedures.”

Other courts have dismissed breach-of-fiduciary-duty causes of action when the research participant failed to present sufficient evidence of the formation of the fiduciary relationship. In *Greenberg v. Miami Children’s Hospital Research Institute*,¹⁷² the plaintiffs sued a researcher, hospital, and research institute for breach of fiduciary duty based on the defendants’ alleged failure to disclose material information relating to their disease research. When the defendants argued that the plaintiffs failed to allege any

context of researchers who conduct neuroimaging studies and who may discover incidental neurological findings).

167. Tovino, *supra* note 146, at 250; *see also Greenberg*, 264 F. Supp. 2d at 1071.

168. *See Suthers*, 372 F. Supp. 2d at 429; Tovino, *supra* note 146, at 250.

169. Tovino, *supra* note 146, at 250; *see also Greenberg*, 264 F. Supp. 2d at 1071.

170. Tovino, *supra* note 146, at 251.

171. 793 P.2d 479 (Cal. 1990).

172. 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

facts showing that the defendants had recognized or accepted the trust, as required to form the fiduciary relationship, the plaintiffs responded by alleging that the defendants impliedly accepted the trust by undertaking research that they represented as being for the benefit of the plaintiffs. The court disagreed, reasoning that the plaintiffs had not sufficiently alleged the second element of a fiduciary relationship—acceptance of trust by the researchers—and that this element cannot be assumed from the subjects’ research participation: “There is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given.”

Other courts also have considered, at least in dicta, the question of whether researchers owe their participants fiduciary duties. *Suthers v. [Amgen Inc.]*,¹⁷³ involved an investigation of an experimental Parkinson’s treatment—glial-derived neurotrophic factor (“GDNF”)—at several sites, including New York University (“NYU”). Amgen, the trial sponsor, discontinued the trials after data indicated that GDNF was neither safe nor effective. Two of the research participants who received GDNF in an extended version of the study conducted at NYU sued Amgen to compel the provision of GDNF, which the participants believed relieved their Parkinson’s symptoms. One of their causes of action was breach of fiduciary duty, which the court refused to impose on Amgen: “[T]here is no basis in fact or law to impose a fiduciary duty running from the sponsor of an independent study to participants who it does not select, has not met, and about whom it may not know the details of their medical conditions.” Because the participants did not name NYU or its researchers as defendants, the court did not address the applicability of the fiduciary duty to the research team, although the court noted in dicta one bioethicist’s criticism of the application of fiduciary duties to researchers.

Notwithstanding these cases, the nature of the relationship between researchers and participants continues to be debated. Some plaintiffs’ lawyers argue that researchers are fiduciaries vis-à-vis their participants. Attorney Alan Milstein, who successfully represented University of Pennsylvania gene therapy participant, and decedent, Jesse Gelsinger, recently stated [that once a research participant] signs . . . [an] informed consent [to research document, the fiduciary relationship has been established].

....

173. 372 F. Supp. 2d 416 (S.D.N.Y. 2005).

Other attorneys and scholars take a middle ground and admit that there are important distinctions between the researcher–participant relationship and the types of relationships traditionally governed by fiduciary principles, although they use the concept of the fiduciary relationship as a framework for thinking about the researcher–participant relationship. Finally, some attorneys and scholars expressly oppose the application of fiduciary duties to researchers, reasoning that the relationship between researcher and participant differs fundamentally from that between physician and patient, that clinical research should not be conflated with medical care, and that the purpose of research is not to benefit individuals.¹⁷⁴

In summary, it is certainly possible for a mobile app mediated research participant to claim that an independent scientist has a fiduciary duty that favorably runs towards the research participant.¹⁷⁵ However, it is unlikely that a court would agree absent an express assumption of trust by the independent scientist or other facts not contemplated by this Article.¹⁷⁶ Even if an independent scientist were found by a court to have a fiduciary relationship with the scientist’s research participants, the case law discussed above does not establish privacy, security, or breach notification standards compliance with which would establish proper fiduciary behavior.¹⁷⁷

In addition to breach of fiduciary duty based on breach of trust or confidence, Florida also recognizes four invasion of privacy torts, including:

(1) appropriation, [which is] the unauthorized use of a person’s name or likeness to obtain some benefit; (2) intrusion, [which is the] physical[] or electronic[] intru[sion] into one’s private quarters; (3) public disclosure of private facts, [which] is the dissemination of truthful private information [that] a reasonable person would find objectionable; and (4) false light in the public eye, [which is the] publication of facts [that] place a person in a false light even though the facts themselves may not be defamatory.¹⁷⁸

174. Tovino, *supra* note 146, at 251–53 (citations omitted) (first quoting Moore, 793 P.2d at 486; then quoting Greenberg, 264 F. Supp. 2d at 1072; then quoting Suthers, 372 F. Supp. 2d at 429).

175. *See id.*

176. *Id.* at 254.

177. *Id.*; *see Suthers*, 372 F. Supp. 2d at 429; Greenberg, 264 F. Supp. 2d at 1072.

178. Allstate Ins. Co. v. Ginsberg, 863 So. 2d 156, 162 (Fla. 2003) (listing the four invasion of privacy torts recognized in Florida).

“All of these actions are tied together by the common thread of privacy, but otherwise they have little in common.”¹⁷⁹ Absent extraordinary facts not contemplated by this Article, the first and the last torts—appropriation and false light—have little application to the issue at hand.¹⁸⁰ Appropriation would require, for example, the independent scientist—or, perhaps, a person who received personal data from the independent scientist—to use the research participant’s name, image, or other comparable research data for commercial or other advantage without the research participant’s prior authorization.¹⁸¹ False light would require the independent scientist—or, perhaps, a person who received personal data from the independent scientist—to publish in a widespread manner facts that place the research participant in a highly offensive, false light.¹⁸² Although one could certainly create a fact pattern involving an independent scientist and mobile research participant that satisfies the elements of one or both torts, such a fact pattern is unlikely.¹⁸³

The second tort—intrusion—has still unlikely but potential application to the issue at hand.¹⁸⁴ “Intrusion involves ‘the unreasonable and highly offensive intrusion upon the seclusion of another.’”¹⁸⁵ Examples of intrusion found to be actionable include “the illegal diversion or interception and opening of one’s mail, peeping into one’s home, the viewing of a department store’s changing room by someone of the opposite sex where no adequate notice has been provided, persistent and unwanted telephone calls, wiretapping, or prying into a plaintiff’s bank account.”¹⁸⁶ An independent scientist who obtains personal data from a research participant’s mobile phone and uses that data for research purposes without providing prior notice to, and without obtaining the authorization of, the research participant could arguably be a proper defendant in an intrusion case.¹⁸⁷ On the other hand, an independent scientist whose mobile app—through an electronic privacy policy or otherwise—notifies the potential research participant of the types of data that will be collected for research purposes and who obtains the individual’s prior and express electronic authorization to such research participation should be able to defeat an intrusion claim.¹⁸⁸

179. Overton & Giddings, *supra* note 45, at 41.

180. *See id.* at 41–43.

181. *See id.* at 41 (explaining the appropriation tort under Florida law).

182. *See id.* at 43 (explaining the false light tort under Florida law).

183. *See id.* at 41–43.

184. Overton & Giddings, *supra* note 45, at 42.

185. *Id.* (quoting W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 117, at 854 (5th ed. 1984)) (explaining the intrusion tort under Florida law).

186. *Id.*

187. *See id.*

188. *See id.*; Moore et al., *supra* note 1, 3–4.

The third tort—public disclosure of private facts—also has unlikely but potential application to the issue at hand.¹⁸⁹ In a case based on public disclosure of private facts, “[t]he plaintiff must allege that facts were made public that would normally [be] kept hidden from the public eye. Moreover, the facts disclosed must be facts that would be highly offensive to a reasonable person.”¹⁹⁰ One can imagine that an independent scientist who made public highly offensive facts collected during research—perhaps sexual behavior or sexual disease information¹⁹¹—might be named as a defendant in a public disclosure of private facts case if the scientist had promised the research participant confidentiality.¹⁹² The case law interpreting both the second and third torts does not contain particular privacy, security, or breach notification standards, compliance with which would defeat the torts.¹⁹³ That said, the privacy concepts of prior notification and prior authorization are referenced in the case law and, if adequately pled by the independent scientist, should be sufficient to defeat a claim.¹⁹⁴

X. CONCLUSION AND PROPOSALS

This Article has carefully examined a variety of provisions within Florida law to determine whether Florida law contains comprehensive privacy, security, and breach notification standards that could apply to independent scientists who conduct mobile app mediated health research.¹⁹⁵ This Article has concluded that Florida law tends to fall into one of two categories—that is: (1) the law contains at least one data privacy, security, and/or breach notification right or standard, but the right or standard is limited in application to certain actors, certain professions, or certain institutions and does not apply to independent scientists; or (2) the law is not necessarily limited in application but the law fails to establish comprehensive privacy, security, and breach notification standards that will drive the implementation of privacy and security best practices by independent scientists.¹⁹⁶ Florida laws that fall into the first category include the Florida

189. Overton & Giddings, *supra* note 45, at 42.

190. *Id.* (discussing the public disclosure of private facts tort under Florida law).

191. *See id.*; *Frequently Asked Questions*, *supra* note 127.

192. *See* Overton & Giddings, *supra* note 45, at 40–42.

193. *Id.* at 42; *Allstate Ins. Co. v. Ginsberg*, 863 So. 2d 156, 160–62 (Fla. 2003); *Doe v. Univision Television Grp., Inc.*, 717 So. 2d 63, 64 (Fla. 3d Dist. Ct. App. 1998).

194. *See Ginsberg*, 863 So. 2d at 160–62; *Doe*, 717 So. 2d at 64.

195. *See* discussion *supra* Parts II–IX.

196. Discussion *supra* Parts II–IX; *see also* FLA. CONST. art. I, § 23; FLA. STAT. §§ 282.318, 381.026, 395.0197, 408.051, 464.0095, 501.171 (2018); *Florida Common Law*, *supra* note 33.

Constitution (privacy), Florida's health institution licensing laws (privacy), Florida's health professional licensing laws (privacy), the Health Records Act (privacy), Florida ITS Act (security), and the Patient Bill of Rights (privacy).¹⁹⁷ Florida laws that fall into the second category include FIPA (security and breach notification) and Florida common law (privacy).¹⁹⁸

FIPA, which contains security and breach notification standards that will apply to some, but not all, independent scientists who conduct mobile app mediated research studies may be the best option for protecting mobile app mediated research data going forward.¹⁹⁹ Several amendments to FIPA would be necessary, however, to make the law apply to all independent scientists who conduct mobile app mediated research.²⁰⁰ First, as currently written, FIPA applies to a *covered entity*, defined to include "a sole proprietorship, partnership, corporation, trust, estate, cooperative, association . . . commercial entity [or governmental entity] that acquires, maintains, stores, or uses personal information."²⁰¹ Because many independent scientists are simply natural persons, an amendment to FIPA's definition of covered entity to include natural person would be helpful to ensuring coverage of all independent scientists.²⁰²

Second, the application of FIPA hinges on whether the *covered entity* acquires, maintains, stores, or uses personal information.²⁰³ Recall that FIPA defines *personal information* as:

"a. [a]n individual's first name or first initial and last name in combination with any one or more of the following data elements for that individual: (I) [a] social security number; (II) [a] driver[']s license or identification card number, passport number, military identification number, or other similar number issued on a government document used to verify identity; (III) [a] financial account number or credit or debit card number, in combination with any required security code, access code, or password that is necessary to permit access to an individual's financial account; (IV) [a]ny information regarding an individual's medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional; or (V) [a]n individual's health insurance

197. See FLA. CONST. art. I, § 23; FLA. STAT. §§ 282.318, 381.026, 395.0197, 408.051; 464.0095.

198. See FLA. STAT. § 501.171; *Florida Common Law*, *supra* note 33.

199. See FLA. STAT. § 501.171(1)(b).

200. See *id.* § 501.171; *Independent Scientists: Young Researchers Producing Removeable Research*, *supra* note 92.

201. FLA. STAT. § 501.171(1)(b).

202. See *id.*; *Independent Scientists: Young Researchers Producing Removeable Research*, *supra* note 92.

203. FLA. STAT. § 501.171(1)(b).

policy number or subscriber identification number and any unique identifier used by a health insurer to identify the individual; [(V)(b)] a user name or e-mail address, in combination with a password or security question and answer that would permit access to an online account.”²⁰⁴

Some mobile apps, including PatientsLikeMe, require the user to enter: (1) the user’s first and last name; and/or (2) a user name or email address combined with a password or security question.²⁰⁵ To the extent the user also provides the app with information regarding the individual’s “medical history, mental or physical condition, or medical treatment or diagnosis by a health care professional,” FIPA would apply.²⁰⁶ Other mobile research apps, such as Kinsey Reporter, allow research participants to supply health information without providing: (1) a first and last name; or (2) a user name or email address combined with a password or security question.²⁰⁷ In the case of these latter mobile research apps, FIPA would not apply.²⁰⁸ In order to cover all mobile research apps, FIPA’s definition of *personal information* should be amended such that a first and last name, or a user name or email address combined with a password or security question, are not required for FIPA to apply.²⁰⁹ One might think that these are the only identifiers that could be used to identify a research participant; however, electronically—and publicly—accessible property records, for example, make it such that other identifiers, such as street number or address, could be used to identify a research participant or a research participant’s family.²¹⁰

204. *Id.* § 501.171(g).

205. *See PatientsLikeMe*, *supra* note 49.

206. FLA. STAT. § 501.171(1)(g)(1)(a)(IV); *see also What Is PII?*, *supra* note 126.

207. *See Kinsey Reporter: Apple Store*, *supra* note 47; *Kinsey Reporter: Google Play*, *supra* note 47.

208. *See* FLA. STAT. § 501.171(1)(g)(1)(a).

209. *See id.*

210. *See Guidance Regarding Methods for De-Identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*, HHS, <http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/index.html#rationale> (last visited May 1, 2019); Cameron F. Kerry, *Why Protecting Privacy Is a Losing Game Today — And How to Change the Game*, BROOKINGS (July 12, 2018), <http://www.brookings.edu/research/why-protecting-privacy-is-a-losing-game-today-and-how-to-change-the-game/>.

To most people, *personal information* means information like social security numbers, account numbers, and other information that is unique to them. [United States] privacy laws reflect this conception by aiming at *personally identifiable information*, but data scientists have repeatedly demonstrated that this focus can be too narrow. The aggregation and correlation of data from various sources make it increasingly possible to link supposedly anonymous information to specific individuals and to infer characteristics and information about them. The result is

In summary, “[t]he aggregation and correlation of data from various sources make it increasingly possible to link supposedly anonymous information to specific individuals and to infer characteristics and information about them.”²¹¹

Once FIPA applies, the law contains a modest reasonable security standard, a modest secure disposal standard, and a comprehensive breach notification standard.²¹² One option is to elevate FIPA’s modest security provisions to the level of comprehensive security standards.²¹³ Other states that have established comprehensive security standards in this context that could serve as a guide include Oregon and Massachusetts.²¹⁴ Florida’s own ITS Act, which also establishes comprehensive security standards, could be used as a guide.²¹⁵ Because FIPA contains no privacy standards, including individual rights provisions or use and disclosure requirements, the Author further recommends that FIPA be amended to include such standards.²¹⁶ The privacy standards set forth within the federal HIPAA Privacy Rule as well as California’s Consumer Privacy Act of 2018 may be used as a guide.²¹⁷

This Article has demonstrated that many Florida laws contain some type of privacy, security, or breach notification standard applicable to health data of the type collected by mobile research applications.²¹⁸ However, these laws tend to be traditional, intra-industry laws that are limited in application to certain individuals—usually licensed health care professionals—and certain institutions—usually licensed health care facilities.²¹⁹ Today,

that today, a widening range of data has the potential to be personal information, i.e. to identify us uniquely. Few laws or regulations address this new reality.

Kerry, *supra*.

211. *Id.*

212. *See* FLA. STAT. § 501.171(2), (4), (8) (reviewing FIPA in detail; noting that FIPA’s security provisions are modest because they pale in comparison to the comprehensive security standards set forth in the HIPAA Security Rule as well as other state laws, including the Florida ITS Act); Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 201, 110 Stat. 1936, 1992 (codified as amended at 42 U.S.C. § 201 (2012)); FLA. STAT. § 282.318(3).

213. *See* Health Insurance Portability and Accountability Act of 1996, § 201, 110 Stat. 1936 at 1992; FLA. STAT. § 501.171(2), (4), (8).

214. *Tovino, supra* note 6, at 54 (discussing the comprehensive data security provisions of Oregon and Massachusetts); *see also* MASS. GEN. LAWS ch. 93H, § 2 (2018); OR. REV. STAT. § 182.122 (2018).

215. *See* FLA. STAT. § 282.318.

216. *See id.* § 501.171(2).

217. *See* Health Insurance Portability and Accountability Act of 1996, § 201, 110 Stat. 1936 at 1992; CAL. CIV. CODE § 1798.120 (West 2018) (this law will be effective on Jan. 1, 2020); *Tovino, supra* note 6, at 52 (discussing the comprehensive privacy standards set forth within the California Consumer Privacy Act of 2018).

218. *See* FLA. STAT. §§ 282.318(3), 395.3025(4), 456.057(4), 501.171(2).

219. *See id.* §§ 395.3025, 456.057.

however, health data is generated not only by individual and institutional members of the health care industry, but also by independent scientists who conduct mobile app mediated research studies as well as a range of other individuals and institutions that are based outside the health care industry.²²⁰ The significant economic, dignitary, and psychological harms associated with health data breaches and the lack of generally applicable federal and state regulations suggests a need for reform in this area.²²¹ It is the Author's hope that the changes recommended to FIPA will better protect the privacy and security of mobile research participant data as well as other forms of health-related big data.*

220. See Klemick, *supra* note 14; Rothstein, *supra* note 19, at 425.

221. See Rothstein, *supra* note 19, at 425–26.

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

TALYA VAN EMBDEN*

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I. INTRODUCTION

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

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

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

2. *Id.*

3. *Id.*

4. *Id.*

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

6. *Id.*

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

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

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

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

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

9. *Id.*

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

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

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

13. *Id.*

14. *Id.*

15. See *id.*

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

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

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

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

II. AN INTRODUCTION TO AI

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

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

19. *Id.*

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

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

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

23. See *infra* Section II.A.

24. See *infra* Section II.A.2–3.

25. See *infra* Section III.A.

26. See *infra* Section III.B.

27. See *infra* Part IV.

28. See *infra* Part V.

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

A. *History of AI*

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

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

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

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

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

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

34. See Simonite, *supra* note 12.

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

36. *Id.*

37. *Id.* at 393–94.

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

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

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

1. What is AI?

In today’s day and age, AI plays a role by “powering . . . technology that impacts people’s daily lives.”⁴⁸ AI is the substructure of nearly every

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

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

41. Simonite, *supra* note 12.

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

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

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

45. *Id.*

46. Simonite, *supra* note 12.

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

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

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

2. ML

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

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

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

51. Goodell, *supra* note 43.

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

53. *Id.*

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

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

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

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

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

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

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

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

59. See Hamet & Tremblay, *supra* note 16, at S37; Goodell, *supra* note 43; Jones, *supra* note 38.

60. See Jones, *supra* note 38.

61. *Id.*

62. *Id.*

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

64. See Jones, *supra* note 38.

65. *Machine Learning Glossary*, GOOGLE DEVELOPER, http://developers.google.com/machine-learning/glossary/?utm_source=google-ai&utm_medium=card-image&utm_campaign=training-hub&utm_content=ml-glossary#m (last visited May 1, 2019).

66. Goodell, *supra* note 43.

67. *Id.*

68. *Id.*

69. *Id.*

70. See *id.*

71. See Goodell, *supra* note 43.

72. See *id.*

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

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

3. DL

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

73. *See id.*

74. *See id.*; Simonite, *supra* note 12.

75. *See* Goodell, *supra* note 43; Jones, *supra* note 38.

76. Simonite, *supra* note 12.

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

78. *See* Goodell, *supra* note 43; Simonite, *supra* note 12.

79. *See* Goodell, *supra* note 43; Simonite, *supra* note 12.

80. Goodell, *supra* note 43.

81. *Id.*

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

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

87. Ariel Bleicher, *Demystifying the Black Box That Is AI*, SCI. AM. (Aug. 9, 2017), <http://www.scientificamerican.com/article/demystifying-the-black-box-that-is-ai/>.

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

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

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

89. Bleicher, *supra* note 87.

90. *Id.*

91. *Id.*

92. *Id.*

93. *See id.*

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

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

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

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

B. *AI in Medicine*

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

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

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*; Goodell, *supra* note 43.

101. Bleicher, *supra* note 87.

102. *Id.*

103. *See id.*

104. Ashok, *supra* note 18.

105. *See id.*

106. *See id.*; Jennifer Bresnick, *Can Healthcare Avoid Black Box Artificial Intelligence Tools?*, HEALTHITANALYTICS.COM: TOOLS & STRATEGIES (Feb. 2, 2018), <http://healthitanalytics.com/news/can-healthcare-avoid-black-box-artificial-intelligence-tools>.

107. Ashok, *supra* note 18.

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

C. *Black-Box Medicine*

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

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

109. *Id.*

110. *See id.* at 17–18.

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

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

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

114. *See id.*

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

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

1. The Diagnosing Devices of AI

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

Watson has worked with over twenty-seven hundred veterans and will continue to do so through 2019.¹²⁴ But how exactly does Watson work?¹²⁵ "Watson [is] powered by DeepQA software," meaning it is using

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

117. *Id.*

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

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

120. *See id.* at 54–55.

121. *Id.* at 54.

122. *Id.*

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

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

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

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

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

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

126. *Id.*

127. *Id.*

128. *Id.*

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

130. *Id.*

131. *See id.*

132. *See id.*

133. *Id.*

134. Bergen, *supra* note 129.

135. *Id.*

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

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

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

136. *Id.*

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

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

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

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

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

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

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

2. Surgical Robots

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

143. See Simshaw et al., *supra* note 142, at 11.

144. See *id.* at 15, 17–20.

145. Norman, *supra* note 142.

146. See *id.*; Simshaw et al., *supra* note 142, at 9.

147. Hamet & Tremblay, *supra* note 16, at S37; Anthea Gerrie, *The da Vinci Code: Why a Robotic System Replaces Chopstick Surgery*, MEDTECH ENGINE: INNOVATION & ENTREPRENEURSHIP (Oct. 14, 2016), <http://www.medtechengine.com/article/da-vinci-surgical-system/>.

148. Simshaw et al., *supra* note 142, at 9.

149. Norman, *supra* note 142.

150. See *id.*

151. *Id.*

152. *Id.*

153. See Simshaw et al., *supra* note 142, at 7, 15, 17–20.

3. Precision Medicine and Drug Discovery

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

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

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

156. Chamraj, *supra* note 154.

157. *Id.*

158. *Id.*

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

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

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

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

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

4. mHealth

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

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

164. *Id.*

165. *Id.*

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

167. *See id.* at 428–29.

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

169. Leswing, *supra* note 141.

170. *Id.*

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

172. *Id.*

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

III. THE FDA: AN OVERVIEW

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

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

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

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

173. Leswing, *supra* note 141.

174. *See id.*

175. *Id.*

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

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

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

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

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

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

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

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

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

182. *Id.* at 1761, 1802.

183. *Id.* at 1761–62.

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

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

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

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

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

189. *Id.* at 1803.

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

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

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

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

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

B. *Regulating Drugs and Devices*

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

193. *See id.* at 1805–06.

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

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

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

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

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

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

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

1. CDER

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

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

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

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

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

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

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

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

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

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

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

210. *Id.*

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

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.*

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

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

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

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

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

2. CDRH

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

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

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

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

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

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

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

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

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

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

227. *Id.*

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

228. *Id.*

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

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

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

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

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

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

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

3. CBER

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

C. *The 21st Century Cures Act*

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

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

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

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

237. *Id.*

238. *Id.*

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

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

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

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

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

IV. REGULATING DR. ROBOT

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

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

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

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

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

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

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

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

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

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

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

250. Marr, *supra* note 29.

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

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

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

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

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

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

257. *Id.*

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

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

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

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

B. *The Risks of Regulating Dr. Robot*

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

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

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

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

263. *Id.*

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

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

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

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

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

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

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

V. CONCLUSION

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

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

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

270. *Id.*

271. *Id.*

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

273. Tuma, *supra* note 137.

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

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

276. *Id.*

277. Tuma, *supra* note 137.

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

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

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

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

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

281. Tuma, *supra* note 137.

282. *Id.*

283. *Id.*

284. *Id.*

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

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





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